Hanspeter Schmidt Rechtsanwalt

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1. SCOF, 114th to 121st meeting, 09.2013 to 09.2014 (Standing Committee on Organic Farming)
2. Commission Decision of 9 December 2013 amending Decision 2010/206/EU appointing the members of the group for technical advice on organic production and drawing up the pool list 2013/C 360/09 (EGTOP)
3. EGTOP Minutes and Mandates 09.2013 to 10.14 – Aquaculture Non Organic Juvenils, Permitted Feed Sources, Rewriting Chapters on Potassium Phosphonate, Ion Exchange Technology, Lignocellulosis, Stocking Density in Aquaculture
4. EGTOP Final Report on Aquaculture (Part A) adopted at the 8th plenary meeting of 03/05 December 2013
5. EGTOP Final Report On Plant Protection Products (II) adopted at the 9th plenary meeting of 28/30 April 2014
6. EGTOP Final Report On Food (II) adopted at the 9th plenary meeting of 28/30 April 2014 at the 9th plenary meeting
7. EGTOP Final Report on Aquaculture (Part B) adopted by written procedure in July 2014

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT
Directorate H. Sustainability and Quality of agriculture and rural development
The Director

Brussels, 30-9-2013 – **ARES 3140283**
JO/sam agri.ddg3.h.3(2013)3343394

Short report of the 114th meeting of the Standing Committee on Organic Farming of 26 September 2013

President: Markus HOLZER

28 Member States were present. Iceland, Norway, Switzerland and the EFTA secretariat were present as observers.

Section A – Opinion of the Committee

1. **Draft Commission Implementing Regulation amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (organic aquaculture)**

   The draft Regulation was presented for the opinion of the Committee.

   Vote: positive opinion (**285 in favour, 22 against, 41 abstentions, 4 not represented**).

Section B – Points for information and/or discussion

2. **Document discussion on working document on amendments to Reg. (EC) N° 889/2008**

   The Commission presented the proposal for amending Annex I and II with fertilisers, soil conditioners and plant protection products, that are in line with the horizontal legislation. After discussion, Delegations were required to submit its comments in writing by 4th October 2013.

3. **Main findings of and experiences gained from the audits on organic production and labelling of organic products carried out by the FVO in Member States**

   Delegations were provided with an overview of the findings of the audits that took place in the EU and in Third Countries.

4. **Reporting and notifications under organic farming legislation**

An overview of notifications and reporting due according to the EU organic production legislation was presented. Information was also provided concerning OFIS.

5. **Review of EU organic framework – state of play and feedback on administrative costs analysis**

The Committee was updated on the policy review process and on the publication on the EU organic website of the results of the online public consultation. Administrative costs and burden resulting from the EU organic legislation were presented, with a detailed feedback on the data collected from the Member States and stakeholders.

6. **Irregularities and controls**

a) An update concerning irregularities in the EU was presented.

b) Update on notification of irregularities concerning imported products.

7. **EGTOP – Greenhouse report**

The Committee was informed officially of the publication of the EGTOP report at the EU organic website. All the delegation were pleased with the finalisation of the greenhouse mandate by the group of experts. The Commission reminded the Delegations that the report presents the views of the independent experts and it do not necessarily reflect the views of the Commission.

8. **Import regime (Regulation (EC) No 1235/2008)**

a) Latest developments concerning OFIS (CB application)

A presentation was given on a newly released module of OFIS, allowing the control bodies and control authorities to apply for being listed as equivalent.

b) Proposition of technical adaptations to the incorporation of organic legislation into the EEA Agreement

Iceland, Norway and the EFTA secretariat presented to the Delegations their proposition of technical adaptations to the incorporation of organic legislation into the EEA Agreement.

c) Overview on third countries and CBs

Delegations were provided with an overview on listed and applicant third countries.

9. Miscellaneous

- DG AGRI Anti-Fraud strategy

  The presentation did not take place. It will be foreseen in a future SCOF meeting.

- BTSF – Organic Farming.

  The new Better Training for Safer Food (BTSF) training cycle 2013-2015 was presented, including details on programme, dates and location of the training sessions. The delegates were invited to identify participants through the BTSF national contact points network.

- Accreditation of control bodies in the EU

  Answers were provided to questions from delegations.

- Documentary evidence

  An overview of the replies received was presented to the delegations.

(signed)
Markus HOLZER
acting Director

Annex: List of participants

List of participants

Standing Committee on Organic Farming of 26 September 2013

Country	Organisation	Number of Participants
BE	SERVICE PUBLIC DE WALLONIE – DG AGRICULTURE, RESSOURCES NATURELLES & ENVIRONNEMENT – DIRECTION	2
	VLAAMSE OVERHEID, AFDELING DUURZAME LANDBOUWONTWIKKELING	
BG	MINISTRY OF AGRICULTURE AND FOOD	2
CZ	MINISTRY OF AGRICULTURE OF CZECH REPUBLIC	2
DK	MINISTRY OF FOOD, AGRICULTURE AND FISHERIES – THE DANISH VETERINARY AND FOOD ADMINISTRATION – DIVISION	3
DE	BUNDESANSTALT FÜR LANDWIRTSCHAFT UND ERNÄHRUNG – BLE	4
	BUNDESMINISTERIUM FÜR ERNÄHRUNG LANDWIRTSCHAFT UND VERBRAUCHERSCHUTZ – BMELV	
	LANDESAMT FÜR NATUR, UMWELT UND VERBRAUCHERSCHUTZ	
EE	MINISTRY OF AGRICULTURE	1
IE	DEPARTMENT OF AGRICULTURE, FISHERIES AND THE MARINE	1
EL	PERMANENT REPRESENTATION	1
ES	MINISTERIO DE AGRICULTURA, ALIMENTACIÓN Y MEDIO AMBIENTE – SUBDIR. GEN. DE CALIDAD DIFERENCIADA Y	1
FR	MINISTRY OF AGRICULTURE	3
	MINISTRY OF FINANCE	
	INAO PARIS	
CR	MINISTRY OF AGRICULTURE	1
IT	MINISTERO DELLE POLITICHE AGRICOLE ALIMENTARI E FORESTALI – UFFICIO PQA5 – AGRICOLTURA BIOLOGICA	2
CY	PERMANENT REPRESENTATION	1
LV	MINISTRY OF AGRICULTURE	1
LT	MINISTRY OF AGRICULTURE –RESOURCES AND QUALITY POLICY DEPARTMENT – AGRI-ENVIRONMENTAL AND ORGANIC	1
LU	MINISTERE DE L'AGRICULTURE, DE LA VITICULTURE ET DU DEVELOPPEMENT RURAL – ADMINISTRATION DES SERVICES	1
HU	MINISTRY OF RURAL DEVELOPMENT – DEPARTMENT OF FOOD CHAIN CONTROL	1
MT	MINISTRY FOR RESOURCES AND RURAL AFFAIRS – ORGANIC FARMING SECTION – AGRICULTURAL RESEARCH AND	1

Country	Organisation	Number of Participants
NL	MINISTRY OF ECONOMIC AFFAIRS	1
AT	BUNDESMINISTERIUM FÜR GESUNDHEIT (BMG)	2
	INSTITUTE OF ORGANIC FARMING AND FARM ANIMAL BIODIVERSITY	
PL	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT – DEPARTMENT OF PROMOTION AND COMMUNICATION	2
	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT – DEPARTMENT OF PROMOTION AND COMMUNICATION	
PT	MINISTRY OF AGRICULTURE, SEA, ENVIRONMENT AND REGIONAL PLANNING – MAMAOT	1
RO	PERMANENT REPRESENTATION	1
SI	MINISTRY OF AGRICULTURE AND THE ENVIRONMENT	1
SK	PERMANENT REPRESENTATION	1
FI	MINISTRY OF AGRICULTURE AND FORESTRY – FOOD DEPARTMENT	1
SE	MINISTRY FOR RURAL AFFAIRS	3
	SWEDISH BOARD OF AGRICULTURE DIVISION FOR HORSES, POULTRY AND FARMED GAME	
UK	DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS (DEFRA) – ORGANIC TEAM	3
EFTA	OFFICER FOOD AND VETERINARY MATTERS - GOODS DIVISION - EFTA - EUROPEAN FREE TRADE ASSOCIATION	2
IS	–	–
NO	NORWEGIAN FOOD SAFETY AUTHORITY	2
	NORWEGIAN MINISTRY OF AGRICULTURE AND FOOD - DEPARTMENT OF FOOD POLICY	
CH	MISSION OF SWITZERLAND TO THE EUROPEAN UNION	1
	EUROPEAN COMMISSION	12

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT
Directorate H. Sustainability and Quality of agriculture and rural development
The Director

Brussels, 04 December 2013
JO/sam agri.ddg3.h.3(2013)3851528

Short report of the 115th meeting of the Standing Committee on Organic Farming of 28-29 November 2013

President: Markus HOLZER

27 Member States were present. Cyprus and Slovakia were represented for the vote. Norway and Switzerland were present as observers.

Section A – Opinion of the Committee

1. **Draft Commission implementing Regulation (EU) No .../..of XXX amending and correcting Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control.** (*Articles 25e and 25o regarding percentage of organic juveniles/seed to be used in organic aquaculture*)

   The document presented by the Commission received a favourable opinion from the Committee by Qualified Majority Vote with BE and RO abstaining.

Section B – Points for information and/or discussion

2. **OFIS (Organic Farming Information System) – Exchange of information between Member States and the Commission, Reporting, Notifications of irregularities – Presentation of different modules**

   A presentation was made concerning the different modules available to Member States for the communication and exchange of information.

3. **Draft Commission implementing Regulation (EU) No .../..of XXX amending and correcting Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control.** (*Annexes I and II*)

   Delegations were provided with a new document and the reasons for the changes made since last discussion at 26 September SCOF. After discussion, The Commission agreed to introduce some minor changes and provisions in the document about Annex I and II,

as well as about substances belonging to Annex V and VI of Regulation 889/2008. A TBT notification will be sent to the WTO for commenting.

4. **Rural development programs in CAP post 2013: Delegated and implementing acts**

Delegations were informed about the latest state of play of the preparation of delegated and implementing acts on CAP post 2013, in particular on the provisions relevant for organic farming.

5. **Accreditation of control bodies in the field of organic production: presentation by the European cooperation for Accreditation (EA) of the new policy to be implemented as from 1 January 2014**

Delegations were provided with a presentation on the general requirements for accreditation and the specific requirements concerning control bodies in the field of organic production, both in the EU and in Third Countries.

6. **Dealing with alleged fraud in the organic sector – lessons learnt from the "Gatto con gli stivali" case (questionnaire to MS) and way forward**

Delegations were provided with an overview of action taken at MS and Commission's level on the massive fraud case uncovered in 2011, and of proposed follow up.

7. **Reporting and notifications under organic farming legislation**

Delegations were provided with updated information concerning the different notifications that are required according to the relevant organic production legislation.

8. **Review of EU organic framework – state of play**

Delegations were informed about the latest situation concerning the review of the political and legislative framework for organic farming.

9. **Irregularities and controls**

a) Update on notification of EU irregularities

An update concerning EU irregularity notifications was provided to the delegations.

b) Update on notification of irregularities concerning imported products

Delegates were briefed on irregularities found in imported products.

10. **EGTOP – follow-up – news on Subgroups Aquaculture & Food II**

The Delegates were informed about the latest meeting of the subgroups(Aquaculture & Food II) and about the rolling programme for next year 2014. The delegations agreed on continuing with new mandates(III) on Aquaculture and Food for the first semester of 2014. A mandate on feed will be also put forward next year.

11. **Import regime (Regulation (EC) No 1235/2008)**

a) CB application 2013 overview, instructions for assessment for co-reporters (CircaBC)

Dossiers for assessment of the 50 applications of CBs 2013 (11 geographical extensions, 28 product scope extension, 4 applications and 7 re-applications) will be

uploaded in CIRCABC until December 06, 2013. Co-reporting MS are asked to complete template for quality assessment and recommendation for listing until 7 January 2014. Documents are confidential.

b) Proposition of technical adaptations to the incorporation of organic legislation into the EEA Agreement

This point of the agenda could not be addressed.

c) Overview on third countries and CBs

Delegations were provided with an overview on listed and applicant third countries (including information about Korea as requested by PL).

12. Miscellaneous[1]

a) Inclusion of selenised yeast in Annex VI – FI;

The Commission understood the problem and importance of the lack of Selenium and its consequences in the milk production in Finland. The Commission will raise the issue at the next meeting of the Expert Group for technical advice on Organic Farming with the aim to look after it as soon as possible.

b) Question on Annex VI (clinoptilolite) – AU;

AU raised that the new Regulation (EU) No 651/2013 authorising clinoptilolite, which is currently in annex VI, will affect the use of this substance from January 2014. Austria asks for a fast reaction due to the new situation. The Commission will amend Annex VI to allow a legal continuous use of Clinoptilolite in organic production. The most efficient way is to do it in the next Draft Commission implementing Regulation amending and correcting Regulation (EC) No 889/2008, together with Annex I and II.

c) Information about Korea – PL.

Information provided on point 11 c).

Markus HOLZER
acting Director
signed

Annex: List of participants

[1] Any subjects that the Member States wish to discuss under Point 'Miscellaneous' need to be submitted to the Commission and the other Member States at the latest one week before the meeting of the Standing Committee on Organic Farming.

List of participants

Standing Committee on Organic Farming of 28-29 November 2013

Country	Organisation	Number of Participants
BE	SERVICE PUBLIC DE WALLONIE – DG AGRICULTURE, RESSOURCES NATURELLES & ENVIRONNEMENT – DIRECTION DE LA QUALITE	3
	MINISTERIE VAN DE VLAAMSE GEMEENSCHAP, AFDELING DUURZAME LANDBOUWONTWIKKELING	
	VLAAMSE OVERHEID, AFDELING DUURZAME LANDBOUWONTWIKKELING	
BG	MINISTRY OF AGRICULTURE AND FOOD	2
CZ	MINISTRY OF AGRICULTURE OF CZECH REPUBLIC	1
DK	MINISTRY OF FOOD, AGRICULTURE AND FISHERIES – THE DANISH VETERINARY AND FOOD ADMINISTRATION – DIVISION FOR FOOD QUALITY, TECHNOLOGY AND MARKETING PRACTICES	2
	MINISTRY OF FOOD, AGRICULTURE AND FISHERIES – AGRI FISH AGENCY	
DE	BUNDESANSTALT FÜR LANDWIRTSCHAFT UND ERNÄHRUNG – BLE	4
	BUNDESMINISTERIUM FÜR ERNÄHRUNG LANDWIRTSCHAFT UND VERBRAUCHERSCHUTZ - BMELV	
	LANDESAMT FÜR NATUR, UMWELT UND VERBRAUCHERSCHUTZ	
EE	MINISTRY OF AGRICULTURE	1
IE	DEPARTMENT OF AGRICULTURE, FISHERIES AND THE MARINE	1
EL	PERMANENT REPRESENTATION	2
ES	MINISTERIO DE AGRICULTURA, ALIMENTACIÓN Y MEDIO AMBIENTE – SUBDIR. GEN. DE CALIDAD DIFERENCIADA Y AGRICULTURA ECOLÓGICA	4
FR	MINISTRY OF FINANCE	4
	INAO PARIS	
	MINISTRY OF AGRICULTURE	
CR	MINISTRY OF AGRICULTURE	1
IT	MINISTERO DELLE POLITICHE AGRICOLE ALIMENTARI E FORESTALI – UFFICIO PQA5 – AGRICOLTURA BIOLOGICA	2
CY	PERMANENT REPRESENTATION	1
LV	MINISTRY OF AGRICULTURE	1
LT	MINISTRY OF AGRICULTURE –RESOURCES AND QUALITY POLICY DEPARTMENT – AGRI-ENVIRONMENTAL AND ORGANIC FARMING DIVISION	3
	EKOAGROS - control body	
LU	MINISTERE DE L'AGRICULTURE, DE LA VITICULTURE ET DU DEVELOPPEMENT RURAL – ADMINISTRATION DES SERVICES TECHNIQUES DE L'AGRICULTURE	1
HU	MINISTRY OF RURAL DEVELOPMENT – DEPARTMENT OF FOOD CHAIN CONTROL	1

Country	Organisation	Number of Participants
MT	MINISTRY FOR RESOURCES AND RURAL AFFAIRS – ORGANIC FARMING SECTION – AGRICULTURAL RESEARCH AND DEVELOPMENT CENTRE	1
NL	MINISTRY OF ECONOMIC AFFAIRS	2
	MINISTRY OF ECONOMIC AFFAIRS AND INNOVATION	
AT	BUNDESMINISTERIUM FÜR GESUNDHEIT (BMG)	3
	INSTITUTE OF ORGANIC FARMING AND FARM ANIMAL BIODIVERSITY	
	AUSTRIAN AGENCY FOR HEALTH AND FOOD SAFETY	
PL	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT – DEPARTMENT OF PROMOTION AND COMMUNICATION	3
	MAIN AGRICULTURAL AND FOOD QUALITY INSPECTION	
PT	MINISTRY OF AGRICULTURE, SEA, ENVIRONMENT AND REGIONAL PLANNING – MAMAOT	1
RO	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT	2
	PAYMENT AGENCY - APIA	
SI	MINISTRY OF AGRICULTURE AND THE ENVIRONMENT	1
SK	–	–
FI	MINISTRY OF AGRICULTURE AND FORESTRY – FOOD DEPARTMENT	1
SE	MINISTRY FOR RURAL AFFAIRS	3
	NATIONAL FOOD AGENCY – FOOD STANDARDS DEPARTMENT	
	SWEDISH BOARD OF AGRICULTURE	
UK	DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS (DEFRA) – ORGANIC TEAM	3
EFTA	–	–
NO	NORWEGIAN FOOD SAFETY AUTHORITY	2
	NORWEGIAN MINISTRY OF AGRICULTURE AND FOOD - DEPARTMENT OF FOOD POLICY	
CH	FEDERAL DEPARTMENT OF ECONOMIC AFFAIRS FDEA - FEDERAL OFFICE FOR AGRICULTURE FOAG - QUALITY AND SALES PROMOTION SECTION	2

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy
The Acting Director

Brussels, 21 February 2014
JO/sam agri.ddg1.b.4(2014)431478

Short report of the 116th meeting of the Standing Committee on Organic Farming of 19 February 2014

President: Michael ERHART

26 Member States were present. Norway and Switzerland were present as observers.

The following Addendum is made at the Report of the 114th meeting of the Standing Committee on Organic Farming:

Section B, point 2 – Document discussion on working document on amendments to Reg. (EC) N° 889/2008

IT expressed its satisfaction for the document presented and underlined the urgency to vote the proposal as soon as possible as these substances are very important for both farmers and manufactures of the substances.

Furthermore IT stressed the importance to harmonized the proposal with the horizontal legislation on pesticides and announced the presentation of writing comments.

Section B, point 7 – EGTOP – greenhouse report

The Italian delegation requested the Commission to provide a detailed discussion on the critical points of the report before presenting the draft proposal. The report in fact shows that in some EU Countries greenhouse productions not fully in line with the OF principles are allowed. The critical points concern:

- the use of crop rotations not in line with the OF principles;
- the use of large amounts of carbon dioxide;
- the soilless productions (limited to a few special cases).

The following Addendum is made at the Report of the 115th meeting of the Standing Committee on Organic Farming:

Section B, point 7 – Rural development programs in CAP post 2013: Delegated and implementing acts

Poland requested information about the obligation to have a national strategy for organic farming to introduce measure "organic farming" art 30 according RDP 2014-2020.

Section A – Opinion of the Committee

1. **Draft Commission implementing Regulation (EU) No .../..of XXX amending and correcting Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control**

   The document presented by the Commission received a favourable opinion from the Committee by Qualified Majority Vote with BE, NL and FI abstaining.

Section B – Points for information and/or discussion

2. **Presentation of working document: Amendment of Regulation (EC) No 1235/2008: Update of Annex IV**

   Presentation and discussion of the document took place.

3. **Reporting and notifications under organic farming legislation**

   Delegations were provided with updated information concerning the different notifications and reports that are required according to the EU legislation on organic production and labelling of organic products.

4. **Review of EU organic framework – state of play**

   The representative of the Commission gave a brief update on the process of the review of the European Union's organic production policy.

5. **Irregularities and controls**

   a) Update on notification of EU irregularities

   An update concerning EU irregularity notifications and other relevant cases was provided to the delegations.

   b) Update on notification of irregularities concerning imported products

   Delegates were briefed on irregularities found in imported products.

6. **EGTOP – update information about the different subgroups, new members of permanent group, 2014 programme and mandates on PPP, Feed and Food.**

Delegations were provided with updated information concerning the different aspects about EGTOP: new Commission Decision (2013/ C 360/9) appointing new members of the group, mandates for PPP II, Feed II and Food III in 2014 first semester and reasons for delaying Aquaculture II mandate.

7. **Import regime (Regulation (EC) No 1235/2008)**

a) Overview on third countries and CBs.

Delegations were provided with an overview on listed and applicant third countries for the purpose of equivalence.

8. **Miscellaneous**

Michael ERHART

signed

Annex: List of participants

List of participants

Standing Committee on Organic Farming of 19 February 2014

Country	Organisation	Number of Participants
BE	SERVICE PUBLIC DE WALLONIE – DG AGRICULTURE, RESSOURCES NATURELLES & ENVIRONNEMENT – DIRECTION DE LA QUALITE	2
	VLAAMSE OVERHEID, AFDELING DUURZAME LANDBOUWONTWIKKELING	
BG	MINISTRY OF AGRICULTURE AND FOOD	2
CZ	MINISTRY OF AGRICULTURE OF CZECH REPUBLIC	1
DK	MINISTRY OF FOOD, AGRICULTURE AND FISHERIES – THE DANISH VETERINARY AND FOOD ADMINISTRATION – DIVISION FOR FOOD QUALITY, TECHNOLOGY AND MARKETING PRACTICES	2
	MINISTRY OF FOOD, AGRICULTURE AND FISHERIES – AGRI FISH AGENCY	
DE	BUNDESMINISTERIUM FÜR ERNÄHRUNG LANDWIRTSCHAFT UND VERBRAUCHERSCHUTZ - BMELV	4
	GERMAN FEDERAL OFFICE FOR FOOD AND AGRICULTURE	
	LANDESAMT FÜR NATUR, UMWELT UND VERBRAUCHERSCHUTZ	
EE	MINISTRY OF AGRICULTURE	1
IE	DEPARTMENT OF AGRICULTURE, FISHERIES AND THE MARINE	1
EL	MINISTRY OF RURAL DEVELOPMENT AND FOOD – DIRECTORATE OF ORGANIC FARMING Unit of Organic Products of Animal Origin	1
ES	MINISTERIO DE AGRICULTURA, ALIMENTACIÓN Y MEDIO AMBIENTE – SUBDIR. GEN. DE CALIDAD DIFERENCIADA Y AGRICULTURA ECOLÓGICA	1
FR	MINISTRY OF AGRICULTURE	3
	MINISTRY OF FINANCE	
	INAO PARIS	
CR	MINISTRY OF AGRICULTURE	1
IT	MINISTERO DELLE POLITICHE AGRICOLE ALIMENTARI E FORESTALI – UFFICIO PQA5 – AGRICOLTURA BIOLOGICA	2
CY	PERMANENT REPRESENTATION	1
LV	MINISTRY OF AGRICULTURE	1
LT	MINISTRY OF AGRICULTURE –RESOURCES AND QUALITY POLICY DEPARTMENT – AGRI-ENVIRONMENTAL AND ORGANIC FARMING DIVISION	1
LU	–	
HU	MINISTRY OF RURAL DEVELOPMENT – DEPARTMENT OF FOOD CHAIN CONTROL	1
MT	–	
NL	MINISTRY OF ECONOMIC AFFAIRS	2
AT	BUNDESMINISTERIUM FÜR GESUNDHEIT (BMG)	2
	INSTITUTE OF ORGANIC FARMING AND FARM ANIMAL BIODIVERSITY	

Country	Organisation	Number of Participants
PL	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT – DEPARTMENT OF PROMOTION AND COMMUNICATION	1
PT	MINISTRY OF AGRICULTURE, SEA, ENVIRONMENT AND REGIONAL PLANNING – MAMAOT	1
RO	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT	1
SI	MINISTRY OF AGRICULTURE AND THE ENVIRONMENT	1
SK	CENTRAL CONTROL & TESTING INSTITUTE IN AGRICULTURE - DEPARTMENT OF ENVIRONMENTAL PROTECTION AND ORGANIC PROTECTION	1
FI	PERMANENT REPRESENTATION	1
SE	MINISTRY FOR RURAL AFFAIRS	3
	NATIONAL FOOD AGENCY – FOOD STANDARDS DEPARTMENT	
	SWEDISH BOARD OF AGRICULTURE	
UK	DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS (DEFRA) – ORGANIC TEAM	2
EFTA	–	
IS	–	
NO	NORWEGIAN FOOD SAFETY AUTHORITY	2
	NORWEGIAN MINISTRY OF AGRICULTURE AND FOOD - DEPARTMENT OF FOOD POLICY	
CH	MISSION OF SWITZERLAND TO THE EUROPEAN UNION	1

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy
The Acting Director

Brussels,
JO/sam agri.ddg1.b.4(2014)1155002

Short report of the 117th meeting of the Standing Committee on Organic Farming of 7-8 April 2014

President: Michael ERHART

28 Member States were present. Norway and Switzerland were present as observers.

Section A – Opinion of the Committee

1. **Draft Commission Implementing Regulation amending Regulation (EC) No 1235/2008 as regards requests for inclusion in the list of third countries recognised for the purpose of equivalence in relation to the import of organic products**

   The draft Regulation was presented for the opinion of the Committee.

   Vote: positive opinion.

Section B – Points for information and/or discussion

2. **Draft Commission Implementing Regulation amending Regulation (EC) No 1235/2008 as regards the recognition of control authorities and control bodies for the purpose of compliance and equivalence in relation to the import of organic products**

   A discussion with the delegations took place.

3. **Follow-up of greenhouse report. Socio-economic Data from MS**

   A table with the MS data on organic greenhouse production was presented by the Commission. The table will be updated for the next SCOF.

4. **Reporting and notifications under organic farming legislation**

   An update of the notifications due by 31 March (list of control bodies and control authorities and annual summary report of authorisations on the use of non-organic seeds and seed potatoes) was provided to the delegations.

5. **Irregularities and controls**

a) Update on notification of EU irregularities

An update concerning EU irregularity notifications and other relevant cases was provided to the delegations.

b) Update on notification of irregularities concerning imported products

Delegates were briefed on irregularities found in imported products.

c) Follow-up to information on the operation "Vertical Bio"

The Commission invited the delegations that have not yet replied to do so; requested the MS concerned by the circulation of allegedly fraudulent products to communicate all necessary information on transactions, and all MS that granted import authorisations to the operators concerned to consider all necessary measures in the light of the currently increased risk profile – so as to examine at next SCOF whether the conditions are still fulfilled; recalled the need to indicate reception of EU funding; and provided examples of good practices. A discussion followed.

6. **EGTOP – update information about the different subgroups, new mandates on Feed and Food. Publication of Aquaculture report.**

The COM updated the SCOF delegates with the latest news from EGTOP. .

The publication of the Aquaculture report was presented by DG MARE.

7. **Import regime (Regulation (EC) No 1235/2008)**

An overview of situation of relations with Third countries was presented, including for China, India, US, Korea and the pending applications.

8. **Miscellaneous**

End of the derogation to use non-organically reared pullets for egg production of not more than 18 weeks.

Inclusion of hydrochloric acid in Annex VIII of Regulation (EC) No 889/2008 for the use as a reagent for dextrin production (preparation of foodstuffs of plant origin)

Michael ERHART

signed

Annex: List of participants

List of participants

Standing Committee on Organic Farming of 7-8 April 2014

Country	Organisation	Number of Participants
BE	SERVICE PUBLIC DE WALLONIE – DG AGRICULTURE, RESSOURCES NATURELLES & ENVIRONNEMENT – DIRECTION DE LA QUALITE	4
	FPS FINANCES – GENERAL ADMINISTRATION OF THE CUSTOMS AND EXCISE; ATTACHÉ – NON FISCAL LEGISLATION	
	MINISTERIE VAN DE VLAAMSE GEMEENSCHAP, AFDELING DUURZAME LANDBOUWONTWIKKELING	
	VLAAMSE OVERHEID, AFDELING DUURZAME LANDBOUWONTWIKKELING	
BG	MINISTRY OF AGRICULTURE AND FOOD	1
CZ	MINISTRY OF AGRICULTURE OF CZECH REPUBLIC	1
DK	MINISTRY OF FOOD, AGRICULTURE AND FISHERIES – THE DANISH VETERINARY AND FOOD ADMINISTRATION – DIVISION FOR FOOD QUALITY, TECHNOLOGY AND MARKETING PRACTICES	2
	MINISTRY OF FOOD, AGRICULTURE AND FISHERIES – AGRI FISH AGENCY	
DE	BUNDESANSTALT FÜR LANDWIRTSCHAFT UND ERNÄHRUNG – BLE	3
	BUNDESMINISTERIUM FÜR ERNÄHRUNG LANDWIRTSCHAFT UND VERBRAUCHERSCHUTZ - BMELV	
	LANDESAMT FÜR NATUR, UMWELT UND VERBRAUCHERSCHUTZ	
EE	MINISTRY OF AGRICULTURE	1
IE	DEPARTMENT OF AGRICULTURE, FISHERIES AND THE MARINE	1
EL	MINISTRY OF RURAL DEVELOPMENT AND FOOD - DIRECTORATE OF ORGANIC FARMING Unit of Organic Products of Animal Origin	1
ES	MINISTERIO DE AGRICULTURA, ALIMENTACIÓN Y MEDIO AMBIENTE – SUBDIR. GEN. DE CALIDAD DIFERENCIADA Y AGRICULTURA ECOLÓGICA	3
	GOBIERNO DE EXTREMADURA	
FR	MINISTRY OF AGRICULTURE	1
	MINISTRY OF FINANCE	3
	INAO PARIS	
CR	MINISTRY OF AGRICULTURE	
IT	MINISTERO DELLE POLITICHE AGRICOLE ALIMENTARI E FORESTALI – UFFICIO PQA5 – AGRICOLTURA BIOLOGICA	2
CY	PERMANENT REPRESENTATION	1
LV	MINISTRY OF AGRICULTURE	1

Country	Organisation	Number of Participants
LT	MINISTRY OF AGRICULTURE –RESOURCES AND QUALITY POLICY DEPARTMENT – AGRI-ENVIRONMENTAL AND ORGANIC FARMING DIVISION	1
LU	MINISTERE DE L'AGRICULTURE, DE LA VITICULTURE ET DU DEVELOPPEMENT RURAL – ADMINISTRATION DES SERVICES TECHNIQUES DE L'AGRICULTURE	1
HU	MINISTRY OF RURAL DEVELOPMENT – DEPARTMENT OF FOOD CHAIN CONTROL	1
MT	MINISTRY FOR RESOURCES AND RURAL AFFAIRS – ORGANIC FARMING SECTION – AGRICULTURAL RESEARCH AND DEVELOPMENT CENTRE	1
NL	MINISTRY OF ECONOMIC AFFAIRS	3
	MINISTRY OF ECONOMIC AFFAIRS AND INNOVATION	
AT	INSTITUTE OF ORGANIC FARMING AND FARM ANIMAL BIODIVERSITY	1
PL	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT – DEPARTMENT OF PROMOTION AND COMMUNICATION	3
	AGRICULTURAL AND FOOD QUALITY INSPECTION	
PT	MINISTER OF AGRICULTURE AND SEA – MAM	1
RO	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT	1
SI	MINISTRY OF AGRICULTURE AND THE ENVIRONMENT	1
SK	CENTRAL CONTROL & TESTING INSTITUTE IN AGRICULTURE - DEPARTMENT OF ENVIRONMENTAL PROTECTION AND ORGANIC PROTECTION	1
FI	PERMANENT REPRESENTATION	2
	MINISTRY OF AGRICULTURE AND FORESTRY – FOOD DEPARTMENT	
SE	NATIONAL FOOD AGENCY – FOOD STANDARDS DEPARTMENT	2
	SWEDISH BOARD OF AGRICULTURE DIVISION FOR HORSES, POULTRY AND FARMED GAME	
UK	DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS (DEFRA) – ORGANIC TEAM	2
EFTA	–	–
IS	–	–
NO	NORWEGIAN FOOD SAFETY AUTHORITY	2
	NORWEGIAN MINISTRY OF AGRICULTURE AND FOOD - DEPARTMENT OF FOOD POLICY	
CH	FEDERAL OFFICE FOR AGRICULTURE FOAG - QUALITY AND SALES PROMOTION UNIT	1

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT
Directorate B. Multilateral relations, quality policy
The Acting Director

Brussels,
JO/sn/agri.ddg1.b.4(2014)677606

Short report of the 118th meeting of the Standing Committee on Organic Farming of 15-16 May 2014

President: Michael ERHART

27 Member States were present. Norway and Switzerland were present as observers.

Section A - Opinion of the Committee

1. **Draft Commission amending Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (products extension, Tunisia, CBs India)**

   The document presented by the Commission received a favourable opinion from the Committee by qualified majority **(284 in favour, 41 abstentions, 27 not represented).** PL was absent at the time of the vote. IT and EL abstained.

Section B - Points for information and/or discussion

2. **Draft Commission Implementing Regulation amending Regulation (EC) No 1235/2008 as regards the recognition of control authorities and control bodies for the purpose of compliance and equivalence in relation to the import of organic products**

   Discussion on this text continued after presentation on 7 April. Commission requests Member States with comments that these should be sent in 2 weeks, with a view of having a next round of discussion in the June SCOF. Commission announced intention to proceed to a vote in the July SCOF.

3. **Information on upcoming amendments to Annexes III and IV to Regulation (EC) No°1235/2008: New Zealand (wine), Libancert, other minor updates**

   The Commission provided information on the content of the upcoming draft regulation amending and correcting Regulation (EC) No 1235/2008.

4. **Follow-up of greenhouse report. Socio-economic updated data from MS**
COM presented an update of the table on MS organic greenhouse production. Several MS and Norway reaffirmed their positions in the greenhouse dossier. The North-South point of view was reconfirmed, although several MS also showed a willingness to introduce the necessary flexibility to cope with the climatic and geographical differences within the EU.

5. **Reporting and notifications under organic production legislation**
An update of notifications was provided to the delegations. The Commission informed about the updated lists of the competent authorities in the EU Member States and, where available, of the EU control bodies and control authorities approved on 31 December 2013 are published on the Organic Farming website: **http://ec.euroDa.eu/aahculture/oraanic/consumer-trust/certification-and- confidence/controls-and-inspections/control-system/index en.htm**

6. **Follow up to irregularities and fraud allegations**

a) Update on notification of EU irregularities

An update concerning EU irregularity notifications and other relevant cases was provided to the delegations and an exchange of views took place.

b) Update on notification of irregularities concerning imported products
Delegates were briefed on irregularities found in imported products.

c) Follow-up to information on the operation "Vertical Bio" as regards import authorisations granted according to Article 19 of Regulation (EC) No 1235/2008

The discussion focused on the information provided by the different delegations and the necessary follow-up.

7. **EGTOP - updated information on current works**

The progress in EGTOP was explained by COM. Two reports, PPP **II** and Food **II,** have been recently published and there are three sub-groups preparing other reports (Aquaculture **B,** Feed **II** and Food **III),** to be discussed in the plenary group later this year.

8. **Import regime (Regulation (EC) No 1235/2008)**

a) Overview on third countries

The Delegations were updated with the state of the situation of the equivalence with Switzerland.

b) Korea

The Delegations were updated on the state of play of the negotiations on equivalence.

c) US

COM briefed MS on the peer review on USNOP carried out on 5-9 May.

9. Miscellaneous[1]

a) **IE - Organic Dairying: Impediments encountered by organic farmers diversifying into organic dairying, [inter alia: availability of suitable organic livestock]**
IE informed the SCOF about the difficulties that dairy farmers find to convert to organic and the lack of incentives to do that. IE will table a reflexion paper about it for future discussion.

b) **DK** - Herbicides found in organic production

Michael ERHART
signed

Annex: List of participants

[1] Any subjects that the Member States wish to discuss under Point 'Miscellaneous' need to be submitted to the Commission and the other Member States at the latest one week before the meeting of the Standing Committee on Organic Farming.

List of participants

Standing Committee on Organic Farming of 15-16 May 2014

Country	Organisation	Number of Participants
BE	SERVICE PUBLIC DE WALLONIE - DG AGRICULTURE, ' RESSOURCES NATURELLES & ENVIRONNEMENT - DIRECTION DE LA QUALITE	2
	VLAAMSE OVERHEID, AFDELING DUURZAME LANDBOUWONTWIKKELING	
BG	MINISTRY OF AGRICULTURE AND FOOD	1
CZ	MINISTRY OF AGRICULTURE OF CZECH REPUBLIC	1
DK	MINISTRY OF FOOD, AGRICULTURE AND FISHERIES - THE DANISH VETERINARY AND FOOD ADMINISTRATION - DIVISION FOR FOOD QUALITY, TECHNOLOGY AND MARKETING PRACTICES	2
DE	BUNDESANSTALT FÜR LANDWIRTSCHAFT UND ERNÄHRUNG -BLE	3
	BUNDESMINISTERIUM FÜR ERNÄHRUNG LANDWIRTSCHAFT UND VERBRAUCHERSCHUTZ - BMELV	
EE	MINISTRY OF AGRICULTURE	1
IE	DEPARTMENT OF AGRICULTURE, FISHERIES AND THE MARINE	1
EL	MINISTRY OF RURAL DEVELOPMENT AND FOOD - DIRECTORATE OF ORGANIC FARMING Unit of Organic Products of Animal Origin	1
ES	MINISTERIO DE AGRICULTURA, ALIMENTACIÓN Y MEDIO AMBIENTE - SUBDIR. GEN. DE CALIDAD DIFERENCIADA Y AGRICULTURA ECOLÓGICA	1
FR	MINISTRY OF AGRICULTURE	1
HR	PERMANENT REPRESENTATION	2
IT	MINISTERO DELLE POLITICHE AGRICOLE ALIMENTARI E FORESTALI - UFFICIO PQA5 - AGRICOLTURA BIOLOGICA	2
CY	-	-
LY	MINISTRY OF AGRICULTURE	1
LT	MINISTRY OF AGRICULTURE -RESOURCES AND QUALITY POLICY DEPARTMENT - AGRI-ENVIRONMENTAL AND ORGANIC FARMING DIVISION	1
LU	MINISTERE DE L'AGRICULTURE, DE LA VITICULTURE ET DU DEVELOPPEMENT RURAL - ADMINISTRATION DES SERVICES TECHNIQUES DE L'AGRICULTURE	1
HU	MINISTRY OF RURAL DEVELOPMENT - DEPARTMENT OF FOOD CHAIN CONTROL	1
MT	MINISTRY FOR RESOURCES AND RURAL AFFAIRS - ORGANIC FARMING SECTION - AGRICULTURAL RESEARCH AND DEVELOPMENT CENTRE	1

Country	Organisation	Number of Participants
NL	MINISTRY OF ECONOMIC AFFAIRS	2
AT	BUNDESMINISTERIUM FUR GESUNDHEIT (BMG)	1
PL	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT - DEPARTMENT OF PROMOTION AND COMMUNICATION	1
PT	MINISTER OF AGRICULTURE AND SEA - MAM	1
RO	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT	
	PERMANENT REPRESENTATION	
SI	MINISTRY OF AGRICULTURE AND THE ENVIRONMENT	1
SK	CENTRAL CONTROL & TESTING INSTITUTE IN AGRICULTURE - DEPARTMENT OF ENVIRONMENTAL PROTECTION AND ORGANIC PROTECTION	1
И	FINNISH FOOD SAFETY AUTHORITY - EVIRA	1
SE	NATIONAL FOOD AGENCY - FOOD STANDARDS DEPARTMENT	2
	SWEDISH BOARD OF AGRICULTURE	
UK	DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS (DEFRA) - ORGANIC TEAM	2
EFTA	-	-
IS	-	-
NO	NORWEGIAN FOOD SAFETY AUTHORITY	2
	NORWEGIAN MINISTRY OF AGRICULTURE AND FOOD - DEPARTMENT OF FOOD POLICY	
CH	FEDERAL DEPARTMENT OF ECONOMIC AFFAIRS FDEA - FEDERAL OFFICE FOR AGRICULTURE FOAG - QUALITY AND SALES PROMOTION SECTION	1

Ref. Ares(2014)2053506 - 23/06/2014

EUROPEAN COMMISSION
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Directorate B. Multilateral relations, quality policy
The Acting Director

Brussels,
JO/sn/agri.ddg1.b.4(2014)2219230

Short report of the 119th meeting of the Standing Committee on Organic Farming of 19 June 2014

President: Michael ERHART

27 Member States were present. Cyprus was absent, and represented by Greece. Norway and Switzerland were present as observers.

Section A – Opinion of the Committee

1. **Draft Commission implementing Regulation (EU) No .../... of XXX amending and correcting Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries**

   Draft Commission Regulation. All delegations voted in favour, totally 352 votes.

Section B – Points for information and/or discussion

1. **Draft Commission Implementing Regulation amending Regulation (EC) No 1235/2008 as regards the recognition of control authorities and control bodies for the purpose of compliance and equivalence in relation to the import of organic products**

   Discussion

2. **Action Plan for the future of Organic production in the European Union COM(2014)179final – presentation by the Commission.**

The Commission presented the new Action Plan for the future organic production in the EU, and answered to the questions of delegates.

1. **Presentation of ongoing work on the electronic certification of imported organic products – Action Plan for the future of Organic Production in the European Union, Action No 12.**

The Commission presented the ongoing work on the development of the electronic certification for imported organic products under the Trade Control and Expert System (TRACES).

2. **Imports of Organic Products (Article 33(2) & (3) of Regulation (EC) No 834/2007): Supervision by the Commission**

The Commission presented a comprehensive overview of monitoring and supervision of imports of organic products under the current three systems for imports: third countries equivalence, control bodies equivalence and import authorisations.

3. **Reporting and notifications under organic production legislation**

An update of the reporting and notifications was provided to the delegations. The Member States were invited to provide in OFIS the missing information due by 1 July 2014.

4. **Irregularities**

a) Update on notification of irregularities concerning EU products

An update concerning EU irregularity notifications and other relevant cases was provided to the delegations and an exchange of views took place.

b) Update on notification of irregularities concerning imported products

Delegates were briefed on irregularities found on imported products.

5. **Examination, according to Article 19 of Regulation (EC) No 1235/2008, of the import authorisations granted to operators concerned by the Vertical Bio operation**

The discussion focused on the information provided by the different delegations and the necessary follow-up.

6. **EGTOP – update information about the different subgroups, Feed II, Food III and Aquaculture**

The COM presented a summary of the EGTOP achievements for the first semester 2014. Four subgroups have met to produce the reports on: PPP (II), Food (III), Feed (II) and aquaculture (B). The recently published PPP (II) report was presented to the delegates..

7. **Import regime (Regulation (EC) No 1235/2008)**

a) Overview on third countries and CBs.

b) Korea, state of play.

The delegations were updated on the state of play of the negotiations on equivalence.

c) Recent on-the spot missions.

The delegations were updated on the state of play of recent on the spot mission to Colombia, Ecuador and Chili and on the reasons for the cancelling of the missions to Thailand and Mexico.

8. Miscellaneous

a) Point raised by AT (*Article 11 of Regulation (EC) n° 834/2007*).

The COM distributed, as agreed in the previous SCOF, the letter replying to the AU question on the interpretation of Article 11 of regulation 834/2007.

b) Commission informed Member States of its intention to propose for vote in the upcoming 8 July meeting a draft regulation extending for 3 years the current derogations on non-organic pullets and allowance for non-organic feed.

c) DE requested information about the recent opinion of EGTOP on potassium phosphonate.

(see point 8)

d) FR wanted to get information on the possible authorisations of the "basic substance" horsetail.

(see point 8)

Addendum to the report of the 118th meeting of the Standing Committee on Organic Farming of 15-16 May 2014

"The DK delegation raised an issue about contamination of Danish apples with an herbicide called "prosulfocarb". According to the Danish administration, traces of this pesticide have been detected on organic farms where apparently the substance was not used but transported by air over large distance. It was detected by a Danish supermarket chain during its own quality control analyses last November 2013. The Danish delegation wanted to inform that they have drawn an action plan which is based on information delivered from stakeholders. The plan contains a broad range of precautionary measures on how to avoid drift and contamination when conventional farmers are using pesticides. They will send a presentation in writing of the case before the next SCOF."

Michael ERHART

Annex: List of participants

List of participants

Standing Committee on Organic Farming of 19 June 2014

Country	Organisation	Number of Participants
BE	SERVICE PUBLIC DE WALLONIE – DG AGRICULTURE, RESSOURCES NATURELLES & ENVIRONNEMENT – DIRECTION DE LA QUALITE	2
	VLAAMSE OVERHEID, AFDELING DUURZAME LANDBOUWONTWIKKELING	
BG	MINISTRY OF AGRICULTURE AND FOOD	1
CZ	MINISTRY OF AGRICULTURE OF THE CZECH REUBLIC	1
DK	MINISTRY OF FOOD, AGRICULTURE AND FISHERIES – THE DANISH VETERINARY AND FOOD ADMINISTRATION – DIVISION FOR FOOD QUALITY, TECHNOLOGY AND MARKETING PRACTICES	2
	MINISTRY OF FOOD, AGRICULTURE AND FISHERIES – AGRI FISH AGENCY	
DE	GERMAN FEDERAL OFFICE FOR FOOD AND AGRICULTURE	3
	LANDESAMT FUR NATUR, UMWELT UND VERBRAUCHERSCHUTZ - NRW	
	BMEL BONN	
EE	MINISTRY OF AGRICULTURE	1
IE	DEPARTMENT OF AGRICULTURE, FISHERIES AND THE MARINE	1
EL	PERMANENT REPRESENTATION OF GREECE TO THE EU	1
ES	MINISTERIO DE AGRICULTURA, ALIMENTACIÓN Y MEDIO AMBIENTE – SUBDIR. GEN. DE CALIDAD DIFERENCIADA Y AGRICULTURA ECOLÓGICA	1
FR	MINISTRY OF AGRICULTURE	2
	INSTITUT NATIONAL DE L'ORIGINE ET DE LA QUALITE	
CR	PERMANENT REPRESENTATION	1
IT	MINISTERO DELLE POLITICHE AGRICOLE ALIMENTARI E FORESTALI – UFFICIO PQA5 – AGRICOLTURA BIOLOGICA	2
CY		-
LV	MINISTRY OF AGRICULTURE	1
LT	MINISTRY OF AGRICULTURE –RESOURCES AND QUALITY POLICY DEPARTMENT – AGRI-ENVIRONMENTAL AND ORGANIC FARMING DIVISION	1

Country	Organisation	Number of Participants
LU	MINISTERE DE L'AGRICULTURE, DE LA VITICULTURE ET DU DEVELOPPEMENT RURAL – ADMINISTRATION DES SERVICES TECHNIQUES DE L'AGRICULTURE	1
HU	MINISTRY OF RURAL DEVELOPMENT – DEPARTMENT OF FOOD CHAIN CONTROL	1
MT	MINISTRY FOR SUSTAINABLE DEVELOPMENT, ENVIRONMENT AND CLIMATE CHANGE	1
NL	MINISTRY OF ECONOMIC AFFAIRS	2
	MINISTRY OF ECONOMIC AFFAIRS AND INNOVATION	
AT	INSTITUTE OF ORGANIC FARMING AND FARM ANIMAL BIODIVERSITY	2
	BUNDESMINISTERIUM FÜR GESUNDHEIT (BMG)	
PL	PERMANENT REPRESENTATION OF POLAND TO THE EU	1
PT	MINISTER OF AGRICULTURE AND SEA – MAM	1
RO	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT	1
SI	MOE	1
SK	PERMANENT REPRESENTATION OF SLOVAKIA TO THE EU	1
FI	PERMANENT REPRESENTATION OF FINLAND TO THE EU	1
SE	NATIONAL FOOD AGENCY – FOOD STANDARDS DEPARTMENT	2
	SWEDISH BOARD OF AGRICULTURE	
UK	NATURAL ENGLAND	2
	DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS (DEFRA) – ORGANIC TEAM	
EFTA		-
IS		-
NO	NORWEGIAN FOOD SAFETY AUTHORITY	2
	NORWEGIAN MINISTRY OF AGRICULTURE AND FOOD - DEPARTMENT OF FOOD POLICY	
CH	FEDERAL DEPARTMENT OF ECONOMIC AFFAIRS FDEA - FEDERAL OFFICE FOR AGRICULTURE FOAG - QUALITY AND SALES PROMOTION SECTION	1

EUROPEAN COMMISSION
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Directorate B. Multilateral relations, quality policy
The Director

Brussels,
JO/sn/agri.ddg1.b.4(2014)3450862

Short report of the 121st meeting of the Standing Committee on Organic Farming of 22-23 September 2014

President: Diego CANGA FANO

28 Member States were present. Norway and Switzerland were present as observers.

Section A – Opinion of the Committee

N/A

Section B – Points for information and/or discussion

1. **Draft Commission Implementing Regulation amending Regulation (EC) No 1235/2008 as regards the recognition of control authorities and control bodies for the purpose of compliance and equivalence in relation to the import of organic products [Ares(2014)432156]**

   The Commission made a presentation on the import of compliant products into the EU.

2. **Draft Regulation amending Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries**

   The Commission presented a working document in relation to the draft Regulation in subject.

3. **Draft Commission implementing Regulation (EU) No …/..of XXX amending and correcting Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control.** (*based on EGTOP Aquaculture reports A and B*)

   Discussion on the Commission proposal which takes into account the EGTOP opinion on Aquaculture A and B reports. Delegations were invited to provide further comments.

4. FVO audits

Presentation by the Commission on the audit working programme for organics in 2015.

5. Reporting and notifications under organic farming legislation

The delegations were updated on the status of received notifications.

6. Irregularities

a) Update on notification of EU irregularities

An update concerning EU irregularity notifications and other relevant cases was provided and an exchange of views took place. Delegations were invited to provide information on specific cases.

b) Update on notification of irregularities concerning imported products

The Commission provided an update of the cases notified between 4/7/2014 and 31/8/2014. Furthermore an analysis of the irregularities notified since 1/1/2013 as regards involvement of Member States and CBs was presented, followed by a discussion on the speed and effectiveness of their handling. Finally, Member States presented five recent cases, followed by a discussion.

7. Chlorate residues in food

The Commission presented the most recent state of play on the recent rise in findings of chlorate residues in food products.

8. Import regime (Regulation (EC) No 1235/2008)

a) Overview on third countries and CBs.

At the Commission's initiative, an authorisation granted pursuant to Article 19 of Regulation (EC) No 1235/2008 was examined by the Committee.

The Commission debriefed the Committee about the last videoconference meeting of the EU-Canada Working Group on organics.

b) Information on the peer review carried out by the USNOP in UK and France on 21-25 July

The Commission presented the findings of the peer review

c) Controls on EU organic dairy production without the use of antibiotics for export to the US under the EU-US equivalence arrangement (outline sent by email to MS delegates on 4 December 2013)

The Commission reminded MS the importance of this outline in the framework of EU-US Equivalence Arrangement.

d) Korea: the state of play was presented

e) OFIS: developments related to the import authorisation module.

The COM informed that no new import authorisations shall be issued in OFIS as of 30 September 2014, due to end of period for granting import authorisations as of 1 July 2014.

9. EGTOP – updated information on current reports: Food III and Feed II

The progress in EGTOP was explained by COM: two draft reports are going to be discussed at the next EGTOP plenary meeting and Aquaculture part B report has been recently published.
The Commission informed delegations about the planning of new mandates for 2015 and asked for comments on the recently updated templates.

10. Miscellaneous[1]

- DE – Imports from Third Countries

The Commission replied to two questions from DE.

- SE – Conditions to be applied to processing of commercial inputs.

The Commission informed that this question could be asked to EGTOP in the framework of the new mandates for 2015.

Diego CANGA FANO

Annex: List of participants

[1] Any subjects that the Member States wish to discuss under point 'Miscellaneous' need to be submitted to the Commission and the other Member States at the latest one week before the meeting of the Regulatory Committee on Organic Production.

List of participants

Standing Committee on Organic Farming of 22-23 September 2014

Country	Organisation	Number of Participants
BE	SERVICE PUBLIC DE WALLONIE – DG AGRICULTURE, RESSOURCES NATURELLES & ENVIRONNEMENT – DIRECTION DE LA QUALITE	2
	VLAAMSE OVERHEID, AFDELING DUURZAME LANDBOUWONTWIKKELING	
BG	MINISTRY OF AGRICULTURE AND FOOD	1
CZ	MINISTRY OF AGRICULTURE OF CZECH REPUBLIC	1
DK	MINISTRY OF FOOD, AGRICULTURE AND FISHERIES – THE DANISH VETERINARY AND FOOD ADMINISTRATION – DIVISION FOR FOOD QUALITY, TECHNOLOGY AND MARKETING PRACTICES	2
	MINISTRY OF FOOD, AGRICULTURE AND FISHERIES – AGRI FISH AGENCY	
DE	BUNDESMINISTERIUM FÜR ERNÄHRUNG LANDWIRTSCHAFT UND VERBRAUCHERSCHUTZ - BMELV	3
	GERMAN FEDERAL OFFICE FOR FOOD AND AGRICULTURE	
	LANDESAMT FÜR NATUR, UMWELT UND VERBRAUCHERSCHUTZ	
EE	MINISTRY OF AGRICULTURE	1
IE	DEPARTMENT OF AGRICULTURE, FISHERIES AND THE MARINE	1
EL	PERMANENT REPRESENTATION	1
ES	MINISTERIO DE AGRICULTURA, ALIMENTACIÓN Y MEDIO AMBIENTE – SUBDIR. GEN. DE CALIDAD DIFERENCIADA Y AGRICULTURA ECOLÓGICA	2
	GOBIERNO DE EXTREMADURA	
FR	MINISTRY OF AGRICULTURE	4
	MINISTRY OF FINANCE	
	INAO PARIS	
	MINISTRY OF ECOLOGY, SUSTAINABLE DEVELOPMENT AND ENERGY	
CR	MINISTRY OF AGRICULTURE	1
IT	MINISTERO DELLE POLITICHE AGRICOLE ALIMENTARI E FORESTALI – UFFICIO PQA5 – AGRICOLTURA BIOLOGICA	2
CY	PERMANENT REPRESENTATION	1
LV	MINISTRY OF AGRICULTURE	2
	CUSTOMS ADMINISTRATION	
LT	MINISTRY OF AGRICULTURE –RESOURCES AND QUALITY POLICY DEPARTMENT – AGRI-ENVIRONMENTAL AND ORGANIC FARMING DIVISION	1
LU	MINISTRY OF AGRICULTURE, VITICULTURE AND CONSUMER PROTECTION	1
HU	MINISTRY OF AGRICULTURE – DEPARTMENT OF FOOD CHAIN CONTROL	1
MT	MINISTRY OF SUSTAINABLE DEVELOPMENT, ENVIRONMENT AND CLIMATE CHANGE	1

Country	Organisation	Number of Participants
NL	MINISTRY OF ECONOMIC AFFAIRS AND INNOVATION	2
AT	MINISTRY OF HEALTH	2
PL	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT – DEPARTMENT OF PROMOTION AND COMMUNICATION	2
	MAIN FOOD AND AGRICULTURAL QUALITY INSPECTION	
PT	MINISTRY OF AGRICULTURE, SEA, ENVIRONMENT AND REGIONAL PLANNING – MAMAOT	1
RO	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT	1
SI	MINISTRY OF AGRICULTURE AND THE ENVIRONMENT	1
SK	CENTRAL CONTROL & TESTING INSTITUTE IN AGRICULTURE - DEPARTMENT OF ENVIRONMENTAL PROTECTION AND ORGANIC PROTECTION	1
FI	PERMANENT REPRESENTATION	1
SE	MINISTRY FOR RURAL AFFAIRS	3
	NATIONAL FOOD AGENCY – FOOD STANDARDS DEPARTMENT	
	SWEDISH BOARD OF AGRICULTURE	
UK	DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS (DEFRA) – ORGANIC TEAM	2
EFTA	–	
IS	–	
NO	NORWEGIAN FOOD SAFETY AUTHORITY	2
	NORWEGIAN MINISTRY OF AGRICULTURE AND FOOD - DEPARTMENT OF FOOD POLICY	
CH	FEDERAL DEPARTMENT OF ECONOMIC AFFAIRS, EDUCATION AND RESEARCH EAER	1

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Brussels,
JO/sn/agri.ddg1.b.4(2014)3195156

Invitation to the meeting of the REGULATORY COMMITTEE ON ORGANIC PRODUCTION

The 121st meeting of the Regulatory Committee on Organic Production will take place on 22 September 2014 from 14:30 until 18:30 & on 23 September 2014 from 09:00 until 18:30 at rue de la Loi 130 – 11th floor - room B

Simultaneous interpretation:
FR-DE-EN-IT-ES to FR-DE-EN-IT-ES

I have the honour to invite the experts from the appropriate departments of the Governments of the Member States to attend a meeting of the Regulatory Committee on Organic Production which will take place on 22 & 23 September 2014 in Brussels at the following address:

European Commission - DG AGRI building
rue de la Loi 130 – B 1049 BRUSSELS
11th floor - room B

AGENDA

Section A – Opinion of the Committee

N/A

Section B – Points for information and/or discussion

1. **Draft Commission Implementing Regulation amending Regulation (EC) No 1235/2008 as regards the recognition of control authorities and control bodies for the purpose of compliance and equivalence in relation to the import of organic products [Ares(2014)432156]**

2. **Draft Regulation amending Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries**

3. **Draft Commission implementing Regulation (EU) No .../..of XXX amending and correcting Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control.** (*based on EGTOP Aquaculture reports A and B*)

4. **FVO audits**

   Presentation of 2015 programme

5. **Reporting and notifications under organic farming legislation**

6. **Irregularities**

   a) Update on notification of EU irregularities

   b) Update on notification of irregularities concerning imported products

   (1) Overview of notifications per 01/09/2014 (pdf attached to invitation and on Circa)

   (a) 26 new cases between 04/07/2014 and 31/08/2014

   (b) Analyses of notifications from 01/01/2013 until 30/08/2014 as regards involvement of Member States and CBs

   (2) Speed and effectiveness of the handling of the 2014 cases. 32 open cases passed their deadline for reply – discussion on possible improvements

   (3) Treatment of cases in which a CB is involved that was removed from the list

   (4) Cases for presentation by the notifying Member State and discussion:

   (a) 9/2014 (BE),

   (b) 18/2014 (DE),

   (c) 28/2014 (DE),

   (d) 54/2014 (IT),

   (e) 26/2014 and 127/2014 (NL)

7. **Chlorate residues in food**

   Information on recent rise in findings of chlorate residues in food products. SANCO E.3 will present latest state of play. (Document 'Guideline on monitoring of chlorates in food and drinking water' posted on Circa)

8. **Import regime (Regulation (EC) No 1235/2008)**

   a) Overview on third countries and CBs.

   b) Information on the peer review carried out by the USNOP in UK and France on 21-25 July

   c) Controls on EU organic dairy production without the use of antibiotics for export to the US under the EU-US equivalence arrangement (outline sent by email to MS delegates on 4 December 2013)

   d) Korea: state of play

   e) OFIS developments related to the import authorisation module.

9. EGTOP – updated information on current reports: Food III and Feed II

10. Miscellaneous[1]

- DE – Imports from Third Countries [Ares(2014)2859782]:

1. How to inform on changes in the standards of equivalent recognized third country.

2. Can a processed product imported from a recognized third country which is composed - like a vanilla paste - of additives which are not listed in the annexes of Regulation (EC) No 889/2008 be used by an operator in the EU as an ingredient of another processed organic product ?

- SE – Conditions to be applied to processing of commercial inputs [Ares(2014)2792963]

***

The Commission will meet the travel expenses of one expert per Member State.

The travelling expenses will be refunded according to the regulation in force and on presentation of the transport document. You are reminded that the banking details, as well as a copy of the transport document, will be required and should be joined to the form of application for reimbursement of expenses.

For each meeting, an application form shall be filled in and signed by the expert.

The original return ticket must be produced during the meeting. You are kindly requested for each meeting to bring with you all travel tickets.

Please ensure that the fare of the travel is shown on the tickets or else provide the relevant invoice.

Please fill in 'the application for reimbursement' form which you have received by email. **Please do not forget your personal label.**

All experts without a label will need to fill in the "expert identification sheet" which you have also received.

Please also read the **Specific Privacy Statement** for processing of personal data related to Comitology Committees on the Organic Farming CIRCABC website:
https://circabc.europa.eu/Agriculture/bio/Library/Specific Privacy Statements

Where a first payment is being made by the Commission or in the case of a new bank account, please see the attached instructions.

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[1] Any subjects that the Member States wish to discuss under point 'Miscellaneous' need to be submitted to the Commission and the other Member States at the latest one week before the meeting of the Regulatory Committee on Organic Production.

If the journey by air involves a flight of 4 hours or more without stopovers the cost of a business class ticket shall be reimbursed.

Air tickets should be booked in economy class, on the basis of the most economical fare available at the moment of the invitation and allowing participation to the meeting and travel during the workweek.

If exceptionally, for reasons beyond the control of experts, seats have to be booked in business class and/or higher rate, the expert must produce with the ticket supporting evidence from the travel agency.

Experts must provide the secretary of the meeting with the documents necessary for their reimbursement, as required by the financial rules applicable in the Commission, by letter, fax or email postmarked or dated no later than 30 calendar days after the final day of the meeting.

Unless the expert can provide a proper justification that is accepted by reasoned decision by the responsible authorising officer, failure to comply with paragraph 2 shall absolve the Commission from any obligation to reimburse travel expenses or pay any allowances.

Yours sincerely,

Diego CANGA FANO

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Ausgabe in deutscher Sprache

Mitteilungen und Bekanntmachungen

56. Jahrgang

10. Dezember 2013

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2013/C 360/02 Genehmigung staatlicher Beihilfen gemäß den Artikeln 107 und 108 des AEU-Vertrags — Vorhaben, gegen die von der Kommission keine Einwände erhoben werden [1] 2

2013/C 360/03 Keine Einwände gegen einen angemeldeten Zusammenschluss (Sache COMP/M.7065 — Triton/Bosch Rexroth Pneumatics Holding) [1] 6

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DE

Preis: 3 EUR

[1] Text von Bedeutung für den EWR

(Fortsetzung umseitig)

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IV *Informationen*

INFORMATIONEN DER ORGANE, EINRICHTUNGEN UND SONSTIGEN STELLEN DER EUROPÄISCHEN UNION

Rat

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DE

BESCHLUSS DER KOMMISSION

vom 9. Dezember 2013

zur Änderung des Beschlusses 2010/206/EU zur Ernennung der Mitglieder der Sachverständigengruppe für technische Beratung bezüglich der ökologischen/biologischen Produktion sowie zur Erstellung der Reserveliste

(2013/C 360/09)

DIE EUROPÄISCHE KOMMISSION —

gestützt auf den Vertrag über die Arbeitsweise der Europäischen Union,

gestützt auf den Beschluss 2009/427/EG der Kommission vom 3. Juni 2009 zur Einsetzung einer Sachverständigengruppe für technische Beratung bezüglich der ökologischen/biologischen Produktion [1], insbesondere auf Artikel 4 Absatz 2

in Erwägung nachstehender Gründe:

(1) Mit dem Beschluss 2004/427/EG hat die Kommission eine Sachverständigengruppe für technische Beratung bezüglich der ökologischen/biologischen Produktion (im Folgenden: „die Gruppe") eingesetzt. Mit dem Beschluss 2010/206/EU der Kommission [2] wurden die ständigen Mitglieder der Gruppe ernannt und eine Reserveliste für einen bestimmten Anwendungszeitraum dieses Beschlusses bis 31. Dezember 2013 erstellt.

(2) Die technische Beratung bezüglich der ökologischen/biologischen Produktion spielt vor dem Hintergrund der Entwicklung des ökologischen Landbaus/der biologischen Landwirtschaft eine wichtige Rolle. Ferner muss die Kontinuität der Arbeit der Gruppe sichergestellt werden. Die Anwendung von Beschluss 2010/206/EU und das Mandat der ständigen Mitglieder sollten daher um weitere drei Jahre verlängert werden.

(3) Gemäß dem Beschluss 2009/427/EG muss ein Zeitraum von drei Jahren für die Mandate der ständigen Mitglieder und den Anwendungszeitraum des Beschlusses festgelegt werden. Die Zulassungsverfahren für Stoffe und Verfahren, einschließlich technischer Beratung, müssen jedoch an bevorstehende rechtliche Entwicklungen im Zusammenhang mit der ökologischen/biologischen Produktion angepasst werden, erforderlichenfalls auch kurzfristig. Die ständigen Mitglieder der Gruppe sollten daher auf eine mögliche Überprüfung ihres Mandats im Zuge der laufenden Überprüfung der Rechtsvorschriften für den ökologischen/biologischen Landbau vorbereitet sein.

(4) Aufgrund des Rücktritts von drei der ständigen Mitglieder der Gruppe werden drei Sachverständige aus der Reserveliste in Anhang II des Beschlusses 2010/206/EU zu ständigen Mitgliedern ernannt. Die Listen in Anhang I und Anhang II des genannten Beschlusses sollten daher aktualisiert werden.

(5) Der Beschluss 2010/206/EU sollte daher entsprechend geändert werden —

BESCHLIESST:

Artikel 1

Der Beschluss 2010/206/EU wird wie folgt geändert:

1. In Artikel 2 wird das Datum „31. Dezember 2013" durch „31. Dezember 2016" ersetzt.

2. Anhang I erhält die Fassung des Anhangs des vorliegenden Beschlusses.

3. In Anhang II werden folgende Namen von der Liste gestrichen:

„— Keith BALL

— Michel BOUILHOL

— Roberto GARCÍA RUIZ"

Artikel 2

Dieser Beschluss tritt am Tag seines Erlasses in Kraft.

Brüssel, den 9. Dezember 2013

Für die Kommission
Dacian CIOLOŞ
Mitglied der Kommission

[1] ABl. L 139 vom 5.6.2009, S. 29.
[2] Beschluss 2010/206/EU der Kommission vom 28. September 2010 zur Ernennung der Mitglieder der Sachverständigengruppe für technische Beratung bezüglich der ökologischen/biologischen Produktion sowie zur Erstellung der Reserveliste (ABl. C 262 vom 29.9.2010, S. 3).

ANHANG

„ANHANG I

A. **Alphabetische Liste der ab 1. Januar 2014 für eine erste Mandatsperiode als ständige Mitglieder der Gruppe ernannten Sachverständigen**

— Keith BALL

— Michel BOUILHOL

— Roberto GARCÍA RUIZ

B. **Alphabetische Liste der ab 1. Januar 2014 für eine zweite Mandatsperiode als ständige Mitglieder der Gruppe ernannten Sachverständigen**

— Alexander BECK

— Jacques CABARET

— Niels HALBERG

— Sonya IVANOVA-PENEVA

— Lizzie Melby JESPERSEN

— Nicolas LAMPKIN

— Giuseppe LEMBO

— Robin Frederik Alexander MORITZ

— Bernhard SPEISER

— Fabio TITTARELLI"

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy
B.4. Organics

Expert Group for Technical Advice on Organic Production (EGTOP)
Sub group on aquaculture

MEETING OF 13-15 NOVEMBER 2013

Summary minutes

1. WELCOME, INTRODUCTION AND ADOPTION OF THE AGENDA

After a welcome speech and introduction by the representative of the Secretariat, the Chair of the group took over.

This introduction was followed by a 'tour de table' for all participants to briefly introduce themselves, presenting their professional background, affiliations and areas of expertise.

When asked to declare interests on matters on the agenda none of the members provided additional information to the interests already declared before the meeting.

All the members signed a declaration of confidentiality and a declaration of commitment.

The Agenda was then adopted (ANNEX I).

2. WORKING METHOD, TERM OF REFERENCE, REPORT

The Secretariat gave an overview of the working procedures of the Group and referred the experts to the internet site http://ec.europa.eu/agriculture/organic for more information.

3. DISCUSSION ON THE ITEMS INTO THE TERMS OF REFERENCE

Discussions on matters included in the terms of reference took place on the first and second day of the meeting. During the third day the Sub-group members reached a final conclusion by consensus on the topics discussed. The final report will be adopted by the Group in plenary session and published on the internet site http://ec.europa.eu/agriculture/organic

ANNEX I

Group meeting of EGTOP on organic aquaculture 13-15 November 2013

DRAFT AGENDA 13 November 2013

1. INTRODUCTION: **9:30 - 11:00**
    - Declaration of interests
    - Declaration of Confidentiality related to this meeting
    - Declaration of commitment
    - Adoption of the agenda
2. Reports and working methods: **11:00 - 12:45**
    - Procedures
    - Reports structure and content
    - Term of reference
3. Any other business **13:45 – 14:00**
4. Discussion on the items into the terms of reference **14:00 – 18:00**

DRAFT AGENDA 14 November 2013

5. Discussion on the items into the terms of reference **9:30 – 12:45**
6. Preparation of the draft report **14:15 – 18:00**

DRAFT AGENDA 15 November 2013

7. Preparation of the draft report **9:30 – 12:45**
8. Preparation of the draft report and conclusions **14:15 – 16:30**

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy
B.4. Organics

SHORT MINUTES

EXPERT GROUP ON TECHNICAL ADVICE ON ORGANIC FARMING (EGTOP)

SUBGROUP ON PLANT PROTECTION PRODUCTS (II) 18-20 MARCH 2014

Chair: Roberto Garcia Ruiz (RGR)
Rapporteur: Bernard Speiser (BS)

Members
Eckhart Reines
Cristina Micheloni
Markus Kelderer
Cornel Adler

Secretariat
João Onofre
Luis Martin Plaza
René L'Her
Suzana Median
Louis Mahy

1. Introduction, agenda and declarations of interests

Following the short introduction by COM and the clarifications on the roles of chairman and rapporteur, some agenda issues were clarified:

- The removal of pyrethroids
- The inclusion of a question regarding pyperonil butoxides.

When asked to declare interests with regard to matters on the agenda none of the members provided additional information to the interests already declared before the meeting. In accordance with Chapter 5.1.2 of the Rules of procedure of the Group, one expert were allowed full participation with the exception of the specific discussion on the conclusions concerning one substance.

All the members signed a declaration of confidentiality and a declaration of commitment.

The Agenda was then adopted as proposed (ANNEX I).

2. Working method, terms of reference, report

The Secretariat gave an overview of the working procedures of the Group and referred the experts to the internet site *www.organic-farming.europa.eu* for more information.

3. Discussion on the items from the terms of reference

Discussions on matters included in the terms of reference took place on all three days of the meeting. During the third day the Subgroup reached a final conclusion by consensus on the topics discussed, except for potassium phosphonate, where the Subgroup remained divided. The final report will be adopted by the Group in plenary session and published on the internet site *www.organic-farming.europa.eu*.

ANNEX 1

Sub-group meeting of EGTOP on Plant Protection (II)

MEETING OF 18 – 20 March 2014

DRAFT AGENDA 18 March 2014

1. **Introduction:** **13:00 – 15:00**
    - Declaration of interests
        - Specific
    - Declaration of Confidentiality related to this meeting
    - Declaration of commitment
    - Adoption of the agenda
2. **Reports and working methods:** **15:00 – 15:15**
    - Procedures
    - Reports structure and content
    - Term of reference
3. **Any other business:** **15:15– 15:30**
4. **Discussion on the items into the terms of reference:** **15:30– 17:00**

DRAFT AGENDA 19 March 2014

5. **Discussion on the items into the terms of reference:** **9:00 – 12:45**
    - Lunch break
6. **Preparation of the draft report:** **13:45 – 17:00**

DRAFT AGENDA 20 March 2014

7. **Preparation of the draft report:** **9:00 – 12:45**
    - Lunch break
8. **Preparation of the draft report and conclusions** **13:45 – 17:00**

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR MARITIME AFFAIRS AND FISHERIES

INTERNATIONAL AFFAIRS AND MARKETS
TRADE AND MARKETS

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate H. Sustainability and Quality of Agriculture and Rural Development
H.3. Organic farming

Expert Group for Technical Advice on Organic Production

Mandate for technical advice on organic aquaculture

▪ Background

Organic aquaculture is a relatively new addition to the scope of EU organic legislation having been added for the first time by Council Regulation 834/2007. The implementing rules were introduced via Commission Regulation 710/2009 which amended the main implementing rules for organic farming introduced by Commission Regulation 889/2008. The rules for aquaculture have applied for almost three years, i.e. since 1 July 2010. The final paragraph of Article 2 of R. 710/2008 states: "This Regulation may be revised on the basis of relevant proposals from Member States, which are accompanied by a duly justified motivation, with a view of the modification of this Regulation from 1 July 2013."

Relevant proposals and dossiers have been received from eight Member States in the period November 2012 to April 2013 and all of the requests except two are the subject of this mandate. Following the circulation of the first draft of this mandate comments and some additional proposals were received from four MS, three which has not made submissions earlier. The request from Belgium, to delete the food additive sodium metabisulphite (E 223), currently permitted for use with crustaceans, from Annex VIII, is covered in the separate Mandate for technical advice on organic food. The UK's request to add Acetic acid as a processing aid for aquaculture products is also contained in the organic food Mandate.

The first four topics have been raised by several Member States and relate to the use of non-organic juveniles, issues relating to maximum production density, the lack of approved substances for cleaning and disinfection in the presence of animals and permitted feed sources and feed additives. Other issues which have been raised in a single request relate to reproduction in shrimps/prawn, the need for specific rules for juveniles, invertebrates and microalgae/plankton.

Prior to the formation of EGTOP via Commission Decision 2009/427 the Commission convened an Ad-hoc group which met in November 2008 to provide advice on the use of certain fish feed additives and cleaning substances in organic aquaculture. While many of the issues from 2008 are the subject of the new requests, it would be pertinent to have EGTOP review and update the 2008 advice also for those issues which are not specifically covered by the seven topics above.

The group is therefore requested to prepare a report with technical advice on the matters included in the terms of reference.

▪ Terms of Reference

In the light of the most recent technical and scientific information available to the experts, the group is requested to report on the following list of requests in two parts.

PART A

1. **The use of non-organic juveniles** in the context of the sequential phasing out of their use by 31.12.2015 (except for the specific cases involving the natural influx of fish and crustaceans, and also European glass eels and wild mollusc seed).

   France, Italy, Germany and Spain have pointed out the lack of organic juveniles and the consequent difficulty in meeting the requirement to ensure that at least half come from organic sources by the end of 2013 and by two years from this date that all juveniles will be from organic sources. France points to the difficulty which the sector is having in meeting these requirements for a wide range of organic aquaculture, including oysters, freshwater fish, marine fish and shrimps and links this to the early stage of development and lack of critical mass of organic production (grow-out) generally. Italy points out that some of the difficulty is related to the need to source from a compartment of equal status under the aquaculture animal health rules (Council Directive 2006/88EC) and that in exceptional cases Member States should be allowed to issue exemptions under the flexibility rules (Article 22(2)(b) of R 834/2007). Spain points to the lack of juveniles for seabass and seabream and Germany to trout. Sweden proposes, in the context of the difficulty experienced in phasing out non-organic juveniles in agriculture that EGTOP consider if there are species, in additional to eels, for which it may be necesary to accept non-organic juveniles for a long time yet (in addition to the exceptions listed in the heading above).

2. **Permitted feed sources and feed additives**. A number of countries (France, Italy and the UK) have questioned the requirement in Article 25k that the raw material for fishmeal and fish oil be restricted to (food) fish trimmings and have requested that this be reviewed and that **fresh raw fish** from sustainable fisheries be permitted. Spain has asked that the **availability of trimmings** from organic aquaculture and sustainable fisheries be assessed. France would like to clarify that trimmings from crustaceans and molluscs can also be used in addition to trimmings of fish. Likewise, in its comments on the draft mandate, Sweden supports a clarification that trimmings from mussels can be used.

   In addition France and Italy have requested that the restrictions in Article 25l (maximum10% fishmeal and fish oil in ration) be reviewed in order to increase that %, particularly as regards *Penaeid* shrimps.

   Linked to the abovementioned restriction on the use of fresh raw fish, the UK has submitted a dossier for the use of the amino acid **histidine** as a feed additive for aquaculture feeds; this has been supported by Ireland. Italy has expressed an interest in the issue of ensuring supply of essential amino acids (histidine and others which are not specified) and linked to this refers to the alternative protein sources permitted in conventional aquaculture feed under

Regulation (EU) No 56/2013. The opinion of EGTOP on the use of such sources in organic aquaculture feeds it therefore requested.

France has requested that conventional sources of **lecithin** and purified **cholesterol** be permitted if organic sources are not available.

PART B

3. **Stocking Density** for the main species or groups of species, other than molluscs, is set out in Annex XIIIa of R.889/2008. Article 25f(2) of the Regulation states that "in considering the effects of stocking density on the welfare of farmed fish, the condition of the fish (such as fin damage, other injuries, growth rate, behaviour expressed and overall health) and the water quality shall be monitored." France has requested that the maximum stocking density for Brown trout and Rainbow trout grown in fresh water be increased from 25 kg/m^3 to 35 kg/m^3 (supported by Bulgaria in comments on the draft mandate) and that the maximum farming yield of freshwater species in fishponds (carp, perch, pike etc.) be reduced from 1 500 kg of fish per hectare per year to 500 kg.(Bulgaria supports annual production below 1500 kg/ha). Italy has requested that the maximum allowed density for trout is reduced from 25 to 20 kg/m^3, and that the maximum density for the charr be increased from 20 to 25 kg/m^3.) Sweden requests that the EGTOP mandate include advice on the possibility to regulate the stocking densities for the crayfish species, *Astacus astacus* and *Pacifastaccus leniusculus*, both in ponds and for larvae and breeding ponds indoors. Sweden also proposes that EGTOP evaluate the pros and cons of closed recirculation systems in relation to Articles 3 to 5 of Regulation 834/2007. Advice on this area should include reference to density.

4. **Substances for cleaning and disinfection in the presence [and absence] of animals** require particular care and measures to ensure that the application in not harmful (according to Recital 17 of R. 710/2009). Currently only two substances are listed in Annex VII(2.2) and several requests have been received to add the following substances:

   - **Chloramine T/ Tosylchloramide sodium** - France has submitted a dossier and the application has been supported by Italy
   - **Hydrogen peroxide** (liquid or powder **(Sodium percarbonate)** - France and Ireland have submitted dossiers and their applications have been supported by Italy and Denmark. This substance is currently permitted for use in the absence of animals
   - **Sodium chloride** – France and Denmark have applied for its inclusion. This substance is currently permitted for use in the absence of animals
   - **Peracetic acid [and peroctanoic acid]** – France, Italy and Denmark have applied for the inclusion of Peracetic acid and France has submitted a dossier with its application for peroctanoic acid. Both substances are currently permitted for use in the absence of animals.
   - **[Hypochlorous acid** – The UK has applied for inclusion of this bleach formulation (active ingredient from potassium monopersulphate in combination) use in absence of animals. It is likely to be safer than sodium hypochlorite bleach (currently permitted for use in the **absence of animals**) as it does not produce toxic chlorine and is considered to have greater efficacy against pathogens].

   Regarding lime (calcium oxide) which is currently permitted in the absence of animals, Denmark has pointed to the need for clarification that this also applies to **slaked lime (calcium hydroxide),** formed when lime is mixed (slaked) with water. Denmark has also

indicated an interest in having slaked lime listed under 2.2 (use in presence of animals) and is willing to prepare a technical dossier.

5. **Reproduction.** Germany has pointed to the need for harmonization of the interpretation of the **prohibition of eyestalk ablation** for reproduction in shrimp. EGTOP should clarify the term ablation in relation to hatchery practices such as ligation, incision, pinching etc. which do not directly remove the eyestalk.

6. **Specific rules for juveniles, invertebrates and microalgae/plankton**. In the context of the lack of organic juveniles mentioned under point 1) above, Spain has pointed to the need to develop **specific rules for the production of juvenile fish** to ensure continuity of production.

   Spain has requested that rules be developed for zooplankton, rotifers, micro-crustaceans, worms and other aquatic feed organisms. Spain has also pointed to the need for rules concerning multicellular marine algae/phytoplankton and microalgae for use as feed and food with particular focus on the use of nutrients of plant or mineral origin listed in Annex 1.

7. **Reconfirmation of ad-hoc Expert advice of 2008.** For the issues not mentioned above it would be useful that the group re-examine the advice provided by the Ad-hoc group five years ago on the other topics with a view to reconfirming or updating it. It should be noted that in the exchanges regarding the EU proposal to include organic aquaculture in Codex Guideline 32-1999 on Organically produced foods, one country has questioned the suitability of potassium permanganate and iodophores for cleaning and disinfection in the absence of animals. This country has also queried the use of sodium chloride and humic acid for the same use (on account of not being familiar with their use for this purpose).

In preparing its report the group is invited to examine technical dossiers provided to the Commission by the Member States.

- ## Deadline

The deadline for adoption of the **Part A final report** is: **5 December 2013.**

The deadline for adoption of the **Part B final report**: **to be determined**

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy
B.4. Organics

Expert Group for Technical advice on Organic Production (EGTOP)
9th PLENARY MEETING
28-30 April 2014

Short Minutes

LIST OF PARTICIPANTS MEMBERS

- Keith Ball
- Alexander Beck (AB)
- Michel Bouilhol
- Jacques Cabaret
- Roberto Garcia Ruiz (RGR)
- Niels Halberg (NH)
- Sonya Ivanova-Peneva
- Nicolas Lampkin (NL)
- Giuseppe Lembo (GL) (Chair)
- Lizzie Melby Jespersen (LMJ) (absent)
- Robin Frederik Alexander Moritz
- Bernhard Speiser (BS) (Rapporteur)
- Fabio Tittarelli (absent)

Secretariat:

- João Onofre (absent)
- Luis Martín Plaza (LMP)
- Suzana Median
- Louis Mahy

MINUTES

The Chair opened the meeting by setting the agenda. This was followed by the discussion on the Food II subgroup report.

WELCOME, INTRODUCTION AND ADOPTION OF THE AGENDA

After a welcome speech, the Secretariat introduced the issues to discuss during the meeting. The agenda was adopted.

FOOD (II) DRAFT REPORT

It was stressed that the Food II mandate mostly covers food flavourings. Ascorbic acid, a widely used product, should be authorized for use in organic production. Also lecithin is accepted for use. The same goes for citric acid, but here again the attention is drawn to possible biotech origins. On carrageenan, the Group concluded that a final decision on its inclusion can only be taken after a re-evaluation of the substance by EFSA. Glycerol and pectin are considered in line with the organic principles, contrary to, hydroxypropyl methyl cellulose, which is considered unnecessary.

PPP (II) DRAFT REPORT

In the PPP subgroup report, potassium phosphonate was the first on the list and showed to be highly controversial. During the revision of the text, several paragraphs had to be rewritten. It was concluded that potassium phosphonate is not in line with the organic principles. Neither was piperonyl butoxide. The use of Kieselgur and CO_2 on the other hand was considered in line with the organic principles. On potassium bicarbonate there was a request to include a remark why this substance should be allowed in addition to other substances already authorized with the same function. With respect to fatty acid potassium salts, the members disagreed on how to interpret the EFSA report, especially because of various data gaps relating to the risk assessment.

On basic substances the Group concluded that there should not be an automatic authorization but possibly a faster *evaluation* procedure. However, how this could take shape has to be decided. The group substances were mostly approved. Copper compounds were dropped from the list of group substances with a special status, and also pheromones needed some revision. After several suggestions concerning the legal context and stakeholders' perception, the correct wording for the issue on the specification of use categories in Annex II was chosen.

DATES FOR FUTURE MEETINGS IN 2014 & RULES OF PROCEDURE

COM presented the EGTOP program for the coming months. The chairs/rapporteurs/members/timing of the aquaculture B, food III and feed II were chosen. Regarding the feed II report, the urgency is confirmed and there were some dossiers added, as well as for aquaculture.

GL introduced the issue of the election of chair and vice-chairs. He informed about the applications received: AB as chair, LMJ and NL as vice-chairs. AB, LMJ and NL were then elected unanimously, respectively chair and vice-chairs.

OTHER BUSINESS

The final report on FOOD (II) and PPP (II) will be published on the http://ec.europa.eu/agriculture/organic

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy
B.4. Organics

Expert Group for Technical Advice on Organic Production

Mandate for technical advice on organic food (III)

▪ Background

In recent years, several Member States have submitted dossiers under the second subparagraph of Article 21(2) of Council Regulation (EC) No 834/2007[1] concerning the possible inclusion, deletion or change of deposition of a number of substances in Annex VIII to Commission Regulation (EC) No 889/2008[2], or more generally, on their compliance with the above-mentioned legislation. Furthermore, several Member States have requested also evaluation of some techniques used in food production in terms of their usefulness to and compliance with the EU organic farming legislation. Besides, in order not to jeopardize the work on the priorities set by the previous mandate, the EGTOP Report on Organic Food 5/2012 did not assess the use of the following substances: ozone as post-harvest treatment of plant products and acetic acid as processing aid in the fish production. Therefore, the Group is requested to prepare report with technical advice on the matters included in the terms of reference.

▪ Terms of reference

In the light of the most recent technical and scientific information available to the experts, the Group is requested:

1. To answer if the use of the below listed **substances/techniques** are in line with the objectives, criteria and principles as well as the general rules laid down in Council Regulation (EC) No 834/2007 and, hence, can be authorised to be used in organic production under the EU organic farming legislation:

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[1] Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91.(O.J. L 189 , 20/07/2007, p. 1.)

[2] Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, OJ L 250, 18.9.2008, p. 1–84

a) **Substances:**

- BE dossier (2012): **Gellan gum** (E 418) as food additive
- BE dossier (2013): **Sodium hydroxide (NaOH)** (E 524) for use as processing aid in the peeling of salsify
- ES dossier (2013): **Potassium ferrocyanide** (E 536) as food additive, in particular anti-caking agent
- ES dossier (2014) : **Sorbic acid** (E-200) as food additive In the processing of beaten egg-free dough baked goods
- UK dossier (2013): **Fruit acid washes** – based formulations composed of citric acid, ethanol, sodium alkyl sulphate, grapefruit oil as processing aid for removal of bacterial load from wash water
- FR dossier (2011): **Acetic acid** (E 260) as processing aid in the fish production
- FR dossier (2011): **Ammonium bisulphate, ammonium sulphate** (E 517), **chitin-glucane** and **chitosan** for use or addition in organic products of the wine sector.
- FR dossier (2013): **Carrageeneans** for all products of animal origin
- CZ dossier (2014): **hydrochloric acid** for the use as a reagent for dextrin production (preparation of foodstuffs of plant origin).
- IT dossier (2014): **Erythritol** in section A to replace sugar in a wide variety of applications

b) **Techniques:**

- NL dossier (2011): **Ozone** as post-harvest treatment of plant products
- ES dossier (2011) supported by comments from AT (2001, 2012), UK (2008) and IT (2013, 2014): **Ion exchange technology** in organic production (i.e. different applications: e.g. starch syrup de mineralisation and purification, whey demineralisation, juice demineralisation and neutralization, gelatine production, glucose and fructose production from grape or other fruit etc.).
- IT dossier (2014): **Chromatographic cation exchange resins** for separation of glucose and fructose from rectified concentrated must.
- NL dossier (2013): **Electroporation** as electronic preservation practice of organic food and feed.

- NL dossier (2013): **Plasma gas technique** as electronic preservation practice of organic food and feed.
- IT dossier (2014): **Mannoproteins** extracted from yeast for tartrate stabilization of wines

2. To reconfirm if the use of the following substance – BE dossier (2012): **sodium metabisulphite** (E 223) – included in the current list in Annex VIII to Commission Regulation (EC) No 889/2008 is still compliant with organic farming principles. The Group should consider possible alternatives to the substances/techniques in question and/or review the specific conditions for the use of the substances/techniques listed therein including the grouping in animal and/or plant products. Any such proposal(s) should be accompanied by a brief explanation of the reasons.

In preparing the final report, the Group may also assess if food processing methods included in the EU organic farming regulation are in line with the organic farming principles.

▪ Deadline

The deadline for adoption of the final report: **31 October 2014**

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy
B.4. Organics

Expert Group for Technical Advice on Organic Production

Mandate for technical advice on feed II

Background

In recent years, several Member States have submitted dossiers under Article 16(3)(b) of Council Regulation (EC) No 834/2007 concerning the possible inclusion of a number of substances in Annex V and VI to Commission Regulation (EC) No 889/2008.

In relation to feed substances, 2011 Austria launched a request concerning lignocellulose. In 2012 Ireland and Italy made a request concerning selenised yeast (selenium in organic form/selenomethionine produced by *Saccharomyces cerevisiae*). Mussel meal, meal from bivalve molluscs as a feed material were requested by Sweden 2009. Belgium submitted a dossier on dicopper chloride trihydroxide and zinc chloride hydroxide monohydrate in 2013.

Terms of reference

In the light of the most recent technical and scientific information available to the experts, the Group is requested to answer if the use of the following substances is in line with the objectives, criteria and principles as well as the general rules laid down in Council Regulation (EC) No 834/2007 and whether they can therefore be authorised in organic production under the EU legislation:

Substances:

- AT dossier (2011): **Lignocellulose**

- IE/IT dossier (2012): **Selenised yeast (Selenium in organic form/selenomethionine produced by *Saccharomyces cerevisiae*)**

- SE dossier (2009): **Mussel meal, meal from bivalve molluscs**

- BE dossier (2013): **Dicopper chloride trihydroxide**

- BE dossier (2013): **Zinc chloride hydroxide monohydrate**

- Three FR dossiers(2014): **Processing aids for alfafa concentrate**

The Commission would like to get also the advice from the group as regards the following:

- Alignments of terms of the EU feed legislation (Regulation (EC) No 1831/2003) and Annex VI to Commission Regulation (EC) No 889/2008, as regards the group of vitamins and provitamins.

- Suckling period that need to be respected for different species of animals.

- Use of additives or processing aids that are already included in the list of food additives for the same use on feed.

-Use of earthworms or insects as a source of protein.

- Update of the 2011 EGTOP report on feed as regards the availability of protein feed, in particular essential amino-acids, for monogastrics. In case of remaining supply difficulties, are there new solutions?

In preparing its final report, the Group may also suggest amendments to the current list in Annex V and VI to Commission Regulation (EC) No 889/2008 as well as take into account possible alternatives to the substances in question. In such cases, the proposal(s) should be accompanied by a brief explanation of the reasons.

Deadline

The deadline for adoption of the final report is 9 of October 2014.

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy
B.4. Organics

Expert Group for Technical Advice on Organic Production

Mandate for technical advice on organic aquaculture (Part B)

▪ Background

Organic aquaculture is a relatively new addition to the scope of EU organic legislation having been added for the first time by Council Regulation 834/2007. The implementing rules were introduced via Commission Regulation 710/2009 which amended the main implementing rules for organic farming introduced by Commission Regulation 889/2008. The rules for aquaculture have applied for almost three years, i.e. since 1 July 2010. The final paragraph of Article 2 of R. 710/2008 states: "This Regulation may be revised on the basis of relevant proposals from Member States, which are accompanied by a duly justified motivation, with a view of the modification of this Regulation from 1 July 2013."

The group is therefore requested to prepare a report with technical advice on the matters included in the terms of reference.

▪ Terms of Reference

In the light of the most recent technical and scientific information available to the experts, the group is requested to report on the following list of requests.

1. **Stocking Density** for the main species or groups of species, other than molluscs, is set out in Annex XIIIa of R.889/2008. Article 25f(2) of the Regulation states that "in considering the effects of stocking density on the welfare of farmed fish, the condition of the fish (such as fin damage, other injuries, growth rate, behaviour expressed and overall health) and the water quality shall be monitored." France has requested that the maximum stocking density for Brown trout and Rainbow trout grown in fresh water be increased from 25 kg/m^3 to 35 kg/m^3 (supported by Bulgaria in comments on the draft mandate) and that the maximum farming yield of freshwater species in fishponds (carp, perch, pike etc.) be reduced from 1500 kg of fish per hectare per year to 500 kg (Bulgaria supports annual production below 1500 kg/ha). Italy has requested that the maximum allowed density for trout is reduced from 25 to 20 kg/m^3, and that the maximum density for charr be increased from 20 to 25 kg/m^3. Sweden requests that the EGTOP mandate include advice on the possibility to regulate the stocking densities for the crayfish species, *Astacus astacus* and *Pacifastaccus leniusculus*, both in ponds and for larvae and breeding ponds indoors. Sweden also proposes that EGTOP evaluate the pros and cons of closed

recirculation systems in relation to Articles 3 to 5 of Regulation 834/2007. Advice on this area should include reference to density.

2. **Substances for cleaning and disinfection in the presence [and absence] of animals** require particular care and measures to ensure that the application in not harmful (according to Recital 17 of R. 710/2009). Currently only two substances are listed in Annex VII(2.2) and several requests have been received to add the following substances:

   - **Chloramine T/ Tosylchloramide sodium** - France has submitted a dossier and the application has been supported by Italy
   - **Hydrogen peroxide** (liquid or powder **(Sodium percarbonate)** - France and Ireland have submitted dossiers and their applications have been supported by Italy and Denmark. This substance is currently permitted for use in the absence of animals.
   - **Sodium chloride** – France and Denmark have applied for its inclusion. This substance is currently permitted for use in the absence of animals.
   - **Peracetic acid [and peroctanoic acid]** – France, Italy and Denmark have applied for the inclusion of Peracetic acid and France has submitted a dossier with its application for peroctanoic acid. Both substances are currently permitted for use in the absence of animals.
   - **Hypochlorous acid** – The UK has applied for inclusion of this bleach formulation (active ingredient from potassium monopersulphate in combination) use in absence of animals. It is likely to be safer than sodium hypochlorite bleach (currently permitted for use in the **absence of animals**) as it does not produce toxic chlorine and is considered to have greater efficacy against pathogens.

   Regarding lime (calcium oxide) which is currently permitted in the absence of animals, Denmark has pointed to the need for clarification that this also applies to **slaked lime (calcium hydroxide),** formed when lime is mixed (slaked) with water. Denmark has also indicated an interest in having slaked lime listed under 2.2 (use in presence of animals) and is willing to prepare a technical dossier.

3. **Reproduction.**

   a. Germany has pointed to the need for harmonization of the interpretation of the **prohibition of eyestalk ablation** for reproduction in shrimp. EGTOP should clarify the term ablation in relation to hatchery practices such as ligation, incision, pinching etc. which do not directly remove the eyestalk.

   b. Spain requested a clarification on the use of hormones (natural or artificial) for certain species as sturgeon, turbot and eels to reach the sexual maturity needed for reproduction.

4. **Specific rules for juveniles, invertebrates and microalgae/plankton**. In the context of the lack of organic juveniles mentioned under point 1) above, Spain has pointed to the need to develop **specific rules for the production of juvenile fish** to ensure continuity of production.

Spain has requested that rules be developed for zooplankton, rotifers, micro-crustaceans, worms and other aquatic feed organisms. Spain has also pointed to the need for rules concerning multicellular marine algae/phytoplankton and microalgae for use as feed and food with particular focus on the use of nutrients of plant or mineral origin listed in Annex 1.

5. **Reconfirmation of ad-hoc Expert advice of 2008.** For the issues not mentioned above it would be useful that the group re-examine the advice provided by the Ad-hoc group five years ago on the other topics with a view to reconfirming or updating it. It should be noted that in the exchanges regarding the EU proposal to include organic aquaculture in Codex Guideline 32-1999 on Organically produced foods, one country has questioned the suitability of potassium permanganate and iodophores for cleaning and disinfection in the absence of animals. This country has also queried the use of sodium chloride and humic acid for the same use (on account of not being familiar with their use for this purpose).

In preparing its report the group is invited to examine technical dossiers provided to the Commission by the Member States.

▪ Deadline

The deadline for adoption of the **Part B final report**: **30 June 2014**

4

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy
B.4. Organics

Expert Group for Technical Advice on Organic Production
EGTOP

Final Report on Aquaculture (part A)

The EGTOP adopted this technical advice at the 8th plenary meeting of 03-05 December 2013

About the setting up of an independent expert panel for technical advice

With the Communication from the Commission to the Council and to the European Parliament on a European action plan for organic food and farming adopted in June 2004, the Commission intended to assess the situation and to lay down the basis for policy development, thereby providing an overall strategic vision for the contribution of organic farming to the common agricultural policy. In particular, the European action plan for organic food and farming recommends, in action 11, establishing an independent expert panel for technical advice. The Commission may need technical advice to decide on the authorisation of the use of products, substances and techniques in organic farming and processing, to develop or improve organic production rules and, more in general, for any other matter relating to the area of organic production. By Commission Decision (EC) No 427/2009[1] of 3 June 2009, the Commission set up the Expert Group for Technical Advice on Organic Production.

EGTOP

The Group shall provide technical advice on any matter relating to the area of organic production and in particular it must assist the Commission in evaluating products, substances and techniques which can be used in organic production, improving existing rules and developing new production rules and in bringing about an exchange of experience and good practices in the field of organic production.

EGTOP Permanent Group

- Alexander Beck
- Michel Bouilhol
- Keith Ball
- Jacques Cabaret
- Niels Halberg
- Sonya Ivanova-Peneva
- Lizzie Melby Jespersen
- Nicolas Lampkin
- Giuseppe Lembo
- Robin Frederik Alexander Moritz
- Roberto Garcia Ruiz
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[1] Commission Decision (EC) No 427/2009 of 3 June 2009 establishing the expert group for technical advice on organic production (O.J. L 139, 5.6.2009, p. 29–31)

The report of the Expert Group presents the views of the independent experts who are members of the Group. They do not necessarily reflect the views of the European Commission. The reports are published by the European Commission in their original language only.
http://ec.europa.eu/agriculture/organic/home_en

Acknowledgments:

Members of the Sub-group are acknowledged for their valuable contribution to this technical advice. The members are:

- Giuseppe Lembo (chair)
- Elena Mente (rapporteur)
- Alicia Estevez Garcia
- Alfred Jokumsen

Secretariat:

- João Onofre
- Luis Martín Plaza
- Eoin Mac Aoidh
- Suzana Median
- Iva Bažon
- Louis Mahy

All declarations of interest of Permanent Group members are available at the following webpage:
http://ec.europa.eu/agriculture/organic/home_en

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1. EXECUTIVE SUMMARY

In consideration of:

- the lack of organic juveniles reported by some MS;
- the restriction on the movement of live animals between countries and regions based on the Council Directive (EC) No 88/2006[2];
- the reluctance of farmers to introduce on their farms animals which could be unsuitable for the local (geographical) environment (e.g. genetic or population traits, resistance to different diseases, growth performances, reproductive cycle, behavioural characteristics, etc.); and
- the lack in the Commission Regulation (EC) No 889/2008[3] of specific organic rules for managing the life cycle stage between the hatching and the weaning of juveniles,

the Group supports the use of non-organic juveniles, for on-growing purposes, when organic aquaculture juvenile animals are not available, subject to the following restrictions/recommendations:

a) Organic juveniles should be used when available.
b) At least the latter two thirds of the duration of the production cycle shall be managed under organic management (Article 25(e)(2) of Commission Regylation (EC) No 889/2008).
c) After the approval of specific organic rules for the life cycle stage between hatching and weaning of juveniles, a transitional period may be established to allow farmers to comply with the new rules.

Furthermore, the Group supports the creation of a database on the availability of organic juveniles produced in each country, comparable to the seed database (Article 48 of Commission Regulation (EC) No 889/2008). Transparency of the use of non-organic juveniles should be ensured in such a database.

Some typical aquaculture practices of extensive fish farming in wetlands, such as brackish water ponds, tidal areas and costal lagoons, closed by levees and banks, have been carried out in Italy and Spain, as well as in other coastal areas of Europe, for many centuries.
The Group recognizes the high value of these extensive aquaculture practices, in terms of cultural heritage, biodiversity conservation and economic perspectives for the local communities.
The Group also recognizes that moving wild fry from the sea into the lagoon does not necessarily affect the stock status of the species concerned.
Therefore, with the exception of eels, the Group considers that restocking of wild fry in the extensive aquaculture farming carried out inside wetlands, such as brackish water ponds, tidal areas and costal lagoons is in line with the objectives, criteria and principles of organic aquaculture production, subject to the following restrictions:

a) A management plan, approved by the local or national authority, that ensures the sustainable exploitation of the species concerned, should be provided.
b) In extensive aquaculture farming carried out inside wetlands, such as brackish water ponds, tidal areas and coastal lagoons, the fish shall be fed with feed naturally available in the environment.

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[2] Council Directive (EC) No 2006/88 of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals

[3] Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control

In the Group's opinion, fish should cover their needs for amino acids and fatty acids primarily through the natural compounds of the feed. In order to comply with the general rules on feed (cfr. Article 25(j) of Council Regulation (EC) No 889/2008), namely: "... optimum performance, animal health, high product quality, including the nutritional composition which shall ensure high quality of the final edible product and low environmental impact", the diet for carnivorous fish should be characterized by a well-balanced proportion of amino acids, fatty acids and lipids.

The Group also recognizes the specific needs of animal protein and lipids in the diet of shrimps, although in different proportion according to life stages. Therefore, the Group supports a limited use of fishmeal and fish oil derived from sustainable fisheries, as a supplement of the feed naturally available in the rearing environment of shrimps. Such feed rations could be up to 10% for the fish oil and up to 25% for the fish meal.

The Group is concerned about the consequences of the listed priorities of sourcing feed as laid down in Council Regulation (EC) No 889/2008 Article 25(k). Indeed, with respect to fish meal derived from trimmings, the risk is that the levels of phosphorus contained in such fish meal might result in conflicts with national environmental legislation.

Since fish meal and fish oil are limited resources, finding alternative protein sources for fish meal is clearly a high priority for organic aquaculture. Similarly, developing production of aquafeeds that: a) satisfy aquatic organisms' nutritional requirements for specific amino acids and fatty acids, b) suit their feeding habits and c) result in a high retention of nutrients to maintain animal health and to achieve good quality final products is a high priority.
As a consequence, the Group supports the use of alternative protein sources in organic aquaculture, when available and appropriate for brood-stock, weaning, and on-growing diets. The development of organic alternative protein sources should be considered a priority.

Considering all these issues, the Group concluded that the following alternative options should be considered, in order of priority:

a) Besides fish meal and fish oil derived from trimmings of fish, crustaceans and molluscs, also fish meal and fish oil derived from "whole fish not used for human consumption", caught in sustainable fisheries, should be allowed as ingredients in feed for organic carnivorous fish. This includes feed for fry and brood-stock, as well as for on-growing fish, until sufficient alternative sources of protein and oil are available.
b) The use of other alternative feed materials consisting of whole micro or macro organisms with high content of essential amino acids and lipids, where possible produced organically, may be needed and are to be preferred to the use of purified or free amino acids as feed supplements/additives.
c) If not available from organic procedures, essential amino acids and lipids obtained by fermentation or other similar procedures should be allowed as ingredients/additives in carnivorous fish feed only if specifically authorised.

In the case of histidine, the approval in the specific context recommended by the Group should not be seen as a precedent for the use of histidine as a feed additive outside aquaculture, nor for the use of other free amino acids as feed additives for any type of livestock. Other uses / substances should be evaluated separately.

2. BACKGROUND

Organic aquaculture is a relatively new addition to the scope of EU organic legislation having been added for the first time by Council Regulation 834/2007[4]. The implementing rules were introduced via Commission Regulation (EC) No 710/2009[5] which amended the main implementing rules for organic farming introduced by Commission Regulation 889/2008. The rules for aquaculture have applied for almost three years, i.e. since 1 July 2010. The final paragraph of Article 2 of Commission Regulation (EC) No 710/2009 states: "This Regulation may be revised on the basis of relevant proposals from Member States, which are accompanied by a duly justified motivation, with a view of the modification of this Regulation from 1 July 2013."
The group is therefore requested to prepare a report with technical advice on the matters included in the terms of reference.

3. TERMS OF REFERENCE

In the light of the most recent technical and scientific information available to the experts, the group is requested to report on the following list of requests.

1. **The use of non-organic Juveniles** in the context of the sequential phasing out of their use by 31.12.2015 (except for the specific cases involving the natural influx of fish and crustaceans, and also European glass eels and wild mollusc seed).
   France, Italy, Germany and Spain have pointed out the lack of organic juveniles and the consequent difficulty in meeting the requirement to ensure that at least half come from organic sources by the end of 2013 and by two years from this date that all juveniles will be from organic sources. France points to the difficulty which the sector is having in meeting these requirements for a wide range of organic aquaculture, including oysters, freshwater fish, marine fish and shrimps and links this to the early stage of development and lack of critical mass of organic production (grow-out) generally. Italy points out that some of the difficulty is related to the need to source from a compartment of equal status under the aquaculture animal health rules (Council Directive (EC) No 2006/88[6]) and that in exceptional cases Member States should be allowed to issue exemptions under the flexibility rules (Article 22(2)(b) of Council Regulation (EC) No 834/2007). Spain points to the lack of juveniles for seabass and seabream and Germany to trout. Sweden proposes, in the context of the difficulty experienced in phasing out non-organic juveniles in agriculture that EGTOP consider if there are species, in additional to eels, for which it may be necessary to accept non-organic juveniles for a long time yet (in addition to the exceptions listed in the heading above).

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[4] Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91.(O.J. L 189 , 20/07/2007, p. 1.)

[5] Commission Regulation (EC) No 710/2009 of 5 August 2009 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007, as regards laying down detailed rules on organic aquaculture animal and seaweed production

[6] Council Directive (EC) No 2006/88 of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (*O.J. L 328, 24.11.2006, p. 14–56*

2. **Permitted feed sources and feed additives.** A number of countries (France, Italy and the UK) have questioned the requirement in Article 25k that the raw material for fishmeal and fish oil be restricted to (food) fish trimmings and have requested that this be reviewed and that fresh raw fish from sustainable fisheries be permitted, Spain has asked that the availability of trimmings from organic aquaculture and sustainable fisheries be assessed. France would like to clarify that trimmings from crustaceans and molluscs can also be used in addition to trimmings of fish. Likewise, in its comments on the draft mandate, Sweden supports a clarification that trimmings from mussels can be used.
In addition France and Italy have requested that the restrictions in Article 251 (maximum 10% fishmeal and fish oil in ration) be reviewed in order to increase that %, particularly as regards Penaeid shrimps.
Linked to the above mentioned restriction on the use of fresh raw fish, the UK has submitted a dossier for the use of the amino acid histidine as a feed additive for aquaculture feeds; this has been supported by Ireland. Italy has expressed an interest in the issue of ensuring supply of essential amino acids (histidine and others which are not specified) and linked to this refers to the alternative protein sources permitted in conventional aquaculture feed under Commission Regulation (EU) No 56/2013[7]. The opinion of EGTOP on the use of such sources in organic aquaculture feeds it therefore requested. France has requested that conventional sources of lecithin and purified cholesterol be permitted if organic sources are not available.

   In preparing its report the group is invited to examine technical dossiers provided to the Commission by the Member States.

[7] Commission Regulation (EU) No 56/2013 of 16 January 2013 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (*O.J. L 21, 24.1.2013, p. 3–16)*

4. CONSIDERATIONS AND CONCLUSIONS

4.1. The use of non-organic juveniles

4.1.1 The lack of organic juveniles

State of the art

The Group recognizes the information provided by the MS delegations of Bulgaria, France, Germany, Italy, Romania, Spain and Sweden, on the lack of organic juveniles, as expressed in the Terms of Reference.

Although there are no official data on the number of certified organic hatcheries in Europe, the Group has information on a few hatcheries (e.g. a trout hatchery in Denmark) that have recently converted or are in the process of conversion to organic production (www.eurofishmagazine.com, June 3/2013).

Therefore, the present production of organic juveniles seems inadequate to supply the growing demand of the organic aquaculture industry.

Main difficulties

Besides the lack of organic juveniles, due to the few hatcheries certified as organic, one of the main difficulties experienced by the sector is the restriction on the movement of live animals between countries and regions based on the "*Directive 2006/88/EC on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals*".

This Directive established five categories of health status in which countries, zones and compartments have to be classified, and rules to be followed for introducing or dispatching animals among areas with different health status classification.

A second barrier to the movements of seed or juveniles among farms is due to the reluctance of farmers to introduce on their farms animals which could be unsuitable for the local (geographical) environment (e.g. genetic or population traits, resistance to different diseases, growth performances, reproductive cycle, behavioural characteristics, etc.).

Furthermore, the Group fully supports the view put forward by Spain concerning the lack in Commission Regulation (EC) No 889/2008 of specific organic rules for managing the life cycle stage between the hatching and the weaning of juveniles. This lack of organic regulation concerns fresh water species (e.g. stocking density, husbandry environment) and, even more, marine species (e.g. phytoplankton and zooplankton production, essential nutrients in the trophic chain, stocking density during larval rearing and weaning, husbandry environment).

The Group considers that production rules for the phase of the life stage between hatching and weaning of juveniles would have a strong influence in determining the characteristics of the adult (e.g. skeletal and pigmentation anomalies, immune resistance, etc.).

Because of the lack of detailed organic rules in this area it is difficult to distinguish organic and non-organic hatcheries.

Conclusions

Owing to the lack of organic juveniles reported by some MS and the main difficulties pointed out above, the Group supports the inclusion of specific rules for the life cycle stage between hatching and weaning of juveniles in the organic regulation, as soon as possible. This would give higher credibility of the rules for both farmers and consumers.

Furthermore, the Group supports the creation of a database on the availability of organic juveniles produced in each country as for the Seed database (ref. Article 48 of Commission Regulation (EC) No 889/2008). Transparency of the use of non-organic juveniles should be ensured in such a database.

Commission Implementing Regulation.(EU) No 1030/2013[8] of 24 October 2013 postponed to January 1, 2015 the compliance deadline in Paragraph 11 of Article 95 of Commission Regulation (EC) No 889/2008, for those aquaculture and seaweed production units which were established and produced under nationally accepted organic rules before 1 January 2009.
Considering the above issues and the new regulation, the Group supports the use of non-organic juveniles, for on-growing purposes, when organic aquaculture juvenile animals are not available, subject to the following restrictions/recommendations:

a) Organic juveniles should be used when available.
b) At least the latter two thirds of the duration of the production cycle shall be managed under organic management (Article 25(e)(2) of Commission Regulation (EC) No 889/2008).
c) After the approval of specific organic rules for the life cycle stage between hatching and weaning of juveniles, a transitional period should be established to allow farmers to comply with the new rules.

4.1.2. Restocking in lakes, earth ponds of tidal areas and costal lagoons

Historical and traditional extensive aquaculture

Some typical aquaculture practices of extensive fish farming in wetlands, such as brackish water ponds, tidal areas and costal lagoons, closed by levees and banks, have been carried out in Italy and Spain, as well as in other coastal areas of Europe, for many centuries. These traditional extensive farming systems involve the control of the hydraulic circulation and water renewal in lagoons as well as selective fish "seeding".
The management of these areas is mainly aimed at the exploitation of euryhaline species migrating into the coastal lagoons from the sea and backwards, in particular with capture systems placed at the communication channels between the lagoon and the open sea, which enable the selective capture of the different species and, in the more complex systems, of different sizes of the same species.
Nowadays, due to the significant decrease of fish immigration from the sea, specific restocking actions are carried out in several coastal lagoons with wild fry, mainly sea bass, sea bream, mullets and eels. Article 25(e) of Commission Regulation (EC) No 889/2008 does not allow such restocking practices, preventing farmers obtaining organic certification for their production.
Extensive aquaculture inside coastal lagoons has been traditionally developed, over a period of three centuries, especially in Northern Italy, along the Adriatic sea coast, as well as along the Mediterranean and Atlantic coasts of Almeria, Cádiz and Huelva in Spain, the Greek coast and the Black Sea coast of Bulgaria.
Coastal lagoons can be regarded as being relevant also from a historical perspective and as a cultural heritage for coastal lagoon communities concerned. For these communities, extensive aquaculture represents also an activity of common interest in terms of preservation of traditional knowledge and biodiversity conservation.
Nevertheless, the Group is concerned about the catching of juvenile eels for organic eel farming because of the declining population due to over-fishing and environmental pollution and because eels are a critically endangered red list species and captured eels cannot breed.

[8] Commission Implementing Regulation (EU) No 1030/2013 of 24 October 2013 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (O.J. L 283, 25.10.2013, p. 15–16)

Conclusions

The Group recognizes the high value of these extensive aquaculture practices, in terms of cultural heritage, biodiversity conservation and economic perspective for the local communities.
The Group also recognizes that moving wild fry from the sea into the lagoon does not necessarily affect the stock status of the species concerned.
Therefore, with the exception of eels, the Group considers that restocking of wild fry in the extensive aquaculture farming carried out inside wetlands, such as brackish water ponds, tidal areas and costal lagoons is in line with the objectives, criteria and principles of organic aquaculture production, subject to the following restrictions:

a) A management plan, approved by the local or national authority, that ensures the sustainable exploitation of the species concerned, should be provided.
b) In extensive aquaculture farming carried out inside wetlands, such as brackish water ponds, tidal areas and costal lagoons, the fish shall be fed with feed naturally available in the environment.

4.2 Permitted feed sources and feed additives

4.2.1. Dietary requirements of carnivorous fish

Sustainable and environmentally-efficient use of aquaculture feed

Fishmeal of high quality provides a balanced amount of all essential amino acids, minerals, phospholipids and fatty acids reflected in the normal diet of fish (Hardy, 2010; Lund et al., 2012). In particular, a diet based on marine sources secures optimum development, growth and reproduction, especially of farmed larvae and brood-stock. Fish oil is a major natural source of the omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which cannot be synthesized by the fish, but are produced by marine phyto- and zooplankton, which are consumed by the wild fish larvae (Baron et al, 2013).
However, the global supply of fish meal and of fish oil is no longer able to meet the increasing demand from an expanding aquaculture industry and, due to the increasing prices of fish meal and fish oil, the aquaculture sector has been forced to look for alternative ingredients including plant products (cf. section 4.2.4) (Gatlin et al., 2007, Hardy 2010).
Replacing fish meal and fish oil is not straightforward due to their unique contents of protein, excellent amino acid profile, high nutrient digestibility, high palatability, adequate amounts of micronutrients, as well as general lack of anti-nutrients in fish meal and the high contents of long-chained polyunsaturated fatty acids in fish oil (Gatlin et al., 2007; Kaushik and Seiliez, 2010; Krogdahl et al., 2010; Lund et al., 2012).
Organic aquaculture is an alternative production approach driven by the growing interest in sustainable utilization of resources (Mente et al., 2011). There is increasing concern about the consumption of fish meal and fish oil. Indeed, the current European regulation on organic aquaculture (Commission Regulation (EC) No 889/2008) does not allow fish meal and fish oil derived from whole fish, but only from trimmings of fish from organic aquaculture or from trimmings of fish already caught for human consumption in sustainable fisheries, in order to reduce the risk that fishing primarily to produce fishmeal will further contribute to fish stock depletion. Further, the regulation does not allow balancing the dietary amino acid profile by supplementing with synthetic free amino acids to fulfil the dietary requirements of the specific organically produced species.
A large number of studies have investigated the effects of replacing fish meal with various plant protein ingredients (Borquez et al., 2011; Glencross et al., 2011; Pratoomyot et al., 2010; Torstensen et al., 2008; Yang et al., 2011). Complete replacement is usually not successful due to problems related to the factors mentioned above and the altered patterns of amino acid uptake

when replacing fish meal with plant based protein ingredients (Bendiksen et al., 2011; Borquez et al., 2011; Espe et al., 2006; Francis et al., 2001; Gatlin et al., 2007; Larsen et. al., 2012; Lund et al., 2011).
High replacement ratios require that anti-nutrients and indigestible substances are efficiently removed from alternative protein ingredients to meet the high protein requirement of fish. Furthermore, it is necessary to ensure that the dietary amino acid profile is optimised, for example by adding free amino acids, and/or by combining several plant protein sources with different amino acid composition (Francis et al., 2001; Kaushik and Seiliez, 2010; Wilson, 2002).
However, as mentioned above supplementation with synthetic amino acids is not allowed according to Council Regulation (EC) No 834/2007 Article. 15 1d. (IV) and currently no amino acids are listed in Annex VI of Commission Regulation (EC) No 889/2008. Furthermore, procedures for the removal of anti-nutrients have to follow organic rules. Finally, there is less availability of relevant organic plant sources to optimize the amino acid profile in comparison to conventional plant sources (Lund et al., 2011; Rembiałkowska, 2007).
Lysine and methionine are often the most limiting amino acids when fish meal is replaced by plant protein sources (Mai et al., 2006). The amino acids which are in excess when the first limiting amino acid runs out will be broken down producing energy and nitrogen (mainly excreted as ammonia with potential adverse environmental impacts) instead of being converted to fish meat. Therefore, a carefully balanced amino acid profile is important for the growth of the fish, as well as the minimization of nitrogen discharge.
The replacement of fish meal by vegetable proteins is further complicated because not only the overall dietary amino acid profile is important for efficient utilisation of amino acids, but also the timing by which amino acids from different protein sources appear in the blood stream after a meal (Larsen et al., 2012)
Larsen et al. (2012) investigated plasma free amino acid concentration patterns in juvenile rainbow trout (*Oncorhynchus mykiss*) fed either a fish meal based diet (FM) or a diet (VEG) where 59% of fish meal protein (corresponding to 46% of total dietary protein) was replaced by a mixture of plant proteins from wheat, peas, field beans, sunflower and soybean. Results showed that the appearance of most amino acids (essential and non-essential) in the plasma was delayed in fish fed the VEG diet compared to those fed the FM diet. Essential and non-essential amino acids furthermore appeared more or less synchronously in the plasma in fish fed the FM diet, while the appearance was less synchronised in fish fed the VEG diet. Further there were 2.7 times more indigestible carbohydrates in the VEG diet than in the FM diet, which suggested that the uptake of amino acids was affected by dietary carbohydrates. In conclusion, the study showed that amino acid uptake patterns were affected when replacing fish meal with plant based protein ingredients.

Further considerations

High quality fish meal with an optimal amino acid profile has a high nutrient digestibility and hence high utilization by the fish that results in minimum discharge of nutrients to the environment.
For larvae and juveniles it is critical to secure optimum feed quality for survival and growth. Similarly for brood stock it is essential to secure optimum egg quality.
Hence, fish meal and fish oil are strategic ingredients to be used at critical stages of the life-cycle, when optimum performance is required.
It should be ensured that the marine ingredients are obtained from sustainable sources, and that the fisheries in question are being managed in compliance with the FAO Code of Conduct for Responsible Fishing. However, the availability and increasing prices of fish meal and fish oil will counteract and limit the inclusion rates of these limited resources and increase the pressure for alternative sources to balance the specific amino acid requirements of farmed fish species.

The issue of how the dietary requirements of carnivorous fish, can be met is addressed in subsequent sections 4.2.3. and 4.2.4.

4.2.2. Dietary requirements of shrimps

Feeding habits

The most important shrimp species in aquaculture are *L. vannamei* (White shrimp), *P. monodon* (Giant tiger shrimp), *M. rosenbergii* (Freshwater prawn) (Valderrama 2011).

Although they are all benthivore species, they have different diets in their natural habitats:

- *M. rosenbergii* is an omnivorous benthivore, and mainly feeds on algae (FAO-FIMA 2011);
- *L. vannamei* is an omnivorous benthivore, and mainly feeds on living preys and detritus (FAO 2011);
- *P. monodon* is a carnivorous benthivore and mainly feeds on worms, crustaceans and molluscs (Tacon 2002, Piedad-Pascual 1984).

These differences in feeding habits are due to the amount of enzymes in the digestive tract of the different shrimps. Carnivorous shrimps have proteolytic enzymes like trypsin and chymotrypsin whereas herbivorous species have more glucolytic enzymes like amylase. This is why carnivorous shrimp have a greater ability to digest protein and herbivorous shrimp have greater ability to digest plant material.

Nutritional requirements

The need for protein varies among species. The life stage of the animal is also important, younger stages have higher needs than older stages (sub-adults and adults) due to the different growth rate (Weir 1998).

According to the available scientific literature, the needs for protein can vary for:

- *P. monodon* between 35 and 50% of the dry matter in feed (Fox et al., 1998; Cousin, 1995; FAO 2011; Dayal et al., 2003; McVey, 1993).
- *L. vannamei* between 20 and 30% of the dry matter in feed (Velasco et al. 2000; Cruz-Suarez et al. 2000; Kureshy and Davis 2002).
- *M. rosenbrergii* between 30 and 38% of the dry matter in feed (Freuchtnicht et al. 1988; Reed and D'Abramo 1989).

Lipids are also essential components of the diet of shrimps. Lipids are mainly used for direct energy production and cell membrane building.

For *P. monodon*, *M. rosenbergii* and *L. vannamei* the optimal lipid level is between 6 and 8% of the feed dry matter (Alday Sanz 2011; Tiwari and Sahu, 1999), but should not be above 10% (Glencross 2002) or below 2% (Chen, 1998).

Some lipids are more important than others because they cannot be synthesized *de novo* or not in sufficient amounts by shrimps. Phospholipids (e.g. lecithin) and cholesterol are the two main categories of essential lipids for shrimps. They are also used as emulsifiers for lipid digestion (Glencross and Smith, 1998). Without phospholipids in their diet, shrimps are unable to digest lipids properly.

According to the available scientific literature, the need for phospholipids is as follows:

M. rosenbergii – around 5% of the diet (Tiwari and Sahu, 1999);

P. monodon – 1% of the diet for post-larvae (Paibulkichakul et al., 1998) and 1.25% for juveniles (Chen 1993);

L. vannamei, – the requirements for lecithin and cholesterol are linked together.

Cholesterol is a ring compound, which is part of cell membranes and is also necessary in the moulting process (see chapter on cholesterol).

According to the literature, the need for cholesterol varies among the different species of shrimps and according to the different life stages.

- For *M. rosenbergii*, cholesterol need is quite high at 0.3-0.6% of the diet (Sahu, 2004), but this species is able to use phytosterols contained in plants instead of cholesterol as ecdysone precursors, so the amount added in the diet can be reduced significantly (Mitra et al., 2005).
- For *P. monodon,* cholesterol need is lower, but it is crucial and cannot be replaced. Requirements are 1% of the diet for post-larvae (Paibulkichakul et al.,1998) and 0.17% of the diet for juveniles (Smith et al., 2001).
- For *L. vannamei*, there is a relationship between cholesterol and phospholipids. A diet with no phospholipids requires 0.35% cholesterol, whereas a diet with 5% phospholipids requires only 0.05% cholesterol (Gong et al., 2000). A good combination seems to be 0.15% of cholesterol for 1% or more phospholipids.

Conclusions

The Group recognizes the clear differences between shrimp species, their feeding habits and their nutrient requirements. Furthermore, all the above considerations show the need for animal protein and lipids in the diet of shrimps, although in different proportions according to their life stages. Therefore the Group recognises the need for the use of fish meal and fish oil in the diet of shrimps.

Article 25.1 of Commission Regulation (EC) No 889/2008 states: "*1. Aquaculture animals as referred to in Annex XIIIa, Section 6, Section 7 and Section 9 shall be fed with feed naturally available in ponds and lakes. ... 3. Where natural feed is supplemented according to paragraph 2 the feed ration of species as mentioned in section 7 and of siamese catfish (Pangasius spp.) as mentioned in section 9 may comprise a maximum of 10 % fishmeal or fish oil derived from sustainable fisheries*".

With reference to the above article, the Group supports a limited use of fishmeal and fish oil derived from sustainable fisheries, as a supplement to the feed naturally available in the rearing environment. In the case of shrimps only, such feed rations should not be above 10% for fish oil, as in the current regulation, but could be up to 25% for fish meal.

4.2.3. Fish meal and fish oil from trimmings

According to Commission Regulation (EC) No 889/2008, feeding regimes shall be designed with the following priorities: (a) animal health, (b) high product quality, including the nutritional composition which shall ensure high quality of the final edible product; (c) low environmental impact.

However, the Group is concerned about the consequences of the listed priorities of sourcing feed as laid down in Commission Regulation (EC) No 889/2008 Article 25k.

The Group considers that the levels of phosphorus in the fish meal derived from trimmings might conflict with national environmental legislations, because this may result in too high P-concentrations. Fish meal from trimmings is lower in protein and higher in phosphorus content compared with high quality fish meal (Eurofins; www.ffskagen.dk). The presence of carcass remnants (head, skin, bones) in trimmings also increases the phosphorus content of the fish meal. Using this meal for feeding fish puts limitations on the inclusion level so as to comply with environmental legislation. Danish environmental legislation only allows the phosphorus content of fish feed to be max. 0.9% (max. 1% on dry weight basis) (www.retsinformation.dk/Forms/R0710.aspx?id=140333).

Eurofins (www.eurofins.dk/dk/f0devarer-agro.aspx) has found phosphorus content of traditional fish meal up to 2.2%, while the phosphorus content of trimmings was 2.4%. Based on these findings, using 41% of traditional fish meal in the diet will theoretically result in 0.9% of phosphorus in the diet, not taking into account other potential phosphorus sources. Under the same conditions, using the same amount of trimming-meal would result in a phosphorus content

of 0.99% in the feed for organic aquaculture. Thus, to comply with the environmental legislation, the diet could contain 37.5% trimming meal, while, conventional fish feeds contains about 25% fish meal, and for conventional feeds a long list of alternatives exists, with the diets balanced by supplementing free amino acids.
The challenges are much higher for producing feeds for organic aquaculture because the list of available ingredients is limited and supplementation with synthetic amino acids is not allowed according to Council Regulation (EC) No 834/2007 Article 15(1)(d) (IV) and currently no amino acids are listed in Annex VI of Commission Regulation (EC) No 889/2008.
Fish meal and fish oil from organic aquaculture trimmings are also not allowed in the feed for aquaculture animals of the same species. As a result, only limited quantities of trimmings from organic farming are available. The current organic fish production (excluding shellfish and others) is about 25,000 t (Zubiaurre, 2013). About 50% of this is sold as whole fish from the farm itself, fish shops etc. and the remaining 50% is processed into fillets, yielding about 50-60%, leaving about 40–50% trimmings. The amount of trimmings available for manufacturing of fish meal and fish oil may therefore be about 5–6,000 t. Assuming a yield of fish meal and oil of max. 20% and 6% respectively, this means a production of approximately 1,000 t of fish meal and 300 t of fish oil. Taking the needs of different species into account, these amounts are only sufficient for a very limited organic production and are below the critical level needed for sustainable manufacturing processes.
The manufacturing process to obtain fish meal and oil from trimmings is similar to that of wild caught industrial fish (Sand eel, blue whiting etc.). However, due to the carcass remnants and the little remaining meat, the protein content of the meal from trimmings is 67–70% and the ash content is about 15%. Further, the digestibility is below 90% (pers. com. Claus Christoffersen, FF, Skagen, Denmark), whilst it should be at least 90% in a high quality fish meal.
Carnivorous fish requires relative high dietary protein content, i.e. 38-48% of the diet, depending on fish size, with the highest requirement and quality for fry and brood-stock. This means that, to produce an adequate feed, the inclusion rate of fish meal from trimmings should be high, which conflicts with the limitations of max. 0.9% dietary phosphorus content. Furthermore, the available organic plant sources are limited and their amino acid profiles are not adequately balanced to make an optimum fish feed (Lund et al., 2011). As discussed previously, the breakdown of surplus amino acids is likely to result in increased environmental impact and reduced growth, health and welfare of the fish.
With reference to the specific question asked by some MS, as regards the eligibility of the use of trimming from crustacean and molluscs, the Group's opinion is that such use is not prohibited by the Commission Regulation (EC) No 889/2008.

Conclusions

In the Group's opinion, the animals' need for amino acids and fatty acids should be met primarily through natural feed compounds. Fishmeal and fish oil are important components of this, particularly for carnivorous aquaculture animals, which have specific amino acid and other nutritional requirements.
However, the Group concluded that, for carnivorous fish, this is not possible using fish trimmings alone, due to its lower quality.
In conclusion, the Group's opinion is that in order to comply with the general rules on feed (cfr. Article 25(j) of Commission Regulation (EC) No 889/2008), namely: "... *optimum performance, animal health, high product quality, including the nutritional composition which shall ensure high quality of the final edible product and low environmental impact*", the diet for carnivorous fish should include fish meal derived not only from trimmings but also from whole fish, not used for human consumption, caught in sustainable fisheries. This includes feed for fry and brood-stock, as well as for on-growing fish, until sufficient alternative sources of proteins and oils are available.

4.2.4. Alternative protein sources

State of the art

Since fish meal and fish oil are limited resources, finding alternative protein sources for fish meal is clearly a high priority for organic aquaculture. Similarly, developing production of aquafeeds that: a) satisfy aquatic organism's nutritional requirements for specific amino acids and fatty acids, b) are suited to their feeding habits and c) result in a high retention of nutrients to maintain animal health and produce a good quality final product, is a high priority. Improvements in protein retention efficiency of farmed aquatic animals are needed to reduce any potential environmental impacts of organic aquaculture and, also, to make more efficient use of dietary protein, the most expensive component of diet formulations for fish. Research into alternatives to fish meal is now an international research priority. A "metabolically" optimized protein and lipid diet formulation per species and per life cycle of farmed aquatic animal is the focus of current aquatic animal nutrition research.

Alternative proteins sources are needed to replace fishmeal, especially for diets of carnivorous species. Plant proteins (soybean, rapeseed, corn gluten, wheat gluten, pea and lupin meals) can replace fishmeal up to 25–35% (Pereira and Oliva-Teles, 2003; Hardy 2010; Enami 2011). The feed ration may comprise a maximum of 60% of organic plant products (Commission Regulation (EC) No 889/2008, Article 25(k)(3)). Mente et al., (2011) reviewed nutrition in organic aquaculture and organic diets. The review showed that an organically certifiable yeast-based protein source could replace up to 25% of the fishmeal without affecting growth rates, feed efficiency or biological indices in cobia fish. Substitution levels above this resulted in decreased performance in all measured parameters. Fishmeal and soybean meal were replaced with an organic diet (yeast), and there was no difference in growth rates in tilapia. Another study replaced fishmeal with a plant-based diet (algal fermentation), in shrimps *Litopenaeus vannamei*, and showed that there were no significant difference in final production, survival and food conversion ratios (FCR). However, fishmeal diet deposited more 22:6n-3 (docosaheaxaenoic acid, DHA) in shrimp's tissues in comparison with the plant-protein diet. The effect of organic fertilization and organic diets on production of channel catfish in earthen ponds was also investigated.

Organically cultivated seaweed or sustainably harvested wild seaweed, including all multicellular marine algae or phytoplankton and microalgae, may be used as feed ingredient.

Other potential sources of proteins, such as wild-harvested and/or cultured annelid worms, insect larvae/pupae, gastropods (e.g. golden apple snail) is also considered promising in order to replace fishmeal in the future (Bergleiter et al. 2009).

Processed animal protein (PAP) is an important ingredient in feeds and provides a valuable source of animal by-product utilization. PAP has a high nutritional value making it an excellent alternative to imported proteins such as soya. It has a significantly higher protein value (45-90% on a fed basis) than plant feed ingredients. PAP contains 10 % phosphorus, which is low in relation to the content of amino acids. While there may be consumer and producer concerns about the feeding of PAP to fish, due to the potential transmission of prions, the scientific panel opinion published by the European Food Safety Authority (EFSA) in 2011 concluded that processed animal protein in feed for food producing non-ruminants, respecting the proposed ban on intra-species recycling, presents a negligible risk to human health (EFSA, 2011).

The use of insects as a source of protein in fish diets is also being explored. The nutritive value of insects as feeds for fish, poultry and pigs has been recognised for some time in China, where studies have demonstrated that insect-based diets are cheaper alternatives to those based on fish meal. The insects used are the pupae of silkworms (*Bombyx mori*), the larvae and pupae of house flies (*Musca domestica*) and the larvae of the mealworm beetle, *Tenebrio molitor*. Silkworm pupae are an important component of cultured carp diets in Japan and China. Dried ground

soldier fly larvae have been fed to chickens and pigs with no detrimental effects (Newton et al., 1977; Hale, 1973). In recent years there has been some interest in the use of housefly maggot meal as a substitute for fish meal in tilapia and African catfish diets (Adesulu and Mustapha, 2000; Fasakin et al., 2003; Ajani et al., 2004; Ogunji et al., 2006). Bondari and Shepherd (1987) observed that channel catfish and blue tilapia fed on soldier fly larvae for 10 weeks were acceptable as food by consumers. Growth and organoleptic quality were not affected when common carp were fed on non-defatted silkworm pupae, a major by-product of the sericulture industry in India (Nandeesha et al., 2000). Ng et al. 2001demonstrated that *T. molitor* larvae meal was highly palatable to the African catfish (*Clarias gariepinus*) and could replace up to 40% of the fish meal component without reducing growth performance.
St-Hilaire et al. (2007) describe a study in which they determined if black soldier fly (*Hermetia illucens*) pre-pupae and housefly pupae could be used as a partial replacement for fish meal and fish oil in rainbow trout (*Oncorhynchus mykiss*) diets. Their data suggest that a rainbow trout diet in which black soldier fly pre-pupae or housefly pupae constitute 15% of the total protein has no adverse effect on feed conversion efficiency over a 9-week feeding period. However, rainbow trout fed on black soldier fly diets low in fish oil had reduced levels of omega-3-fatty acids in the muscle. According to the researchers, modifying the diet of the fly larvae could improve digestibility and fatty acid content of the pre-pupae, which in turn could enhance the fatty acid profile of the fish fed on the fly pre-pupae. The use of the black soldier fly in manure management, yields abundant numbers of fly pre-pupae. The authors of the study suggest that fly pre-pupae may be an economical and sustainable feed ingredient for carnivorous fish diets. However, before fly pre-pupae can be used commercially in rainbow trout diets, a larger trial over a longer period should be conducted to confirm their preliminary results. The CAB Abstracts database contains some 700 records describing research on alternative protein sources for use in aquafeeds.

Main difficulties

Plant proteins are probably the most widely used alternative to fishmeal, but they can cause problems, including lower crude protein levels, palatability issues, amino acid deficiencies and the occurrence of anti-nutritional factors such as trypsin inhibitors, as well as phosphorus and nitrogen release to the environment (Hardy and Tacon 2002). The quality of the plant ingredients that can be used in the organic diets can have an effect on the final product quality like fat content, colour and texture (Lunger et al. 2007). Furthermore, research has not determined clearly the proportions of protein of animal and plant origin that should be used in organic feed. The formulation of "ideal protein contents" and how to increase dietary energy levels also need to be explored. The potential use of alternative proteins in feeds for organic aquatic animals should be further investigated over larger trials and longer periods per species and per life cycle to confirm these preliminary results.

Conclusions

PAP, insects and plant ingredients could be used in organic aquaculture up to different species-specific percentages, but consideration on the final product quality and taste is important and needs further investigation. The difficulties in formulation of test diets to secure acceptability to fish, maximize growth of fish and nutrient retention efficiency are the most important factor in using alternative protein sources. New organic feeds with alternative organic protein sources, as well as evidence on the effects of these on fish growth and fish physiology and health performance are needed for organic aquaculture.
The Group supports the importance of considering the use of alternative proteins sources in organic aquaculture, whenever they are available and appropriate for brood-stock, weaning, and on-growing diets. These alternative organic protein sources should be considered a priority. In general the use of feedstuffs consisting of whole micro or macro organisms with high contents of

essential amino acids is to be preferred to the use of purified or free amino acids as feed supplements/additives.

4.2.5. Histidine

Identification of substance, terminology, synonyms

Histidine (His) is an essential amino acid ($C_6H_9N_3O_2$) which cannot be synthesized by fish or any other aquatic animal and therefore must be supplied in the diet.

His is a very important precursor for the synthesis of proteins, vitamins (e.g. Vit C) and enzymes and it plays a vital role in the structure and binding functions of haemoglobin.

Synonyms of L-Histidine: 2-amino-3-(3H-imidazol-4-yl) propanoic acid; Imidazole alanine; α-amino-1H-imidazole-4-propanoic acid; 4-(2-amino-2-carboxyethyl)imidazole; α-amino-1H-imidazole-4-propionic acid; α-amino-4-imidazolepropionic acid; Glyoxaline-5-alanine (Ref: http://www.chem.qmul.ac.uk/iupac/AminoAcid/).

The original request is to use His of 98% purity and produced by a specific strain of bacteria as an additive in the nutrition of organic salmonid fish species. The Group does not want to restrict its findings to a specific commercial product, and has therefore widened the scope of this discussion to "histidine produced by fermentation", without restrictions on purity or microbial species.

Authorization in general agriculture/aquaculture or feed/food processing

The use of His as an additive in the nutrition of salmonid fish is authorized under EU legislation (Commission Regulation (EC) No 244/2007[9]). His is also positively evaluated as a feed ingredient in salmonid diets by EFSA (2005).

Technological or physiological functionality for the intended use

Amino acids are the building block of proteins. The various proteins are built up of amino acids in specific patterns and sequences. All amino acids resemble each other to a certain extent, some of them so much that fish can synthesize them from others. Some, however, are essential as they cannot be synthesized by the fish itself. They must therefore be supplied in the feed, since each amino acid has its own specific function in the fish (Wilson, 2003).

The amino acid profile of the feed, e.g. the proportions and the amounts of various amino acids, must be balanced with the protein requirements of the fish to be utilized efficiently.

Therefore the essential amino acids in the diet must be in adequate amounts. As discussed previously, if one amino acid is limiting, other surplus amino acids will be broken down and excreted.

Therefore, a carefully balanced amino acid profile is critical for the growth of the fish, as well as the minimization of nitrogen discharge as ammonia.

An unbalanced diet recipe for *conventional* aquaculture feed may be balanced by adding specific external amino acids, e.g. His, to ensure optimum utilization of the other dietary amino acids present. As an essential amino acid His has to be provided in adequate amounts in any feed for aquaculture. The provision of His has been shown to prevent cataracts in salmonids. Cataract is permanent lens opacity of both eyes (Waagbø et al, 2010).

[9] Commission Regulation (EC) No 244/2007 of 7 March 2007 concerning the authorisation of L-histidine monohydrochloride monohydrate as a feed additive (O.J. L 73, 13.3.2007, p. 6–8)

Necessity for intended use and known alternatives

His is an essential amino acid, which is very important for fish diets. Salmonids have a particular need for His, in order to prevent cataracts. Klein and Halver (1970) indicated that coho salmon, has a minimum His requirement of 0.7% of a dry diet or 1.7% of the dietary protein or 7 g His/kg diet (40% dietary protein) whereas Waagbø et al. (2010) indicated that 17.6 g His/kg of the diet mitigated cataract formation in salmon smolts (37% dietary protein). However, at present, it is still unclear how His prevents or mitigates cataract development and the molecular basis of cataractogenesis in salmon.

Marine raw materials vary significantly in composition and quality according to species and season, as well as to the production, processing and storage conditions. This variation in quality affects both extruded feed quality and fish performance. Certain types of fish meal from South America also contain high levels of His but this is only available from whole fish, which is banned by the Article 25(k) of Commission Regulation (EC) No 889/2008.

Up to 1995, animal by-products have been used widely in fish feeds, and supplied sufficient levels of His (e.g. blood meal from non-ruminants contains sufficient levels of His). However, the use of PAP (Processed Animal Protein) has been banned in the EU and only recently has been re-admitted with the Commission Regulation (EC) No 56/2013. In addition, at present, the availability of PAP originated from organic farming is not known. Nevertheless, many consumers may be reluctant to accept the use of blood meal as a fish feed ingredient. Therefore further research is needed which aims: a) to identify and study protein feed resources e.g. insect meal in accordance with the organic principles and the animal's health, b) to identify differences between fish genotypes and c) to study consumer preferences in relation to feeds used in organic aquaculture.

Origin of materials, methods of manufacture

L-histidine monohydrochloride monohydrate can be produced in a fermentation process using a natural strain of Escherichia coli. Production of the raw material takes place in fermenters, and then undergoes several steps of purification. The fermentation medium used is a mixture of glucose syrup, ammonium sulphate, corn steep liquor and minerals. His is isolated from the fermentation broth, acidified, purified (including an ion exchange procedure) and de-colourised. After addition of hydrochloric acid the solution is concentrated and L-Histidine·HCl·H_2O is crystallized and dried (EFSA 2005). His produced by fermentation can be considered as a natural substance of microbial origin.

The strain ATCC-21318 of the bacterium *Escherichia coli*, which is currently used for the production of His, is not a GMO (EFSA 2005). In addition, it is possible to produce His with a non-GM fermentation medium, although this would not be required according to Article 9 of Council Regulation (EC) No 834/2007.

However, other potential commercial production approaches should be evaluated separately.

Environmental issues

A balanced fish diet is crucial for nutrition, growth, health and welfare, as well as for environmental reasons. Unbalanced diets, i.e. amino acid profile of the diet which is not balanced to the requirements of the fish species, will result in bad protein utilization, which means break down of proteins and excretion of nitrogen as ammonia. Therefore, a balanced amino acid profile of fish diets is crucial for the organic aquaculture. EFSA (2005) identified no adverse influence on the environment by production and feeding with His of microbial origin.

Animal welfare issues

Fish health and welfare is largely dependent on a well-balanced diet with appropriate proportions of nutrients, including amino acids. His deficiency causes disease, mainly cataract. His supplementation has been shown to prevent cataract in salmon (Waagbø et al., 2010). Supplementation of His is, therefore, clearly positive from the point of view of animal health and welfare.

Human health issues

His is an essential amino acid in human nutrition as well. EFSA (2005) identified no risks for consumers, and no specific risks for workers and users.

Food quality and authenticity

Food quality and authenticity, in the sense of final fish product for human consumption, is not supposed to be affected by supplementation of His in the fish diet.

Traditional use and precedents in organic production

Materials of microbial origin are widely authorized in organic production. This includes their use as feed materials (Annex V) and as feed additives (Annex VI) in many areas of organic production. The following items are listed in the Commission Regulation (EC) No 889/2008: phaffia yeast Article 25(K); mushroom culture wastes, composted or fermented mixture of vegetable matter (Annex I); spinosad (Annex II); *Saccharomyces cerevisiae* and *S. carlsbergiensis* (yeasts) (Annex V); enzymes, yeasts and bacteria (Annex VI); yeasts (Article 27(1)(b) and Annex VIIIa).

Aspects of international harmonization of organic farming standards

At the moment, neither the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods (GL 32-1999, last amended 2013) nor the National Organic Program (USA) cover aquaculture.

Further considerations

All the above considerations show how His supply is important in the nutrition of salmonid fish. By definition, the same is true for all essential amino acids. Lysine (Lys) and arginine (Arg) requirements in fish nutrition are considered to be the first limiting amino acids in fish and the level of Lys, Arg and methionine (Met) in plant-protein meals are often low, compared to fish meal. In fish, it has been demonstrated that Lys and Arg supplementation may enhance protein synthesis and deposition, growth and reduce nitrogen losses (Kaushik, S.J. and Seiliez, I., 2010). However, the metabolic pathways by which dietary essential amino acids influence growth performance require further investigation. Fish and crustaceans have high dietary protein requirements (30–65% DM; NRC, 1993). Significant inter-species differences with regard to protein and amino acid requirements exist in fish. The variations in amino acid requirements can be attributed to a number of factors, such as differences in basal diet composition, size and age of fish, genetic differences, feeding rate and culture conditions and experimental design and choice of response criterion, all of which affect the overall growth rate, health and welfare.

The application of natural compounds derived from a variety of sources including yeasts, botanical peptides and animal by-products is at the top of the agenda of the researchers in the different fish species. Indeed, natural compounds can contribute to bactericidal action, digestive stimulation, immune stimulation, anti-oxidants, anti-parasitic effects in aquatic species and their use as alternatives to antibiotics and synthetic products is growing in the feed industry.

Finally, the Group considers that a better supply of essential amino acids would also improve the welfare and health of other aquatic species and that the supplementation of His should not be restricted to salmonids.

However, it should be outlined that the Group does not support the use of His to neutralize inadequate management practices. In the Group's opinion, animals should cover their need for amino acids primarily through the feed. Therefore, the Group recommends that supplementation with a preferably un-purified histidine source, additive or feed material, should only be used to balance the dietary composition of amino acids to avoid deficiency diseases (mainly cataracts in salmonids). The Group does not accept this practice in cases where the only justification is faster growth and/or a lower price of the feed.

Conclusions

The Group concluded that the essential amino acid histidine is very important for fish diets, particularly for salmonids. Therefore, if natural sources of histidine, such as certain types of fish meal, are not allowed/available, the use of supplementary histidine sources in the fish diet is considered in line with the objectives, criteria and principles of organic aquaculture production. Histidine should therefore be included in Annex VI of Commission Regulation (EC) No 889/2008 with the following priorities:

1. Use of un-purified fermentation products as a feed stuff, produced by organic procedures where possible.
2. Use of purified histidine as a feed additive only if option 1 is not possible.

4.2.6. Cholesterol

Identification of substance, terminology, synonyms

Cholesterol ($C_{27}H_{45}OH$) is a lipid (a sterol), composed of four carbon rings. In addition to its importance within cells, cholesterol also serves as a precursor for the biosynthesis of steroid hormones, bile acids, and vitamin D. Cholesterol is the principal sterol synthesized by animals. The Group was asked whether conventional cholesterol could be used.

Authorization in general agriculture or feed/food processing

Cholesterol is considered to be a raw material for feedstuffs and is therefore not in the list of feed additives. Cholesterol is also used in cosmetic products, like makeup, skin and hair care products. It is used as an emulsifier, as well as to increase the viscosity of personal care products (www.cosmeticsinfo.org; http://www.dishmangroup.com/index.asp; http://www.solvayvitamins.nl/).

Technological or physiological functionality for the intended use

Moulting is an essential process for growth of crustaceans. Cholesterol is a precursor of ecdysone, a steroid prohormone needed for moulting. For some species, it is the only precursor and hence it is very important to meet the cholesterol requirements for shrimps and other crustaceans. Dietary cholesterol deficiency may cause reduced growth rates leading to low survival and even death. The process involving cholesterol in the growth of shrimp is similar to vitamins in mammals (Williams et al., 2004). Cholesterol is crucial for many physiologically active compounds including adrenal corticoids, bile acids and vitamin D (Akiyama et al., 1992; Sheen et al., 1994). However, it does not increase growth rates.

Necessity for intended use and known alternatives

To the Group's knowledge, shrimps are the only aquatic animal species that require dietary cholesterol (see section 4.2.2). Crustaceans are not able to synthesize cholesterol *de novo*. Cholesterol is necessary for the nutrition of crustaceans because, it has a crucial role in the moulting process and it is important in maintaining the integrity and chemical permeability of

cell walls. Therefore it is crucial to have cholesterol in their feed (Teshima and Kanazawa, 1971). A dietary cholesterol deficiency is most commonly manifested as a reduced growth rate (reviewed by Teshima, 1997). According to the literature, the requirements of cholesterol vary among the different species of crustaceans and according to their life stage.

- For *M. rosenbergii*, cholesterol needs are high: 0.3-0.6% of the diet (Sahu, 2004) but this species is able to use phytosterols contained in plant instead of cholesterol as ecdysone precursors, so the amount added in the diet can be reduced significantly (Mitra et al., 2005).
- Cholesterol requirement for *P. monodon* is lower, but it is crucial and cannot be replaced. Needs are 1% of the diet for post-larvae (Paibulkichakul et al.,1998) and 0.17% for juveniles (Smith et al., 2001). The survival rate of sub-adult shrimps fed with 0.02% and 0.95% of cholesterol in the diet was only 13.3% and 33.3%, respectively, after two months. While, survival rate for shrimp fed diets containing amounts of cholesterol between the two above mentioned levels was between 83.3% and 93.3% (Sheen et al.,1994).
- For *L. vannamei*, there is a relationship between cholesterol and phospholipids. Indeed, a diet with no phospholipids requires 0.35% of cholesterol, whereas a diet with 5% of phospholipids requires only 0.05% of cholesterol (Gong et al., 2000). A good combination seems to be 0.15% of cholesterol for 1% or more phospholipids.

For those shrimp species that require a cholesterol-rich diet, it may be necessary to supplement the feed. A feed with 10% of fishmeal (the maximum allowed by the Commission Regulation (EC) No 889/08) contains an average of only 0.05% cholesterol. With such a low level, there is a high risk of mortality for sub adults shrimps and even higher for post-larval stages. Furthermore, it is very difficult to predict the quality of the natural feed produced by the environment where shrimps are reared (e.g. ponds) and the quantity consumed. Farmers, on the other hand, cannot only rely on annual fluctuations of the natural productivity of the rearing shrimp ponds.

Origin of materials, methods of manufacture

Natural cholesterol is produced from only one source so far, i.e. it is extracted from sheep wool grease, but the yields are very limited. Other potential sources of cholesterol are egg yolk, animal by-products, shellfish (Dong, 2009).

Cholesterol is extracted from lanolin, which comes from sheep wool grease, in a multistep extraction procedure. The lanolin can be refined to produce pure cholesterol (91%), which is added into the feed for shrimp.

Environmental issues

Cholesterol is a by-product of wool industry and it is not considered harmful to the environment in its production process. Its inclusion in the feed for shrimps is not considered to cause any changes in the pond water quality.

Animal welfare issues

Dietary cholesterol is considered an essential nutrient for good growth, including moulting and high survival in crustaceans. Only adequate dietary contents will secure growth performance and welfare of the animal. In fact, less than 0.02% and more than 0.95% of cholesterol in the diet of sub-adults caused mortality (Paibulkichakul et al 1998; Smith et al 2001; FAO-FIMA 2011; Alday-Sanz V. 2011; Piedad-Pascual, F. 1984; Chen 1998).

Human health issues

Supplemented cholesterol in the feed for crustaceans is necessary for the moulting process and it is not supposed to be detected in the final product. Therefore in this context cholesterol is not considered to have any impact on human health.

Food quality and authenticity

Supplementation with cholesterol in the shrimp diet does not affect food quality of the final product for human consumption.

Traditional use and precedents in organic production

According to the French National organic regulation, cholesterol is authorized as follows:
CC- REPAB F 05/05/2008
Annex P – 1
PART A – Raw materials or simple feeds
4) Specific products for shrimp diet: -Cholesterol.
Cholesterol can be utilised under the following conditions

- Cholesterol is purified at 85% and comes from wool grease;
- Guarantee to provide: Flocks are free of scrapie.

This has been extended by the Commission Implementing Regulation (EU) No 1030/2013 until January 2015 to those aquaculture and seaweed production units which were established and produced under nationally accepted organic rules before 1 January 2009. The ad-hoc expert group on "Use of certain fish feed additives and cleaning substances in organic aquaculture" held in Brussels on 19 and 20 November 2008 concluded that cholesterol may be used in organic crustacean farming, preferentially using organic sources.

Aspects of international harmonization of organic farming standards

At the moment, neither the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods (GL 32-1999, last amended 2013) nor the National Organic Program (USA) cover aquaculture.

Further considerations

The Group acknowledges that a feed with an adequate supply of cholesterol would secure the growth rate, the welfare and health of the crustaceans. However, it should be outlined that the Group does not support the use of cholesterol to neutralize inadequate management practices. In the Group's opinion, animals should cover their need for cholesterol primarily through the feed. Therefore, the Group recommends the supplementation of cholesterol only to secure the quantitative dietary needs in the feed for crustaceans. By contrast, the Group does not accept this practice in cases where the only justification is faster growth and/or a lower price of the feed. However, establishment of an organic procedure for the extraction of cholesterol from wool is needed.
The ad-hoc expert group on "Use of certain fish feed additives and cleaning substances in organic aquaculture" held in Brussels on 19 and 20 November 2008 concluded: Cholesterol may be used in organic crustacean farming. The source of cholesterol should follow the priority list given below:

a) For preference, sustainable marine sources or organically certified sources such as highly purified cholesterol from sheep's wool should be used.
b) If unavailable, non-organic natural sources may be used.

To clarify the availability of organic cholesterol, a market analysis should be carried out. This would provide the data necessary for an evidence-based decision that organic cholesterol is not available in sufficient quantities.

Conclusions

The Group concluded that the use of cholesterol as raw material in the feed for supplementing the diet of shrimps is in line with the objectives, criteria and principles of organic production. It should, therefore, be admitted by the Commission Regulation (EC) No 889/2008 with the following priorities:

1. If organic cholesterol is available, this source should be used as priority.
2. As an alternative, cholesterol derived from shellfish and other sources can be used when no organic or wool-derived cholesterol is available.

4.2.7. Lecithin

Introduction

The Group was asked whether conventional sources of lecithin could be permitted, if organic sources are not available. This topic has been addressed previously by an ad-hoc expert group on the "use of certain fish feed additives and cleaning substances in organic aquaculture" (Brussels, 19 and 20 November 2008). Because of this, the Group only dealt with selected aspects.

Authorization in organic production

Lecithin is currently authorized by Commission Regulation (EC) No 889/2008, as reported in the following Annexes:
ANNEX II (Pesticides - plant protection products referred to in Article 5(1)), as a Fungicide;
ANNEX VI (Feed additives used in animal nutrition referred to in Article 22(g), Article 24(2) and Article 25(m)(2)), (c) Emulsifying and stabilising agents, thickeners and gelling agents, only if derived from organic raw material. Use restricted to aquaculture animal feed; ANNEX VIII A as additive for all plant based products and for animal products restricted to Milk products. Based on Article 27(1)(a) of Commission Regulation (EC) No 889/2008.

Aspects of international harmonization of organic farming standards

At the moment, neither the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods (GL 32-1999, last amended 2013) nor the National Organic Program (USA) cover aquaculture.
In the rules for food processing, the National Organic Program states that organic forms of lecithine must be used. As an exception, non-organic de-oiled lecithin may be used only when an organic form of de-oiled lecithin is not commercially available (NOP Rule 205.606). The details are as follows:
Lecithin de-oiled
Status: Allowed with Restrictions
Class: Processing Agricultural Ingredients and Processing Aids
Origin: Non-synthetic
Description: Non-organic de-oiled lecithin may be used in processed products labelled as 'Made with Organic [specified ingredients]' provided that the de-oiled lecithin is not produced or handled with the use of sewage sludge, genetic engineering, genetically modified organisms (GMOs), or ionizing radiation. Nonorganic de-oiled lecithin may also be used in or on processed products labelled as 'organic' only when the certifier determines that the ingredient is not commercially available in an organic form and that it meets the requirements of 205.301(b) and 205.301(f).

Necessity for intended use

Lecithin is one of the two main categories of essential lipids, and is therefore necessary for shrimp aquaculture. Details are described in section 4.2.2.

Reflections of the Group

The ad-hoc expert group on "Use of certain fish feed additives and cleaning substances in organic aquaculture" held in Brussels on 19 and 20 November 2008 concluded: "... *For preference, lecithin from organically certified sources such as organic soybean, may be used following mechanical extraction. If unavailable, non-organic natural sources may be used provided they are of non-GMO origin*".

The applicants did not provide detailed quantitative documentation about a shortage of organic lecithin. As lecithin is a by-product of the oil industry, the potential availability of organic lecithin can be estimated from the trade volume of organic oils. Based on the information available to the Group, global production of organic lecithin is about 2000 t/y, and greatly exceeds the demand.

To further clarify the availability of organic lecithin, a market analysis should be carried out. This would provide the data necessary for an evidence-based decision on the availability of organic lecithin in sufficient quantities.

The use of lecithin for organic flavourings in the food industry will be discussed in the EGTOP report on food (II). In the Group's opinion, the use of conventional vs. organic lecithin should be regulated in the same way in food and in feed.

Conclusions

On the basis of the above information, the Group reconfirms the advice provided by the ad-hoc expert group in 2008.

4.2.8. General conclusions and recommendations

Article 25(k) of Commission Regulation (EC) No 710/2009[10] states "*Feed for carnivorous aquacultural animals shall be sourced with the following priorities:*

a) *Organic feed products of aquaculture origin;*
b) *Fishmeal and fish oil from organic aquaculture trimmings;*
c) *Fishmeal and fish oil and ingredients of fish origin derived from trimmings of fish already caught for human consumption in sustainable fisheries;*
d) *Organic feed materials of plant origin and of animal origin as listed in Annex V and the restriction laid down therein complied with.*

In the Group's opinion, aquaculture animals should cover their needs for amino acids and fatty acids primarily through the natural compounds of the feed. In order to comply with the general rules on feed (cfr. Article 25(j) of Commission Regulation (EC) No 889/2008), namely: "*...animal health, high product quality, including the nutritional composition which shall ensure high quality of the final edible product and low environmental impact*", the diet for carnivorous fish should be characterized by a well-balanced proportion of amino acids, fatty acids and lipids.

[10] Commission Regulation (EC) No 710/2009 of 5 August 2009 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007, as regards laying down detailed rules on organic aquaculture animal and seaweed production (O.J. L 204, 6.8.2009, p. 15–34)

The Group also recognizes the specific needs of animal protein and lipids in the diet of shrimps, although in different proportion according to life stages. Therefore, the Group supports a limited use of fishmeal and fish oil derived from sustainable fisheries, as a supplement of the feed naturally available in the rearing environment of shrimps. Such feed rations could be up to 10% for fish oil and up to 25% for fish meal.

The Group is concerned about the consequences of the listed priorities of sourcing feed as laid down in Commission Regulation (EC) No 889/2008 Article 25(k), reported at the beginning of this page. Indeed, with respect to fish meal derived from trimmings, the risk is that the levels of phosphorus contained in such fish meal might result in conflicts with national environmental legislation.

Since fish meal and fish oil are a limited resource, finding alternative protein sources to replace fish meal is clearly a high priority for organic aquaculture. Similarly, developing production of aquafeeds that: a) satisfy aquatic organisms' nutritional requirements for specific amino acids and fatty acids, b) suit their feeding habits and c) result in a high retention of nutrients to maintain animal health and to achieve good quality final products is a high priority. As a consequence, the Group supports the use of alternative proteins sources in organic aquaculture, when available and appropriate for brood stock, weaning, and on-growing diets. The development of organic alternative protein sources should be considered a priority.

Considering all these issues, the Group concluded that the following alternative options should be considered, in order of priority:

a) Besides fish meal and fish oil derived from trimmings of fish, crustaceans and molluscs, also fish meal and fish oil derived from "whole fish not used for human consumption", caught in sustainable fisheries, should be allowed as ingredients in feed for organic carnivorous fish. This includes feed for fry and brood-stock, as well as for on-growing fish, until sufficient alternative sources of fish meal and fish oil are available.
b) In addition, the use of other alternative feed materials consisting of whole micro or macro organisms with high contents of essential amino acids and lipids, where possible produced organically, may be needed and are to be preferred to the use of purified or free amino acids as feed supplements/additives.
c) If not available from organic procedures, essential amino acids and lipids obtained by fermentation or other similar procedures should be allowed as ingredients/additives in carnivorous fish feed only if specifically authorised.

In the case of histidine, the approval in the specific context recommended by the Group should not be seen as a precedent for the use of histidine as a feed additive outside aquaculture, nor for the use of other free amino acids as feed additives for any type of livestock. Other uses / substances should be evaluated separately

5. MINORITY OPINION

In the conclusions of the paragraph *4.1.2. Restocking in lakes, earth ponds of tidal areas and costal lagoons* is stated: "the Group recognizes the high value of these extensive aquaculture practices, in terms of cultural heritage, biodiversity conservation and economic perspective for the local communities."
Later in the paragraph, is stated: "Therefore, with the exception of eels, the Group considers that restocking of wild fry in the extensive aquaculture farming carried out inside wetlands, such as brackish water ponds, tidal areas and costal lagoons is in line with the objectives, criteria and principles of organic aquaculture production, subject to the following restrictions:

a) A management plan, approved by the local or national authority, that ensures the sustainable exploitation of the species concerned, should be provided. ..."

The Group did not find, however, an agreement in relation to the exclusion of the eels from the restocking practices considered in line with the objectives, criteria and principles of organic aquaculture production. The majority of the Group supported the need for such an exception because the eel is considered an overfished/endangered species.

The following is the minority opinion expressed by the Chair of the EGTOP Group Mr Giuseppe Lembo.
Considering that everyone in the Group agrees "... that restocking of wild fry in the extensive aquaculture farming carried out inside wetlands, such as brackish water ponds, tidal areas and costal lagoons is in line with the objectives, criteria and principles of organic aquaculture production, subject to the following restrictions: a) A management plan, approved by the local or national authority, that ensures the sustainable exploitation of the species concerned, should be provided. ....". Furthermore, considering that there is a general agreement on the overfished/endangered condition of the eel, it is likely that the reasons for the disagreement among the Group arises from a lack of a thorough knowledge about the role assigned to the "Management Plans" by the European Regulations.
Indeed, specific provision on management plans are included in the European regulations, both in general terms (in the context of the CFP), and with specific reference to the eel.

Management plan in the CFP
Management plans were previously regulated by the Council Regulation (EC) No 2371/2002[11] on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy.
In particular, the following provisions were included in the Article 6 of Council Regulation (EC) No 2371/2002:
" ... 2. Management plans shall include conservation reference points such as targets against which the maintenance of stocks within such limits shall be assessed. ...
3. Management plans shall be drawn up on the basis of the precautionary approach to fisheries management and take account of limit reference points recommended by relevant scientific bodies. They shall ensure the sustainable exploitation of stocks and that the impact of fishing activities on marine eco-systems is kept at sustainable levels. ... The management plans shall be multi-annual and indicate the expected time frame for reaching the targets established".
Council Regulation (EC) No 2371/2002 has been then replaced by the Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013[12]. This new

[11] Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy (O.J. L 358, 31.12.2002, p. 59–80)

Regulation, however, does not change the previous direction in favour of conservation reference points.
In particular, the following provisions are included in the Article 9 of the Regulation (EU) No 1380/2013:
"1. Multiannual plans shall be adopted as a priority, based on scientific, technical and economic advice, and shall contain conservation measures to restore and maintain fish stocks above levels capable of producing maximum sustainable yield in accordance with Article 2(2)."
The provision of article 2 are:
"1. The CFP shall ensure that fishing and aquaculture activities are environmentally sustainable in the long-term and are managed in a way that is consistent with the objectives of achieving economic, social and employment benefits, and of contributing to the availability of food supplies.
2. The CFP shall apply the precautionary approach to fisheries management, and shall aim to ensure that exploitation of living marine biological resources restores and maintains populations of harvested species above levels which can produce the maximum sustainable yield. In order to reach the objective of progressively restoring and maintaining populations of fish stocks above biomass levels capable of producing maximum sustainable yield, the maximum sustainable yield exploitation rate shall be achieved by 2015 where possible and, on a progressive, incremental basis at the latest by 2020 for all stocks.
3. The CFP shall implement the ecosystem-based approach to fisheries management so as to ensure that negative impacts of fishing activities on the marine ecosystem are minimised, and shall endeavour to ensure that aquaculture and fisheries activities avoid the degradation of the marine environment. ... "

Management plan with specific reference to the eel
Council Regulation (EC) No 1100/2007 of 18 September 2007[13] establishes specific measures for the recovery of the stock of European eel. In particular, Article 2 of the Regulation states:
"Establishment of Eel Management Plans.

1. Member States shall identify and define the individual river basins lying within their national territory that constitute natural habitats for the European eel (eel river basins) which may include maritime waters. If appropriate justification is provided, a Member State may designate the whole of its national territory or an existing regional administrative unit as one eel river basin.
2. In defining eel river basins, Member States shall have the maximum possible regard for the administrative arrangements referred to in Article 3 of Directive 2000/60/EC of the European Parliament and of the Council[14].
3. For each eel river basin defined under paragraph 1, Member States shall prepare an Eel Management Plan.
4. The objective of each Eel Management Plan shall be to reduce anthropogenic mortalities so as to permit with high probability the escapement to the sea of at least 40 % of the silver eel biomass relative to the best estimate of escapement that would have existed if

[12] Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (O.J. L 354, 28.12.2013, p. 22–61)

[13] Council Regulation (EC) No 1100/2007 of 18 September 2007 establishing measures for the recovery of the stock of European eel (O.J. L 248, 22.9.2007, p. 17–23)

[14] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (O.J. L 327, 22.12.2000, p. 1–73)

no anthropogenic influences had impacted the stock. The Eel Management Plan shall be prepared with the purpose of achieving this objective in the long term.

5. The target level of escapement shall be determined, taking into account the data available for each eel river basin, in one or more of the following three ways:
   a) use of data collected in the most appropriate period prior to 1980, provided these are available in sufficient quantity and quality;
   b) habitat-based assessment of potential eel production, in the absence of anthropogenic mortality factors;
   c) with reference to the ecology and hydrography of similar river systems.
6. Each Eel Management Plan shall contain a description and an analysis of the present situation of the eel population in the eel river basin and relate it to the target level of escapement laid down in paragraph 4.
7. Each Eel Management Plan shall include measures to attain, monitor and verify the objective set out in paragraph 4. The Member States may define the means depending on local and regional conditions.
8. An Eel Management Plan may contain, but is not limited to, the following measures:
   - reducing commercial fishing activity,
   - restricting recreational fishing,
   - restocking measures,
   - structural measures to make rivers passable and improve river habitats, together with other environmental measures,
   - transportation of silver eel from inland waters to waters from which they can escape freely to the Sargasso Sea,
   - combating predators,
   - temporary switching-off of hydro-electric power turbines,
   - measures related to aquaculture.
9. Each Eel Management Plan shall contain a time schedule for the attainment of the target level of escapement laid down in paragraph 4, following a gradual approach and depending on an expected recruitment level; it shall include measures that will be applied as of the first year of application of the Eel Management Plan.
10. In the Eel Management Plan, each Member State shall implement appropriate measures as soon as possible to reduce the eel mortality caused by factors outside the fishery, including hydroelectric turbines, pumps or predators, unless this is not necessary to attain the objective of the plan.
11. Each Eel Management Plan shall include a description of the control and enforcement measures which will apply in waters other than Community waters in accordance with Article 10.
12. An Eel Management Plan shall constitute a management plan adopted at national level within the framework of a Community conservation measure as referred to in Article 24(1)(v) of Council Regulation (EC) No 1198/2006 of 27 July 2006[15] on the European Fisheries Fund (1)".

[15] Commission Regulation (EC) No 1198/2008 of 1 December 2008 establishing a prohibition of fishing for Greenland halibut in NAFO 3LMNO by vessels flying the flag of Estonia (O.J. L 323, 3.12.2008, p. 24–25)

In conclusion:

1) In light of the above information provided on the role assigned to the "Management Plans" by the European Regulations;
2) bearing in mind that the above mentioned regulations provide for control procedures, alongside Member States, for the compliance with the measures adopted in the management plans;
3) considering that the recalled regulations seem properly detailed and effective to achieve the intended purposes;
4) in view of the restriction established by the Group, for which: "A management plan, approved by the local or national authority, that ensures the sustainable exploitation of the species concerned, should be provided" in order to consider that "... restocking of wild fry in the extensive aquaculture farming carried out inside wetlands, such as brackish water ponds, tidal areas and costal lagoons is in line with the objectives, criteria and principles of organic aquaculture production";
5) with reference to the general principle that protection should be ensured to all overfished/endangered species, not only to the eel.

All the above considered, it seems that there are no reasons to believe that a "Management Plan" is effective in protecting any overexploited or endangered species, with the only exception of the eel.

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7. GLOSSARY

Weaning
Weaning is the time when the juveniles shift from natural feed to pellet feed.

Extensive aquaculture
Extensive aquaculture is a practice where the feeding is only provided by the natural carrying capacity of the natural environment.

Anti-nutrient
Anti-nutrients are substances present in vegetable protein sources, which impair protein digestion and utilization in the fish. Indeed, the digestive system of carnivorous fish has not evolved to deal with the wide variety of anti-nutritional factors (ANFs) that are present in most plant-based feedstuffs, and which may interfere with fish performance and health due to impaired nutrient utilization.

Phaffia yeast
Phaffia yeast consists of the cells of the yeast *P. rhodozyma* that are produced by pure culture fermentation and subsequently killed by heat and dried. The major components of phaffia yeast are proteins, carbohydrates, and lipids produced by the yeast cells. The primary colouring substance in phaffia yeast is astaxanthin. Astaxanthin is the carotenoid responsible for the orange-red colour of marine seafood, such as trouts, salmons and crustaceans. The high conjugated carbon-carbon double bonds give to astaxanthin both the properties of a potent antioxidant and a colorant.

PAP
Processed Animal Protein (PAP) means animal proteins (entire bodies or parts of animals or products of animal origin not intended for human consumption) derived entirely from category 3 material, which have been treated in accordance with Chapter II of annex V of the Commission Regulation (EC) No 1774/2002[16]. The Commission Regulation (EU) No 56/2013 allows the use of processed animal protein, derived from non-ruminants, for feeding aquaculture animals.

Retention efficiency
Improvements in protein retention efficiency is decisive to maintain animal health and welfare. A "metabolically" optimized protein and lipid diet formulation, for feeding farmed aquatic animals, allows a higher retention of nutrients, a higher feed conversion ratio and a reduced environmental impacts due to the lower amount of nitrogen discharge.

Euryhaline species
Euryhaline fish species are able to adapt to a wide range of salinities. An example of a euryhaline fish is the sea bream (*Sparus aurata*) which can live in brackish or salt water. Euryhaline organisms are commonly found in habitats such as estuaries and tide pools or lagoons, where the salinity changes regularly. However, some organisms are euryhaline because their life cycle involves migration between freshwater and marine environments because of reproductive needs. The salmon (anadromous fish) is one which migrate from the sea into fresh water to spawn and the eel (catadromous fish) is one which migrate from fresh water into the sea to spawn.

[16] Commission Regulation (EC) No 1774/2004 of 14 October 2004 amending Regulation (EC) No 1623/2000 laying down detailed rules for implementing Regulation (EC) No 1493/1999 on the common organisation of the market in wine with regard to market mechanisms (O.J. L 316, 15.10.2004, p. 61–63)

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy
B.4. Organics

Expert Group for Technical Advice on Organic Production

EGTOP

Final Report On Plant Protection Products (II)

The EGTOP adopted this technical advice at the 9th plenary meeting
of 28 – 30 April 2014

About the setting up of an independent expert panel for technical advice

With the Communication from the Commission to the Council and to the European Parliament on a European action plan for organic food and farming adopted in June 2004, the Commission intended to assess the situation and to lay down the basis for policy development, thereby providing an overall strategic vision for the contribution of organic farming to the common agricultural policy. In particular, the European action plan for organic food and farming recommends, in action 11, establishing an independent expert panel for technical advice. The Commission may need technical advice to decide on the authorisation of the use of products, substances and techniques in organic farming and processing, to develop or improve organic production rules and, more in general, for any other matter relating to the area of organic production. By Commission Decision 2009/427/EC of 3 June 2009, the Commission set up the Expert Group for Technical Advice on Organic Production.

EGTOP

The Group shall provide technical advice on any matter relating to the area of organic production and in particular it must assist the Commission in evaluating products, substances and techniques which can be used in organic production, improving existing rules and developing new production rules and in bringing about an exchange of experience and good practices in the field of organic production.

EGTOP Permanent Group

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- Michel Bouilhol
- Jacques Cabaret
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The report of the Expert Group presents the views of the independent experts who are members of the Group. They do not necessarily reflect the views of the European Commission. The reports are published by the European Commission in their original language only.
http://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports/index_en.htm

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With regard to their declared interests, the following members did not participate in the adoption of conclusions on the substances mentioned below:

- Bernhard Speiser (potassium phosphonates)

External experts:
None

Observers:
None

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- João Onofre
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All declarations of interest of Permanent Group members are available at the following webpage: http://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/declaration-of-interests/index_en.htm

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1. EXECUTIVE SUMMARY

The EGTOP (thereafter called 'the Group') has evaluated a number of topics relevant for the use of plant protection products in organic production in accordance to the request set out in the second EGTOP plant protection product mandate. The Group concluded the following:

The use of potassium phosphonates is not in line with the objectives and principles of organic production as laid down in Council Regulation (EC) No 834/2007. If the objective is to reduce copper use by regulation at national or European level, then alternative options compatible with the regulation should be exploited. The Group underlines that copper use should be minimised.

The use of kieselgur for the control of stored product pests and poultry mites is in line with the objectives, criteria and principles of organic farming. 'Kieselgur (diatomaceous earth)' should therefore be included in Annex II without restrictions of target species. If a 'basic list of active substances' is established in Annex II (see chapter 4.10), kieselgur should be included there. When used in animal buildings, appropriate measures must be taken to avoid negative effects on animal health, in particular through inhalation.

The use of carbon dioxide for the control of stored product pests is in line with the objectives, criteria and principles of organic production. It should therefore be included in Annex II. No restrictions are necessary in the Group's opinion. If a 'basic list of active substances' is established in Annex II (see chapter 4.10), carbon dioxide should be included there.

The use of piperonyl butoxide is not in line with the objectives, criteria and principles of organic farming. It should therefore not be included in Annex II, and the tolerance of its use should be phased out.

The use of potassium bicarbonate as an insecticide is in line with the objectives, criteria and principles of organic farming. The Group recommends that the restriction 'fungicide' should be deleted. As a less preferred alternative, the use 'insecticide' could be added.
If a 'basic list of active substances' is established in Annex II (see chapter 4.10), potassium bicarbonate should be included there.

The use of soft soap for disease control is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007 and recommends appropriate modifications of the present listing of soft soap in Annex II, in accordance with pesticide registrations. The Group recommends to delete the restriction 'insecticide'. As a less preferred option, the use 'fungicide' could be added. The use as herbicide should not be authorised. If a 'basic list of active substances' is established in Annex II (see chapter 4.10), soft soap should be included there.

The Group does not recommend that substances authorised as 'basic substances' under Reg. 1107/2009 are automatically considered as included in Annex II of Reg. 889/2008.

The Group is against automatic approval of low risk substances in organic farming.

For the 'group substances' currently authorised for organic production, the Group sees no need for further specifications in Reg. 889/2008. On the contrary, there could be reflected on whether it would be appropriate to replace some of the current listings of individual substances by newly

formed groups. Before bringing a new group on the list, it must be very carefully evaluated whether there are substances inside the group that do not comply with the principles of organic farming. Depending on this evaluation, it should be decided whether the group is included as a whole, or whether a further discrimination is required. For all groups, only the substances authorized under Reg. 540/2011 can be used.

In the Group's opinion, restrictions of use category in Annex II should be limited to those cases where further limitations are needed from an organic farming point of view, beyond the limitations already imposed by pesticide approval (Reg. 540/2011). For other cases, specifications of use category should be deleted. The Group recommends to include a 'basic list of active substances' (as shown in chapter 4.10) in Annex II.

2. BACKGROUND

In recent years, several Member States have submitted dossiers under Article 16(3)(b) of Council Regulation (EC) No 834/2007[1] concerning the possible inclusion of a number of substances in Annex II to Commission Regulation (EC) No 889/2008[2] or, in general, on their compliance with the above mentioned legislation.

In 2012, Belgium introduced a request on potassium bicarbonate and Germany submitted a dossier on diatomaceous earth. In 2013, Sweden requested the evaluation of fatty acid potassium salt (soft soap) and Germany presented a dossier on the use of potassium phosphonates (Potassium phosphite) as an alternative of using copper compounds. The Commission also would like to have the Group's advice on automatic authorization of basic substances, low risk substances, on the need for further specification of group substances, and on the use of carbon dioxide and piperonyl butoxide.

Therefore, the Group is requested to prepare a report with technical advice on the matters included in the terms of reference.

3. TERMS OF REFERENCE

In the light of the most recent technical and scientific information available to the experts, the Group is requested to answer if the use of the below listed substances are in line with the objectives, criteria and principles as well as the general rules laid down in Council Regulation (EC) No 834/2007 and, hence, can be authorised to be used in organic production under the EU organic farming legislation.

Substances:

- BE dossier (2012): Potassium bicarbonate (Potassium hydrogen carbonate).
- DE dossier (2012): Diatomaceous earth.
- DE dossier (2013): Potassium phosphonates (Potassium phosphite).
- SE dossier (2003 and 2012): Fatty acid potassium salt (soft soap).
- SL dossier: the use of synergist substances, in particular piperonyl butoxide.
- Com: the use of carbon dioxide in storage.

The Commission would like to get also the advice from the group as regards the following:

- The authorisation of the so called, "basic substances" according to with article 23 of Regulation 1107/20093 has been pointed out by some Member States during discussion of the latest amendments of Annex II at the Standing Committee of Organic

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[1] Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91.(O.J. L 189, 20/07/2007, p. 1.)

[2] Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, 5OJ L 250, 18.9.2008, p. 1–84.

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, (OJ L 309, 24.11.2009, p. 1–50)91/414/EEC, (OJ L 309, 24.11.2009, p. 1–50).

Farming. It was asked whether the basic substances such as the recently authorised Horsetail, could be automatically considered as included into the Annex II to Commission Regulation 889/2008 once they have been authorised under Regulation 1107/2009 (Link with the discussion under the third indent below).

- The automatic authorization of "low risk substances", similar to the basic substances.
- -Authorisation of group substances: should the relevant rows of the Annex to Commission Implementing Regulation (EU) 540/20111 be specified in the organic legislation? Or is the mentioning of the general group name a better approach?
- Priority assessment of requests: due to the high number of dossiers presented to the Commission, transparent criteria should be developed for the assessment of the priority of requests, in light of the limitations of the EGTOP capacity.

In preparing its report the group is invited to examine technical dossiers provided to the Commission by the Member States and suggest amendments to the current list in Annex II of Regulation 889/2008.

4. CONSIDERATIONS AND CONCLUSIONS

4.1 Potassium phosphonates (potassium phosphite)

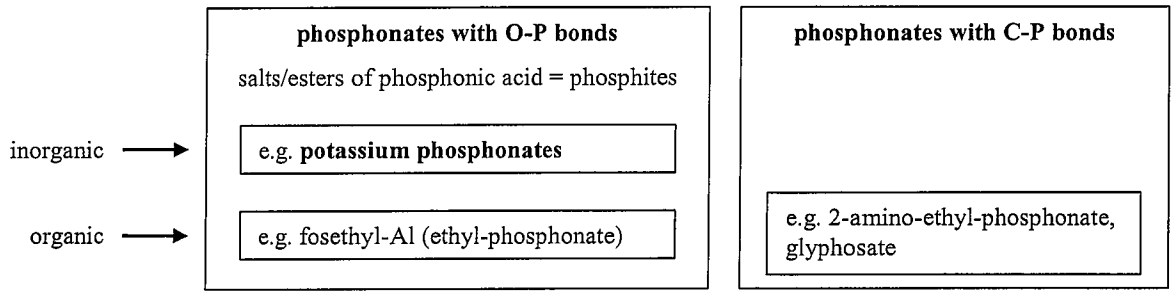
Introduction, scope of this chapter

This substance is known by several names. The active substance is a reaction mixture of phosphonic acid (H_3PO_3) and potassium hydroxide (KOH), containing a mixture of potassium hydrogen phosphonate (KH_2PO_3) and dipotassium phosphonate (K_2HPO_3). Under EU pesticides legislation, the latter two substances are collectively called 'potassium phosphonates' (EFSA 2012b); in the literature, they are mostly referred to as 'potassium phosphonate', 'potassium phosphite', 'phosphonic acid' or 'phosphorous acid'. In aqueous solution, the substances dissociate into the potassium ion (K^+) and the ions hydrogen phosphonate ($H_2PO_3^-$) and phosphonate (HPO_3^{2-}).

Potassium phosphonates are inorganic phosphonates, and the phosphorus is bound exclusively with O-P bonds. They have similar properties to the synthetic fungicide fosethyl-Al, which is also characterised by O-P bonds. There is scope for confusion, because the term 'phosphonate' is also used for another group of substances with quite different properties: the organic phosphonates characterised by C-P bonds. This latter group comprises a wide range of substances occurring in living organisms, but also synthetic substances such as the herbicide glyphosate (Guest and Grant 1991). The relationship between these groups is shown in figure 1. In this chapter, the term 'potassium phosphonates' is used in consistency with EU pesticide legislation. The evaluation is limited to potassium phosphonates, and does not include organophosphonates with C-P bonds. None of these substances should be confused with phosphate (PO_4^{3-}), phosphoric acid (H_3PO_4) or phosphine (PH_3). Other inorganic phosphonates such as calcium phosphonate would have a similar effect, but they are not registered as active substances in the EU, and are not discussed here.

This chapter focuses largely on grapevine, as only this use was requested by the applicant.

Figure 1: Overview over the various substances called 'phosphonates'.



Authorization in general agriculture and in organic farming

Since October 2013, potassium phosphonates are registered at EU-level as active substances for fungicides. The representative use approved by the Commission is in grapevines, but the Group expects that uses on a number of other crops will be authorised at Member state level. For example, a product is registered in France for use not only on grapes, but also on various vegetables (lettuce, tomato, pepper, artichoke, chicory, *Cucurbita* spp.,), and uses on similar crops are registered in Switzerland.

Before October 2013 (i.e. before they were approved as fungicides), products based on potassium phosphonates were listed as plant strengtheners in Germany for many years. For some years, the contents of potassium phosphonates were declared, while later it was declared as algae extract. For a shorter time, such products were also listed as plant strengtheners in some other European countries (e.g. Austria, Czech Republic, Slovakia, Hungary).

There is also widespread marketing of fertilizers containing potassium phosphonates (Brunings et al. 2012; Leymonie, JP. 2007; Wollenweber et al. 2011). However, there is no evidence that plants can utilise phosphorus which is supplied in the form of phosphonate (Deliolopoulos et al. 2010). By calling such products 'fertilisers', they can be marketed without undergoing the costly and time-consuming procedures of pesticide registration (McDonald et al. 2001). The Group does not know whether the marketing of such fertilizers is still possible in the EU after October 2013. Other phosphonates (Na, NH_4, Ca) are also marketed as fertilizers.

Potassium phosphonates were never explicitly authorised for organic farming, neither as pesticide nor as fertilizer. However, products listed as plant strengtheners may be used in organic farming (Art. 16 of Reg. 834/2007). Thus, potassium phosphonates could be legally used in organic farming without explicit listing in Reg. 889/2008, but since October 2013 they can no longer be used like that.

Agronomic use, mode of action, physiological functionality for the intended use

Potassium phosphonates are effective against a number of fungal plant pathogens from the group of the oomycetes, especially against *Phytophthora* spp., *Plasmopara* and *Alternaria* spp. Examples of crops where phosphite salts are effective are given by Deliolopoulos (2010; Tab. 5). They include grapes, fruit and berries (apple, orange, papaya, strawberry), vegetables (cabbage, cucumber, pepper), arable crops (potato, maize) and some other crops (lupin, tobacco, *Banksia*).

Potassium phosphonates are most commonly applied as a foliar spray, but other application methods such as root drench, trunk injection or addition to irrigation water also occur (Deliolopoulos 2010). They are taken up by leaves and roots, and are translocated through the entire plant, and incorporated into cells as phosphonate ions. They are not significantly oxidised to phosphate within the plant (EFSA 2012b). Because the phosphonate anion has one oxygen

atom less than phosphate, it does not act in the same manner as phosphate in plants. It does not appear to be involved in any phase of phosphorus metabolism. Potassium phosphonates have a dual mode of action: they have a direct impact on pathogens such as downy mildew, but they also stimulate the plants' natural defence system (France 2005; section B.3.1.5.1). Potassium phosphonates have a systemic mode of action (EFSA 2012b). Other substances allowed in organic farming (e.g. neem, quassia) also have a systemic mode of action. In the soil, phosphonate is converted to phosphate by bacteria, and can then be taken up and metabolised by plants. This conversion is slow and is not thought to be a very efficient means of phosphorus delivery to plants, when compared with phosphate fertilizers.

On grapevines, potassium phosphonates could technically be applied throughout the growing season, and this is allowed in conventional farming. With the aim to minimise phosphonate residues, the recommendation in organic wine growing in Germany is to limit their use until close to the end of flowering (BBCH-scale : 68). The applicants state that 3 – 5 applications are foreseen, but do not specify the amounts applied. Based on Kauer (2011), a total of 3 – 7 kg/ha/year can be assumed for a minimised application strategy. Nevertheless, there was no legal obligation to follow this recommendation for plant strengtheners. For the newly registered plant protection products, there is no limitation of application time. Thus, applications after flowering are common in conventional farming and could potentially also happen in organic farming, unless if they are explicitly excluded by organic legislation.

Necessity for intended use, known alternatives

Downy mildew (*Plasmopara viticola*) is one of the most dangerous diseases of grapevines worldwide. In many areas, it can have a severe impact and needs to be managed.

The Group felt that the motivations for using potassium phosphonate can only be understood, if regional climatic conditions, available alternatives and copper regulation are considered. Therefore, a brief overview of these aspects is given here. However, the Group does not want to confuse the discussion on potassium phosphonate with the discussion on copper or on other substances.

There are management practices which can reduce the impact of downy mildew. There are grape cultivars which show some degree of field resistance to downy mildew (including traditional varieties, new varieties and interspecific hybrids). However, the introduction of new varieties is never easy, particularly in areas with traditional wines. The Group underlines that from an organic principles point of view, such practices are preferable to the use of any plant protection products. In grapes, however, resistant cultivars have limited potential and their effect is not sufficient in many cases.

Copper compounds are the most effective substances against downy mildew in organic farming. The substitution of copper compounds is a declared priority in the EU organic legislation (Reg. 473/2002). In the last 10 – 20 years, there has been a great technical development leading to a more efficient copper use, based on monitoring and forecasting systems (more efficient use of copper by choice of optimal application timing, and only in case of need), advanced spraying technology and advanced formulations of copper fungicides. As a result of copper minimization strategies (which included the use of alternative substances such as phosphonates or aluminium sulfate), it was possible to reduce the use of copper. Some practitioners are successfully managing vineyards with low amounts of copper, and in the most favourable areas even without copper (Mazzilli 2014). In parallel, the amounts of copper were limited in organic farming. The limitation process started in the year 2000, with a limitation of 8 kg/ha in the IFOAM basic standards. This limitation was taken up by the EU regulation (Reg. 473/2002). The limit was 8 kg/ha/year until 2005, and then reduced to 6 kg/ha/year (with the possibility to make an average

over 5 years in perennial crops). In addition, the registration of copper compounds as pesticides is under pressure. In some countries (e.g. NL, DK), their use in agriculture is forbidden, and in other countries, there is a lower quantitative limit (e.g. 3 kg/ha/year in Germany that follows a previous limitation by private organic standards). Further quantitative limitations are likely for the future. The approval period for copper products in part A of the annex to Reg. 540/2011 expires 31 January 2018 (EC 2014).

There is research on alternative substances to copper[4], but complete alternatives are not available yet. Acidified clays (aluminium sulphate) were listed as plant strengtheners in Germany and as micro-nutrient fertilizers in Italy and had an important role in the past. They cannot be used at present, because they are not listed as plant strengtheners/fertilizers any more. They are authorised as fungicides in Switzerland, and are also authorised for organic farming. In Switzerland, they are important products for organic viticulture and apple growing, and have helped to limit copper to 4 kg/ha/year in grapes, and 1.5 kg/ha/year in apples. Laminarin is authorized for organic farming. It has been shown to reduce downy mildew in grapes (Aziz et al. 2003), and could therefore potentially be used in copper minimisation strategies. However, the Group found no evidence that it is currently authorized for use against downy mildew in grapes. Potassium phosphonates could be another alternative to copper fungicides. The applicants propose a plant protection strategy, in which grapevines are sprayed with potassium phosphonates until the end of flowering, and later with copper fungicides. It seems that such a strategy could do with 3 kg/ha/year of copper, which is one-half of the amount currently permitted by Reg. 889/2008.

The need for a product to control downy mildew, e.g. potassium phosphonates, is most pronounced in countries with a low limit for copper fungicides. In Germany, copper has been limited to 3 kg/ha/year for many years, and at the same time potassium phosphonates were available for organic wine growers. Organic viticulture without phosphonates would be a challenge under these conditions.

Origin of raw materials, methods of manufacture

Potassium phosphonates for commercial use are synthetically manufactured.
Because phosphonates with O-P bonds are not stable under normal atmospheric conditions, their occurrence in nature is rare. A literature review concluded that they seem to occur on meteorites, and that they might also have occurred on the earth in geological times (Hofmann 2012). Recently, phosphite has been found in pristine geothermal pools in California (Pech et al. 2009), and in the eutrophic lake Taihu in China (Han et al. 2012). In conclusion, the group recognises that phosphonates have been detected in extraordinary, rare natural environments.

The discussion regarding the natural occurrence has sometimes been misled by the fact that the term 'phosphonates' refers to the salts/esters of phosphonic acid and/or to the organophosphorous substances with C-P bonds (see figure 1). The latter group occurs widely in nature (for a review see Hilderbrand and Henderson, 1983), but is not relevant for the evaluation of potassium phosphonates, because it has different chemical properties.

[4] For example the EU-funded research project 'CO-FREE' (http://www.co-free.eu/index.html) and nationally funded projects (http://kupfer.jki.bund.de/index.php?menuid=33).

Environmental issues, use of resources, recycling

Potassium phosphonates are relatively stable in the soil, but are finally oxidised to phosphate (Adams & Conrad 1953; EFSA 2012b). The Group has not identified inacceptable negative impacts on the environment.

The group believes that reduction/elimination of copper fungicides would be beneficial for soil health. Various methods (not only potassium phosphonates) could contribute to this goal.

Animal welfare issues

No issues identified.

Human health issues

Potassium phosphonates have shown low toxicity in rodents after oral administration as well as after dermal administration and inhalatory exposure. No safety concerns were identified for operators and bystanders, nor for consumers. Potassium phosphonates are neither skin sensitizers nor skin or eye irritants (EFSA, 2012).

Food quality and authenticity

Organic wine is a new market product, defined by EU legislation only since 2012. In the last decade, the market has grown rapidly[5].

The application of potassium phosphonates usually leads to phosphonate residues in wine, but their level depends on the application strategy. Early on-farm trials were carried out in Switzerland from 1988 and 92 (Speiser et al. 2000). In these trials, two applications per season were made on average, and a total of 7 kg/ha phosphonate was applied. Although residues varied greatly, they were mostly in the range of 6 – 20 mg/kg. Later trials in Germany were designed to minimise residues (Kauer 2011). When phosphonate was applied until the beginning of ripening of berries (BBCH 80), residues were above 20 mg/kg, but when application was limited to the end of flowering (BBCH 68), residues were 2 – 5 mg/kg. According to preliminary results, phosphonates are persistent in grapevines, and can be found one or two years after treatment (Kauer 2011). Residues in wine are somewhat higher than those in grapes (processing factor = 1.3; EFSA 2012b).

There has been an intensive debate, mainly among German organic wine growers, whether phosphonate residues are acceptable in organic wines (for an example, see the conference dedicated to phosphonates held in 2010; Kühne 2011). The authorization criteria in the organic regulation (Art. 16 of Reg. 834/2007) gives limited guidance on the issue of pesticide residues. Recital no 6 of Reg. 889/2008 states 'The use of pesticides, which may have detrimental effects on the environment or result in the presence of residues in agricultural products, should be significantly restricted. Preference should be given to the application of preventive measures in pest, disease and weed control'. The Group underlines that the discussion of residues is not limited to potassium phosphonate. Some other, authorised substances such as spinosad, pyrethrum or azadirachtin also regularly cause residues (Bienzle 2013). However, spinosad, pyrethrum or azadirachtin are quickly degraded, while phosphonates are very stable, and persist within plants for up to several years.

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[5] For an example, see http://www.winemonitor.it/en/follow-wine-monitor-en/item/510-organic-wines-sales-keep-growing-in-the-italian-and-us-markets.html (accessed on May 7, 2014).

Fosethyl-Al (a closely related synthetic fungicide used in conventional farming) has been used as a fungicide for many years. Inside plants, it breaks down to phosphonate. Therefore, maximum residue limits (MRLs) have been set for phosphonates as part of the registration of fosethyl-Al. Fosethyl and phosphonates can be detected separately, but for the moment, residues have to be expressed as fosethyl (=sum fosethyl + phosphorous acid and their salts). If potassium phosphonates are authorised for organic farming, this will cause a problem, because the residues of an authorised substance would have to be expressed as a non-authorised substance. In the case that potassium phosphonate is allowed for organic farming, the Group recommends to revise the residue definition.

Wine is stored for several years. The group assumes that a number of organic winegrowers, wine sellers and consumers have stocks of wine from organic grapes which contain phosphonate residues caused by legal application of potassium phosphonates in the past. A solution needs to be found for the future marketing of such stocks.

Traditional use and precedents in organic production

In Germany, potassium phosphonates have been traditionally used as plant strengtheners in organic viticulture since the 1980ies. For a shorter time, they were also used in some other Central and Eastern European countries.

Aspects of international harmonization of organic farming standards

Potassium phosphonates are neither authorised according to the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods, nor for organic production in the USA. They are also not mentioned in the IFOAM standards.

Other relevant issues

If potassium phosphonates are to be authorised for organic farming, it should be clarified whether the authorization is limited to grapes (table and/or wine grapes). However, in case of such a limitation the Group expects that uses on other crops will be requested in the near future. There are other crops which have huge problems with downy mildew and other disease which could be controlled by phosphonates (tomatoes, potatoes, apples, citrus, some vegetables etc.). Although large parts of this evaluation apply to all crops, need and residues must be assessed separately for other crops.

The use of potassium phosphonates is a source of synthetic potassium and (after oxidation by soil microorganisms) of synthetic phosphate. The Group thinks that the amounts of P and K brought into the soil are not high. For a minimised application strategy in grapes, the Group assumes application of 3 – 7 kg/ha/a potassium phosphonates, which is equal to about 1.6 – 3.8 kg K/ha and 0.43 – 1.0 kg P/ha.

Phosphonates are potent fungicides, and their availability could reduce the motivation for the development of other copper alternatives.

Reflections of the Group / Balancing of arguments in the light of organic farming principles

The evaluation of potassium phosphonates involves a trade-off between their agronomic advantages and their negative impact mainly on product quality/public perception (persistence in plants, residues). This is complicated by the fact that both advantages and disadvantages can be

seen differently from different viewpoints, and that the advantages are linked to the availability of copper fungicides, which are themselves under discussion.

Necessity may be seen differently, depending mainly on climatic conditions and on copper authorization. The advantages can be seen as follows: (1) In countries where a severe quantitative restriction of copper is imminent, or where copper fungicides have already been restricted, potassium phosphonates are one important tool (among others) for the maintenance of organic viticulture. (2) In other countries, potassium phosphonates can be seen as one tool (among others) for ensuring yield security. (3) From an environmental perspective, potassium phosphonates can be seen as one tool (among others) which allows to reduce (but not to replace) the use of copper fungicides. The use of copper has a negative public perception.

A disadvantage is that potassium phosphonates cause residues in wine. The presence of pesticide residues is a major concern of European consumers and a major motivation to buy organic food. The Group is concerned that the presence of phosphonate residues could put the market potential of organic wine at risk. The same is true for other crops, if phosphonates would be allowed for use on them.

Another argument against allowing potassium phosphates in organic production is that this will make it difficult for consumers and others to distinguish the organic growing practice from conventional farmers using other systemic and synthetic fungicides.

The acceptance of potassium phosphonate as a fungicide in organic agriculture is not consistent with the organic regulation in so far as it is a synthetic, systemic chemical substitute for copper fungicides and does not comply with Article 5 and Article 12 of reg. 834/2007 which emphasise the maintenance of plant health by preventive measures, such as the choice of appropriate species and varieties resistant to pests and diseases, appropriate crop rotations, mechanical and physical methods and the protection of natural enemies of pests.

Its adoption may delay the development of such agro-ecological solutions.

Conclusions

The Group underlines that copper use should be minimised, but in the Group's opinion, the use of potassium phosphonates is not in line with the objectives and principles of organic production as laid down in Council Regulation (EC) No 834/2007. If the objective is to reduce copper use by regulation at national or European level, then alternative options compatible with the regulation should be exploited.

4.2 Kieselgur (diatomaceous earth)

Introduction, scope of this chapter

The Group was asked whether diatomaceous earth should be re-authorised as an insecticide. Diatomaceous earth is also known as 'diatomite' or as 'kieselgur'; the latter term is used in EU pesticides legislation. Kieselgur consists of fossilised remains of diatoms, a type of hard-shelled algae which are among the most common types of phytoplankton. These shells consist of amorphous (non-crystalline) silicon dioxide (SiO_2; also known as 'silica'). Kieselgur for use in pest control should be 'a highly pure amorphous silica, having particles of equal diameter (< 10 μm), pH<8.5, containing the least possible number of clay particles and less than 1 % crystalline silica' (Korunic 1998). Commercial products used today typically contain more than 96 % kieselgur (Erb-Brinkmann 2000). Diatomaceous earths from different sources have different

biological effects. It seems that this is related to the type and structure of skeletons of which they consist.

There are also other forms of silica: Kieselgur chemically resembles quartz, which is also silicon dioxide. However, quartz has a crystalline structure, while kieselgur has an amorphous structure. Quartz is the second most abundant mineral in the earth's continental crust, and the main constituent of sand. Quartz can be used as a repellent for mammals.
Amorphous silica can also be manufactured synthetically. This is called 'silica gel', and is a widely used desiccant. It has the same chemical composition as kieselgur (SiO_2), but a different structure. The term kieselgur, as used in this chapter, does not include synthetic forms of silica.
The applicants requested only the use in stored products, but the use in animal husbandry is also briefly discussed in this chapter.

Authorization in general agriculture and in organic farming

Silicates were reported to have been used in historic grain storages from around 1250 AD. The Slavic tribes inhabiting a village, located today in the southwest of Berlin (Museumsdorf Dueppel) used the dusts to protect their stored grains (oral comm., Prof. Plarre, Freie Univ. Berlin). A plant protection product based on kieselgur was authorised in Germany in 1996 and is commercially available in a number of EU countries. Before this, there already had been an authorization in Germany from around 1935 to 1942. Other products are authorised in Canada and the USA. It was authorised for many years in Germany for the control of cat lice.

Kieselgur is authorised under pesticide legislation for the control of insect and mite pests. The major use is for treatment of empty storage rooms and on grains. In addition, it is authorised under biocide legislation for the treatment of poultry stables, to control 'poultry mites' (*Dermanyssus gallinae*). It is also used to control stable flies. Further uses, e.g. on greenhouse crops, are under development.

In 1991, when the first EU organic regulation (Reg. 2092/91) was adopted, 'diatomaceous earth' was explicitly listed. In 1997, the list of pesticides was revised by Reg. 1488/97, and diatomaceous earth was no longer listed. At the same time, a number of new pesticides were added to the list, including quartz sand. The Group is not aware that there has been a discussion on kieselgur (diatomaceous earth), and Reg. 1488/97 gives no clear explanation in the recitals.
Under today's organic regulation, substances authorised as pesticides can also be used for the elimination of insects and other pests in buildings and other installations where livestock is kept (Reg. 889/2008, Art 23(4)).

Agronomic use, technological or physiological functionality for the intended use

Kieselgur is used as desiccant against arthropods on surfaces in empty rooms (dosage: of 10 g/m^2 surface). It can also be applied directly to the grain (max. dosage 1 – 2 kg/t of grains). Usually, only the top layer in a silo is treated, to prevent pests from migrating into the stored cereal. For a comprehensive review, see Subramanyam and Roesli (2000).

Kieselgur is active against a wide range of insect and mite pests. Among stored product arthropods, the Confused flour beetle *Tribolium confusum* is described as most tolerant to desiccation by kieselgur, with lethal exposure times of 3 – 5 days (Mewis and Reichmuth 1999). Kieselgur is removed from the grains during cleaning in the mill.

Kieselgur has a simple physico-chemical mode of action. If an insect comes into contact with kieselgur, the latter sticks to the wax layer on the epicuticle, removes it partly, and increases the external surface. Increased evaporation leads to desiccation and mortality. In addition, particles of kieselgur penetrate into various articulations. As a reaction, the pests make cleaning movements, but this allows more particles to enter the articulations. Fine particles of up to 50µm are described to have a stronger insecticidal effect than coarser ones. Lipophilic kieselgur is more effective than hydrophilic one. Kieselgur is very stable and can have a long-lasting effect, particularly inside inaccessible gaps or cracks.

As a secondary use, kieselgur is used in animal husbandry against the red bird mite (*Dermanyssus gallinae*) in poultry. Poultry houses are treated in the absence of poultry, to reduce the risk of inhalation.

Necessity for intended use, known alternatives

Protection of stored products against pests is of high importance form a hygienic and economic point of view, and to avoid food waste.

Prevention and control methods include insect-proof storage sites/packaging, cooling, sanitation (cleaning of sites and equipment), product drying, controlled/modified atmosphere, biological control, physical control (freezing, heating, mechanical percussion). Direct control includes the use of pyrethrum. Monitoring is done by trapping, thermometry, visual inspection or acoustics.
Because there are many different stored products, different storage conditions and different pests (over 100 important species), different methods are needed. For the treatment of empty rooms (prevention) and for long-term storage, kieselgur is preferable to these alternatives, because it has a long-term effect and is cheap. For storage rooms which are not gas-tight, kieselgur is a good preventive method. This is the case for most on-farm storage of organic grains.

Origin of raw materials, methods of manufacture

Kieselgur is of natural origin. It consists of the fossil remains of diatoms, which lived in lakes as phytoplankton and sedimented to the lake bottom after death. There are many deposits of kieselgur. Commercially utilized kieselgur originates mainly from northern and south-eastern Europe, as well as South America. Kieselgur is harvested by surface or deep mining. Afterwards, it is mechanically treated (crushed, dried and purified by air separation). It may contain a proportion of particles in the nanometre scale ('nanoparticles').
Kieselgur has a wide range of technical and industrial applications. For example, it is used as a filtering agent for drinking water, waste water, swimming pools, oils and beers, as an additive for concrete, paints, plastic paper and tablets, as a feed, as a carrier for fertilizers, pesticides and biocides and in the production of margarine and fats. It is a food additive (E 551), the abrasive agent in tooth paste, the carrier agent for medication in pills, and for ink in overhead slides.
Thus, the amounts used for insect control are tiny in comparison to the total worldwide usage.

Environmental issues, use of resources, recycling

As kieselgur is used indoors, the exposure of the environment is negligible (see EFSA 2012a). No negative effects on the environment are expected. Silicate dusts are very common but may be risky for young vertebrates or electronic equipment. They may stay effective for almost unlimited time.

Taking into account the small proportion of kieselgur used for plant protection, the Group has no concerns over the environmental impacts of mining and of waste disposal.

Animal welfare issues

As kieselgur is used indoors, the exposure of wild animals is negligible.

The treatment of poultry houses is positive for the welfare of poultry. Mortality has occasionally been reported in young poultry directly treated with kieselgur against red bird mite. However, this is an effect of overdose and inhalation of airborne dust due to wrong application, and may be minimised when kieselgur is applied correctly (i.e. only empty houses are treated).

Human health issues

Kieselgur can be purchased in drugstores to improve intestinal motility, bone structure and finger nails. In view of the widespread use of silica as a carrier and as a food additive (E 551), EFSA (2012) identified no concerns regarding oral exposure to kieselgur. Inhalation may have local lung effects, and dusts may affect the eyes. Impurities of crystalline silica are much more dangerous than kieselgur. Manufacturers must therefore ensure to use appropriate qualities of raw material. Kieselgur needs to be tested for residual levels of crystalline sands. Levels below 4 % are generally regarded as safe. Reg. 540/2011 requires a maximum of 0.1 % crystalline particles.

Because it is applied as an airborne dust and also because it is a desiccant, protective equipment (including a mask) is required for the application of kieselgur.

Impact on food quality

Grains treated with kieselgur contain residues of it. For high levels of residues, the following concerns apply: weight/volume ration is decreased; mild infestations by *Penicillium* cannot be detected (visual confusion with the kieselgur); retention of untypical smells; stated stronger abrasion of milling equipment.

To avoid these problems, grains must be cleaned as much as possible before processing, but complete removal is difficult. Levels below 100 g/ton grain can be achieved. At these levels, the above problems do not occur.

In any case, kieselgur is not of toxicological concern, and no MRL is set.

Traditional use and precedents in organic production

The use of kieselgur for control of stored products pests was authorised in EU organic production from 1991 – 97. It seems that most certifiers are still tolerating its use, assuming that it is indirectly covered by the listing of quartz sand, which has the same chemical composition. Kieselgur is authorised as a feed additive (Annex VI), as a food additive as an anti-caking agent (Annex VIII A) and as a food processing aid for gelatine production (Annex VIII B).

Aspects of international harmonization of organic farming standards

According to the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods, kieselgur may be used for plant protection, if the need is recognised by the certification body or authority. 'Non-synthetic' kieselgur (as discussed in this chapter) may be used in US organic production for 'processing pest control' in conjunction with facility pest management practices, and only if those practices are not effective to prevent or control pests, and for livestock health maintenance.

Reflections of the Group / Balancing of arguments in the light of organic farming principles

The Group sees a necessity for using kieselgur. The negative effects on product quality and worker health can be managed, and are of minor importance.

Conclusions

The Group concluded that the use of kieselgur for the control of stored product pests and poultry mites is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. 'Kieselgur (diatomaceous earth)' should therefore be included in Annex II without restrictions of target species. If a 'basic list of active substances' is established in Annex II (see chapter 4.10), kieselgur should be included there.
When used in animal buildings, appropriate measures must be taken to avoid negative effects on animal health, in particular through inhalation.

4.3 Carbon dioxide

Introduction, scope of this chapter

When discussing alternatives to kieselgur (see chapter 4.2), the Group noticed that carbon dioxide is not listed in Annex II, although it is also effective against stored products pests.

Authorization in general agriculture and in organic farming

Carbon dioxide is approved under pesticide legislation (Reg. 540/2011), for use as a fumigant against insects and mites in stored products, with or without air pressure (SANCO 2013b).
It is not listed in Annex II of Reg. 889/2008.

Agronomic use, technological or physiological functionality for the intended use

Carbon dioxide is applied to stored products as a fumigant. It can be used for pest control at ambient or at high pressure. At 20 °C and ambient pressure, some three weeks exposure time are needed in grain treatments to control all developmental stages of the rather tolerant weevils of the genus *Sitophilus*. By contrast, application times can be reduced to approximately 3 h at high pressure (20 bar). Carbon dioxide at ambient pressure is authorised for the disinfestation of infected grains, grain products and oilseeds. At high pressure, it is authorised for the disinfestation of infected grain products, tobacco, oilseeds, dried fruits, tea, spices and medical plants.

Carbon dioxide acts on pests by suffocation and by acidification. For this, a minimum concentration of 40 – 60 % carbon dioxide in the air is necessary. This can only be achieved in enclosures which are airtight. The use of carbon dioxide on stored products has gained importance in recent years.

Necessity for intended use, known alternatives

Protection of stored products against pests is of high importance form a hygienic and economic point of view, and to avoid food waste. Because there are many different stored products, different storage conditions and different pests (over 100 important species), different methods are needed. For an overview of preventive methods, see kieselgur (chapter 4.2). As a gas (and unlike kieselgur), carbon dioxide can enter into a large mass of bulk grain (e.g. peas or cocoa beans) and even kill beetles or developmental stages developing inside a grain kernel. This is important for the control of cereal grain pests such as weevils of the genus *Sitophilus*, grain borers like *Rhizopertha* or *Prostephanus*, grain moths like *Sitotroga* or bean weevils like *Callosobruchus* or *Acanthoscelides*.

While kieselgur is often used to prevent infestation, carbon dioxide is used for treating stocks which have already been infected. For the application of kieselgur, the grain would have to be moved which would spread the infestation to conveyor belts and other parts of the premise. In case of a severe infestation, fumigation with carbon dioxide is an efficient way of pest control. By contrast, biological control is more effective in preventing infestations.

Nitrogen gas is another potential fumigant to be used for pest control in stored products. Treatment with nitrogen gas is slower than with carbon dioxide (some 5 weeks for the control of all stages of the genus *Sitophilus*, as opposed to 3 weeks for carbon dioxide). The reason is that nitrogen gas acts only by absence of oxygen, and not by acidification.

Origin of raw materials, methods of manufacture

Storage houses normally use bottled carbon dioxide. There are various origins (see report EGTOP/6/13).

Environmental issues, use of resources, recycling

For this purpose (unlike greenhouses), carbon dioxide is hardly ever obtained by burning fossil fuels. As a consequence, the environmental impact is negligible.

Animal welfare issues

No issues identified.

Human health issues

Higher concentrations of carbon dioxide are dangerous. Carbon dioxide is heavier than air. In case of leakage, it can therefore accumulate close to the ground, and especially in cellars. To manage these risks, there need to be detectors with alarm.

Impact on food quality

On some dried fruits, discoloration and temporary fizzy sensation by high pressure carbon dioxide have been observed. In many other dried fruits, no such effect occurs, and they are widely treated with carbon dioxide. On other durables, no negative impact on food quality is known. Pesticide registration requires a minimum purity of 99.9 % (SANCO 2013b), therefore the Group has no concerns over potential contaminants present in the carbon dioxide.
The prevention of pest infestation is beneficial for product quality.

Traditional use and precedents in organic production

Carbon dioxide is authorised as a food additive for plant and animal products (Annex VIII A) and as a processing aid for plant and animal products (Annex VIII B). It is also authorised for

organic wine making. The use of high pressure carbon dioxide is apparently judged as a physical method and tolerated by some certifiers.

The use of carbon dioxide in organic greenhouses was previously discussed by the Group (see report EGTOP/6/13). The Group accepted the practice of CO_2 enrichment, but was concerned about the widespread tendency of burning fossil fuels in summer for the main purpose of obtaining CO_2, and recommended that CO_2 should preferably be used from natural sources, from processing or from burning of biomass sources.

Aspects of international harmonization of organic farming standards

According to the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods, carbon dioxide may be used for plant protection, if the need is recognised by the certification body or authority. Carbon dioxide may be used in US organic production for 'processing pest control'.

Reflections of the Group / Balancing of arguments in the light of organic farming principles

The Group sees a necessity for using carbon dioxide. Worker health can be managed with safety measures.

Conclusions

The Group concluded that the use of carbon dioxide for the control of stored product pests is in line with the objectives, criteria and principles of organic production as laid down in Council Regulation (EC) No 834/2007. It should therefore be included in Annex II. No restrictions are necessary in the Group's opinion. If a 'basic list of active substances' is established in Annex II (see chapter 4.10), carbon dioxide should be included there.

4.4 Piperonyl butoxide

Introduction, scope of this chapter

The Group was asked whether it is possible to use pyrethrins without piperonyl butoxide (from an efficacy point of view), what alternatives to pyrethrins would exist, and whether the use of piperonyl butoxide would be compatible with the principles of organic farming.

The Group noted that the situation regarding the use of piperonyl butoxide in organic farming is unclear at the moment. This chapter discusses the use in plant protection, although piperonyl butoxide could potentially also be used for the control of parasites in animal husbandry.

Authorization in general agriculture and in organic farming

Under pesticide legislation, piperonyl butoxide is considered as a 'synergist'. Synergists are substances or preparations which, while showing no or only weak activity [...], can give enhanced activity to the active substance(s) in a plant protection product (Reg. 1107/2009, Art 2.3(b)).

Only active substances are listed in Annex II of Reg. 889/2008 at the moment, thus synergists are out of the scope of Annex II. Piperonyl butoxide was never listed in the organic regulation. However, the first version of 2092/91 listed pyrethrins with the comment 'possibly containing a synergist'. Its use in organic farming is tolerated, if it is authorised at member state level.

Agronomic use, technological or physiological functionality for the intended use

Piperonyl butoxide contains the functional group methylenedioxyphenyl, which inhibits enzymatic breakdown (detoxification) of pyrethrin within the insect body. It is added to some commercial formulations of pyrethrin (and other insecticides) to increase their efficacy.

Necessity for intended use, known alternatives

The efficacy of pyrethrum products can be increased not only with piperonyl butoxide, but also with other oils such as sesame oil. These alternatives are already in use for a number of years. They are not as effective as piperonyl butoxide, but satisfactory for the use in practice.

Origin of raw materials, methods of manufacture

The material of origin, sassafras oil, is distilled from the root bark or the fruit of a few tree species, especially the sassafras tree (*Sassafras albidum*). Sassafras oil is then chemically processed to obtain piperonyl butoxide, which has a very similar structure. The Group found no indication for natural occurrence of piperonyl butoxide, but its functional group methylenedioxyphenyl occurs in sassafras oil and in sesame oil (Franklin 1976).

Environmental issues, use of resources, recycling

Because piperonyl butoxide is not considered to be an active substance, no EFSA evaluation report is available.

Animal welfare issues

For mammals, piperonyl butoxide has a low oral toxicity and a very low toxicity when inhaled, adsorbed by the skin or exposed to eyes (EMEA 1999). The Group has no concerns over animal welfare and health issues.

Human health issues

Because piperonyl butoxide is not considered to be an active substance, no EFSA evaluation report is available. Toxicological data were summarised in 1999 by the Veterinary Medicines Evaluation Unit (EMEA 1999). Acute toxicity is low, but long-term exposure may lead to liver damage. The WHO has set an acceptable daily intake of 0.2 mg/kg, which indicates no major toxicological concerns. No MRL for piperonyl butoxide is fixed within EU.

Impact on food quality

Piperonyl butoxide leaves residues on food, which can be detected with standard pesticide screening methods. For a discussion on residues, see chapter 4.1 (potassium phosphonates).

Traditional use and precedents in organic production

The use of piperonyl butoxide has been tolerated in EU organic farming for a long time.

Aspects of international harmonization of organic farming standards

According to the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods, piperonyl butoxide is excluded from use since 2005. The use of piperonyl butoxide is prohibited in US organic production.

Other relevant issues

It is possible that in some EU member states, all registered pyrethrin products contain piperonyl butoxide at the moment. In order to ensure continuous use of pyrethrin by organic farmers, an adequate transition period should be allowed, during which the manufacturers can modify their pyrethrin products (to substitute piperonyl butoxide), and register the new formulations.

Reflections of the Group / Balancing of arguments in the light of organic farming principles

The main advantage of piperonyl butoxide is that it increases efficacy of pyrethrin products and that it therefore reduces the use of pyrethrin. The disadvantages are its negative impact on the environment and on human health, and that it leaves residues.
Piperonyl butoxide is not necessary in the Group's opinion, because there are effective, preferable natural alternatives.

Conclusions

The Group concluded that the use of piperonyl butoxide is not in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. It should therefore not be included in Annex II, and the tolerance of its use should be phased out.

4.5 Use of potassium bicarbonate (potassium hydrogen carbonate) as an insecticide

Introduction, scope of this chapter

In this chapter, the term 'potassium bicarbonate' is used, which is the traditional term for this substance under organic legislation (Reg. 889/2008). Under pesticide legislation (Reg. 1107/2009) and recently also under Reg. 889/2008, however, the substance is now called 'potassium hydrogen carbonate'.

Potassium bicarbonate is authorised for use as a fungicide. This chapter evaluates whether its use should be extended to the use as insecticide. This chapter only discusses aspects which are new for this use. For other aspects, the previous evaluation made in 2008 should be consulted.

Authorization in general agriculture and in organic farming

Potassium bicarbonate was approved in 2008, as a fungicide against powdery mildew of grapes (*Uncinula necator*) and apple scab (*Venturia inaequalis*) (SANCO 2008). In 2012, the use as an insecticide against pear suckers (*Psylla pyri*, *P. pyricola*) was added (SANCO 2012). The Group could verify registrations for use as an insecticide on pear for Belgium and the United Kingdom.

The use of potassium bicarbonate in organic farming was evaluated in 2008 (Forster et al. 2008) and authorised in the same year (Reg. 404/2008). At that time, its effect against pear suckers was unknown.

Agronomic use, technological or physiological functionality for the intended use

According to the technical documentation, potassium bicarbonate is lethal for larvae of pear suckers, and repellent for adults, thus reducing egg laying. It has to be applied at weekly intervals. In the UK, a maximum of 9 sprays with 6.8 kg/ha of potassium bicarbonate are authorised.

Necessity for intended use, known alternatives

In regions where pear suckers occur, there is a great need for a control method against this pest. Kaolin is a potential alternative, but plant protection products may not be registered in all member states. Its authorization for organic farming was recommended earlier by the Group (see report EGTOP/3/2011), and it is now authorised for organic farming (Reg. 354/2014). In the Group's opinion, potassium bicarbonate and kaolin are similarly acceptable for use in organic farming.

Origin of raw materials, methods of manufacture

Forster et al. (2008) concluded that both potassium and bicarbonate are ubiquitous in nature. The commercial substance is manufactured from potassium chloride and carbon dioxide.

Environmental issues, use of resources, recycling

Forster et al. (2008) did not see the need to reassess these issues.

Animal welfare issues

No issues identified.

Human health issues

Forster et al. (2008) did not identify any issues.

Food quality and authenticity

No issues identified.

Traditional use and precedents in organic production

Potassium bicarbonate is traditionally used in organic farming.

Aspects of international harmonization of organic farming standards

According to the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods, it may be used for plant protection, without further restrictions. It is included in the IFOAM standards. Potassium bicarbonate may be used for disease control in US organic production, but not for pest control.

Reflections of the Group / Balancing of arguments in the light of organic farming principles

Potassium bicarbonate is already authorised as a fungicide, and the Group sees no arguments against its use also as an insecticide.

Conclusions

The Group concluded that the use of potassium bicarbonate as an insecticide is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. The Group recommends that the restriction 'fungicide' should be deleted. As a less preferred alternative, the use 'insecticide' could be added.

If a 'basic list of active substances' is established in Annex II (see chapter 4.10), potassium bicarbonate should be included there.

4.6 Use of fatty acid potassium salt (soft soap) for disease control

Introduction, scope of this chapter

In chemistry, 'soap' is a salt of a fatty acid. Sodium salts are called 'Marseille soap', while potassium salts are called 'soft soap' (for details, see chapter 'group substances' below). In this chapter, they are discussed collectively under the term 'soft soap', which was chosen for being short.

Soft soap is authorised in organic farming for use as an insecticide. The Group was asked whether its use should be extended to the use as a fungicide. In addition, other potential uses are also briefly discussed.

Authorization in general agriculture and in organic farming

Soft soap was last evaluated in 2013 (EFSA 2013a). It is currently authorised as an insecticide, acaricide and plant growth regulator, but also as an herbicide. For a soft soap based on coconut oil, registration as an adjuvant is pending in Germany. The same product is registered as a fungicide in Switzerland, for use against sooty blotch on apples.

Agronomic use, technological or physiological functionality for the intended use

The available data suggest that soft soap has a limited potential to be used against crop diseases. The mode of action is not clear to the Group; it could be either as an adjuvant to enhance the effect of a fungicide, or as a fungicide itself.

Necessity for intended use, known alternatives

Sooty blotch (*Gloeodes pomigena*) is a disease which attacks apples from the end of July until harvest. Symptoms develop only during harvest, and may cause severe losses. Sooty blotch is well controlled as a side-effect of copper fungicides applied for scab control (Höhn et al. 2012). Only when the cultivation of scab-resistant apple varieties (which do not need to be treated with copper fungicides) started, sooty blotch gained economic importance. In the cultivation of scab-resistant apple varieties, soft soap is highly necessary.

As far as other crops are concerned, the Group thinks that the available scientific data do not support a level of efficacy which is promising for practical use as a fungicide. Nevertheless, it has a potential use as an acaricide and as an adjuvant. Herbicides: see below.

Origin of raw materials, methods of manufacture

Fatty acids can be obtained from various natural sources, for example coconut oil. They are treated with potassium hydroxide to obtain soft soap.

Environmental issues, use of resources, recycling

In its latest evaluation of the outdoor uses of soft soap, EFSA (2013) identified a risk for aquatic organisms and bees. For potassium salts of fatty acids, EFSA identified data gaps to address the following aspects of the ecotoxicological risk assessment: aquatic organisms, bees, non-target arthropods, earthworms and soil microorganisms. A low risk to birds, mammals, non-target plants and sewage treatment organisms was concluded. When soft soap is used correctly (according to label instructions) and not applied to watercourses, the Group has no concerns.

Animal welfare issues

No issues identified.

Human health issues

No issues identified.

Food quality and authenticity

No MRLs are required for soft soap, and the group has no concerns over possible residues of soft soap.

Control of sooty blotch is necessary to maintain good quality of apples during storage.

Traditional use and precedents in organic production

Soft soap is traditionally used in organic farming, and has been authorized for EU organic farming since 1991.

Aspects of international harmonization of organic farming standards

According to the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods, soft soap may be used for plant protection, without further restrictions. In US organic production, soft soap may be used as an active ingredient for pest control, but not for disease control. However, it may be used as a formulating agent (inert ingredient), and may thereby also occur in fungicides. Use as an herbicide is allowed, but only for farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.

Other relevant issues

Soft soap is also registered for use as an herbicide, but the Group did not evaluate this use. The Group emphasises that the use of any substance as herbicide has no precedent in EU organic farming.

Reflections of the Group / Balancing of arguments in the light of organic farming principles

Soft soap is traditionally used in organic farming (as insecticide) and has a very low toxicity and hardly any negative impact on the environment. Based on current experience, the Group sees effectiveness against sooty blotch, but expects only limited effectiveness as a fungicide in most other crops. The Group sees no major argument against its use as a fungicide in organic farming.

Conclusions

The Group concluded that the use of soft soap for disease control is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007 and recommends appropriate modifications of the present listing of soft soap in Annex II, in accordance with pesticide registrations.

The Group recommends to delete the restriction 'insecticide'. As a less preferred option, the use 'fungicide' could be added. The use as herbicide should not be authorised. If a 'basic list of active substances' is established in Annex II (see chapter 4.10), soft soap should be included there.

4.7 'Basic substances'

Introduction, scope of this chapter

The Group was asked whether substances authorised as 'basic substances' under Art. 23 of Reg. 1107/2009 could automatically be considered as included in Annex II of Reg. 889/2008. 'Basic substances' are substances which are not predominantly used for plant protection (a full definition is given in Art. 23 of Reg. 1107/2009).

Authorization of 'basic substances' under Reg. 1107/2009

The procedures and data requirements for registration of pesticides have been tailored to modern, synthetic pesticides, for which applications are typically submitted by a commercial agrochemical company. When the new pesticides regulation 1107/2009 was elaborated, a second registration pathway was established for so-called 'basic substances'. These are substances which are useful in plant protection, but are not predominantly used for this purpose. The category of 'basic substances' is new, and experience is still very limited. So far, the 'guidance document' is not yet finalised, and only one pilot dossier has undergone the entire evaluation procedure.

Once that a substance has been granted the status of 'basic substance', it can be sold and used freely, and there is no legal protection for the applicant. Commercial companies are therefore unlikely to submit applications for basic substances. Unlike normal pesticides, however, applications for basic substances can be submitted by any interested party. It is likely that applications will be submitted mainly by governmental agencies or non-profit organisations such as organic farmers' associations.

Not every substance which is predominantly used for purposes other than plant protection will be applied for / granted the status of 'basic substance'. Those substances which have been registered through the 'normal' pathway are likely to keep their status as registered pesticides, such as spearmint, orange and rape seed oil, ethylene, soft soap, paraffin oil and quartz sand.

Range of substances which might qualify as 'basic substances'

At this stage, it is difficult to foresee the range of substances which will be applied for this category. In June 2013, the Commission has compiled a draft list of possible candidates for basic substances, which were identified by EU member states and stakeholders (SANCO 2013a). This list contains 49 substances, some of which are discussed below. However, the Group cannot exclude that other substances will be proposed as basic substances in the future.

Possible candidates with a traditional use in organic farming (calcium hydroxide, gelatine, lecithin and Quassia)

Among the possible candidates for basic substances, calcium hydroxide, gelatine, lecithin and *Quassia* extract are of particular interest. These substances have a traditional use in organic plant protection, but could not be re-authorised during the 4th stage of pesticide re-evaluation. For these substances, continued use in EU organic farming can only be ensured, if they are authorised as basic substances. At the moment, these substances are still included in Annex II of Reg. 889/2008, and the Group has no objections to their continued use, if they should be approved as basic substances. If these substances are approved as basic substances; the Group recommends that their use in organic production should be allowed immediately, with no need to consult the Group.

Horsetail

Dried horsetail (*Equisetum arvense* L.) is the first substance for which an application as basic substance was submitted. EFSA has completed the consultation with member states, and published its conclusions (EFSA 2013b). However, a final decision on its authorization has not yet been published. According to the application (EC 2013), horsetail is intended to be used on fruit trees, grapevines, cucumber and tomato, for the control of a range of foliar diseases. The application gives no details regarding the effectiveness of such treatments, therefore the Group could not evaluate the necessity for its use, which is required by Art. 16(2) of Reg. 834/2007.

The Group has not attempted a full evaluation of horsetail. The facts that horsetail is a plant, and that horsetail decoctions have traditionally been used in organic farming, are arguments in favour of its inclusion in Annex II. However, EFSA mentions some toxicological concerns over certain constituents of horsetail.

Possible candidates which are foodstuffs

Among the possible candidates for basic substances, there are numerous foodstuffs. The definition of foodstuff in Art. 2 of Reg. 178/2002 includes all kinds of 'regular foods' as well as food additives and similar substances (e.g. flavours). The list contains substances of plant or animal origin such as beer, cinnamon, fructose, glucose, milk, molasses, sucrose, starch and sunflower oil. On the other hand, the list also contains synthetic food additives such as citric acid (E 330), magnesium chloride (E 511), potassium chloride (E 508) and sodium hydrogen carbonate (E 500).

Concerning the use of 'regular foods' of plant or animal origin, the Group has no toxicological and very little ecotoxicological concerns. However, issues of food waste should be considered.
In the case of synthetic food additives, it should be evaluated case by case whether their use for plant protection purposes is consistent with the principles of organic production. The Group would be concerned about automatic approval of such substances.
In all cases, GMO origin must be excluded.

Possible candidates which occur in nature, but have no traditional use in organic farming

The list of possible candidates contains also a number of other substances which occur in nature, but have no traditional use in organic farming. Some of these are discussed below:

- 1-Octen-3-ol is a metabolite of micro-organisms and edible mushrooms, and occurs also in a number of plants. It is used as an attractant for mosquitoes and flies. For commercial purposes, it is chemically synthesised.
- Dimethyl disulfide (DMDS) occurs is the mushroom *Phallus impudicus*, known colloquially as the common stinkhorn. It is used as a flavour for foods, and also in the petrochemical industry. For commercial purposes, it is chemically synthesised.
- Lactoperoxidase is a component of the immune system and occurs in humans and most animals. Lactoperoxidase is an effective antimicrobial agent, and is used for preserving food and cosmetics, and also in medicine (e.g. dental and wound treatment).
- Salicylic acid occurs in various plants. It is used in cosmetics and medicine. For commercial purposes, it is chemically synthesised.

In conclusion, some of these substances might prove to be acceptable for organic farming, but this is not certain at the moment. The Group recommends that each of them should be fully evaluated, and would be concerned about automatic approval of such substances.

Possible candidates which are synthetic substances

The Group cannot exclude that synthetic substances or substances with negative side-effects might be approved as basic substances in the future. Their use would not comply with the objectives and principles of organic farming, and automatic approval would clearly be undesirable (Art 4c of Reg. 834/2007).

Reflections of the Group / Balancing of arguments in the light of organic farming principles

The main advantage of automatic authorization of basic substances is that this saves time, efforts and costs. In the case of automatic authorization, substances would be immediately available for organic farmers after their approval as basic substances. In the past until now, the inclusion of new substances has often taken several years.

The main disadvantage of automatic authorization of basic substances is that the organic sector loses control over the substances authorised for plant protection. In public perception, the range of substances authorised for plant protection plays an important role. It is seen as an important factor determining the environmental impact of organic farming, but also determining food quality (residues).

According to Article 16.2 of Reg. 834/2007, substances must be necessary, in order to be authorized for organic production. In the Group's opinion, the concept of 'automatic authorization' is contradictory to this principle.

In the Group's opinion, it is crucial that the range of substances authorised for plant protection remains fully under the control of the organic sector. Thus, the disadvantages of automatic approval outweigh the advantages.

However, in the Groups opinion, a faster evaluation procedure for basic substances could be considered.

Conclusions

The Group does not recommend that substances authorised as 'basic substances' under Reg. 1107/2009 are automatically considered as included in Annex II of Reg. 889/2008.

4.8 'Low risk substances'

Introduction, scope of this chapter

There is also a group of low risk substances in pesticide legislation (Art. 22 of Reg. 1107/2009). These substances are plant protection products. At the moment, neither the criteria nor potential candidates for low risk substances are known.

Reflections

In the Group's opinion, it is crucial that the range of substances authorised for plant protection remains fully under the control of the organic sector.

Conclusions

The Group is against automatic approval of low risk substances in organic farming.

4.9 'Group substances'

Introduction

When an active substance is authorised as a pesticide, it is added to the Annex of Reg. 540/2011. In most cases, the listing refers to a chemically well-defined substance. In a few cases, however, the listing is broader and covers a group of substances. The Group was asked whether there is a need for discrimination between individual substances within a group, when such 'group substances' are included in the Annexes in Reg. 889/2008.

The Group could find neither an official definition of 'group substances', nor an official list of such substances.

'Group substances' in the organic regulation

Grouping of similar substances can be useful, and has been practiced not only in pesticide registration (Reg. 540/2011), but also in the organic regulation (Reg. 889/2008). In Annex II, several group substances are mentioned. In most cases, these groups also contain some substances which are not authorized under Reg. 540/2011:

- hydrolysed proteins;
- 'plant oils (e.g. mint oil, pine oil, caraway oil)';
- 'micro-organisms; Products as specified in the Annex to Implementing Regulation (EU) No 540/2011 and not from GMO origin';
- pheromones;
- fatty acid potassium salt (soft soap);
- paraffin oil.

More examples can be found in Annex I, such as 'products and by-products of plant origin for fertilisers'. In all these cases, it has been a deliberate decision to authorise an entire group of substances, which can be evaluated similarly form the point of view of organic farming.

Hydrolysed proteins

Hydrolysed proteins are authorised as attractants. They are mixtures of various amino acids. These occur in nature as mixtures, and are usually not separated during the manufacturing process. As described below for fatty acids, any further specification would impose a need for separation of substances during the manufacturing process, which is not desirable from an organic point of view. The Group does not see any amino acid which should be excluded from organic production. In conclusion, the Group sees no need for further specification of hydrolysed proteins in the organic legislation.

Plant oils

Plant oils are authorised as a group in the organic legislation, but are registered as pesticides individually. Currently, citronella oil, clove oil, spear mint oil and rape seed oil are registered, while many other oils have not been approved. In Reg. 540/2011, they are listed with the prefix 'Plant oils / [...]'. This prefix could give the wrong impression that all plant oils are registered. However, in the context of Reg. 889/2008 this is of no concern, because this regulation indeed authorises all plant oils.

Citronella oil is authorised as an herbicide. This use is not acceptable for organic farming (see fatty acids, chapter 4.6). The other plant oils are authorised as insecticides, acaricides, fungicides, bactericides or sprouting inhibitors. These uses are acceptable for organic farming. The Group can imagine other uses to be developed in the future, for example repellent,

nematicide, rodenticide, fruit thinning, molluscicide. In the Group's opinion, all uses except the use as herbicide are acceptable.

Micro-organisms

The use of biocontrol agents, including micro-organisms, is one of the most preferable methods of pest/disease control in organic farming. For micro-organisms which have been approved as pesticides, their use has very few negative side-effects on the environment and is harmless for the operator. Microbial biocontrol is a rapidly developing field, and new micro-organisms are regularly approved under Reg. 540/2011.

The Group does not see any micro-organisms which should be excluded from organic production, except for GMOs.

The Group recommends that the present listing of micro-organisms as a group should be maintained, with the restriction that they must not be GMOs.

Pheromones

A large number of pheromones are approved under Reg. 540/2011. Under Reg. 889/2008, all pheromones were traditionally authorised, but their use was limited to traps and dispensers. Recently, the range of substances has been limited to numbers 255, 258 and 259 of Reg. 540/2011.

Pheromones have some very beneficial properties: (1) very low toxicity to humans, (2) very low toxicity to non-target organisms and very little negative side-effects on the environment, (3) they are used in low doses (OECD 2001), and (4) they are usually not applied onto the crops, but in traps or dispensers. For practical reasons, it is not possible to extract pheromones from their natural sources (i.e. the pests), so they are manufactured synthetically. In some cases, the synthesized molecules deviate slightly from the natural form, but they are functionally identical. In the Group's opinion, the use of pheromones is clearly preferable to the use of insecticides. The Group is even willing to accept the use of non-natural pheromones, as long as they are not directly applied to crops. For synthetic pheromones, however, it should be checked whether they are similarly host-specific as their natural analogues.

The Group concluded: (1) for pheromones used in traps and dispensers, not only numbers 255, 258 and 259, but also new substances are in line with the principles of organic production. (2) new pheromones sprayed onto plants could be acceptable, but they should be evaluated case by case, and listed individually in Reg. 889/2008.

Fatty acid potassium salt (soft soap)

Fatty acids potassium salts are a group of substances with variable chemical composition, but similar chemical properties and similar effects as pesticides. Numerous fatty acids occur in nature. They can be roughly categorised by their chain length (number of C-atoms), and by the presence or absence of double bonds (unsaturated vs. saturated). Well-known examples include formic and acetic acid. Fatty acids can be obtained from fats of plant or animal sources. These fats are always a mixture of several fatty acids. The product used for plant protection is normally a potassium salt of mixture of fatty acids with chain lengths of 7 – 18 C-atoms (CAS number 67701-09-1). Certain fatty acids are also marketed as pure compounds, e.g. pelargonic acid (C9). Mixtures of fatty acids with chain lengths of 7 – 18 C-atoms are authorised for use as pesticides. From an organic point of view, each individual fatty acid could be evaluated similarly, and similarly to the mixture. Thus, further specification has no added value. These fatty acids occur in nature as mixtures, and are usually not separated during the manufacturing process. Any

further specification would impose a need for separation of substances during the manufacturing process, which is not desirable from an organic point of view. The Group does not see any fatty acid potassium salts which should be excluded from organic production. In conclusion, the Group sees no need for further specification of fatty acids in the organic legislation.

Paraffin oil

Paraffin oils are mixtures of hydrocarbons, containing molecules of various chain lengths (11 – 31 C atoms). Under Reg. 540/2011, three mixtures are approved as a group (CAS No 64742-46-7, No 72623-86-0 and No 97862-82-3), while a fourth mixture is approved individually (CAS No 8042-47-5). From an organic point of view, each individual hydrocarbon and each mixture could be evaluated similarly. Thus, further specification has no added value. The Group does not see any individual hydrocarbon or mixture of hydrocarbons which should be excluded from organic production. In conclusion, the Group sees no need for further specification of paraffin oils in the organic legislation.

Repellents by smell of animal or plant origin

The following repellents by smell of animal or plant origin are listed in Reg. 540/2011: fish oil, sheep fat, tall oil crude and tall oil pitch. Sheep fat has recently been authorised for organic farming, while the other substances are not authorised. Sheep fat has been discussed in report EGTOP/3/2011, and has recently been authorized for organic farming (Reg. 354/2014).
For the moment, the Group has not studied fish oil, tall oil crude and tall oil pitch in detail, and therefore cannot recommend to list all these repellents as a group.

Other relevant issues

There may be other groups in the future. These would need to be considered case by case, before they are included.

Conclusions

For the 'group substances' currently authorised for organic production, the Group sees no need for further specifications in Reg. 889/2008. In the contrary, it could be reflected whether it would be appropriate to replace some of the current listings of individual substances by newly formed groups.
Before bringing a new group on the list, it must be very carefully evaluated whether there are substances inside the group that do not comply with the principles of organic farming. Depending on this evaluation, it should be decided whether the group is included as a whole, or whether a further discrimination is required.
For all groups, only the substances authorized under Reg. 540/2011 can be used.

4.10 Specification of use categories in Annex II ('basic list of active substances')

Introduction

The first EU organic regulation (Reg. 2092/91) listed all authorised pesticides in Annex II B, without restrictions in their use. Specifications of the use category (e.g. 'insecticide', 'fungicide') were added in 1997 (Reg. 1488/97). Today, the use category is specified for all products listed in Annex II, except for micro-organisms.

For pesticides, the use category is primarily specified by Reg. 540/2011. Pesticide registration is a dynamic process. New uses are regularly approved, and old uses are withdrawn. In recent

years, the specifications in Annex II of Reg. 889/2008 were therefore often outdated. This has caused considerable efforts for updating of Annex II, and it has delayed the implementation of newly approved uses on organic farms. The following proposal aims to improve this situation.

Use categories defined by pesticide legislation

This paragraph lists all use categories currently found in the EU pesticides database.

- Control of pests/diseases: insecticide, acaricide, molluscicide, nematicide, rodenticide, bactericide, fungicide, attractant, repellent, elicitor, plant activator, virus inoculation, synergist, soil treatment. Some of these categories describe the target species (e.g. insecticide), while others describe the mode of action (e.g. attractant) or the site of application (soil treatment).
- Control of weeds/algae: herbicide, algicide, safener. Again, some categories describe the target species (e.g. algicide), while others describe the mode of action (safener).
- Other uses: plant growth regulator, pruning, desiccant, other treatment.

In the Group's opinion, it would be sufficient for the first group to specify that they can be used for the control of pests/diseases, and no more detailed specification is necessary. By contrast, all other potential uses are critical with respect to organic farming principles, and detailed specification is adequate.

Details of the proposal for currently listed substances

The Group proposes the establishment of a 'basic list of active substances' as the first sub-chapter within Annex II. This should contain selected substances from Annex II. The proposal is limited to substances of natural origin, for which the use in organic plant protection is not controversial (see below). For all cases where there could be concerns about certain uses, authorized uses should be specified as until now.

In most of these substances, the Group proposes to delete the specifications. Some plant oils, soft soaps and micro-organisms have herbicidal activity and could potentially be used as herbicides. To avoid any misunderstandings, the use as herbicides should therefore be excluded for the entire 'basic list of active substances'.

Basic list of active substances

Substances not to be used as herbicides, but only for the control of plant pests and diseases.

Name of substance	New conditions for use	Change from present conditions
Lecithin*	(no specification)	delete 'fungicide'
Plant oils	Use also as sprout inhibitors. Products as specified in the Annex to Commission Implementing Regulation (EU) No 540/2011.	delete 'insecticide, acaricide, fungicide'
Micro-organisms	Products as specified in the Annex to Commission Implementing Regulation (EU) No 540/2011 and not from GMO origin.	none
Pheromones	only in traps and dispensers Products as specified in the Annex to Commission Implementing Regulation (EU) No 540/2011 (numbers 255, 258 and 259)	delete 'attractant, sexual behaviour disrupter'.

Fatty acid potassium salt (soft soap)	(no specification)	delete 'insecticide'
Quartz sand	(no specification)	delete 'repellent'
Kaolin	(no specification)	delete 'repellent'
Laminarin	(no specification)	delete 'elicitor of crop's self-defence mechanisms'
Potassium hydrogen carbonate (aka potassium bicarbonate)	(no specification)	delete 'fungicide'
Kieselgur	(no specification)	(new substance, inclusion proposed in chapter 4.2 of this report)
Carbon dioxide	(no specification)	(new substance, inclusion proposed in chapter 4.3 of this report)

*subject to approval under pesticides legislation.

Implementation of the proposal with new substances

Before a new substance is included in Annex II, it should be reflected whether specifications of the use category are necessary or not. Specifications should only be added, if there is a doubt that future uses might not comply with organic farming principles. Based on these considerations, the substance may be included in the 'basic active substances', or elsewhere in Annex II.
For the substances evaluated in this report, the Group has already adopted this approach.

Justification of the proposal

The proposal is limited to non-controversial substances (see above) for which no concerns have been raised in the organic sector; for all other substances (e.g. ethylene), the Group fully supports the current practice of specifying uses in Annex II.

With respect to *non-controversial substances*, the Group points out the following arguments:

- Even for substances where no specifications are given in Annex II, the use must follow the specifications laid down in Reg. 540/2011.
- With respect to organic farming principles, there is no added value in repeating these specifications.
- For the EU authorization process, these specifications represent an extra burden, because use categories must regularly be updated (for examples, see the evaluations of potassium bicarbonate and of soft soap above).
- For organic farmers, these specifications unnecessarily delay the adoption of newly approved uses.
- In the case of emergency measures against newly upcoming and spreading pests/diseases, these specifications present unnecessary difficulties for the implementation on organic farms.
- For input manufacturers, these specifications represent a second hurdle (besides pesticide registration) which further delays the marketing to organic farmers. By deleting the specifications for substances in the 'basic list of active substances', the development of new plant protection products and/or the registration of new uses can be encouraged for these substances.

The approach of authorizing a 'basic list of active substances' of substances without further restrictions was first proposed by the Group for selected food additives, with the aim to facilitate the sector in creating a wide variety of high quality organic foods (see report EGTOP/5/2012). Later, the Group concluded that a 'basic list of active substances' might also be useful for disinfectants (see report EGTOP/6/13). The 'basic list of active substances' is thus in line with similar proposals for other kinds of inputs, listed in other Annexes of Reg. 889/2008. The aim is the same: to give some flexibility to the sector (within clearly defined limits), so that it can develop improvements on its own.

Conclusions

In the Group's opinion, restrictions of use category in Annex II should be limited to those cases where further limitations are needed from an organic farming point of view, beyond the limitations already imposed by pesticide approval (Reg. 540/2011). For other cases, specifications of use category should be deleted.

The Group recommends to include a 'basic list of active substances' (as shown above) in Annex II.

4.11 Priority assessment of requests

During the discussions on this mandate, the issue of priority-setting for requests was raised by the Commission. The Group decided to make a proposal in this report, although this is relevant not only for plant protection.

A large number of requests concerning different areas of organic production are continuously presented to the Commission, some of which are passed on to the EGTOP. Due to limitations in capacity, some of these proposals have to be postponed for some time, before they can be dealt with. In this situation, it would be useful to have transparent criteria for the assessment of the priority of requests.

To this end, the group has identified a number of questions, which will be useful for an evidence-based priority setting. However, the final priority-setting remains a task for the Commission, and the Group has not attempted to develop a 'mathematical formula' for calculation of priority.

The existing 'dossier templates' for requests should be amended with a chapter containing all information necessary to evaluate the relevance and priority of a request at the European scale. To avoid duplication, similar questions should be deleted from the existing templates, where necessary.

Relevance and priority of the request at the European scale

Geographical relevance of the request (member states, regions, ...)
Socio-economic relevance of the request (acreage, turnover, number of operators/stakeholders affected, ...; as far as known)
Sectors affected (details ...)
Severity and immediacy of the problem addressed (impact on human, animal or plant health, ...)
Stakeholder engagement/consultation in dossier preparation
Aspects of international harmonization / market distortion

A (possible) authorization leads to amendment(s) in the respective Annex[6]
Other aspects justifying high priority, such as • relevance for the development of a new organic production sector, • addressing of a newly upcoming problem in production or a quarantine organism, • addressing a recent development in agricultural policies, • addressing a new trend in consumer preferences/nutritional habits or new developments in food technology, • addressing a declared goal of organic farming.

[6] It should be carefully analysed whether the specific use of a substance is already (implicitly) authorized or not. This is to avoid the following conclusion: "The group considers that the use of ... is in line with objectives, criteria and principles of the organic regulation. There is no need for amendment of the specific conditions of Annex ...."

5. LIST OF ABBREVIATIONS / GLOSSARY

Annex II	Annex II to Regulation 889/2008
BBCH-scale	The BBCH-scale is a scale used to identify the phenological development stages of a plant. 'BBCH' stands for 'Biologische Bundesanstalt, Bundessortenamt und Chemische Industrie'
DG SANCO	Health and Consumers Directorate-General of the European Commission
SCLPs	Straight Chain Lepidopteran Pheromones (see chapter 4.9)
The Group	The Expert Group for Technical Advice on Organic Production (EGTOP)

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy
B.4. Organics

Expert Group for Technical Advice on Organic Production

EGTOP

Final Report On Food (II)

The EGTOP adopted this technical advice at the 9th plenary meeting
of 28 – 30 April 2014

About the setting up of an independent expert panel for technical advice

With the Communication from the Commission to the Council and to the European Parliament on a European action plan for organic food and farming adopted in June 2004, the Commission intended to assess the situation and to lay down the basis for policy development, thereby providing an overall strategic vision for the contribution of organic farming to the common agricultural policy. In particular, the European action plan for organic food and farming recommends, in action 11, establishing an independent expert panel for technical advice. The Commission may need technical advice to decide on the authorisation of the use of products, substances and techniques in organic farming and processing, to develop or improve organic production rules and, more in general, for any other matter relating to the area of organic production. By Commission Decision 2009/427/EC of 3 June 2009, the Commission set up the Expert Group for Technical Advice on Organic Production (EGTOP).

EGTOP

The Group shall provide technical advice on any matter relating to the area of organic production and in particular it must assist the Commission in evaluating products, substances and techniques which can be used in organic production, improving existing rules and developing new production rules and in bringing about an exchange of experience and good practices in the field of organic production.

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The report of the Expert Group presents the views of the independent experts who are members of the Group. They do not necessarily reflect the views of the European Commission. The reports are published by the European Commission in their original language only, at the following webpage:
www.organic-farming.europa.eu

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All declarations of interest of Permanent Group members are available at the following webpage:
www.organic-farming.europa.eu

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EXECUTIVE SUMMARY

The EGTOP has evaluated a number of topics relevant for the use of flavours in organic products and the production of organic flavours in accordance with the requests set out in the second EGTOP food mandate.

Because there is a risk of misleading the consumer (Article 6(6) and 19(3)) of Council Regulation (EC) No 834/2007) we propose to not permit substances referred to in labelling requirements under Article 16 (6) of the new flavouring regulation (Regulation (EC) 1334/2008). The group proposes to establish a link in the Organic Regulation to the new flavouring regulation. This link should allow flavour extracts (Article 3(2)(d)) and "natural" flavours (Article 3(2)(c)) restricted to those natural flavourings as defined in Article 16(4),(5) of Regulation (EC) No 1334/2008.
Further, we propose to restrict the use of natural flavourings to specific processed food product groups e.g. tea products, sweets, milk products.

The group proposes the following, in order of priority:

1. Flavourings should be calculated as ingredients of agriculture origin.
2. Only organic carriers (ethanol, oil, fat, maltodextrin, etc) should be allowed and included in the calculation of the percentage of agricultural ingredients
3. As long as glycerol and sodium alginate are not available in organic quality they should be allowed as conventional carriers and must not be part of the percentage calculation of agricultural ingredients. (ref. Chapter 7.5, 7.7). In this case and in accordance with Article 19 (2a) of regulation 834/2007, the majority, over 50%, of all ingredients should be from organic origin.
4. Only natural flavourings as defined in Article 16 (4) and 16 (5) of Regulation EC No. 1334/2008 are in the scope of the organic regulation.
5. Regulation EC 1334/2008 (Art 16) establishes a quantitative relationship between the flavouring component responsible for the flavour and taste and the source material referred in labelling qualified as natural. However, for organic flavourings, all of these flavour component must be organic.
6. Additives, solvents and processing aids must be used in organic form when available.

The use of ascorbic acid as a food additive (antioxidant) is in line with the objectives, criteria and principles of organic regulation. Therefore the group does not see any need to change the specific conditions for ascorbic acid. Nevertheless the group highlights that in the implementation, the use of ascorbic acid according Article 4 of Council Regulation (EC) No 834/2007, regarding synthetic products and products from GM origins, should be considered.
The use of tocopherol rich extract as a food additive (antioxidant) in flavours is in line with the objectives, criteria and principles of organic regulation. Therefore the group does not see any need to change the specific conditions for tocopherol rich extract in Annex VIII, with the exception of the need to delete the wording "for fats and oils"
The use of lecithin as a food additive (antioxidant) in flavourings is in line with the objectives, criteria and principles of the organic regulation. Therefore the group does not see any need to change the specific conditions for lecithin, with the exception of the need to add the wording "in organic form only."

The use of citric acid as a food additive is in line with the objectives, criteria and principles of organic regulation for use in flavourings. Therefore the group does not see any need to change the specific conditions for Citric acid.

The use of sodium alginate as a food additive for plant products and for milk based products is in line with the objectives, criteria and principles of organic farming, also for use in flavourings. Therefore the group does not see any need to change the specific conditions for sodium alginate. Organic sources should be preferred.

The use of carrageenan as an additive is in line with the objectives, criteria and principles of the organic regulation for the use in flavourings from a technical perspective. However, because of the newest toxicological findings the group sees the need for a re-evaluation of this additive by EFSA. In line with the precautionary principle, the Group proposes to postpone any decisions on the use of carrageenan until all doubts concerning possible human health effects have been removed. The Group does not recommend the use of carrageenan in organic production until these concerns have been addressed

The use of glycerol as a food additive for plant products is in line with objectives, criteria and principles of the organic regulation also for use in flavourings. However the group sees the need to expand the specific conditions set up in Annex VIII. The previous EGTOP report on Food, recommended changing the wording of the specific condition from "for plant extracts" to "from plant origin". Now we propose the specification "for plant extracts and flavourings".

The use of pectin as a food additive is in line with objectives, criteria and principles of the organic regulation also for use in flavourings. Therefore the group does not see any need to change the specific conditions for pectin. Organic sources should be preferred.

The use of HPMC as a food additive for encapsulation of flavourings is not in line with the principles, criteria and objectives of the organic regulation because of the concern that encapsulation of flavourings is misleading to the consumer (Council Regulation (EC) No. 834/2007 Article (6) (c)) and the substance is not necessary for the production (EC Reg 834/2007 Art 21.1.II) of an organic product. The current specific conditions for HPMC should be rephrased to allow encapsulation only for capsules for food supplements.

The group is of the opinion that the use of sodium hydroxide for acidity regulation in flavours is in line with objectives, criteria and principles of the organic regulation. The specific conditions for use of sodium hydroxide should be amended in Annex VIII to read "Surface treatment of Laugengebäck and regulation of acidity in organic flavourings."

The group considers that the use of magnesium carbonate is in line with objectives, criteria and principles of the organic regulation. There is no need for amendment of the specific conditions of Annex VIII.

The group considers that the use of silicon dioxide is in line with the objectives, criteria and principles of the organic regulation. Natural sources of silicon dioxide should be preferred. The specific conditions for silicon dioxide, currently written as "anti-caking agent for herbs and spices" should be amended by the addition of the following: "... and flavourings"

The use of liquid smoke flavours is not in line with the objectives, criteria and principles of organic regulation because there is no need for their use in line with article 21.1. and there is a risk that the consumer will be misled contrary to Article 6 (c) and 19 (3) of the Council Regulation (EC) No, 834/2007. In particular some consumers may be confused as to whether a

product has been smoked or been treated with smoke flavouring. Wood used for smoking should not be treated with chemical substances at all. Advanced smoking method should be preferred.

The group sees the possibility to neutralise all oils by the mean of NaOH in line with the objectives and principles of organic regulation. Because of the carcinogenic effects of 3-MCDP and the need of refining for a reasonable amount of organic oils, as due to the negative effects from high temperature applications toward formation of 3 MCPD, the group proposes to delete in Annex VIII B for NaOH the specific condition "Oil production from rape seed (Brassica spp)" and replace it by "Oil production".

The group considers that the use of silicon dioxide as anti-caking agent in propolis is in line in line with the objectives, criteria and principles of organic regulation. The specific conditions for silicon dioxide, currently written as "anti-caking agent for herbs and spices" (plus amendments proposed in chapter 7.12) in Annex VIII A should be amended to add and for propolis.

1. BACKGROUND

In recent years, several Member States have submitted dossiers under the second subparagraph of Article 21(2) of Council Regulation (EC) No 834/2007[1] concerning the possible inclusion, deletion or change of deposition of a number of substances in Annex VIII to Commission Regulation (EC) No 889/2008[2], or more generally, on their compliance with the above-mentioned legislation. Furthermore, several Member States have requested also evaluation of some techniques used in food production in terms of their usefulness to and compliance with the EU organic farming legislation. Besides, in order not to jeopardise the work on the priorities set by the previous mandate, the EGTOP Report on Organic Food 5/2012 did not assess the use of the following: possible changes of the specific conditions for substances already mentioned in Annex VIII for the production of organic flavours. Therefore, the Group is requested to prepare report with technical advice on the matters included in the terms of reference.

2. TERMS OF REFERENCE

In the light of the most recent technical and scientific information available to the experts, the Group is requested:

1. To provide technical advice on matters concerning flavours and their use in organic food processing, in particular:

a) FR dossier (2013): Allowance for the use of the following substances listed in Annex VIII in all organic flavourings:

Ascorbic acid (E 300) as antioxidant
- Tocopherol-rich extract (Tocopherols) (E 306) as agent preventing flavourings from oxidation
- Lecithins (E 322) as emulsifier
- Citric acid (E 330) as acidity regulator
- Sodium alginate (E 401) as carrier/stabiliser
- Carrageenan (E 407) as carrier/stabiliser

[1] Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91.(O.J. L 189 , 20/07/2007, p. 1.)

[2] Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, OJ L 250, 18.9.2008, p. 1–84

– Glycerol (E 422) as carrier
– Pectin (E 440 (i)) as stabiliser /emulsifier/carrier
– Hydroxypropyl methyl cellulose (E 464) as carrier
– Magnesium carbonates (E 504) as anti-caking agent
– Sodium hydroxide (E 524) as acidity regulator
– Silicon dioxide (E 551) as anti-caking agent

b) Requirements and techniques for the production of organic flavours
– Technical requirements for the production of organic flavours
– Extraction technologies and solvents

c) SE dossier (2011): Smoke condensates/smoke flavours

In preparing the final report, the Group may assess if food processing methods included in the EU organic farming regulation are in line with the organic farming principles. The Group may also suggest amendments to the current list in Annex VIII and consider possible alternatives to the substances in question and/or review the specific conditions for the use of the substances listed therein. Any such proposal(s) should be accompanied by a brief explanation of the reason.

3. GENERAL REFLECTION ON FLAVOURS USED IN ORGANIC FOODS AND "ORGANIC" FLAVOURS

Flavourings are added as ingredient to food in order to improve and/or change the original flavour or to add a new flavour. They are added to significantly influence the sensory profile of a food. Sometimes they help to create completely new types of foods.
To use flavourings in organic food or to produce such flavourings in organic quality means to find a good balance in between working for "producing a wide variety of foods ... that respond to consumers' demand for goods produced" (Article 3 (c) Council Regulation (EC) No 834/2007) and "the exclusion of substances and processing methods that might be misleading regarding the true nature of the product" (Article 6 (c)) Council Regulation (EC) No 834/2007).

Flavours are substances falling under the legal definition of food (Regulation (EC) No 178/2002[3] Article 2). Flavouring substances stimulate the taste and flavour receptors. Flavours are constituents of food or can be added as ingredient. Regarding adding them as ingredients, different categories need to be distinguished; flavourings, flavouring substances, natural flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings. (See definitions in Regulation (EC) No 1334/2008[4]). At the moment for the production of organic foods all flavour extracts and natural flavour preparations are allowed with the exception of those produced from or by GMOs (Article 4 (a) (iii) Council Regulation (EC) No. 834/2008).

There is an inherent contradiction between the principles that the organic product should not mislead regarding the true nature and the use of flavours. Using flavours in food production means, in general, that there is a potential to mislead the consumer (Koerber Kv. 1995, Grim H.-U. 1999, Weiss G. 2001, Becker U. 2003) on the true nature of a product or to correct the results of negligence or losses of flavour during processing and handling. Whether this is the case, depends on the specific use of flavouring in production of a specific product and cannot be judged during the evaluation work for additives used for organic flavours within this mandate. The organic consumer has a specific perception toward the restrictive use of flavours in organic foods (Onyango B.M. 2007)

There is a need to adopt the requirements given for flavouring by Article 27 (1) c) of Commission Regulation (EC). No 889/2008 to the new horizontal flavouring regulation (Regulation (EC). No 1334/2008, see chapter 4 of this report). Enabling the production of organic flavours will help to meet the requirements of Organic Regulation. "Organic flavouring preparations" are "food" by definition of Regulation (EC) No 178/2002 and have to be seen within the scope of Organic Regulation (Article 1 of Council Regulation (EC) No 834/2007). They must be produced from organic raw materials using methods, processing aids, carriers, extraction material and additives which fulfil the requirements of the Organic Regulation. To discuss such substances, conditions and requirements-will be the main target of this report.

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[3] REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

[4] REGULATION (EC) No 1334/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC

Organic flavourings must meet the criteria given in the Organic Regulation. Several times (Hoffmann S. 2011, Bioland 2008) it was stressed that the requirements for the production of organic food in the Organic Regulation needs to be a partly justified in order to build an adequate framework for "organic flavourings" because of the specific meaning of such substances.

There is a specific characteristic of flavourings compared to other food. In flavouring preparations the "characterising flavour components", responsible for the flavour and taste, is often only present in a very small amount. This has two possible critical consequences based on current Organic Regulation which have a potential to mislead the consumer.

1. There is a risk that the characterising flavour components in an organic flavouring do not come from organic source because the amount of these characterising flavours used is very low. Further on in calculating the proportions of flavourings the flavour ingredients are not calculated as ingredients of agricultural origin within the 95% concept.
2. There is a risk that the characterising flavouring components in an organic flavouring preparation does not come from the named (characterising) plant mentioned on the labelling and therefore mislead the consumer on the main characteristic of the product.

There is a specific group of flavours known as top notes, which are added to fruit preparations to replace flavours and aromas lost during processing (concentration) of the juice. The group is of the opinion that these must be from organic fruit in order for the juice to be labelled as organic.

The group has the opinion that in a middle timescale the use of conventional natural flavourings should be completely phased out and that their use should be replaced by organic flavourings. Therefore we ask for a clear legal mechanism to enforce this process.

This process can start with restricting use of conventional natural flavours (Chapter 4 in this report).

Furthermore there is a clear need for defined requirements in order to facilitate the production and processing of organic flavourings (Chapter 5.1).

4. REVISION OF THE CURRENT REQUIREMENT IN EUROPEAN REGULATUION COMMISSION (EC) NO 889 ART 27 (1) (C)

The current Commission Regulation (EC) No 889/2008 Art 27 (1)(c)) refers to the old flavouring regulation. This requirement needs to be adapted to those of the new flavouring Regulation (EC) 1334/2008 (See Annex I).

In the old flavour Directive 88/388/CEE[5] there was no strict and quantitative relationship between the source material qualified as "natural" on the labelling and the raw material effectively responsible of the final flavour perception and taste, and therefore a risk of misleading consumers.
The new flavour Regulation 1334/2008 does not substantially change the principles for natural flavourings processing. However, this new regulation delivers new labelling requirements with

[5] COUNCIL DIRECTIVE of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production

more developed possibilities for distinguishing the raw material origin responsible for the flavour. If a source is mentioned, at least 95% of the flavouring component should be obtained from the material referred to. As the use of flavourings should not mislead the consumer, the other maximum 5 % cannot reproduce the flavour profile.

The new flavour regulation defines 3 new labelling wording using the term "Natural" referring to a source material X:

Article 16.4 Natural "X" flavouring
The term "natural" may only be used in combination with a reference to a food, food category or a vegetable or animal flavouring source if the flavouring component has been obtained exclusively or by at least 95% by w/w from the source material referred to.
NB: the 5% part left cannot reproduce the total flavour profile. This means all flavouring compounds are derived from the product they are named after.

Article 16.5 Natural "X" flavouring with other natural flavourings
The term "natural food(s) or food category or source(s) flavouring with other natural flavourings" may only be used if the flavouring component is partially derived from the source material referred to, the flavour of which can easily be recognised.
This means that some of the flavouring compounds are derived from the product they are named after.

Article 16.6 Natural flavouring
The term "natural flavouring" may only be used if the flavouring component is derived from different source materials and where a reference to the source materials would not reflect their flavour or taste.
In this case the source of the flavouring compound is natural but has no relation to the product that the flavour tastes/smells of.

Reflection of the group
The Group has the opinion that consumers expect by buying organic foods that the flavouring component responsible for the flavour and taste of the product should come from the material referred to (named fruit). Therefore it seems to be appropriate to restrict the use of natural flavours to those natural flavours where the identity of the flavour characteristic and the material referred to (named fruit) is guaranteed.
This can be granted by a clear reference to the requirements for source material in labelling of natural flavouring substances and flavouring preparations in Regulation (EC) No 1334/2008.

Private organic foods standards setters (Demeter 2013; BioSuisse 2013) in some European countries have for many years limited the products to which flavours may be added. The group sees that this trend should be continued by establishing this concept in the Organic Regulation.

Current requirements on conventional natural flavours should be restricted and eventually phased out, step by step without disturbing the market

Conclusion
Because there is a risk of misleading the consumer (Article 6 (6) and 19 (3)) of Council Regulation (EC) No 834/2007) we propose to not permit substances referred to in labelling requirements under Article 16 (6) of the new flavouring regulation (Regulation (EC) 1334/2008). The group proposes to establish in Organic Regulation a link to the new flavouring regulation. This link should allow flavour extracts (Article 3 (2) d)) and "natural" flavours (Article 3 (2) c)

restricted to those natural flavourings as defined in Article 16 (4), (5) of Regulation (EC) No 1334/2008.
Further, we propose to restrict the use of natural flavourings to specific processed food product groups e.g. tea products, sweets, milk products.

5. REQUIREMENTS AND TECHNIQUES FOR THE PRODUCTION OF ORGANIC FLAVOURINGS

Flavours are in the scope of organic regulation when they come from agricultural origin. Flavours are foods in accordance with Article 2 of the Regulation (EC) 178/2002. Based on Article 1 (2) b) of organic Council Regulation (EC) No 834/2007 the substances are in the scope of organic regulation and can be produced in organic quality. In a Delphi survey the hypotheses that flavours should be certified organic had high levels of acceptance with of 66.3% agreement (KRETZSCHMAR U. 2006).

The production of flavours and especially of natural flavours has some specifics. Therefore we propose to establish some additional specific requirements for organic flavour processing.

5.1. Proposed additional requirements

Flavours and some carriers are currently not part of the percentage calculation with the 5% concept of organic labelling. Theoretically this means conventional flavours (extracts and natural ones) and some carriers can be used in an organic product without limitation (Article 27 (2) (b)) of Regulation EC 889/2008 and Article 23 (4)(a)(ii) of Council Regulation (EC) 834/2007). This is in the opinion of the group not acceptable for "organic" flavourings because of the potential for misleading the consumers (Article (6) (c) Council Regulation (EC) 834/2007).).

All the carriers positively evaluated in this report have the potential to be produced in organic quality. Nevertheless they are not currently available organically; therefore we propose to allow them in conventional quality. In order to create sensible requirements the majority of the total weight of ingredients of organic flavouring should come from organic origin. Otherwise there is a risk that organic flavours will be made with over 50% of non-organic carriers. This should be seen as a transitional mechanism only while these carriers are not available in organic form.

As proposed in chapter 4, only natural flavourings in accordance to Articles 16 (4) and 16 (5) of the new flavourings regulation should be allowed for organic food processing. Consequently, only those flavourings should be in the scope of organic flavouring certification.

The Group has the opinion that consumers expect by buying organic foods that the flavouring component responsible for the flavour and taste of the product should come from the material referred to (named fruit). This means for organic flavouring that all the compounds responsible for the flavour and taste must be from organic origin.

Proposals

The group proposes the following, in order of priority:

1. Flavourings should be calculated as ingredients of agriculture origin.
2. Only organic carriers (ethanol, oil, fat, maltodextrin, etc.) should be allowed and included in the calculation of the percentage of agricultural ingredients
3. As long as glycerol and sodium alginate are not available in organic quality they should be allowed as conventional carriers and must not be part of the percentage calculation of agricultural ingredients. (ref. Chapter 7.5, 7.7). In this case in accordance with Article 19

(2)(a) of Council Regulation 834/2007 the majority of the ingredients should be from organic origin. The Group proposes to define this majority as more than 50%.

4. Only natural flavourings as defined in Article 16 (4) and 16 (5) of Regulation EC No. 1334/2008 are in the scope of the organic regulation.
5. Regulation (EC) No 1334/2008 (Article 16) defines a quantitative relationship between the flavouring component responsible for the flavour and taste and the source material referred in labelling qualified as natural is established. However, for organic flavourings, all of these flavour component must be organic.
6. Additives, solvents and processing aids must be used in organic form when available.

In general, processing of an organic flavouring must follow the requirements of the regulation including the technical details given in article 27 and Annex VIII of Commission Regulation (EC) No 889/2008.

5.2. Transitional permissions system for conventional flavourings

In order to reduce the use of conventional flavourings and transfer their use to organic flavourings, a mechanism should be established to ensure that if organic flavourings are available in sufficient quantity and quality, they must be used.

6. INTRODUCTION REMARKS TO THE SUBSTANCES UNDER EVALUATION

In the dossier presented to EGTOP all substances mentioned are currently listed in Annex VIII of European Commission (EC) No 889/2008.

For a number of these (Tocopherol rich extract, Glycerol, Silicon dioxide, Sodium hydroxide, Hydroxypropyl methyl cellulose) substance specific conditions in annex VIII are defined. Others (Ascorbic acid, Lecithin, Citric acid, Sodium alginate, Carrageen, Pectin, Magnesium carbonate) are generally authorised for plant derived organic foods. The majority of substances have specific conditions defined for foods from animal origin.

Flavours are predominantly produced from plant material but sometimes animal based materials are involved. This means a number of the substances requested could already be used on the basis of the current regulation for flavours based on (mainly) plant products but not for products based on animal products. The other substances requested are currently limited by Annex VIII not appropriate for application in flavourings. Therefore the target of this report is to clarify the "Specific conditions" for the requested substances.

In general organic flavours and flavourings have to fulfil following technological properties. In order to keep the intensity, quality and diversity of the flavour the organic flavours need to be resistant against; heat applications, reaction with the constituents of food, a low pH, oxidation, storage life, off flavour and must be soluble in different systems (water, fat, solid). Further, the flavour should not have negative influence on the overall appearance of the product for example by haze formation in soft drinks.

It should be noted that in most instances flavourings are used to add flavour and diversity to products but in some instances, such as soya based products the flavourings are used partly to overcome the natural flavours

Based on the list from Hoffmann (2011) the following are the most important areas where flavourings are used in organic products.

Whey drinks
Fruit yoghurts
Quark
Buttermilk products
Desserts
Soya drinks & yoghurts
Fruit products for pastries
Soft drinks
Sweets
Tea.

7. CONSIDERATIONS AND CONCLUSIONS

7.1 Ascorbic acid as antioxidant for organic flavourings

Introduction, scope of this report

The request refers to the possible use of ascorbic acid / L-ascorbic acid (E300) as a food additive (antioxidant) (Annex VIIIA to Commission Regulation (EC) No 889/2008 in the production of organic flavourings. Ascorbic acid is currently authorised as food additive in Annex VIIIA for food of plant origin and for food of animal origin (only for meat products). It is also authorised in ANNEX VIIIA as food additive for organic products of the wine sector.

Authorisation in general food processing and production of flavours

Ascorbic acid is authorised as food additive (E300) in Regulation (EC) No 1333/2008[6] of the European Parliament and of the Council (EC, 2008b).
Ascorbic acid is authorised as food additive in flavourings in Annex III Regulation (EC) No 1333/2008 following the quantum satis principle. (See definitions below.)

Agronomic use, technological or physiological functionality for the intended use

According to Codex General Standard for Food Additives (GSFA) functional classes of ascorbic acid are:
- Acidity regulator
- Antioxidant
- Flour treatment agent.

"Antioxidant properties of ascorbic acid are exploited in food processing (25% of total production of ascorbic acid) and beverage manufacturing (15%) to prevent pigment discoloration and enzymatic browning, to protect flavour and aroma and to protect or enhance nutrient content" (Hancock, and Viola, 2002)

Specific Uses in Flavouring

According to the relevant dossier ascorbic acid due to its reducing properties can be used to prevent flavourings from oxidation. Because of its hydrophilic nature, it is preferably used in

[6] REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives

aqueous products (e.g. seafood extracts), in emulsions and/or in flavourings for beverages. It is often used for its synergistic effect with other antioxidants like tocopherols.

Known alternatives

As antioxidant for flavourings in hydrophilic systems ascorbic acid is the only one available in Annex VIIIA.

Origin of raw materials, methods of manufacture

According to the definition of Commission Regulation (EU) No 231/2012 ascorbic acid is white to pale yellow, odourless crystalline powder.

Commercial production of ascorbic acid:
Earlier ascorbic acid has been made commercially by extracting it from plants. This is considered the most natural method of production.
Later ascorbic acid was chemically synthesised. Presently it is being made by two processes.

The Reichstein process is a seven step combination of synthesis and microbial conversion. This process is used to produce the majority of commercial ascorbic acid.

The alternative is the more recent double fermentation process. This process is more natural than the Reichstein process, but is subject to concerns regarding the use of genetically modified organisms.

Environmental issues, use of resources, recycling

Although the Reichstein process has all the efficiency advantages that would be expected after >60 years development, it is still highly energy consuming and requires high temperatures and/or pressures for many steps. In addition, most of the chemical transformations involve considerable quantities of organic and inorganic solvents and reagents such as acetone, sulphuric acid and sodium hydroxide. Although some of the compounds can be recycled, stringent environmental control is required, resulting in significant waste disposal costs (Hancock and Viola, 2002).

The use of solvents and precipitation processes during the isolation and purification uses strong acids and alkalis which cause concern.

Animal welfare issues

No specific concerns

Human health issues

An ADI of 0–15mg/kg per kg bodyweight was allocated by the Joint Food Agriculture Organisation and World Health Organisation (FAO/WHO) experts Committee on Food Additives (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53.). The Committee concluded: "Animal studies reveal that ascorbic acid is not toxic after a single or repeated administration of relatively large doses. Studies in man indicate that ascorbic acid has a diuretic effect at 5mg/kg b.w. in children and adults and glycosuria was observed with doses of 30-100mg/kg. Daily doses, of the order of 200mg/kg, have been taken over periods of time for a therapeutic effect which has not been unequivocally demonstrated. The recommended dietary allowances range from 30-75mg with a minimum of 5-10mg/day. It is estimated that the daily intake of ascorbic acid is between 30-100mg from natural sources."

Food quality and authenticity

Due to the small quantities of flavourings added to food, ascorbic acid as a flavouring additive will not change the authenticity of the foods.

Traditional use and precedents in organic production

Ascorbic acid is currently authorised as a food additive in Annex VIIIA for food of plant origin and for food of animal origin (only for meat products). It is also authorised in ANNEX VIIIA as a food additive for organic products of the wine sector.

Aspects of international harmonisation of organic farming standards

According to the Codex Alimentarius Commission "Guidelines for the production, processing, labelling and marketing of organically produced foods Annex 2: Permitted substances for the production of organic foods" ascorbic acid is permitted in food of plant origin provided insufficient natural sources are available (it is permitted, although exclusions of the GSFA still apply). Ascorbic acid is permitted in products of animal origin provided insufficient natural sources are available (only processed meat, poultry, and game products in whole pieces or cuts; Processed comminuted meat, poultry and game products; Edible casings (e.g., sausage casings)).

Permitted under USDA National Organic Programme §205.605 b Synthetics Allowed, without restriction.

In Japanese Organic Standards (JAS), Ascorbic Acid is permitted as an additive with the following condition. Limited to be used for processed foods of plant origin.

Ascorbic acid is permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive without restrictions.

Necessity for intended use

Because of its hydrophilic nature, it is preferably used in aqueous products (e.g. seafood extracts), in emulsions and/or in flavourings for beverages. It is often used for its synergic effect with other antioxidants like tocopherols.

Other relevant issues

None

Reflections of the Group

The argument in the dossier to authorise the use of ascorbic acid as a food additive for organic flavourings production is based on technical reasons. In particular ascorbic acid is clearly needed as the best available antioxidant in water based systems.

In the particular case of flavourings the quantity used is small and there should therefore be sufficient ascorbic acid produced from plant material. This material would be considered natural and so more compatible with natural flavourings.

The group expressed general concern over the fact that most commercial ascorbic acid is partially synthesised and the product from fermentation would be preferred if sufficient could be available from fermentation without using GM technology.

Conclusions

The use of ascorbic acid as a food additive (antioxidant) is in line with the objectives, criteria and principles of organic regulation. Therefore the group does not see any need to change the specific conditions for ascorbic acid.

Nevertheless the group would like to highlight that in implementation, use of ascorbic acid according Article 4 of Council Regulation (EC) No 834/2007, regarding synthetic products and products from GM origins, should be considered.

7.2 Tocopherol-rich extracts as agent preventing organic flavourings from oxidation

Introduction, scope of this report

The request refers to the possible use of tocopherol-rich extract (tocopherols) (E306) as food additive (agent preventing flavourings from oxidation) (Annex VIII A to Commission Regulation (EC) No 889/2008 in the production of certain organic flavourings. Tocopherol-rich extract is currently authorised as an antioxidant (Annex VIII A) for organic food of plant and animal origin (only in fats and oils).

Authorisation in general food processing and production of flavours

Tocopherol-rich extract is authorised as food additive (E306) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).

Tocopherol-rich extracts are authorised as food additive in flavourings in Annex III to Reg. 1333/2008 following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use
Tocopherol-rich extracts are used as antioxidants in food and in feed.

Specific Uses in Flavouring

According to the relevant dossier tocopherol-rich extract can be used to protect flavourings from oxidation, especially flavourings containing essential oils (esp. from citrus, or having a high aldehyde and/or terpene content that are subject to oxidation) or containing vegetable oils or other fats.

Known alternatives

Organic Rosemary extract may be used as an antioxidant for some oil based systems, but this may provide a flavour itself. It is also not allowed as an antioxidant for flavourings. Commission Regulation (EU) No 1130/2011 7 also allows Rosemary Extract to be used as an antioxidant for flavours in Annex III Part 4. This use is also permitted in Annex VIII of Commission Regulation (EC) No 889/2008.

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[7] COMMISSION REGULATION (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients

Origin of raw materials, methods of manufacture

According to the definition of Commission Regulation (EU) No 231/2012 tocopherol-rich extract is a product obtained by the vacuum steam distillation of edible vegetable oil products, comprising concentrated tocopherols and tocotrienols. It may contain α-, β-, γ -, and δ-tocopherols and tocotrienols. It is brownish red to red, clear, viscous oil having a mild, characteristic odour and taste. It may show a slight separation of wax-like constituents in microcrystalline form.

"Tocopherols and tocotrienols are extremely valuable compounds because of their activity as anti-oxidising agent. Newer findings have shown that it is only the α-tocopherol form that contributes to the vitamin E activity. Nordic Nutrition Recommendations NNR 2004 [1] and National Academy of Science, Food and Nutrition Board: Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids (2000). http://www.nap.edu/openbook.php?record_id=9810&page=1 and it has become an important additive to all kind of food products. Today, most tocopherols are obtained by vacuum distillation of deodorising-step residues generated in the refining of vegetable oils. Throughout this process, that includes several steps such as solvent recovery and purification, copious amounts of organic solvents and energy are required, and thermal degradation of tocopherol is commonly encountered.

Increasing interest in both, detection and search for new alternative tocopherol extraction and isolation techniques has been observed. Among them, supercritical fluid technology has been applied to extract tocopherols from natural materials such as palm oil, rice bran or soybean, obtaining enrichment factors up to 4 with respect to the solvent-obtained extracts. Residues and by-products have also been used for extraction purposes." (de Lucas et al 2002)

Environmental issues, use of resources, recycling

For vacuum steam distillation large quantities of organic solvents and energy are required

Commercially tocopherol-rich extract can be extracted from cottonseed, maize, rapeseed, rice germ, soya been oil, wheat germ, or green leaves and may, therefore, come from genetically modified sources.

Animal welfare issues

No specific concerns

Human health issues

An ADI of 0–2mg/kg bodyweight (calculated as alpha-tocopherol) was allocated for alpha-tocopherol and mixed tocopherols concentrate by the Joint Food Agriculture Organisation and World Health Organisation (FAO/WHO) experts Committee on Food Additives (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53). The Committee concluded: "Though the toxicological studies are less than would normally be required for foreign substances used as food additives, it is considered that alpha-tocopherol is a nutrient. The clinical experience with this vitamin is used as the basis for the evaluation."

Food quality and authenticity

Due to the small quantities of flavourings added to food tocopherol-rich extract as flavouring additive will not change the authenticity of the foods.

Traditional use and precedents in organic production

Tocopherol-rich extract is currently authorised as an antioxidant (Annex VIII A) for organic food of plant and animal origin (only in fats and oils).

Aspects of international harmonisation of organic farming standards

According to the Codex Alimentarius Commission "Guidelines for the production, processing, labelling and marketing of organically produced foods Annex 2: Permitted substances for the production of organic foods" tocopherol-rich extract is permitted in food of plant origin, although exclusions of the GSFA still apply. It is permitted in all mixed products of animal origin allowed under the General Standard for Food Additives and Standards adopted by the Codex Alimentarius Commission

Permitted under USDA National Organic Programme §205.605 Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as "organic" or "made with organic (specified ingredients or food group(s)). Section b Synthetics Allowed, with the following conditions: "Tocopherols derived from vegetable oil when rosemary extracts are not a suitable alternative."

In Japanese Organic Standards (JAS) E307b Mixed tocopherols are allowed with the following condition: "In case used for processed foods of animal origin, limited to be used for processed meat."

It is also permitted as an additive in the IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids, as an additive, without restriction.

Necessity for intended use

Technical reasons mentioned in the dossier support the change of disposition in Annex VIII.

Other relevant issues

None.

Reflections of the Group

The argument in the dossier to authorise the use of tocopherol-rich extract as a food additive for organic food production is based on technical reasons.

The group notes that the current entry for tocopherol rich extract in Annex VIIIA of Commission Regulation (EC) No 889/2008 refers to its use as an antioxidant for fats and oils only. The wording "fats and oils" seems superfluous as this material will not be used for aqueous products.

The group considers that the organic food sector should be encouraged to produce tocopherol rich extract in certified organic form, from organically grown agricultural ingredients.

Organic Rosemary extract is available as an antioxidant for many systems, but is not applicable to all due to its strong flavour.

Conclusions

The use of tocopherol rich extract as a food additive (antioxidant) in flavours is in line with the objectives, criteria and principles of organic regulation. Therefore the group does not see any

need to change the specific conditions for tocopherol rich extract in Annex VIII, with the exception of the need to delete the wording "for fats and oils"

7.3 Lecithins as emulsifier for organic flavourings

Introduction, scope of this report

The request refers to the possible use of lecithins (E322) (Synonyms: Phosphatides, Phospholipids) as a food additive (emulsifier) (Annex VIII A to Commission Regulation (EC) No 889/2008 (EC, 2008a) in the production of certain organic flavourings. Lecithins are currently authorised as a food additive (Annex VIIIA) for all organic food of plant origin and for organic food of animal origin (only in milk products).

Authorisation in general food processing and production of flavours

Lecithins are authorised as food additive (E322) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).

Lecithins are authorised as food additive in flavourings in Annex III Council Directive No 95/2/EC following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

Typical functions of lecithins in food production are: improvement of volume, fat dispersion, anti-stalling, reduction of viscosity, prevention of crystallisation, wetting, dispersion, stabilisation of product, prevention of spattering, browning and dispersion of the sediment.
The surface activity and ultimately the performance of commercial lecithin can be improved by physical, chemical or enzymatic methods. In contrast to normal trade lecithin, which complies with regular trade specifications and is produced straight after the degumming process, special lecithins are defined as products which have been processed in such a way that a specific surface activity has been achieved. (Van Nieuwenhuyzen 1981)

Specific Uses in Flavouring

According to the relevant dossier lecithins can be used as emulsifier for miscibility of flavourings ingredients, which can be hydrosoluble or not. E.g. to mix lipophylic flavouring preparations (e.g. spices or oleoresins) with an aqueous carrier.

Known alternatives

There are alternatives to lecithins, such as mono- and diglycerides, but these are not permitted for use in organic products, in Annex VIIIA of regulation 889/2008.

Origin of raw materials, methods of manufacture

Lecithin is a natural lipid and is found in all living cells. It may be found in high quantities in egg yolks and in many oil-producing plants, for example, soya.

In the definition of Commission Regulation (EU) No 231/2012[8] lecithins are mixtures or fractions of phosphatides obtained by physical procedures from animal or vegetable foodstuffs,

[8] COMMISSION REGULATION (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council

they also include hydrolysed products obtained through the use of harmless and appropriate enzymes. The final product must not show any signs of residual enzyme activity. The lecithins may be slightly bleached in aqueous medium by means of hydrogen peroxide. This oxidation does not chemically modify the lecithin phosphatides. Lecithins are brown liquids or viscous semi-liquids or powder. Hydrolysed lecithins are light brown to brown viscous liquids or paste.

Animal lecithin products are derived from milk, eggs and brain. Vegetable lecithins, containing primarily Phosphatidyl Choline, PC, Phosphatidyl Ethanolamine, PE and Phosphatidyl Inositol, PI, are derived commercially from oil-bearing seeds such as soybeans, sunflower kernels and rapeseed (Van Nieuwenhuyzen & Mabel 2008).
Note that in the production of organic lecithin the use of hydrogen peroxide for bleaching is not permitted.

Environmental issues, use of resources, recycling

There is significant concern over the fact that the majority of lecithin is produced from soya, which may be subject to significant contamination with GM.

The use of acids and alkalis during production of modified lecithins and extraction solvents such as acetone may create environmental concerns.

Animal welfare issues

No specific concerns

Human health issues

The Joint Food Agriculture Organisation and World Health Organisation (FAO/WHO) experts Committee on Food Additives estimated that acceptable daily intake of lecithins for man is not limited (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539;FAO Nutrition Meetings Report Series, 1974, No. 53.)
In the Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives (Wld Hlth Org. techn. Rep. Ser., 1974, No. 539) and in the FAO Nutrition Meetings Report Series (1974, No. 53) it is stated: "Lecithin is an essential constituent of all cells of the human body. The organism is able to synthesise phosphatides and the pathway of catabolism of lecithin in the organism is well-known. The average diet provides a daily intake of several grams of lecithin (approximately 1-5g).

No information on the LD50 of lecithin has been found in the literature. Rapid infusion into cats of a 1.2% egg-yolk phosphatide emulsion containing 5% glucose (1 ml/kg/min) had no effect on the respiratory and circulatory systems; rapid infusion of soybean phosphatides caused a fall in blood pressure with apnoea (Schuberth & Wretlind, 1961).
Egg-yolk soybean and hydrogenated soybean phosphatides are used for the preparation of fat emulsions for parenteral nutrition. The newer fat emulsions prepared using well-purified phosphatide preparations show a small incidence of side-effects in animals and man. Lecithin can be considered a non-toxic substance, even when given parenterally.

Although fewer toxicological studies have been conducted than would normally be required for substances used as food additives, it is considered that nutritional and clinical experience with lecithin is sufficiently extensive to compensate for the incompleteness of the experimental data. Since many observations have been made in man it is not considered necessary to calculate the safe intake level from animal experiments. The ADI level is "not specified".

Food quality and authenticity

Due to the small quantities of flavourings added to food, lecithins as flavouring additive will not change the authenticity of the foods.

Traditional use and precedents in organic production

Lecithins are currently authorised as a food additive (Annex VIIIA) for all organic food of plant origin and for organic food of animal origin (only in milk products).

Aspects of international harmonisation of organic farming standards

According to the Codex Alimentarius Commission "Guidelines for the production, processing, labelling and marketing of organically produced foods Annex 2: Permitted substances for the production of organic foods"(Codex Alimentarius 1999, revision 2013) lecithins are permitted for all technical functions with exclusion of bleached lecithins and lecithins obtained with organic solvents. The Codex Alimentarius permits the use of lecithins in organic food of plant origin although, exclusion of the GSFA still apply and in organic food of animal origin (only in: Dairy products and analogues, excluding products of food category 02.002.0; Fats and oils, and fat emulsions; Emulsified sauces (e.g. mayonnaise, salad dressing; Infant formulae and follow-on formulae; Complementary foods for infants and young children.

Permitted in USDA NOP Regulations under §205.606 Non-organically produced agricultural products allowed as ingredients in or on processed products labelled as organic. p) Lecithins – de oiled. No reference to bleaching.

Permitted under Japanese Organic Standards (JAS) with the condition Lecithin (Vegetable-, Yolk-, Fractionated-) "Limited to those obtained without any bleaching treatment and in case used for processed foods of animal origin, limited to be used for dairy products, baby foods derived from milk, fat and oil products or dressing.

Permitted as both an additive and processing aid in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive with the condition "Obtained without bleaches".

Necessity for intended use

Technical reasons mentioned in the dossier support the use of lecithins for organic flavourings in Annex VIII.

Other relevant issues

None

Reflections of the Group

The argument in the dossier to authorise the use of lecithins as emulsifier for the production of organic flavourings is based on technical reasons. There is a clear need for an emulsifier for use with organic flavourings and lecithin is considered the most appropriate of those available in the organic regulations.

The group considers that organic lecithin is now available and that only this source should be permitted for use as an additive. Organic lecithin is currently being exported in significant quantities from the EU to the US. The prohibition of bleaching in production of organic lecithin and the associated environmental and human health benefits is a further reason for moving to this form of lecithin for all uses in organic products.

Conclusions

The use of lecithin as a food additive (antioxidant) in flavourings is in line with the objectives, criteria and principles of organic regulation. Therefore the group does not see any need to change the specific conditions for lecithin, with the exception of the need to add the wording "in organic form only."

7.4 Citric acid as acidity regulator for organic flavourings

Introduction, scope of this report

The request refers to the possible use of citric acid (E330) as food additive (acidity regulator) (Annex VIIIA of Commission Regulation (EC) No 889/2008 (EC, 2008a) (hereafter called Annex VIIIA)) in the production of organic flavourings. Citric acid is currently authorised as a food additive (Annex VIIIA) for organic food of plant origin and for organic food of animal origin (only crustaceans and molluscs). It is also authorised as processing aid (Annex VIIIB) for organic food of animal origin (only for regulation of the pH of the brine bath in cheese production) and for organic food of plant origin (only for oil production and hydrolysis of starch). Moreover citric acid is in Annex VIIIC for the regulation of the pH in production of organic yeast.

Authorisation in general food processing and production of flavours

Citric acid is authorised as food additive (E330) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).

Citric acid is authorised as food additive in flavourings in Annex III EC reg. 1333/2008 following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

Citric acid in food industry is used because of its: sour flavour, preservative quality and ability to act as a pH buffer.

Approximately 50% of the world's citric acid production is used as a flavour enhancer in beverages. Citric acid is used in soft drinks, teas, juices, and other beverages to create a slightly tart, refreshing flavour and to balance sweetness.
The acidic pH of citric acid also makes it useful as a preservative. Since many bacteria are unable to grow in an acidic environment, citric acid is often added to jams, jellies, candy, canned foods and even meat products as a preservative.
Citric acid is sometimes used to create an acidic environment and facilitate the ripening process when making cheese, particularly mozzarella. Citric acid is also used to adjust the pH of solutions when brewing both beer and wine

Specific Uses in Flavouring

According to the relevant dossier citric acid is used for two main functions and one secondary function:
1. (Main) Use as acid in the technological meaning: it allows the flavourings pH adjustment in order to compensate acidity variations of the natural raw materials and of extracts thereof; for adapting the pH of the flavouring to the specific technological requirements of the flavoured foodstuffs manufacturing. It is especially the case for dairy products (e.g. yoghurt) and beverages.

2. (Main) Use as acids in organoleptic meaning: naturally present in a large variety of fruits, citric acid used in flavourings contributes to the perception of certain flavour (e.g. some red fruits such as cranberries or yellow fruits such as apricot).
3. (Secondary) Citric acid, by decreasing pH of the flavouring, participates in the preservation of the flavouring. This effect could be useful and wanted when the alcoholic level of the flavouring has to be limited (case also of high level of use, or specific requirements of the user)."

Known alternatives

The alternatives to citric acid could be lemon juice (but this is not applicable for flavourings in a powder form).

Origin of raw materials, methods of manufacture

According to the definition of Commission Regulation (EU) No 231/2012 citric acid is produced from lemon or pineapple juice, or by fermentation of carbohydrate solutions or other suitable media using Candida spp. or non-toxicogenic strains of Aspergillus niger. Citric acid is a white or colourless, odourless, crystalline solid, having a strongly acid taste.

Citric acid is a natural, weak organic acid that is found in many fruits and vegetables, especially citrus. Because citric acid is also a by-product of the citric acid cycle, it is also produced by many living organisms, including fungi.

The supply of natural citric acid is limited and the demand can only be satisfied by biotechnological fermentation processes. Citric acid has been produced using various fungi since 1917 and by yeasts since 1960s. Nowadays, Aspergillus niger is almost exclusively used for industrial scale production of citric acid. More than 600,000 metric tons are produced annually worldwide." (Lotfy et al. 2007)

Environmental issues, use of resources, recycling

"The fermentation process is advantageous as it is based on renewable sources, it facilitates use of waste for productive purpose, and useful by-products are formed. It involves very mild environment friendly conditions and also consumes less energy. It also faces some drawbacks some of which are:
(i) Use of large quantities of water
(ii) Due to high BOD (biological oxygen demand) he waste requires treatment before disposal.
(iii) Infection by foreign microbes can reduce the yield...." (Angumeenal & Venkappayya 2013)

On the one hand the biotechnological process of citric acid production using Aspergillus niger cause large amounts of wastes, which have to be removed (Moeller et al. 2007), on the other hand the citric acid effluent (CAE) can be utilised as the feedstock for algae growth as a renewable way to produce biodiesel (fatty acid methyl esters, FAME) while removing the carbon, nitrogen and phosphorous components of CAE (https://sites.google.com/site/biomassgroup18/feasibility-analysis).

The citric acid industry causes pollution concerns such as COD (chemical oxygen demand) and emissions of soot, sulfur dioxide and citric acid wastewater. China is the largest citric acid producer and exporter in the world. If sugar beet or maize is used as raw materials for fermentation they may be genetically modified.

Animal welfare issues

No specific concerns

Human health issues

The Joint Food Agriculture Organisation and World Health Organisation (FAO/WHO) experts Committee on Food Additives estimated that acceptable daily intake of citric acid for man is not limited (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53.)

In the Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives (Wld Hlth Org. techn. Rep. Ser., 1974, No. 539) and in the FAO Nutrition Meetings Report Series (1974, No. 53) it is stated: "Citric acid is an intermediary substance in oxidative metabolism, being engaged in the tricarboxylic acid cycle. Citric acid occurs in many foods and are normal metabolites in the body (Gruber & Halbeisen, 1948). There is no reason to believe that the use of these citrates as food additives constitutes a significant toxicological hazard to man.
Ingestion of citric acid frequently or in large doses may cause erosion of teeth and local irritation, apparently because of the low pH: the effects also occur with lemon juice which contains about 7% citric acid and has a pH of less than 3. A 1% solution has been used as a cooling drink in fever (Martindale, 1972).
In evaluating the acceptance of citric acid, emphasis is placed on its well-established metabolic pathways. Toxicological studies on animals supplement this information. Citric acid and its calcium, potassium and sodium salts do not constitute a significant toxicological hazard to man." (FAO WHO http://www.inchem.org/documents/jecfa/jecmono/v05je24.htm)

Product might still contain mould and sulphur/sulphites not filtered out completely during the production (Sulphur dioxide and other sulphites (also referred to as sulphites), causing asthmatic and allergic reactions.) http://www.traditionaloven.com/articles/122/

Food quality and authenticity

Due to the small quantities of flavourings added to food citric acid as flavouring additive will not change the authenticity of the foods.

Traditional use and precedents in organic production

Citric acid is currently authorised as a food additive (Annex VIIIA, Regulation 889/2008) for organic food of plant origin and of animal origin (only crustaceans and molluscs). It is also authorised as processing aid (Annex VIIIB Regulation 889/2008) for organic food of animal origin (only for regulation of the pH of the brine bath in cheese production) and for organic food of plant origin (only for oil production and hydrolysis of starch) and for the regulation of the pH in production of organic yeast (Annex VIIIC Regulation 889/2008).

Aspects of international harmonisation of organic farming standards

According to the Codex Alimentarius Commission "Guidelines for the production, processing, labelling and marketing of organically produced foods Annex 2: Permitted substances for the production of organic foods" (Codex Alimentarius 1999, revision 2013), citric acid is included in the lists:
1. "Additives permitted for use under specified conditions in certain organic food categories or individual food items" for: food of plant origin - Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes and aloe vera), for seaweeds, for nuts and seeds; for food of animal origin As a coagulation agent for specific cheese products and for cooked eggs, Cheese and analogues, Fats and oils essentially free from water, Egg and egg products.
2. "Processing aids which may be used for the preparation of products of agricultural origin referred to in section 3 of these guidelines - Specific conditions" for pH adjustment.

Permitted in USDA National Organic Standards. §205.605 a Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as "organic" or "made with organic (specified ingredients or food group(s)). a) Non synthetics allowed, with the specific condition: produced by microbial fermentation of carbohydrate substances.

Permitted in Japanese Organic Standards, JAS as an additive with the specific condition: Limited to be used as pH adjuster or used for processed vegetable products or processed fruit products.

Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive, without restriction.

Necessity for intended use

Technical reasons mentioned in the dossier support the use of Citric Acid for organic flavourings in Annex VIII.

Other relevant issues

None

Reflections of the Group

The argument in the dossier to authorise the use of citric acid as a food additive for organic food production is based on the technical reasons.
There are clearly two sources, the fermentation product and the isolation from natural citrus juices. Many applications may be able to use concentrated organic lemon juice instead of purified citric acid. Citric acid may be isolated as a purified product from natural organic lemon juice, i.e. as organic citric acid. Furthermore, where organic lemon juice is not possible alternative citric acid extracted from organic lemons would be preferable to the current non-organic citric acid from biotechnology. Alternatively organic citric acid may be produced by fermentation of organic molasses.

Conclusions

The use of citric acid as a food additive is in line with the objectives, criteria and principles of organic regulation for use in flavourings. Therefore the group does not see any need to change the specific conditions for Citric acid.

7.5 Sodium alginate as carrier stabiliser for organic flavourings

Introduction, scope of this report

The authorisation, uses, sources and concerns relating to the use of Sodium Alginate (E401) as a carrier/stabiliser in organic flavourings

Authorisation in general food processing and production of flavours

Permitted as Food additive (Reg. (EC) No 1333/2008). Listed in Group 1 which allows use at quantum satis in a wide range of food products.
Already authorised in Annex VIIIA of Regulation (EC) No 889/2008 as food additive in organic foodstuffs of plant origin and milk-based products.

Sodium alginate is authorised as food additive in flavourings in Annex III to EC Reg. 1333/2008 following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

Used as a gelling agent/thickener in foods. Used to improve sliceability in meat products. (This would not be permitted for organic products.)

Specific Uses in Flavouring

Used as a carrier/stabiliser

Known alternatives

Other polysaccharides such as pectin and carrageenan may provide alternatives, but the specific properties of each are not sufficiently clear to be certain that sodium alginate could be replaced by these in all uses in flavourings.

Origin of raw materials, methods of manufacture.

Alginic acid is extracted from seaweed, such as *Ascophyllum nodosum*, by extraction of the seaweed with hot sodium carbonate. This is filtered, with difficulty due to the viscosity, to remove cellulose etc. The alginates can be precipitated as calcium alginate by addition of calcium salts or as alginic acid by addition of acid. Sodium alginate is then manufactured by reacting the calcium alginate or alginic acid with sodium hydroxide.

Environmental issues, use of resources, recycling

Environmental issues relate to harvesting of seaweed, which may or may not be done sustainably. Certified organic seaweed harvesting, for which the harvesting is certified as sustainable is carried out but the use of acids and alkalis in manufacture prevents production of organic Sodium Alginate under current organic regulations. Harvesting issues include both the loss of seaweed itself, the loss of habitat for other wildlife due to harvesting and pollution and other environmental damage due to the harvesting operation.
Environmental issues must also be considered for the manufacture of sodium alginate, such as the use of large quantities of acid and alkali and the manufacture thereof.

Animal welfare issues

None.

Human health issues

None reported at high dosage. (Ref: http://www.ncbi.nlm.nih.gov/pubmed/1778263)
No concerns over toxicity, terratogenicity etc. identified.

The ADI has been calculated for humans at 0-25mg/kg b.w., calculated as alginic acid.

Food quality and authenticity

In normal food use, Alginates may be used to add mouth-feel and texture to products such as ice cream, masking issues caused by over processing. Also used in meat production to create mouth-feel in reconstituted ham products (although not permitted for this use in organic production). Also used as a processing aid as a coagulation agent in beers and wines.
Due to the small quantities of flavourings added to food alginates as flavouring additive will not change the authenticity of the foods.

Traditional use and precedents in organic production

No traditional use. Permitted in organic production for use with plant products and milk based animal products.

Aspects of international harmonisation of organic farming standards

According to the Codex Alimentarius Commission "Guidelines for the production, processing, labelling and marketing of organically produced foods Annex 2: Permitted substances for the production of organic foods" (Codex Alimentarius 1999, revision 2013), Sodium alginate and Potassium alginate are included in the list in: Table 3: Ingredients of non-agricultural origin referred to in section 3 of these guidelines, 3.1 Food additives, including carriers, without restrictions.

Permitted in US National Organic Programme List of permitted substances §205.605 Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as "organic" or "made with organic (specified ingredients or food group(s))", section b Synthetics allowed.

Permitted as an additive in Japanese Organic Standards (JAS), only for use with plant derived products.

Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive without conditions.

Necessity for intended use

It is clear that some polysaccharide carriers are needed in flavourings. The respective need for different polysaccharides is not clear. Nevertheless we see a necessity for sodium alginate, particularly in view of our view regarding carrageenan, below.

Other relevant issues

None

Reflections of the Group

There is a potential for Sodium Alginate to be produced in organic quality from organically grown or harvested seaweed. (Ref. http://www.fao.org/docrep/006/y4765e/y4765e08.htm).
The group considers that the organic food sector should be encouraged to produce sodium alginate in certified organic form from organically harvested or cultured seaweed.

Conclusions

The use of sodium alginate as a food additive for plant products and for milk based products is in line with objectives, criteria and principles of organic farming also for use in flavourings. Therefore the group does not see any need to change the specific conditions for sodium alginate. Organic sources should be preferred.

7.6 Carrageenan as carrier and stabiliser for organic flavourings

Introduction, scope of this report

This report covers the proposal for addition to Regulation 889/2008 of carrageenan (E407) as a carrier/stabiliser for organic flavourings.

Authorisation in general food processing and production of flavours

Permitted as Food additive (Reg. (EC) No 1333/2008). Listed in Group 1 which allows use at quantum satis in a wide range of food products.

Carrageenan is authorised as food additive in flavourings in Annex III EC reg. 1333/2008 following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

Carrageenan is used in foods as a thickener/gelling agent. Also as a carrier.
The general definition of a carrier is a food additive that is used to dissolve, dilute, extract, disperse, deliver or otherwise physically modify a component, ingredient, food additive or other food, without exerting any other effect on its own.

Specific uses in flavourings

Specific use applied for is as a carrier/stabiliser.

Known alternatives

Other similar plant or seaweed derived polysaccharides such as agar, pectin, alginates etc. may do similar functions, but the affinity of different polysaccharides for different compounds is complex so it is not clear whether carrageenan has specific uses as a carrier that cannot be done by other hydrocolloides.

Origin of raw materials, methods of manufacture

Carrageenans are extracted from seaweed. Most is produced from cultivated seaweed in the Philippines. It is extracted using hot water or dilute alkali so does not require the high quantity and strengths of acids and alkalis needed to produce sodium alginate.

Environmental issues, use of resources, recycling

Cultivation and harvesting of seaweed may create environmental concerns due to habitat damage, over harvesting or pollution associated with the harvesting or cultivation processes, unless produced from organically cultivated or harvested seaweed.

Preparation of carrageenan will be expected to have less environmental effect than sodium alginate due to the lower use of acids and alkalis.

Animal welfare issues

None.

Human health issues

The human toxicological position of Carrageenan was last evaluated by the EC Scientific Committee on food in 1992. (Ref: http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_35.pdf)

Subsequent studies have shown that low molecular weight carrageenans can cause gut inflammation and may be associated with precancerous changes in the gut.

However, commercial carrageenan is purified to remove the low molecular weight polymers. One key question is whether there is breakdown of the high molecular weight product to low molecular weight in the gut. This may occur due either to simple acid hydrolysis or to enzymatic breakdown caused be production of carrageenanase by some gut bacteria. There is significant argument over this issue in current literature. (Ref: http://www.cornucopia.org/DrTobacmanComment_to NOSB.pdf)

A study reported ulceration of the intestine of guinea pigs fed high doses of carrageenan, but this was not replicated in a study with rats, which identified no unreversible changes and no histopathology.

Studies of the carcinogenicity of carrageenan in rats have shown no effect. In addition, the results of assays for the genotoxicity of carrageenan have been negative. A proliferative response of the mucosa of the gastrointestinal tract of rats fed two forms of carrageenan at 2.6 or 5% of the diet has been reported; the response was reversible in the study in which 5% carrageenan was given. (Ref: http://www.inchem.org/documents/jecfa/jecmono/v042je08.htm)

There was evidence that carrageenan can affect the immune response of the gastrointestinal tract; however, no validated tests for assessing the nature and potential consequences of such an effect were available. (Ref: http://www.inchem.org/documents/jecfa/jecmono/v042je08.htm)

No ADI has been set and the high molecular weight product is generally regarded as safe.

Food quality and authenticity

Like sodium alginate, carrageenan has been used in pates and processed meats to correct texture and sliceability missing from highly processed meat products. This use would not be permitted in organic products. It is also used to increase viscosity of ice creams, dressings etc. It can therefore be used to hide processing defects.

Due to the small quantities of flavourings added to food carrageenan as flavouring additive will not change the authenticity of the foods.

Traditional use and precedents in organic production

Carrageenan has been used as a gelling agent and clarification agent for many years. It is permitted for use as an additive in organic products under regulation 889/2008. The permission for use as an additive in animal derived products is limited to dairy products only.

Aspects of international harmonisation of organic farming standards

Permitted under §205.605 of the US National Organic Programme. Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as "organic" or "made with organic (specified ingredients or food group(s)). Section a. Non Synthetics allowed.

Permitted in Japanese Organic Standards (JAS). Table 1. Food additives. Limited for animal products to dairy products only.

Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive.

Necessity for intended use

It is clear that some polysaccharide carriers are needed in flavourings. The respective need for different polysaccharides is not clear. It may be therefore that carrageenan is not required in flavours, due to the availability of alternatives.

Reflections of the Group

In view of the concerns over immune & inflammatory response in the intestinal tract and the availability of similar polysaccharides as additives in the organic farming regulations the group considers that the presence of carrageenan in Annex VIIIA of regulation 889/2008 should be reconsidered.

The group sees a potential contradiction to the requirement of Article 3 (c) of EC Reg. 834/2007 that organic products should not harm human health.

Further on because of the positive evaluation of other carriers and stabilisers within this report, where no such concerns occur, the group do not see a necessity (Art 21 (1) (i) and (ii) EC Reg. 834/2007) for accepting carrageenan as an another carrier and stabiliser because of its specific technological properties

There is a potential for carrageenan to be produced in organic quality from organically grown or harvested seaweed. The group considers that if it is to continue to be permitted, the organic food sector should be encouraged to produce carrageenan in certified organic form from organically harvested or cultured seaweed.

Conclusions

The use of carrageenan as an additive is in line with the objectives, criteria & principles of organic regulation for use in flavourings, from the technical perspective.

However, because of newest toxicological findings the group sees the need for a re-evaluation of this additive by EFSA. In line with the precautionary principle, the Group proposes to postpone any decisions on the use of carrageenan until all doubts concerning possible human health effects have been removed.

The Group does not recommend the use of carrageenan in organic production until these concerns have been addressed.

7.7 Glycerol as carrier for organic flavourings

Introduction, scope of this report

This report covers the application for addition of glycerol (E422) as a carrier for use in organic flavours.

Authorisation in general food processing and production of flavours

Permitted as Food additive (Reg. (EC) No 1333/2008). Listed in Group 1 which allows use at quantum satis in a wide range of food products.
Already authorised in Annex VIIIA of Regulation (EC) No 889/2008 as food additive in organic foodstuffs with the specific condition, "For plant extracts". Therefore not permitted for use with animal products.

Glycerol is authorised as food additive in flavourings in Annex III EC Reg. 1333/2008 following the quantum satis principle and is therefore authorised for the use in flavourings.

Agronomic use, technological or physiological functionality for the intended use

It is used as a humectant (moisturising agent) in many foods such as tortillas, icing, cakes etc. This use would not be permitted in organic products. It is also used as thickener and as a carrier and solvent in plant extracts such as tinctures, oils etc.

Specific Uses in Flavouring

Glycerol is used in flavourings to carry and dissolve flavour components for liquid flavourings or as a carrier for flavour components onto solid compounds.
It is also used as a solvent to extract specific flavours from plant materials.

Known alternatives

Ethanol may be an alternative carrier and solvent for some plant extracts, but it does not have the same range of solubilising ability as glycerol and is unacceptable to some due to religious constraints. Further, glycerol has specific technological properties because of the high evaporating temperature compared to other carriers available for organic flavours and has therefore a specific relevance. (Hoffmann, 2011)

Origin of raw materials, methods of manufacture.

Glycerol is manufactured from fats and oils by two processes. Firstly by saponification, which involves heating the fat or oil with alkali, such as sodium or potassium hydroxide. This produces the respective salt of the fatty acid and glycerol.

The alternative is production as a by-product of the manufacture of biodiesel, whereby oils are transesterified with enzymes producing the pure fatty acid which forms biodiesel and glycerol as a by-product. (Yang, et al 2012)

Environmental issues, use of resources, recycling

There is an excess production of glycerol as it is a by-product of biodiesel manufacture.

Animal welfare issues

None

Human health issues

Glycerol is of low toxicity when ingested, inhaled or by contact with the skin. (Ref: http://www.inchem.org/documents/sids/sids/56815.pdf)

There is no published evidence to indicate that glycerol is carcinogenic or harmful in any other way.

It is a natural constituent of all animals as a basic molecule produced in energy metabolism and used in production of fats.

The risk of contaminants must be considered particularly if glycerol is to be derived as a by-product from the production of bio-diesel, where the purity of raw materials may lack control.

Food quality and authenticity

Glycerol may be used to make products appear moist and retain that feel for longer, e.g. baked goods and tortillas. It may also be used to improve mouth-feel of alcoholic drinks & liqueurs and to substitute for fats in low calorie products etc. so can be used to create non-authentic qualities in foods. However, none of these uses would be permitted in organic foods.

Due to the small quantities of flavourings added to food glycerol as a carrier will not change the authenticity of the foods.

Traditional use and precedents in organic production

Glycerol is not a traditional ingredient, as its isolation and characterisation were fairly recent and it was not traditionally extracted from saponified fats. It is only used in organic production as a carrier and solvent for plant extracts. It is naturally produced in several foods including wines, due to formation by yeast as a by-product of fermentation. However, its uses has been permitted in organic production since the inception of EU regulation 2092/91.

Aspects of international harmonisation of organic farming standards

Permitted under §205.605 of the US National Organic Programme. Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as "organic" or "made with organic (specified ingredients or food group(s)). Section b. Synthetics allowed, as glycerine with the specific condition that it is only allowed if produced by hydrolysis of fats and oils. This would appear to preclude the use of glycerine (glycerol) made by transesterification of oils.

NOT permitted as an additive in Japanese Organic Standards (JAS).

NOT Permitted in IFOAM_Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive.

Necessity for intended use

Glycerol is an ideal solvent and carrier for ingredients of flavours due to its low toxicity, high capacity to dissolve oil and water based components, its high evaporation point and its non-extraction/dissolution of undesirable plant materials such as tannins. It is also acceptable to religious minorities and infants where ethanol would be an unacceptable alternative.

Further glycerol when used as a carrier for flavourings in heated products such as baked products, helps to prevent evaporation of the flavours.

It is clear that some solvents are required in flavourings, other than water and ethanol. Glycerol has significant advantages in some cases over and above water & ethanol.

Other relevant issues

None

Reflections of the Group

The group sees a necessity for having glycerol available as a solvent and carrier for organic flavourings because of its specific technological properties.

The previous EGTOP discussed the origin of glycerol. That group was of the opinion that the source of glycerol should be restricted to plant derived material. There is a potential for glycerol to be produced in organic quality from organically grown plant oils. The group considers that the organic food sector should be encouraged to produce glycerol in certified organic form from organically grown crops. The group like to refer to the recommendations made on glycerol in the first EGTOP food mandate.

Conclusions

The use of glycerol as a food additive for plant products is in line with objectives, criteria and principles of the organic regulation also for use in flavourings. However the group sees the need to expand the specific conditions set up in Annex VIII.

The previous EGTOP report on Food, recommended changing the wording of the specific condition from "for plant extracts" to "from plant origin". Now we propose the specification "for plant extracts and flavourings".

7.8 Pectin as stabiliser and carrier for flavourings

Introduction, scope of this report

This report covers the application of Pectin (E440(i)) as a stabiliser/emulsifier/carrier in organic flavours.

Authorisation in general food processing and production of flavours

Permitted as Food additive (Regulation (EC) No1333/2008). Listed in Group 1 which allows use at quantum satis in a wide range of food products.

Permitted as a food additive (E440) for use as gelling agent, emulsifier, stabiliser and thickener. It is permitted in two forms E440a which is non-amidated and E440b which is amidated.

Non-amidated pectin E440a is available in pure pectin form E440a(i) or in sodium, potassium or ammonium forms as E440a (ii), (iii) or (iv) respectively.

Of these only E440a(i) is permitted as an additive in Commission Regulation (EC) No 889/2008. It is permitted for plant based products and for milk based products in the section of animal derived products.

Pectin is authorised as food additive in flavourings in Annex III EC Reg. 1333/2008 following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

It is used in foods as gelling and thickening agent, especially jams, marmalades.

Specific Uses in Flavouring

Used as a carrier/ bulking agent in flavourings.

Known alternatives

Other similar polysaccharides such as carrageenan, alginates etc. have similar functions, but they are not available in organic form. However the detailed comparison of the properties of each are not clearly available to make the comparison as to whether some would do all functions.

Origin of raw materials, methods of manufacture

The main raw-material for pectin production is citrus peel or apple pomace, the by-products of juice production.

From these materials, pectin is extracted by adding hot dilute acid (eg Hydrochloric Acid Ref http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1259415/?page=3)) at pH-values from 1.5–3.5. During several hours of extraction, the protopectin loses some of its branching and chain-length and goes into solution. After filtering, the extract is concentrated in vacuum and the pectin may be precipitated by adding ethanol or isopropanol. Alcohol-precipitated pectin is then separated, washed and dried. (Williams P., et al 2011)

Environmental issues, use of resources, recycling

It is a valuable by-product of juice production. No significant environmental issues

Animal welfare issues

None

Human health issues

Pectin is reported as having positive effects on human health as it is a soluble fibre. It is associated with reduction in blood cholesterol, by binding cholesterol in the gut. It has a probiotic effect, by stimulating growth of gut micro-organisms.

There is no proposed ADI "except for good manufacturing practice" (Ref: http://www.inchem.org/documents/jecfa/jecmono/v46aje55.htm)

Food quality and authenticity

Traditionally used to prepare jams, fruit jellies, etc.
Due to the small quantities of flavourings added to food pectin as flavouring additive will not change the authenticity of the foods.

Traditional use and precedents in organic production

Pectin has been used unknowingly to create thickened preserves for many hundreds of years, for example by the addition of quince or apple to strawberries during manufacture of jam to help thickening. Since characterisation it has been sold as a preparation for thickening jams and preserves.

Aspects of international harmonisation of organic farming standards

Permitted in National Organic Programme List of permitted substances §205.606 of the US. Non-organically produced agricultural products allowed as ingredients in or on processed products labelled as "organic." (Non-amidated only)

Permitted as an additive in Japanese Organic Standards (JAS).

Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive. Unmodified, ie non-amidated form only.

Necessity for intended use

It is clear that some polysaccharide carriers are needed in flavourings. The respective need for different polysaccharides is not clear. Nevertheless we see a necessity for Pectin.

Reflections of the group

Polysaccharides are required for organic flavourings and pectin would appear to be one of the most preferable. In particular it is produced as a by-product of food production and has none of the potential environmental concerns provided by harvesting of seaweeds.

There is a large potential for pectin to be produced in organic quality from organically grown crops (citrus or apples.)

The group considers that the organic food sector should be encouraged to produce pectin in certified organic form from organically harvested crops.

Conclusions

The use of pectin as a food additive is in line with objectives, criteria and principles of the organic regulation also for use in flavourings. Therefore the group does not see any need to change the specific conditions for pectin.

Organic sources should be preferred.

7.9 Hydroxypropyl methyl cellulose as carrier for organic flavourings

Introduction, scope of this report

The request refers to the possible use of Hydroxypropylmethyl cellulose (E464) as a food additive (Annex VIIIA to Commission Regulation (EC) No 889/2008 (EC, 2008a) (hereafter called Annex VIIIA) in the production of certain organic foodstuffs (organic flavours). Hydroxypropylmethyl cellulose is currently authorised in Annex VIIIA of Regulation (EC) No 889/2008 as Food additive as encapsulation material for capsules in organic foodstuffs of plant and animal origins.

Authorisation in general food processing and production of flavours

Hydroxypropylmethyl cellulose (HCMC) is authorised as food additive (E464) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).
Food categories in which Hydroxypropylmethyl cellulose can be used (following the quantum satis principle) are listed in Annex II Part E of this Regulation.

Hydroxypropylmethyl cellulose is authorised as food additive according to EC Regulation 1333/2008 and authorised as carrier for flavourings in Annex III.

Agronomic use, technological or physiological functionality for the intended use

Hydroxypropylmethyl cellulose is used in food as a thickening agent, stabiliser or emulsifier.
Typical functions of Hydroxypropylmethyl cellulose in food production are:
Improvement of volume, stabilising hot emulsions and suspensions, delayed release of flavours, and resorption of vitamins in the intestine, improving the creaminess of ice cream and better adhesion and lower fat intake in sauces and dips, for example. However it is not permitted for these uses in organic production. (Ref; Annex VIIIA of regulation 889/2008).

Specific Uses in Flavouring

This additive is used as a carrier, for encapsulation or pre-coating, and increases the thermal stability, resistance to abrasion and stability during storage of the flavourings.

Known alternatives

The additive hydroxypropylmethyl cellulose is currently not available in organic quality. Its use is compatible with the principles of organic food processing. Alternatively, organic gelatine could be used.

Origin of raw materials, methods of manufacture

Hydroxypropylmethyl cellulose is cellulose obtained directly from strains of fibrous plant material and partially etherified with methyl groups and containing a small degree of hydroxypropyl substitution.

The chemical belonging to the group of hydroxypropylmethyl cellulose is a derivative of cellulose (E460). In contrast to this hydroxypropylcellulose is readily soluble in water. It gives a viscous liquid consistency, and when heated, forms strong gels. Their chemical structure gives the compound beyond emulsifying and stabilising properties.

There are significant quantities of organic cottonseed available from which HPMC could be prepared.

Environmental issues, use of resources, recycling

The production of HPMC uses waste raw materials such as cellulose fibres from seeds.

However organic solvents and strong acids are used in the manufacture of HPMC from the cellulose fibres

Animal welfare issues

No specific concerns

Human health issues

The Joint Food Agriculture Organisation and World Health Organisation (FAO/WHO) experts Committee on Food Additives proposed an unconditional ADI of 0–30 mg/kg body weight is proposed, but a conditional limit is proposed for dietary or calorie control purposes. (Ref: http://www.inchem.org/documents/jecfa/jecmono/40abcj18.htm)

Food quality and authenticity

Due to the small quantities of flavourings added to food hydroxypropylmethyl cellulose as flavouring carrier will not change the authenticity of the foods. However, it is clear that encapsulated flavours may be used to hide the authentic nature of the food.

Traditional use and precedents in organic production

The function of hydoxypropylmethyl cellulose as a thickening agent which has a good solubility in cold water and which is forming gels at higher temperatures. This is different to other thickeners as gelatine, carrageen and pectin. Hydroxypropylmethyl cellulose is currently authorised in Annex VIII-A of Regulation (EC) No 889/2008 as an encapsulation material for capsules.

Aspects of international harmonisation of organic farming standards

According to the Codex Alimentarius Commission "Guidelines for the production, processing, labelling and marketing of organically produced foods Annex 2: Permitted substances for the production of organic foods" hydroxypropylmethyl cellulose is not permitted in food of plant origin.

Not permitted in US National Organic Programme List of permitted substances §205.606
Not listed as a permitted additive in Japanese Organic Standards (JAS).

NOT permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 –

Other relevant issues

None

Necessity for intended use

It is clear that HPMC is required for encapsulation of flavourings as there are no compounds that will carry out the same function in particular due to its temperature stability. (Ref Council Regulation (EC) No 834/2007 Article 21(1)(i)).

However the group expressed concerns that encapsulation of flavours for organic foods may not be in agreement with the principles of organic regulation. Council Regulation (EC) No 834/2007 21(1)(ii) as it is possible to produce and preserve the food without these substances.

Reflections of the Group

To increase flavour of organic products, operators may use more or better organic ingredients, add flavours or add encapsulated flavours.

The objective of encapsulation is to increase the keeping time of flavours. This technology is only available to larger producers, limiting choice of products and hiding the true nature of the product. (Ref Article 6 (c) Reg. 834/2007). Its availability also reduces the use of organic food ingredients. This happens because flavourings may be used to replace some organic ingredients.

Further, the consumer cannot verify the quality of flavour of encapsulated products by smell, as the aroma is only released on solubilisation. This is considered as misleading. (Ref Article 6 (c) Reg. 834/2007).

Finally it is possible to produce and preserve the food without these substances and therefore the substance does not fulfil the requirements set by Council Regulation (EC) No 834/2007 Art 21(1)(i).

Annex VIII of regulation 889/2008 confirms that HPMC is currently allowed for use as an "encapsulation material for capsules". This is not clear. We propose to clarify the wording to the extent that the term "capsules" is currently intended to cover food supplements. There should be specific reference to the relevant legislation on supplements.

We propose that HPMC should only be allowed for encapsulation of food supplements.
There is a potential for HPMC to be produced from organically grown crops, but not in certified organic form due to the reagents needed to convert cellulose to HPMC.

Conclusions

The use of HPMC as a food additive for encapsulation of flavourings is not in line with the principles, criteria and objectives of the organic regulation because of the concern that encapsulation of flavourings is misleading to the consumer (Council Regulation (EC) No. 834/2007 Article (6) (c)) and the substance is not necessary for the production (EC Reg. 834/2007 Art 21(1)(ii)) of an organic product.

The current specific conditions for HPMC should be rephrased to allow encapsulation only for capsules for food supplements.

7.10 Sodium hydroxide as acidity regulator for organic flavourings

Introduction, scope of this report

The request refers to the possible use of sodium hydroxide (E 524) as a food additive (Annex VIII A to Commission Regulation (EC) No 889/2008 (EC, 2008a). Sodium hydroxide is currently listed in Annexes II and III to Regulation (EC) No 1333/2008 as food additive as a material for acidity regulation in organic foodstuffs.

Authorisation in general food processing and production of flavours

Sodium hydroxide is authorised as food additive (E464) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).
Sodium hydroxide is authorised as food additive in flavourings in Annex III to EC reg. 1333/2008 following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

Sodium hydroxide is used for application in food and during processing of food. It increases the pH of foodstuff. Sodium hydroxide can stabilise flavourings when they are affected by acidity.

Known alternatives

The additive sodium hydroxide is not available in organic quality. In the preparation is a chemical reaction not related to the principles of organic food processing.

Origin of raw materials, methods of manufacture

Sodium hydroxide is an artificial product and is produced from sodium chloride by electrolysis. The electrolysis is done in different ways, i.e. membrane, amalgam or diaphragm technology.

Environmental issues, use of resources, recycling

The electrolytic conversion of sodium chloride to sodium hydroxide and chlorine produces reactive chlorine molecules that are hazardous. However, this risk is managed if correctly produced and handled according to EU environmental legislation. Further the amount of sodium hydroxide in flavours is miniscule and there are no environmental concerns in that production, due to the small quantity involved and the fact that no emissions result.

Animal welfare issues

No specific concerns

Human health issues

Not limited ADI level.

Food quality and authenticity

Due to the low level of flavourings added to foodstuff, the carry-over of sodium hydroxide will be very low and has no technological function in the foodstuff.

Traditional use and precedents in organic production

Sodium hydroxide is used in the production of pretzel, pretzel sticks and pretzel rolls (Laugengebäck) to get the typical brown colour at the surface. The use in peeling fruits and vegetables is also common, but this use is not permitted in organic production.

Other relevant issues

None

Aspects of international harmonisation of organic farming standards

According to the Codex Alimentarius Commission "Guidelines for the production, processing, labelling and marketing of organically produced foods Annex 2: Permitted substances for the production of organic foods".

Permitted in National Organic Programme List of permitted substances §205.606 of the US. Non-organically produced agricultural products allowed as ingredients in or on processed products labelled as "organic" with the following condition; prohibited for use in lye peeling of fruits and vegetables.

Permitted as an additive in Japanese Organic Standards (JAS), as an additive and post-harvest treatment with the condition: For sugar processing and for the surface treatment of traditional bakery products.

Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive. For sugar processing and for the surface treatment of traditional bakery products only.

Necessity for intended use

The group does see the necessity for the use of sodium hydroxide for acidity regulation in organic flavourings. I.e. the requirements of Articles 21(1)(i) & 21(1)(ii) of regulation 834/2007 are both fulfilled.

Reflections of the Group

The group considers that there is a necessity for this use. There is therefore a need to revise the specific conditions whereby it is currently only allowed for surface treatment of Laugengebäck.

Conclusions

The group is of the opinion that the use of sodium hydroxide for acidity regulation in flavours is in line with objectives, criteria and principles of the organic regulation. The specific conditions for use of sodium hydroxide should be amended in Annex VIII to read "Surface treatment of Laugengebäck and regulation of acidity in organic flavourings."

7.11 Magnesium carbonates as anti-caking agent for organic flavourings

Introduction, scope of this report

The request refers to the possible use of magnesium carbonates (E504) as food additive (Annex VIIIA to Commission Regulation (EC) No 889/2008 (EC, 2008a) (hereafter called Annex VIIIA) in the production of certain organic foodstuffs (organic flavours). Magnesium carbonates are currently authorised in Annex VIIIA of Regulation (EC) No 889/2008 as anti-caking agent in organic foodstuffs of plant origin.

Authorisation in general food processing and production of flavours

Magnesium carbonate is authorised as food additive (E504) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).
Magnesium carbonate is authorised as food additive in flavourings in Annex III EC Reg. 1333/2008 following the quantum satis principle.

Agronomic use, technological or physiological functionality for the intended use

Magnesium carbonate is added to flavourings based on carriers such as maltodextrin and sugar as an anti-caking agent to prevent the caking of the carriers due to absorption of water. This use is considered essential.
Magnesium carbonates
- prevents caking,
- enhances the flowing ability of powder flavourings,
- makes mixing of the flavouring in the foodstuff easier.

Known alternatives

An alternative to magnesium carbonate as an anti-caking agent is silicon dioxide, which has significant advantages over magnesium carbonate as it is effective at lower proportions and as it does not have any adverse effect on pH of the additive or reaction with constituents that could cause "off flavours".

The additive magnesium carbonate is not possible in organic quality as it is a mineral and not of agricultural origin.

Origin of raw materials, methods of manufacture

Magnesium carbonate occurs naturally in drinking and mineral water as "hardness", in rocks mostly as a companion of calcium and in seawater at an average concentration of 1.4g/l Mg. Pure magnesium carbonate is extracted from dolomite (Magnesium & calcium carbonate) by the Pattinson process. (Ref: http://www.mercury-

emmissions.com/brome/brome.nsf/viewAllByUNID/6BE203A282A84F44C22570C800315201/$file/The_Pattinson_Process.pdf)

Environmental issues, use of resources, recycling

No significant environmental issues caused by Magnesium carbonate are evident. It is widely available in various forms and its use is not reported to cause any concerns. Disposal of small amounts of Magnesium carbonate would not be expected to create any environmental concerns. High concentrations of Magnesium in water contribute to water hardness which has been associated with cardiovascular disease but the contribution of Magnesium carbonate in organic food would be minor in this respect.

Animal welfare issues

No specific concerns

Human health issues

The Joint Food Agriculture Organisation and World Health Organisation (FAO/WHO) experts Committee on Food Additives estimated that acceptable daily intake of magnesium carbonate for man is not limited (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53.)

It is clear that milling of magnesium carbonate will result in creation of some nanoparticles. Most will agglomerate after production, but some may be left (Kohlhuber 2010). On the basis of presently available information there is no indication of health concerns, however the indication that magnesium carbonate for this use may contain nanoparticles should result in a re-evaluation of the safety of this ingredient.

Food quality and authenticity

Due to the low level of flavourings added to foodstuffs, quantities of magnesium carbonate carried over to the foodstuffs are very low and have no more technological function in it.

Aspects of international harmonisation of organic farming standards

According to the Codex Alimentarius Commission "Guidelines for the production, processing, labelling and marketing of organically produced foods Annex 2: Permitted substances for the production of organic foods" Magnesium carbonate is permitted in food of plant origin.

Permitted in National Organic Programme List of permitted substances §205.606 of the US. Non-organically produced agricultural products allowed as ingredients in or on processed products labelled as "organic" with the following condition; for use only in agricultural products labelled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labelled as "organic".

Permitted as an additive in Japanese Organic Standards (JAS), as an additive and post-harvest treatment with the condition: Limited to be used for processed foods of plant origin

Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids as an additive, without conditions.

Necessity for intended use

The conclusion of all is that there is a necessity for magnesium carbonate for production of organic flavourings.

The dossier submitted makes the case for its use as anti-caking agent for flavourings. The group agrees with this case.

Other relevant issues

None

Reflections of the Group

The group agrees with the request in the dossier for addition of magnesium carbonate as an anti-caking agent for organic flavours.

Conclusions

The group considers that the use of magnesium carbonate is in line with objectives, criteria and principles of the organic regulation. There is no need for amendment of the specific conditions of Annex VIII.

7.12 Silicon dioxide as anti-caking agent for organic flavourings

Introduction, scope of this report

The request refers to the possible use of silicon dioxide (E551) as food additive (Annex VIIIA to Commission Regulation (EC) No 889/2008 (EC, 2008a) (hereafter called Annex VIIIA) in the production of certain organic foodstuffs (organic flavours). Silicon dioxide is currently authorised in Annex VIIIA of Regulation (EC) No 889/2008 as anti-caking agent in organic foodstuffs.

Authorisation in general food processing and production of flavours

Silicon dioxide is authorised as food additive (E551) in Regulation (EC) No 1333/2008 of the European Parliament and of the Council (EC, 2008b).

Silicon dioxide is authorised as food additive in flavourings in Annex III EC reg. 1333/2008 following the quantum satis principle.

In accordance to Commission Regulation (EU) No 257/2010 [9] silicon dioxide will be revaluated by EFSA before 31 of December 2016.

Agronomic use, technological or physiological functionality for the intended use

The addition of anti-caking agent such as silicon dioxide is essential in most of powder flavouring, mix of liquid flavouring materials on a powder carrier (maltodextrins, sugars, etc.). Silicon dioxide prevents caking, enhances the flowing ability of powder flavourings & makes mixing of the flavouring in the foodstuff easier.

[9] COMMISSION REGULATION (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives

Known alternatives

An alternative could be magnesium carbonate or talc but the quantities needed to obtain the same result are much higher (i.e. 10-15% of talc compared with 0.1-0.3% silicon dioxide) and the use of talc is restricted to 1% in health supplements.

Origin of raw materials, methods of manufacture

Silicon dioxide occurs naturally as a mineral and is the most common mineral of earth´s crust. Artificially produced silicon dioxide is mostly an amorphous substance. For manufacturing of the product a chemical reaction is used either by a vapour hydrolysis process, yielding fumed silica, or by a wet process, yielding precipitated silica, silica gels, or hydrous silica.

Environmental issues, use of resources, recycling

Mineral with no significant environmental issues.

Animal welfare issues

No specific concerns

Human health issues

Prolonged inhalation of silica dust may be associated with irritations of the respiratory tract. Therefore personal protection during production or use is necessary. Silicon dioxide is used for more than 40 years in food technology and the structure and the scale of particles have not changed in this time. It seems to be safe in food and the ADI level is not specified.

Silicon dioxide may be produced in particle sizes less than 100micron diameter. These are normally considered as nanoparticles. In practice most silicon dioxide particles less than 100micron tend to agglomerate to produce non-nanoparticles, but this cannot be guaranteed. The production of nanoparticles is a by-product of the production process, rather than a direct objective of the production. No specific legal approval of silicon dioxide as a nanoparticle is currently required.

Some papers do indicate possible health concerns with nanoparticles of silicon dioxide (Kohlhuber 2010)

Food quality and authenticity

Due to the low level of flavourings added to foodstuffs, quantities of silicon dioxide carried over to the foodstuffs are very low and have no more technological function in it.

Traditional use and precedents in organic production

Silicon dioxide has been used in agriculture traditionally. According to Annex VIIIA of regulation 889/2007, it is permitted for use as an anti-caking agent in organic agriculture for herbs and spices only

Aspects of international harmonisation of organic farming standards

According to the Codex Alimentarius Commission "Guidelines for the production, processing, labelling and marketing of organically produced foods Annex 2: Permitted substances for the production of organic foods" Silicon dioxide is permitted in food.

Permitted in National Organic Programme List of permitted substances §205.606 of the US. Non-organically produced agricultural products allowed as ingredients in or on processed

products labelled as "organic" with the following condition; Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

It is permitted as an additive in Japanese Organic Standards (JAS), as an additive and post-harvest treatment with the condition: Limited to be used for processed foods of plant origin as gel or colloidal solution.

Permitted in IFOAM Norms for Organic Production and Processing. Appendix 4 – Table 1: List of approved additives & processing /post-harvest handling aids in amorphous form only, as a post-harvest treatment only. Not permitted as an additive.

Necessity for intended use

Already authorised (in Annex VIII of regulation 889/2008) for herbs and spices, silica is used in many formulations for health supplements but only if they contain herbs or spices. During storage of powder systems, silica reduces caking and blocking.

Other relevant issues

None

Reflections of the Group

Natural sources of silicon dioxide must be preferred to synthetic products. Ref A4 of regulation 834/2007.

It is clear that milling of silicon dioxide will result in creation of some nanoparticles, but production of synthetic silicon dioxide will create a greater proportion of these. Most will agglomerate after production, but some may be left (Kohlhuber 2010). A re-evaluation process of the substance by EFSA is ongoing. On the basis of information available there is no clear indication of health concerns.

Conclusions

The group considers that the use of silicon dioxide is in line with the objectives, criteria and principles of the organic regulation. Natural sources of silicon dioxide should be preferred.
The specific conditions for silicon dioxide, currently written as "anti-caking agent for herbs and spices" should be amended by the addition of the following: "... and flavourings"

(See requirements in chapter 9.2)

8. Smoke condensates/smoke flavours

Introduction, scope of this report

The request refers to the possible use of smoke condensates/smoke flavours in organic food products according to Council Regulation (EC) no 834/2007.

Smoke condensates/smoke flavours are currently not authorised to be used in or on organic foods in EU.

Definitions:
Smoke condensates are products obtained by controlled thermal degradation of wood in a limited supply of oxygen (pyrolysis), subsequent condensation of the resulting smoke vapours, and fractionation of the resulting liquid products (WHO, 2009).

According to *Regulation (EC) 2065/2003*[10] *on smoke flavourings used or intended for use in or on foods,* the following definitions are stated in art. 3:
1) "*primary smoke condensates*" shall refer to the purified water-based part of condensed smoke and shall fall within the definition of "*smoke flavourings*".
2) "*primary tar fraction*" shall refer to the purified fraction of the water-insoluble high-density tar phase of condensed smoke and shall fall within the definition of "*smoke flavourings*".
3) "*primary products*" shall refer to primary smoke condensates and primary tar fractions.
4) "*derived smoke flavourings*" shall refer to flavourings produced as a result of the further processing of primary products and which are used or intended to be used in or on foods in order to impart smoke flavour to those foods.

Authorisation in general agriculture or food processing

According to *Regulation (EC) 2065/2003 on smoke flavourings used or intended for use in or on foods,* the Scientific Committee on Food concluded that because of the wide physical and chemical differences in smoke flavourings used for flavouring food, it is not possible to design a common approach to their safety assessment and, accordingly, toxicological evaluation should focus on the safety of individual smoke condensates (8).

Smoke flavourings therefore should undergo a safety assessment through a Community procedure before placing on the market or used in or on foods within the Community in order to protect human health (2065/2003 (4)).

With reference to Art. 4(1) in the reg. 2065/2003: the use of smoke flavourings in or on foods shall only be authorised if it is sufficiently demonstrated that

- it does not present risks to human health,
- it does not mislead the consumers

Derived smoke flavourings must be evaluated by the European Food Safety Authority (EFSA), and a list of primary products authorised for the production of derived smoke flavourings shall be established (2065/2003,Art. 6(1)). The risk assessment of smoke flavourings is carried out by EFSA´s Panel on food contact materials, enzymes, flavourings and processing aids (CEF).
Until the list of authorised primary products is established, only primary products for which a valid application has been submitted before 16 June, 2005 can continue to be placed on the market (Reg. 2065/2003, Art 20).

In the first phase, EFSA received applications for 16 notified primary products that were already on the market. 14 of those were considered as valid applications and subject to evaluation. The other two applications were not considered to be valid and therefore were withdrawn from the market. After the start of the evaluation, applications for three more notified products were withdrawn from the market, thus EFSA having to evaluate only 11 notified products (EFSA 2012a).

[10] REGULATION (EC) No 2065/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 10 November 2003 on smoke flavourings used or intended for use in or on foods

For only three of the evaluated products, the margin of safety were large enough not to give rise to safety concerns at the levels of use as specified by the applicants, whereas for the others, a safety concern was raised (EFSA 2012a).

When evaluating the safety of smoke flavourings, the CEF-panel did not anticipate that smoke flavourings would be used in food specifically designed for infants (0-12 months) and young children (12-36 months). Therefore the safety of use of the evaluated primary products in food for infants and young children was not assessed (EFSA 2012b).

Each smoke flavouring (primary products) is authorised for specific products, conditions for its use in or on food products and levels of use for the specific products (Reg. (EC) No 2065/2003, Art. 6(2)).

Agronomic use, technological or physiological functionality for the intended use

Smoke flavourings are used to improve or modify the odour and taste of foods. Liquid smoke flavourings are increasingly added to food to replace the flavour and taste from traditional smoking or to impart smoke flavour to foods that are traditionally not smoked (such as soups, sauces or confectionary) (EFSA J. 2012a;10(10):s1007). Smoked flavour is also used to give flavour to e.g. soy tofu, which has traditionally never been smoked.

Technical application

Smoke condensates can be used in a variety of ways (SE dossier 2011):
1) Showered: The smoke is showered on the food and thereby the smoke comes in contact with the food for a certain period of time as the smoke condensate is circulated through nozzles or cascade pans to provide even coverage of the smoke on the food.
2) Directly addition: Smoke flavour can be added directly to the food as in a sauce, in a meat emulsion, injected into hams and bacon, or to a seasoning blend that can be applied to a food.
3) Smoke regeneration: In this method, the smoke and air are forced through a high pressure nozzle to break the smoke into gaseous particles. These particles come out of the nozzle as a dry cloud. The smoke will be regenerated into a smokehouse for a period of time to fill the smokehouse. When it is full, the regeneration system is turned off and the circulation fans are turned on. The fans evenly distribute the smoke cloud throughout the chamber.
4) Dipping: With dipping, the food is immersed into a solution of smoke condensate for a specific period of time.

By using smoke flavourings one can prevent the drying loss which normally takes place during the smoking process and the production time can be reduced. The traditional smoking process is normally combined with drying whereby the weight of the product is reduced. By using smoke flavourings, the food product does not lose weight and this affects the quality and the price of the product. A reduction of processing time is regarded as an advantage as it can often reduce the price of the product sold to the consumer or give a better profit to the producer (Council of Europe Publishing 1992a).

Labelling

Consumers should be informed if the smoky taste of a particular food is due to the addition of smoke flavourings. The labelling should not confuse the consumer as to whether the product is smoked conventionally with fresh smoke or treated with smoke flavourings (Reg.1334/2008(27)).

The list of ingredients for a food product should be labelled "smoke flavouring(s)", or "smoke flavouring(s) produced from "food(s) or food category or source(s)"" (e.g. smoke flavouring produced from beech), if the flavouring component contains smoke flavourings and imparts a smoky flavour to the food (1334/2008 Art. 29, Annex III, 1).

Known alternatives

Traditional smoking of foods is a known alternative for smoke flavourings and is already approved for use for production of organic foods.

Smoking of foods such as meat and fish has been used for centuries and its main purpose was originally to preserve food by drying in the fireplace. Later on the process was developed and changes in combination with other processes to obtain satisfactory shelf-life of food. Most food items have both been smoked or either salted, dried, fermented or preserved in another way too, as smoking alone does not ensure the food's proper lifespan (Council of Europe Publishing 1992a). The traditional smoking has in addition to flavour also influence on the water activity by reducing the water content resulting in prolonged shelf life and changed texture.
Application of liquid smoke flavours does not have the same effect on water activity as the drying process. Therefore, products prepared with liquid smoke flavours will end up in a different product and must be handled differently to naturally smoked products to avoid microbiological risks.

The traditional smoking methods are characterised by the temperature used (Council of Europa, 1992a):
Cold smoking where the temperature normally is 18-20°C. The process is typically used for salmon, salamis, kippers, hams and special cheese. A cold smoking process may last for several weeks. Normal cold smoking process lasts for 6-24 hours.
Warm smoking by a temperature around 40°C is used for bacon, sirloin and some types of sausage.
Hot smoking is a combination of strong heating and smoke, which gives a temperature in the product of 70-90°C. Warm smoking is a combination of drying, cooking and smoking process. This process normally takes hours, but the smoking part of the process is only part of this time. Products like herrings, eel and some sausages are smoked by this way.

Research is still ongoing to improve the industrialised direct smoking methods to decrease the content of polycyclic aromatic hydrocarbons (PAH) available (Schwägele and Jira 2010, Hitzel et al 2013, Pohlmann et al 2013). Ciecierska and Obiedziński (2007) compared different direct smoking methods used for smoking of meat, and they found that irrespectively of smoking method applied, the content of benzo[a]pyrene's was much lower than maximum tolerable limit of 5 µg/kg, which was set for smoked meat products in Commission Regulation (EC) No.

208/2005[11].). Ziegenhals (2008) has directly compared liquid smoke flavours, traditional smoke methods (Glimmrauch) and advanced smoke methods (Friction smoke). Friction smoke means, the smoke generator produces aromatic smoke by pressing a wooden stick (dimensions 8 x 8 x 70/100 mm) onto a fast rotating, diagonally-toothed friction wheel. The wooden stick is pressed pneumatically by means of a wood clamp. Such advanced smoking methods resulted in the same level of contamination with PAH in the final products as the application with liquid smoke flavours. Both were much better than traditional smoking methods (Glimmrauch) (Ziegenhals 2008)

Origin of raw materials, methods of manufacture

The smoke condensates are obtained by condensing smoke and they may be further fractioned, purified or concentrated. The purpose of the fractionation steps is to obtain products of interesting olfactory properties and to reduce the concentration of undesirable by-products of the smoke. The smoke condensates are generally not used as such for the flavouring of food but are used as the basis for smoke flavouring preparations (Council of Europe Publishing 1992b).
Smoke is generated from wood. The chemical composition of smoke is complex and depends among other things on the type of wood used, the method used for developing smoke, the water content of the wood and the temperature and oxygen concentration during smoke generation 2065/2003 (6).

There is a list of wood traditionally used for smoke preparation and which is acceptable for production of smoke flavourings (Council of Europe Publishing 1992b):

The wood used for production of primary products shall not have been treated, whether intentionally or unintentionally, with chemical substances during six months immediately preceding felling or subsequent thereto, unless it can be demonstrated that the substance used for the treatment does not give rise to potentially toxic substances during combustion (2065/2003, Art. 5,1).

Herbs, spices, twigs of juniper and twigs, needles and cones of *Picea* may be added if they are free of residues of intentional or unintentional treatment or if they comply with more specific Community legislation. The source material is subjected to controlled burning, dry distillation or treatment with superheated steam in a controlled oxygen environment with a maximum temperature of 600 °C (2065/2003 Annex I, 1).

The smoke is condensed with a condenser temperature of less than 60°C. The smoke condensate is then further cooled to room temperature and water is added (Dossier SE2011).

Water and/or, without prejudice to other Community legislation, solvent may be added to achieve phase separation. Physical processes may be used for isolation, fractionation and/or purification to obtain the following phases (2065/2003, Annex I, 2):
(a) a water-based "primary smoke condensate" mainly containing carboxylic acids, carbonylic and phenolic compounds, having a maximum content of:

Benzo[a]pyrene 10 µg/kg

[11] COMMISSION REGULATION (EC) No 208/2005 of 4 February 2005 amending Regulation (EC) No 466/2001 as regards polycyclic aromatic hydrocarbons

Benz[a]anthracene 20 µg/kg

(b) a water-insoluble high-density tar phase which during the phase separation will precipitate, and which cannot be used as such for the production of smoke flavourings but only after appropriate physical processing to obtain fractions from this water-insoluble tar phase which are low in polycyclic aromatic hydrocarbons, already defined as "*primary tar fractions*", having a maximum content of:

Benzo[a]pyrene 10 µg/kg
Benz[a]anthracene 20 µg/kg

(c) a "water-insoluble oily phase".
If no phase separation has occurred during or after the condensation, the smoke condensate obtained must be regarded as a water-insoluble high-density tar phase, and must be processed by appropriate physical processing to obtain primary tar fractions which stay within the specified limits.

According to 2065/2003 Art. 5(2), the water-insoluble oily phase which is a by-product of the process shall not be used for the production of smoke flavourings.

Environmental issues, use of resources, recycling

PAH may be formed when burning organic material and are widespread in the environment (Council of Europe Publishing 1992a). They are primarily formed by incomplete combustion or pyrolysis of organic matter during various industrial processes. For smokers, the contribution from smoking may be significant, while for non-smokers the major route for exposure is consumption of food (EFSA, 2008).

Total diet studies from UK and other countries, however, show that the largest amount of carcinogenic PAH-components in the food do not come from smoked fish and meat products, but from plant foods polluted from the air. (Council of Europe Publishing 1992a). Generating smoke, whether for natural smoking or for production of condensates generates carbon dioxide, although the source is sustainable.

Animal welfare issues

No specific concerns

Human health issues

The major contributors to intakes of PAH are cereals and cereal products (owing to high consumption in the diets) and vegetable fats and oils (owing to higher concentrations of PAH in this food group). Generally, despite their usually higher concentration of PAH, smoked fish and meats and barbecued foods do not contribute significantly, particularly as they are small components of the diet. However, they do make larger contributions leading to higher PAH intakes where these foods make up a large part of the diet (WHO 2009).

Smoked foods in general give rise to health concerns, especially with respect to the possible presence of polycyclic aromatic hydrocarbons (PAH). Because smoke flavourings are produced

from smoke which is subjected to fractionation and purification processes, the use of smoke flavourings is generally considered to be a less significant health concern than the traditional smoking process. However, the possibility of wider applications of smoke flavourings in comparison to conventional smoking has to be taken into account in safety assessments (Reg. 2065/2003, (6))

The composition of smoke is very complex, more than 400 volatile substances having been identified in wood smoke. The chemical composition depends among other things on the temperature of the smoke generation, the kind of wood used, the method used for developing the smoke, the water content in the wood, and addition of air and water. From a health point of view, the most important chemical substances in smoke are nitrogen oxides and polycyclic aromatic hydrocarbons (Council of Europe Publishing 1992a).

Nitrogen oxides

The nitrogen oxides in smoke can react with myoglobin in meat and give colour to the food, or these gasses may react with amines from the food and form nitrosamines. Nitrosamines are among the most carcinogenic substances which have been studied in animals. Nitrogen oxides should not be present in smoke condensates (Council of Europe Publishing 1992a).

Polycyclic aromatic hydrocarbons

The PAH-component benz(a)pyrene and approximately 10 other components from this group have proved to be both mutagenic and carcinogenic in experimental studies. Depending on which way the substances have been administrated to the test animals, they can cause cancer of skin, lung, mammalian tissue, stomach, intestine, liver or lymph. The carcinogenic effects of these components have been seen after doses of only a milligram per kg. bodyweight per day (Council of Europe Publishing 1992a).

High amount of PAH can be found especially on the surface of smoked products, and mainly on products smoked for a long time with direct smoking at higher temperatures (Council of Europe Publishing 1992a). Often the surface of the smoked product is not eaten as the fish skin and surface of hams. The content of PAH in the inner part of smoked meat is low (Ciecierska and Obiedziński, 2007).

Test of smoke flavourings for toxicity

According to the "Guidance on submission of a dossier on a Smoke Flavouring Primary Product for evaluation by EFSA", smoke flavourings should be individually tested for toxicology and the toxicolocical data presented. This should comprise 1) "Subcronic toxidity" by a 90-day feeding study in rodents, preferably in rats; 2) "Genotoxicity" i) a test for induction of gene mutation in bacteria; ii) a test for induction of gene mutations in mammalian cells *in vitro;* iii) a test for induction of chromosomal aberrations in mammalian cells *in vitro* (EFSA 2004).

As a summary of the findings of the EFSA in evaluation of smoke condensates, only three of the 14 products evaluated were found that to have large enough margin of safety not to give rise to safety concerns (EFSA, 2010).

In a summary of the opinions on smoke flavourings adopted by EFSA´s CEF panel in 2009, the reported toxicological effects were: "increase in kidney weight in rats"; "increased kidney weights in female rats"; "increase in relative kidney weight and related changes in blood biochemistry and haematology"; "reduction in white blood cell count (both sexes) and reduction of lung weight in male rats"; "decreased body weight gain in rats (both sexes)".

Food quality and authenticity

There is a potential in the use of smoke flavourings to mislead the consumer in contradiction of article 6(c) and 19(3) of Council Regulation (EC) No 834/2007 because consumers expect that traditional smoking methods were applied.

This may be handled by clear appropriate labelling as required by regulation 2065/2003, but how this should be labelled is not clearly spelled out as to the nature of that labelling.

Traditional use and precedents in organic production

There is no precedent of using smoke flavours in organic food production.

Aspects of international harmonisation of organic farming standards

The use of smoke flavourings seems not to be allowed in the USA and Canada as only flavours that can be labelled as natural are allowed in organic food.

The USDA National Organic Program (NOP) and the Canadian Organic Regime (COR) allow only the use of certain natural substances, including flavours, in products labelled as "Organic" or "Made with Organic" (Quality Assurance International 2013).

The question "Can natural smoke flavouring be listed as natural flavour?" was raised to USDA Food science Inspection Service (FSIS), and they answered: "No, the labelling of natural smoke flavourings is covered by 9 Code of Federal Regulations 317.2 (j) (3) and 381.119 (a) and by Policy Memo 117, "Smoke Flavouring." Natural smoke flavouring may not be listed as "natural flavour" or "flavour" in the ingredients statement. It may be declared as "natural smoke flavouring" or "smoke flavouring." Artificial smoke flavouring must be labelled as such." (USDA Food science Inspection Service, 2010)

In US natural liquid smoke flavour derived from wood chips and physical processes, and condensed in water would be considered a "natural flavour" listed on 7 CFR 205.605(a) and can therefore be used for the processing of organic foods. Synthetic liquid smoke flavours are prohibited. There is at least one USDA certified organic liquid smoke on the market. The NOP does currently not require the use of organic natural flavours for organic products as long as the flavours as below 5% of the weight of the product net of water and salt.

According to US FDA, Code of Federal Regulations (CFR) Title 21 Food and drugs, Chapter 1, subchapter B, Food for human consumption. Art. 6, 2013, the smoke flavours are defined as artificial flavours:
"Any pyroligneous acid or other artificial smoke flavours used as an ingredient in a food may be declared as artificial flavour or artificial smoke flavour. No representation may be made, either directly or implied, that a food flavoured with pyroligneous acid or other artificial smoke flavour has been smoked or has a true smoked flavour, or that a seasoning sauce or similar product

containing pyroligneous acid or other artificial smoke flavour and used to season or flavour other foods will result in a smoked product or one having a true smoked flavour".

Necessity for intended use

Due to the authorisation of traditional smoking methods for organic foods there is no need for smoke flavours in the sense of article 21(1)(i),(ii) of regulation 834/2007.

Other relevant issues

None.

Reflections of the Group

The group has the opinion that there is no need to introduce smoke flavours into the organic regulations because there is the clear alternative of smoking processes already allowed in organic food production (Reg. 889, art. 26.1, 834 art. 21 (i), (ii)).

Allowing smoke flavours will create conflict within the organic regulations by potentially misleading consumers (834, art 6(c)). Products with added smoked flavour are different from smoked products. The changed product profile has an effect on the microbiological stability compared to the traditional products.

There does not seem to be an evident for better toxicological profile from liquid smoke flavours compared to updated traditional smoking method to be used today. Only three of the primary smoke products tested by EFSA had margins of safety large enough not to give rise to safety concerns at the levels of use.

Conclusions

The use of liquid smoke flavours is not in line with the objectives, criteria and principles of organic regulation because there is no need for their use in line with article 21(1) and there is a risk that the consumer will be misled contrary to Article 6(c) and 19(3) of Council Regulation (EC) No 834/2007. In particular some consumers may be confused as to whether a product has been smoked or been treated with smoke flavouring.

Wood used for smoking should not be treated with chemical substances at all. Advanced smoking method should be preferred.

9. Other issues

9.1. Neutralisation of oils by sodium hydroxide

Introduction

Currently sodium hydroxide (NaOH) is only accepted as processing aid in Annex VIII B of European Commission (EC) No 889/2008 for sugar production and for the production of oil from rape seed. NaOH in oil refinement is used for neutralisation therefore for removal of Free Fatty Acids (FFA) and impurities.

When refinement is required for organic oils in order to remove unacceptable taste and smell as products of fat oxidation and FFA, it is done by deodorisation because of the limits for processing aids set by organic regulation.

Depending on the degree of impurities and level of FFA the temperatures up to 260°C needs to be applied for a successful deodorisation. The heat application leads to formation of 3 MCPD (3-Chlor-1,2-propandiol) in relevant amounts (Lindhauer M. G. 2011) Actual scientific findings have concluded that 3-MCPD is a carcinogen substance (BFR 2012.). Because of that, the 3 MDCP level of organic refinement oil has a tendency to be higher than in oil from conventional production.

If NaOH, which is currently only accepted for the neutralisation of organic rape oil, could be used for the production of organic oils from other sources, FFA could be neutralised and a high temperature deodorisation avoided with the consequence of lower 3-MCPD levels in organic refined oils.

Reflections of the group

The group considers that this subject does need urgent discussion and therefore accepts this topic to be evaluated in this mandate.

Currently NaOH is only allowed for rapeseed oil. But the issue discussed here could be relevant for all types of oils (sunflower, flax, grapeseed oils).

From a food safety point of view there is a need to reduce the presence of carcinogenic substances in food as much as possible. NaOH is a simple inorganic substance, easily neutralised. NaOH does not cause environmental or health concerns. In an appreciation of values it seems to be more acceptable to allow NaOH than to accept the risk of a presence of carcinogen substances in organic food.

The group considered whether processing such as deodorisation or other refinement should be labelled. The consumer understands terms such as cold pressed, virgin oil etc., but would be likely to be put off by phrases such as refined, deodorised etc.

Conclusion

The group sees the possibility to neutralise all oils by the mean of NaOH in line with the objectives and principles of organic regulation. Because of the carcinogenic effects of 3-MCDP and the need of refining for a reasonable amount of organic oils, as due to the negative effects from high temperature applications toward formation of 3-MCPD, the group proposes to delete in Annex VIII B for NaOH the specific condition "Oil production from rape seed (Brassica spp)" and replace it by "Oil production".

9.2 E 551 Silicon dioxide as anti-caking agent for propolis

In chapter 7.12, we have discussed the topic of silicon dioxide (SiO_2) as an anti-caking agent for organic flavours. For the next mandate already proposed for spring 2014 another SiO_2 dossier is delivered by France. Again the dossier is asking for changing the specific conditions of SiO_2 for plant products. This time the applicant is asking for allowing $Si0_2$ as anticaking agent for

propolis and health supplement made out of propolis. The technological conditions for the use of SiO_2 (see Chapter7.12) are quite similar to those in herbs spices, flavours or other applications in powders.

Furthermore we find that, based on information based of legislative and traditional background in the different member countries, it is often not clear what exactly is a spice or herb or what has to be seen as a fruit or vegetable. This causes misunderstanding in the market and problems among the producers. Clarification is needed.

Reflections of the group.

See Chapter 7.12

Conclusion

The group considers that the use of silicon dioxide as anti-caking agent in propolis is in line in line with the objectives, criteria and principles of organic regulation.

The specific conditions for silicon dioxide, currently written as "anti-caking agent for herbs and spices" (plus amendments proposed in chapter 7.12) in Annex VIII A should be amended to add "and for propolis".

9.3.Topics for consideration in the future

The group is of the opinion that important topics such as the use of enzymes, the potential presence of Nano-particles in additives in Annex VIII and the unrestricted use of micro-organisms and technical enzymes should be added to future agendas for EGTOP food subgroups.

10. LIST OF ABBREVIATIONS / GLOSSARY

Annex VIII	Annex VIII of Regulation 889/2008
The Group	Experts of the sub group on Food EGTOP
MS	Members States
Quantum satis	The term "quantum satis" is applied to usage for a large number of additives. "Quantum satis" indicates that no maximum level is specified. However, additives must be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided that they do not mislead the consumer. Ref http://www.fsai.ie/faqs/additives/food_additive_legislation.html#quanu

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Annex I

Directive 88/388/CEE on flavours

A.1. Definition of Natural flavouring substances and flavouring preparation and the process allowed to produce them

Art. 1) paragraph 2) point b)i- and c)

2)-[...]

(b) 'flavouring substance' means a defined chemical substance with flavouring properties which is obtained:

(i) by appropriate physical processes (including distillation and solvent extraction) or enzymatic or microbiological processes from material of vegetable or animal origin either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and fermentation)

c) 'flavouring preparation' means a product, other than the substances defined in (b) (i), whether concentrated or not, with flavouring properties, which is obtained by appropriate physical processes (including distillation and solvent extraction) or by enzymatic or Microbiological processes from material of vegetable or animal origin, either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction

and fermentation)

A.2. Requirement set for the use of the term "natural" in labelling
Art. 9 paragraph 1 point d) and paragraph point 2)
[…]
2. Without prejudice to paragraph 1 (d), the word 'natural', or any other word having substantially the same meaning, may be used only for flavourings in which the flavouring component contains exclusively flavouring substances as defined in Article 1 (2) (b) (i) and/or flavouring preparations as defined in Article 1 (2) (c). If the sales description of the flavouring contains a reference to a foodstuff or a flavouring source, the word 'natural', or any other word having substantially the same meaning, may not be used unless the flavouring component has been isolated by appropriate physical processes, enzymatic or microbiological processes or traditional food- preparation processes solely or almost solely from the foodstuff or the flavouring source concerned.

Commission regulation (EC) no 1334/2008
Ref. Art. 3) paragraph 2 – c).
[..]
(c) 'natural flavouring substance' shall mean a flavouring substance obtained by appropriate physical, enzymatic or microbiological processes from material of vegetable, animal or microbiological origin either in the raw state or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II. Natural flavouring substances correspond to substances that are naturally present and have been identified in nature;

B.2. A quantitative and explicit relationship between the flavouring component responsible for the taste and the source material referred to in labelling qualified as 'natural' // NEW !

Considering (25) and (26)
(25) Flavouring substances or flavouring preparations should only be labelled as 'natural' if they comply with certain criteria which ensure that consumers are not misled.

(26) Specific information requirements should ensure that consumers are not misled concerning the source material used for the production of natural flavourings. In particular, if the term natural is used to describe a flavour, the flavouring components used should be entirely of natural origin.
In addition, the source of the flavourings should be labelled, except when the source materials referred to would not be recognised in the flavour or taste of the food. If a source is mentioned, at least 95 % of the flavouring component should be obtained from the material referred to. As the use of flavourings should not mislead the consumer, the other maximum 5 % can only be used for standardisation or to give a, for example, more fresh, pungent, ripe or green note to the flavouring. When less than 95 % of the flavouring component derived from the source referred to has been used and the flavour of the source can still be recognised, the source should be revealed together with a statement that other natural flavourings have been added, for example cacao extract in which other natural flavourings have been added to impart a banana note.

[B.3] Definition of requirements for 3 new labeling wording using the term "Natural" referring to a source material X // NEW !

Article 16 point 4), 5) and 6).

Article 16.4 Natural "X" flavouring

The term "natural" may only be used in combination with a reference to a food, food category or a vegetable or animal flavouring source if the flavouring component has been obtained exclusively or by at least 95% by w/w from the source material referred to.
NB : the 5% part left cannot reproduce the total flavour profile.

Article 16.5 Natural "X" flavouring with other natural flavourings
The term "natural food(s) or food category or source(s) flavouring
with other natural flavourings" may only be used if the flavouring component is partially derived from the source material referred to, the flavour of which can easily be recognised.

Article 16.6 Natural flavouring
The term "natural flavouring" may only be used if the flavouring component is derived from different source materials and where a reference to the source materials would not reflect their flavour or taste.

7

Directorate-General for Agriculture
and Rural Development

Expert Group for Technical Advice on Organic Production

EGTOP

Final Report

On

Aquaculture (Part B)

The EGTOP adopted this technical advice by written procedure
in July 2014

About the setting up of an independent expert panel for technical advice

With the Communication from the Commission to the Council and to the European Parliament on a European action plan for organic food and farming adopted in June 2004, the Commission intended to assess the situation and to lay down the basis for policy development, thereby providing an overall strategic vision for the contribution of organic farming to the common agricultural policy. In particular, the European action plan for organic food and farming recommends, in action 11, establishing an independent expert panel for technical advice. The Commission may need technical advice to decide on the authorisation of the use of products, substances and techniques in organic farming and processing, to develop or improve organic production rules and, more in general, for any other matter relating to the area of organic production. By Commission Decision 2009/427/EC of 3 June 2009, the Commission set up the Expert Group for Technical Advice on Organic Production.

EGTOP

The Group shall provide technical advice on any matter relating to the area of organic production and in particular it must assist the Commission in evaluating products, substances and techniques which can be used in organic production, improving existing rules and developing new production rules and in bringing about an exchange of experience and good practices in the field of organic production.

EGTOP Permanent Group

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The report of the Expert Group presents the views of the independent experts who are members of the Group. They do not necessarily reflect the views of the European Commission. The reports are published by the European Commission in their original language only.

http://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports/index_en.htm

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All declarations of interest of Permanent Group members are available at the following webpage:

http://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/declaration-of-interests/index_en.htm

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1. EXECUTIVE SUMMARY

The EGTOP (thereafter called 'the Group') has evaluated a number of topics relevant for organic aquaculture.

With respect to stocking densities, the Group concluded the following: (1) for Arctic charr, the Group recommends to increase the stocking density limit to 25 kg/m^3 per year. (2) For carp, the Group recommends to reduce the maximum limit of farming yield to 500 kg/ha per year. (3) For small-sized crayfish (<20 mm), the Group recommends a maximum stocking density of 100 individuals per m^2; for crayfish of intermediate size (20 - 50 mm) a stocking density of 20 – 30 individuals per m^2 and for adult crayfish (>50 mm) a maximum stocking density of 5 individuals per m^2. (4) Besides, the Group does not consider any further modifications of the figures in the Annex XIIIa of Regulation (EC) 889/2008 (as amended by Reg. (EC) 710/2009) to be appropriate.

With respect to intensive Recirculation Aquaculture Systems (RAS), the Group concluded that they should remain prohibited for on-growing purposes. However, re-use of water is clearly in line with organic principles of sustainable and responsible use of resources, and is to be encouraged and further explored.

With respect to eyestalk ablation, the Group concluded the following: (1) The techniques of pinching, enucleation/slittering, cautering and ligation all have to be considered as forms of eyestalk ablation, and are therefore currently prohibited. (2) In the Group's opinion, all forms of eyestalk ablation should remain prohibited.

With respect to the use of hormones, the Group recommends not to allow the use of hormones for the production of caviar or juveniles in sturgeons.

With respect to the production of phytoplankton, the Group sees no possibility for applying the overall principle of fertilization with low solubility fertilizers (currently applied for terrestrial plants) to phytoplankton. Also, the Group considers that it would be difficult to define production of 'organic phytoplankton' which would be sufficiently different from conventional phytoplankton to justify its existence as a separate, organically certified product. In view of the necessity to use phytoplankton in hatchery, the Group recommends that for the time being, the use of phytoplankton should be authorized without requiring organic certification. GMO strains of algae must not be allowed.

With respect to the production of zooplankton, the Group recommends that in the absence of better alternatives, the use of non-organic zooplankton should be allowed.

With respect to the production of fish larvae, the Group recommends that, for larval rearing of marine species, methods such as the 'mesocosm' or 'large volume rearing' should be used. The specific requirements for such rearing systems include: (1) an initial stocking density below 20 eggs or larvae/litre, (2) a larval rearing tank volume of minimum 20 m^3, and (3) feeding of larvae on the natural plankton developing in the tank that is supplemented by externally produced phytoplankton and zooplankton.

With respect to disinfection and management of aquatic environment, the Group concluded the following:

- The use of tosylchloramide sodium (cloramine T) for disinfection is not in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. It should therefore not be included in Annex VII.
- The use of hydrogen peroxide/sodium percarbonate in the absence as well as in the presence of animals is in line with the objectives, criteria and principles of organic farming, and the Group recommends to include both substances in Annex VII, in the 'basic list of substances for management of aquatic environments'.
- The use of peracetic and peroctanoic acid in the absence as well as in the presence of animals is in line with the objectives, criteria and principles of organic farming, and the Group recommends to include both substances in Annex VII, in the 'basic list of substances for management of aquatic environments'.
- The use of hypochlorous acid produced from mixtures of potassium peroxomonosulphate and sodium chloride in the absence of animals is in line with the objectives, criteria and principles of organic farming. It should be included in Annex VII, along with sodium hypochlorite and calcium hypochlorite.
- The use of saltwater and freshwater is in line with the objectives, criteria and principles of organic farming. The Group recommends: (1) to include sodium chloride in Annex VII, in the 'basic list of substances for management of aquatic environments', and (2) to amend Art. 25s(6) as follows: "For biological control of ectoparasites preference shall be given to the use of cleaner fish, and to the use of freshwater, marine water and sodium chloride solutions".
- The use of slaked lime in the absence of animals, e.g. pre-treatment of water before it enters the rearing ponds/tanks, is in line with the objectives, criteria and principles of organic farming. In Annex VII, the entry 'lime' should be replaced by 'quicklime (calcium oxide) and slaked lime (calcium hydroxide)'.

The Group further recommends re-structuring section 2 of Annex VII of Reg. (EC) 889/2008 (as shown in chapter 4.6.2). Section 2 should be renamed to 'Substances for use in aquaculture and seaweed production'. It should be subdivided into three sub-sections. Section 2.1 should be named 'basic list of substances for management of aquatic environments'. Substances in this section may be used for all purposes authorized under general legislation. Section 2.2 should be named 'Substances for cleaning and disinfection of equipment and facilities, in the absence of aquaculture animals'. Substances in this section may be used for all purposes in the absence of aquaculture animals authorized under general legislation. Section 2.3 should be named 'Substances for limited use in aquatic environments'. Substances in this section may be used for very limited purposes indicated there.

The Group was asked to reconfirm the advice on various substances given in 2008 by an ad-hoc expert group. Due to time constraints, the Group could not make full evaluations, but it has indicated in which areas clarifications are most needed.

2. BACKGROUND

Organic aquaculture is a relatively new addition to the scope of EU organic legislation having been added for the first time by Council Regulation 834/2007. The implementing rules were introduced via Commission Regulation 710/2009 which amended the main implementing rules for organic farming introduced by Commission Regulation 889/2008. The rules for aquaculture have applied for almost three years, i.e. since 1 July 2010. The final paragraph of Article 2 of R. 710/2008 states: "This Regulation may be revised on the basis of relevant proposals from Member States, which are accompanied by a duly justified motivation, with a view of the modification of this Regulation from 1 July 2013."
The group is therefore requested to prepare a report with technical advice on the matters included in the terms of reference.

3. TERMS OF REFERENCE

In the light of the most recent technical and scientific information available to the experts, the group is requested to report on the following list of requests.

1. **Stocking Density** for the main species or groups of species, other than molluscs, is set out in Annex XIIIa of R.889/2008. Article 25f(2) of the Regulation states that "in considering the effects of stocking density on the welfare of farmed fish, the condition of the fish (such as fin damage, other injuries, growth rate, behaviour expressed and overall health) and the water quality shall be monitored." France has requested that the maximum stocking density for Brown trout and Rainbow trout grown in fresh water be increased from 25 kg/m^3 to 35 kg/m^3 (supported by Bulgaria in comments on the draft mandate) and that the maximum farming yield of freshwater species in fishponds (carp, perch, pike etc.) be reduced from 1 500 kg of fish per hectare per year to 500 kg (Bulgaria supports annual production below 1500 kg/ha). Italy has requested that the maximum allowed density for trout is reduced from 25 to 20 kg/m^3, and that the maximum density for the charr be increased from 20 to 25 kg/m^3. Sweden requests that the EGTOP mandate include advice on the possibility to regulate the stocking densities for the crayfish species, *Astacus astacus* and *Pacifastaccus leniusculus*, both in ponds and for larvae and breeding ponds indoors. Sweden also proposes that EGTOP evaluate the pros and cons of closed recirculation systems in relation to Articles 3 to 5 of Regulation 834/2007. Advice on this area should include reference to density.
2. **Substances for cleaning and disinfection in the presence [and absence] of animals** require particular care and measures to ensure that the application is not harmful (according to Recital 17 of R. 710/2009). Currently only two substances are listed in Annex VII(2.2) and several requests have been received to add the following substances:
   - **Chloramine T/ Tosylchloramide sodium** - France has submitted a dossier and the application has been supported by Italy
   - **Hydrogen peroxide** (liquid or powder **(Sodium percarbonate)** - France and Ireland have submitted dossiers and their applications have been supported by Italy and Denmark. This substance is currently permitted for use in the absence of animals
   - **Sodium chloride** – France and Denmark have applied for its inclusion. This substance is currently permitted for use in the absence of animals
   - **Peracetic acid [and peroctanoic acid]** – France, Italy and Denmark have applied for the inclusion of Peracetic acid and France has submitted a dossier with its application for peroctanoic acid. Both substances are currently permitted for use in the absence of animals.

- **Hypochlorous acid** – The UK has applied for inclusion of this bleach formulation (active ingredient from potassium monopersulphate in combination) use in absence of animals. It is likely to be safer than sodium hypochlorite bleach (currently permitted for use in the **absence of animals**) as it does not produce toxic chlorine and is considered to have greater efficacy against pathogens].

Regarding lime (calcium oxide) which is currently permitted in the absence of animals, Denmark has pointed to the need for clarification that this also applies to **slaked lime (calcium hydroxide),** formed when lime is mixed (slaked) with water. Denmark has also indicated an interest in having slaked lime listed under 2.2 (use in presence of animals) and is willing to prepare a technical dossier.

3. **Reproduction.**
   a. Germany has pointed to the need for harmonization of the interpretation of the **prohibition of eyestalk ablation** for reproduction in shrimp. EGTOP should clarify the term ablation in relation to hatchery practices such as ligation, incision, pinching etc. which do not directly remove the eyestalk.

   b. Spain requested a clarification on the use of hormones (natural or artificial) for certain species as sturgeon, turbot and eels to reach the sexual maturity needed for reproduction.

4. **Specific rules for juveniles, invertebrates and microalgae/plankton**. In the context of the lack of organic juveniles mentioned under point 1) above, Spain has pointed to the need to develop **specific rules for the production of juvenile fish** to ensure continuity of production.

   Spain has requested that rules be developed for zooplankton, rotifers, micro-crustaceans, worms and other aquatic feed organisms. Spain has also pointed to the need for rules concerning multicellular marine algae/phytoplankton and microalgae for use as feed and food with particular focus on the use of nutrients of plant or mineral origin listed in Annex 1.

5. **Reconfirmation of ad-hoc Expert advice of 2008.** For the issues not mentioned above it would be useful that the group re-examine the advice provided by the Ad-hoc group five years ago on the other topics with a view to reconfirming or updating it. It should be noted that in the exchanges regarding the EU proposal to include organic aquaculture in Codex Guideline 32-1999 on Organically produced foods, one country has questioned the suitability of potassium permanganate and iodophores for cleaning and disinfection in the absence of animals. This country has also queried the use of sodium chloride and humic acid for the same use (on account of not being familiar with their use for this purpose).

   In preparing its report the group is invited to examine technical dossiers provided to the Commission by the Member States.

6. **Deadline**
   The deadline for adoption of the **Part B final report**: **30 June 2014**

4. CONSIDERATIONS AND CONCLUSIONS

4.1 Stocking density

Introduction, scope of this chapter
A considerable number of studies have investigated stocking densities in relation to fish welfare, i.e. performance (e.g. mortality, feed intake, feed conversion ratio, growth), condition (e.g. fin and gill condition), and stress levels (e.g. plasma cortisol, plasma glucose, hematocrit, energetic metabolism). It is generally concluded, that despite the lack of clear evidence, high stocking density may compromise fish welfare. However, a low density may also be detrimental to welfare, as it may result in extremely aggressive behaviour between conspecifics (Ellis et al., 2002).

Impact of stocking density and other factors on animal welfare and health

Trout: A range of studies have investigated the relationship between stocking density and rearing or environmental conditions on different aspects of growth performance and welfare in rainbow trout (*Oncorhynchus mykiss*). North et al. (2006) studied the impact of stocking densities of 10, 40 and 80 kg/m^3 on a variety of physiological and morphometric indicators. They demonstrated that being held at high density (80 kg/m^3) did not have consistent effects on growth rates or physiological indicators of welfare, but increased fin erosion. Furthermore, they found evidence for stronger dominance hierarchies at low density (10 kg/m^3). Consequently, it was concluded that both low and high stocking densities had the potential to compromise welfare. Two studies have investigated the combined effects of stocking density (~ 25 and ~ 100 kg/m^3, respectively) and sustained exercise (water current of 0.9 body length/sec.). The first study showed that high density, irrespective of water current, resulted in a lower growth performance. Furthermore, water current was shown to have a positive effect on energetic budgets, reducing metabolic rate irrespective of density, and was attributed to induce schooling behavior thereby reducing aggressive behavior and stress (Larsen et al., 2012). The second study showed that growth rates were reduced at high stocking density, irrespective of water current and this was attributed to high energy costs. The authors concluded that this was unlikely to be due to chronic stress, as cortisol values were low at all densities, but may have been due to an alteration in physiological state (McKenzie et al., 2012). Interestingly, what is considered low density and what is considered high density appears to be quite ambiguous, as these 'definitions' vary between studies. Furthermore, the results of these studies clearly illustrate the complex nature of the interaction between stocking density, fish welfare and several environmental factors, which may influence indicators of welfare, performance and stress resilience.

Sea bass: A number of studies have been carried out with sea bass reared at different stocking densities. In a study with sea bass of approximately 135 g, four densities (10, 40, 70, 100 kg/m^3) were tested over a 63-day period (Sammouth et al 2009). Fish performance, stress indicators and water quality were compared. Up to a density of 70 kg/m^3, no significant differences in daily feed intake were observed. Density above 70 kg/m^3 showed a negative impact on growth performance, and at 100 kg/m^3 specific growth rate was decreased by 14 %. Santos et al. (2010) showed that high densities may act as a chronic stressor to the fish, leading to a reduced feed intake and growth. Carbonara et al. (2014) studied the relationships between stocking density and fish welfare. Adult sea bass were reared at either low (10 kg/m^3) or high (50 kg/m^3) stocking density for 84 and 116 days. In the higher density, the activity level (energetic expenditure), measured by U_{crit} and electromiograms (EMG) was about twofold higher than that in the lower density. Furthermore, the higher density group exhibited a decrease in the reserve of metabolic energy. In conclusion, the authors highlighted that EMG can better represent the integrated

response of the whole fish organism to stress conditions. In other words, the amount of energy reserves (anaerobic metabolism) that fish could use to cope with stress conditions (Lembo et al. 2007).

Arctic charr: A relevant number of studies have also been carried out for assessing the suitable stocking density for breeding the arctic charr (*Salvelinus alpinus*). The general conclusion is that arctic charr tolerate relatively high stocking densities and, providing that water quality is secured, there is no evidence of stress conditions which may compromise fish welfare (Wallace et al., 1988; Brown et al., 1992; Christiansen et al., 1992; Jörgensen et al., 1993; Metusalach et al., 1997; Brännäs and Linnér, 2000; Gunnarsson et al., 2011; Dalsgaard et al., 2012).

Carp: Carp is mainly farmed in central European countries, where the most suitable farming conditions for carp have been identified; i.e. high fecundity, good growth rate, tolerance to unstable environmental conditions, good ability to utilize available natural food, as well as low-protein feeds (Adamek et al., 2012). The main producers are the Czech Republic and Poland, each producing about 18000 t in 2010, followed by Germany and Hungary each producing about 10000 t in 2010 (Adamek et al., 2012). The main farmed species of carp is Common carp (*Cyprinus carpio*). It is mainly produced extensively and semi-intensively in ponds based on natural food – zooplankton and zoobenthos. About 25 % of the carp production is semi-intensive, using barley and wheat as supplementary feed (Adamek et al., 2012). The average farming yield under traditional farming conditions is about 500 kg/ha (Adamek et al., 2012; Adamek, pers. comm.). However, organic carp can also be produced intensively with artificial feed (i.e. cereals of organic origin), which increases the production capacity to more than 1000 kg/ha. There seems to be a public opinion among Czech consumers that extensively/semi-intensively farmed carps have a better flesh quality than intensively farmed carps (Adamek, pers. comm.).

Crayfish: According to the existing literature, the signal crayfish (*Pacifastacus leniusculus*) and the noble crayfish (*Astacus astacus*) are cultured in Europe, mainly in Finland, Sweden, Poland, Bulgaria, United Kingdom, Germany and Spain. Crayfish is cultured either for direct human consumption or for restocking purposes, combining intensive and semi-intensive/extensive techniques. In intensive culture, densities of up to 1000 juveniles per m^2 have been used in the case of *P. leniusculus*, with relatively good results (Savolainen et al., 2004; González et al., 2010, 2011a), although the authors recommend lower number of juveniles (100 – 200 per m^2). For *A. astacus,* densities up to 500 juveniles per m^2 have been cultured using recirculating aquaculture systems (Abeel et al., 2012). In semi-intensive/extensive aquaculture, densities of 10 – 150 juveniles of 20 – 50 mm size and 5 – 30 individuals for adolescent and adult crayfish per m^2 are commonly used (Ackefors, 2000). Due to the moulting process during growth of crayfish and the vulnerability of the animals to cannibalism, it is necessary to provide the animals with refuges/shelters i.e. PVC pipes (Ackefors, 2000; González et al., 2011b; Savolainen et al, 2003, 2004) and keep low densities (Wolf, 2004).

Reflections of the Group / Balancing of arguments in the light of organic farming principles
It is a challenge to identify appropriate density limits that promote optimal welfare in fish. This is in part due to a lack of understanding of how the different environmental factors interact with each other and with stocking density to affect welfare (Ashley, 2007). Another reason is that the effect of density measures on welfare may vary greatly between studies, due to the study-specific nature of experiments. For example, studies vary in experimental duration, water quality, density levels used, feeding methods, size of the fish, life history of the fish, level of domestication, type of rearing system used and environmental conditions. A density threshold for one set of conditions may, therefore, not be relevant for another (Ashley, 2007) and makes comparison of the results between studies difficult. High stocking density potentially increases the risk of

prevalence of diseases, but incidence of disease may as well be related to water quality, environmental and management conditions.
Therefore, the Group considers stocking density as an appropriate fish welfare indicator only when it is considered in a holistic approach and linked to environmental conditions, water quality, feeding quality, life history of the fish, level of domestication, type of rearing system used, etc.
However, the Group recognizes the need to establish a synthetic indicator of the fish welfare, which could be easily understood, communicated and monitored (according to the Reg. EC 889/2008, Art. 25f, paragraph 2) together with fish conditions such as fin damage, other injures, growth rate, behaviour expressed, overall health and water quality.
The figures in Annex XIIIa are threshold values which, on average, represent safer fish welfare conditions. These limits are based on practical experience. On the whole, these limits have been successfully applied over the last few years in EU organic aquaculture. Even if slightly higher stocking densities might be possible under specific, local conditions, this does not mean that this would be possible for the whole sector. In the Group's opinion, in the case of the arctic charr there is no scientific evidence for setting the limit of the stocking density at a lower level than for the rainbow trout.
Regarding carp, very little scientific evidence is available to the Group. However, the Group thinks that the maximum yields for organic production should not exceed the yields under extensive and semi-intensive conventional production. The Group therefore recommends to reduce the maximum yields for carp from 1500 kg/ha to 500 kg/ha per year.
In the case of crayfish, densities should be adapted to the developmental stage and the rearing system used. For small (<20 mm) juveniles, a density of 100 individuals per m^2 is recommended, for animals of 20 – 50 mm size, density should be kept at 20 – 30 individuals per m^2 whereas for adult animals (>50 mm), the maximum density should be 5 per m^2.

Conclusions

- For arctic charr, the Group recommends to increase the stocking density limit from 20 kg/m^3 to 25 kg/m^3 per year.
- For carp, the Group concluded that the maximum limit of farming yield should be reduced from 1500 kg/ha per year to values which are typical for extensive and semi-intensive production (i.e. 500 kg/ha per year).
- For small-sized crayfish (<20 mm), the Group recommends a maximum stocking density of 100 individuals per m^2. For crayfish of intermediate size (20 – 50 mm), the Group recommends a maximum stocking density of 20 – 30 individuals per m^2. For adult crayfish (>50 mm), the Group recommends a maximum stocking density of 5 individuals per m^2.
- For the time being, the Group does not consider any further modifications of the figures in the Annex XIIIa to be appropriate.

4.2 Recirculation Aquaculture Systems for on-growing

Introduction
According to Art. 2j of Reg. 889/2008 a 'closed recirculation aquaculture facility' is defined as 'a facility where aquaculture takes place within an enclosed environment on land or on a vessel involving the recirculation of water, and depending on permanent external energy input to stabilize the environment for the aquaculture animals'. In a *closed recirculation aquaculture system (RAS)* new water is mainly supplied for filling up and to replace water lost by evaporation. The degree of recirculation can be of about 95 % (Jokumsen & Svendsen, 2010).

Description of Recirculation Aquaculture System (RAS)
Intensive Recirculated Aquaculture Systems (RAS) are used in aquaculture production to minimize water consumption, as well as the environmental impact of the water discharge. RAS can use the same water many times and hence includes a wide range of waste water treatment devices (Martins et al., 2010; Dalsgaard et al., 2012). As a matter of fact, the use of RAS disconnects the production from the external environment. A sketch of a RAS is given below:

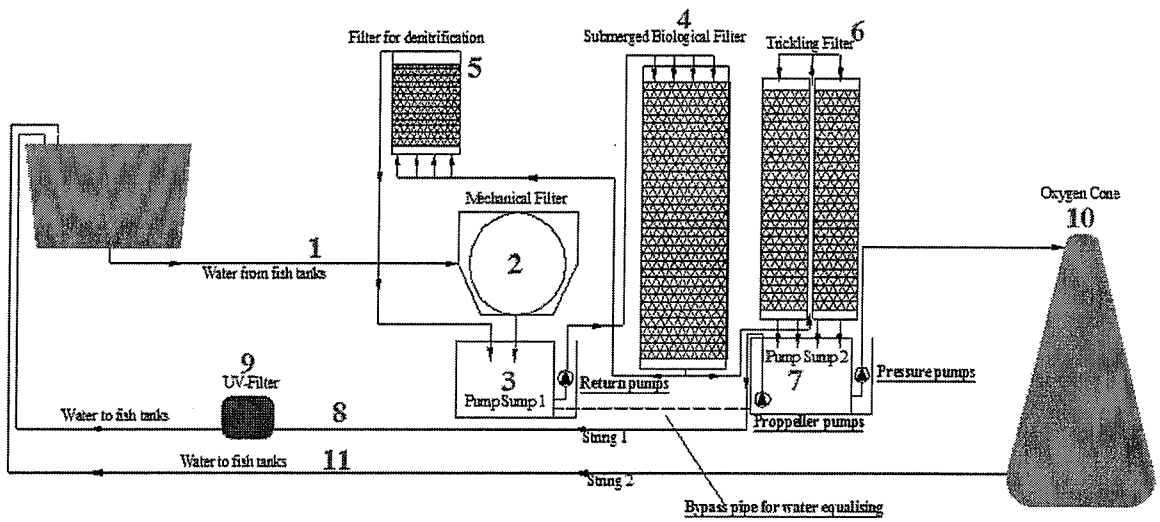

Figure 1: Sketch of a Recirculated Aquaculture System (RAS). The numbers in the figure are referred to (in brackets) in the text. Source: Billund Aquakulturservice ApS, Denmark.

The water supply for an intensive RAS freshwater farm is typically ground water, in the case of marine farms the water is pumped directly from the sea by means of submersible pumps. The production water from the fish tanks (1) passes through a mechanical filter (2), i.e. a microsieve (mesh size of about 60 µm). The microsieve separates particulate matter, which is flushed as sludge to a sludge storage tank until it can be used as agricultural fertilizer or for production of biogas. From the microsieve (2) the water is pumped (3) to the biofilters (4), where the dissolved fractions, especially ammonia (NH_4^+), are converted into nitrate (NO_3^-). In a separate biofilter (5) with anoxic (no oxygen) conditions (a denitrification filter), the NO_3^- is anaerobically converted into N_2 gas under consumption of easily degradable organic matter (Van Rijn et al. 2006; Suhr et al., 2013). The recirculated water passes on to a trickling filter (6) for degassing (N_2, CO_2) and aeration before it enters (7-8) the fish tanks. Before entering the fish tanks, the water passes an UV radiation device (9) to kill micro-organisms, especially bacteria. However, a portion of the aerated water from the trickling filter is pumped through an oxygen cone (7-10) for oxygenation before it enters (11) the fish tanks. In addition, pure oxygen may be added at each tank/section (Chen et al., 2006, Pedersen et al., 2012; Van Rijn, 2013) and the temperature

can be adjusted using devices for heating or cooling the water. The amount of new water consumed in the RAS corresponds to the amount required to flush the microsieves (2) and the biofilters (4), to compensate for evaporation, and to keep the temperature at an appropriate level. The water consumption in RAS is more than 100 times less, i.e. less than 500 l/kg feed fed to the fish than in traditional flow through systems (Jokumsen & Svendsen, 2010). Obviously, RAS requires input of external energy for pumping water around, water treatment, and aeration of the water, as well as that required in the buildings. The advanced technologies, management, comprehensive surveillance systems, working processes, and hygienic procedures in a RAS farm requires well-educated and trained personnel with the competence required to achieve optimum productivity. The high degree of recirculation makes it critical to continuously monitor and control the water quality within narrow limits, and the extensive use of alarm systems is necessary for several parameters (Jokumsen & Svendsen, 2010).

Comparison of Recirculation Aquaculture Systems (RAS) and flow-through systems
In the following table, a comparison has been set up between a traditional flow through system in organic farming and an intensive recirculated aquaculture system (RAS).

Flow-through organic system	RAS
Advantages • Production in common with nature • Favours biological diversity and animal welfare • Natural temperature and light conditions • Lower stocking density • Behavioural needs can be met • Renewable energy use, e.g. for aerators • Environmentally sustainable **Disadvantages** • Dependent on external conditions (weather, temperature fluctuations, water quality) • Risk of escape • Risk of ingress of pathogens	**Advantages** • Low water consumption • Recycling of water • Stable farming conditions/water quality • Control of water temperature • No environmental impact • Prevents ingress of pathogens • Prevents escapes • Recycling/collection of waste nutrients (fertilizer) • Easy to disinfect/clean **Disadvantages** • Energy consuming • Use of pure oxygen • Higher stocking density • In case of disease, risk of boosting prevalence

Re-use of water
An alternative strategy is re-use of water which, to some extent, combines the advantages of both flow through systems and RAS, without compromising organic principles. Re-use of water means a kind of *extensive* recirculation in *out-door* systems with up to 70 % of reuse of the water (Colt, 2006). Instead of being discharged, the water is pumped back to the inlet and re-used in the fishponds, tanks or raceways after passing waste water treatment devices such as natural-filter beds, settlement ponds, mechanical or biological filters to collect waste nutrients, and/or using seaweeds and/or bivalves and algae, which contribute to improving the quality of the effluent. The type(s) and capacity of waste water treatment device(s) depend(s) on the specific conditions on the specific farm – related to production capacity/intensity approved and fulfilment of water quality criteria.
To comply with the species-specific physiological requirements of the fish, the proper oxygen saturation in the aquatic environment shall be achieved only by using mechanical aerators. This means that there should be a well- balanced equilibrium between the stocking density, the efficiency of the waste water nutrients removal and the amount of water re-used for the proper operation of the organic farm.

Reflections of the Group / Balancing of arguments in the light of organic farming principles
Most of traditional organic farms are open-air flow through systems. However, due to the limitations of water resources, national regulations in some countries require that farms are only allowed to take a limited amount of new water from the water courses. In such cases the re-use of water could be a solution in line with the principles of organic production.
Closed recirculated systems (RAS) have several environmental advantages, but require significant input of external energy, high stocking densities (for economic reasons), advanced waste water treatment devices, use of UV radiation and use of pure oxygen. All the above, together with the disconnection of the aquaculture production from the external natural aquatic environment, makes the closed recirculated systems (RAS) not in line with the principles of organic production.

Conclusions
The Group concluded that RAS should remain prohibited for on-growing purposes (see glossary). However, re-use of water is in line with organic principles of sustainable and responsible use of resources, and is to be encouraged and further explored.

4.3 Reproduction

4.3.1 Eyestalk ablation in shrimps

Introduction, scope of this chapter
Eyestalk ablation is currently prohibited in organic production (Reg.889/2008, Annex XIIIa, section 7). The Group was asked for clarification regarding the interpretation of the prohibition of eyestalk ablation for reproduction in shrimp. The Group was also asked to clarify the term ablation in relation to hatchery practices such as ligation, incision, pinching etc.

Necessity for eyestalk ablation, known alternatives
The crustacean eyestalk is the location for the X-organ sinus gland that contains a heat-stable factor which inhibits gonadal maturation (Quackenbush & Herrkind, 1981), a gonad inhibitory hormone (GIH) that occurs in nature in the non-breeding season and is absent or present only in low concentrations during the breeding season (Bray and Lawrence, 1992). The reluctance of most shrimp to routinely develop mature ovaries in captivity is a function of elevated levels of GIH, and eyestalk ablation lowers the high haemolymph titer of GIH. The effect of eyestalk ablation is not on a single hormone such as GIH, but rather affects several physiological processes. Besides the GIH evidence, another hypothesis suggests that eyestalk ablation also reduces light sensitivity and thereby induces ovarian maturation. In the banana prawn (*P. merguiensis*), dim light favours ovarian maturation and spawning. There are several direct and indirect effects of eye ablation in female shrimps, including;

- increases total egg production by producing more frequent spawning, but not larger spawns
- moult cycle duration is shorter
- increases mortality
- deteriorates female condition
- in some instances, produces lower hatch rate of eggs
- leads to changes in ovarian colour
- increases energetic demands
- leads to eventual loss in egg quality

Without ablation, shrimp hatcheries would have to rely on natural breeding. This is slow and unpredictable, especially for species like *Penaeus monodon*, therefore it would lead to shortages of the small shrimp needed to stock ponds. The aim of ablation, under these circumstances, is to stimulate the female shrimp to develop mature ovaries and spawn. Even in conditions where a given species will develop ovaries and spawn in captivity, use of eyestalk ablation may increase total egg production and increases the percentage of females in a given population that will participate in reproduction. Once females have been subjected to eyestalk ablation, complete ovarian development often ensues within as little as 3 to 10 days.
Many researchers are looking into ways to reduce or inhibit the hormones preventing breeding by using either molecular substances such as GIH-dsRNA and anti-GIH antibody that can be injected into female broodstock of shrimp to deplete GIH and neutralize its activity (Treerattrakool et al., 2008, 2014) or Serotonin (5HT) injections (Wongprasert et al., 2006). Also, some breeding programmes (Benzie, 2009; Preston and Clifford, 2002) are trying to develop shrimp breeds that are able to breed more efficiently without needing ablation.

Techniques of eyestalk ablation
There are four main techniques used for eyestalk ablation: pinching, enucleation/slitting, cauterisation and ligation.

Pinching is the most common technique used for ablation. One eyestalk is pinched between the thumb and index finger and squeezed. This destroys one of the glands producing the hormone that prevents breeding. This type of ablation is practical, as it is quick, cheap and can be done by one person. If a razor blade is used in conjunction with this technique, it speeds up the process. This method may leave an open wound.
Enucleation is the method of slitting one eye with a razor blade, then crushing the eyestalk, with thumb and index fingernail, beginning one-half to two-thirds down the eyestalk and moving distally until the contents of eyes have been removed. This leaves behind the transparent exoskeleton, so that clotting of haemolymph and closure of the wound, may occur more rapidly.
Cauterisation uses either an electrocautery device or an instrument such as a red-hot wire or forceps that are applied to the base of the eyestalk. This is a relatively low-stress method as the wound is sealed quickly and shrimp usually resume eating soon after ablation. If performed correctly, this method closes the wound and allows scar tissue to form more readily. A variation of this technique is to use scissors or a sharp blade to sever the eyestalk, and then to cauterise the wound.
Ligation means tying off the eyestalk tightly with surgical or other thread. This method also has the advantage of immediate wound closure. The thread is then tightened to limit the blood supply to the eyestalk. After ligation, the eyestalk falls off after a couple of days. The recovery rate for ligation is good and the shrimp are active soon after the tie is attached, and spawning and maturation are observed as normal.

Animal welfare issues
Shrimp have a very simple nervous system and there is no scientific evidence that they have feelings corresponding to the feeling of 'pain' in humans. However, in aquaculture facilities it is important to consider the animal's state of health and the amount of stress it faces. Thus, a more comprehensive welfare definition should comprise a) the animal's physiological and psychological capability to cope with its environment, b) the integrated response of the whole organism to stress conditions.
Ablation appears to be a relatively minor discomfort, as ablated shrimp might begin to behave and feed normally quite soon after the operation is completed. The speed with which the shrimp begins to feed is used as an indicator of the stress levels (if the ablation is done well, feeding will begin very soon after the procedure). Anaesthesia has been tried, but does not seem to improve recovery. It has been reported that in the tiger prawn (*Penaeus monodon*), the eyestalks fully regenerate in less than 6 months.
Nevertheless, physiological responses to stress should be regarded, first and foremost, as a condition of adaptive defense of the organism, that has the fundamental function of preserving the individual life.

Reflections of the Group / Balancing of arguments in the light of organic farming principles
Without eyestalk ablation, production of juveniles is unpredictable and does not allow a guaranteed production cycle. The alternative of collecting breeders in the wild, in absence of a well-documented management plan, is not desirable.
Although a lot of research activities have been made so far, most of the breeding programmes still have to rely on eyestalk ablation. To date, domesticated strains have played a dominant role in seed production for only *P. vannamei* and *P. stylirostris* (Benzie 2009), while for *P. monodon* real alternatives still need to be developed (e.g. varieties which do not need eyestalk ablation).
The Group accepts that ablation appears to be a relatively minor discomfort, as ablated shrimp might begin to behave and feed normally quite soon after the operation is completed. However, organic principles, and consumer expectations, are that organic animal husbandry avoids

mutilations in all animals. The Group thinks that for the sake of integrity of organic production, this fundamental principle should be uniformly applied for all animals.
Furthermore, the Group recognizes that there are different techniques for eyestalk ablation. If eyestalk ablation is to be authorized, the Group thinks that the technique of ligation would be more acceptable than pinching, enucleation/slittering, cauterisation or other methods.

Conclusions
The Group considers the techniques of pinching, enucleation/slittering, cauterisation and ligation as forms of eyestalk ablation, which are not in line with the principles of organic production.
In the Group's opinion, all forms of eyestalk ablation in shrimps should remain prohibited.

4.3.2 Use of natural/artificial hormones

Introduction, scope of this chapter
The Group was asked to clarify whether natural or artificial hormones can be used in fish such as sturgeon, turbot and eels. In this chapter, the question is mainly discussed for sturgeon. In the case of turbot, current aquaculture practices do not use hormones for reproduction. In eel, there is not yet any commercial breeding and/or production of elvers.
Many sturgeon species are threatened with extinction, being listed in CITES since 1998. The first trials in sturgeon farming started in the middle of the 19th century, mostly to help in the conservation of wild populations through restocking. However, great advances in its culture have only been achieved in the last decades. Nowadays some sturgeon species are successfully being reproduced and raised in captivity (Coppens International, 2007). They are considered as slow growers in the wild, although under culture conditions some species have proven to have very high growth rates and to be tolerant to extremely high stocking densities (60-70 kg per m^3 with a survival rate of 50-80% from fry stage to marketable size) (Mims et al, 2002). There are several challenges for their production such as:

- supplies of brood stock and fry are very limited;
- there is a very long maturation period before females produce ripe eggs for reproduction;
- they need moderate temperature and ample supply of water;
- high initial investments;
- feed quality and proper management are requisites for proper reproduction.

Caviar (unfertilized eggs) and meat are the main products in sturgeon aquaculture. Nowadays, most caviar comes from aquaculture.

Necessity of using hormones, known alternatives
Sturgeon are slow to reach sexual maturity; some females cannot produce eggs until they reach an age of 30 years or more in the wild. Sometimes brood stock in the fish farms comes directly from the wild, although nowadays capture of wild fish is regulated by law and an increasing amount of brood stocks are reared in captivity. Under optimal culture conditions, and fed with high nutritional quality feeds, sturgeons reared in captivity can reach sexual maturatity in 1/3 – 1/2 of the time span needed in the wild. Gonad maturation requires 1 – 2 months at a water temperature below 10°C and final ripening is mediated by an increase in water temperature above 14°C using a slight increase in day length. Once they reach maturatity males and females are selected for spawning by determining the stage of gonadal maturity. In the case of males sperm is obtained by stripping, and in the case of females the maturatity of the eggs can be checked either by stripping or cannulation from the urogenital opening.
Certain fish, such as sturgeon or grouper, do not spawn in captivity and need supplementary hormones (via injection, slow-release pellets or water supplies) for final spermiation and final

egg maturation and ovulation (Mims et al, 2002; Coppens International, 2007). Hormonation can be done using, sturgeon (SP) and common carp (CCP) pituitaries, LH-RHa or a combination of both (Mohler and Fletcher, 1999). Optimum dosing is critical and depends on the species and body weight. 80 – 90% of females respond to the hormone injection with ovulation. Females are then checked for behavioral changes (they swim at the wall of the tanks, rubbing the walls) and when free adhesive eggs are observed in the tank, the eggs are removed from the female. There are several techniques to remove the eggs without sacrificing the female, such as caesarean section and minimal invasive surgical technique (MIST). MIST method is more rapid and consists in performing a small section in the posterior-ventral area of the oviduct that permits ovulated eggs to pass from the body cavity through the gonopore without going through the oviducts. With caesaran or MIST, only 50-90% of the eggs can be removed (Mims et al., 2002)
According to the information available to the Group, almost all conventional caviar producers currently use hormones. However, a few producers claim to produce caviar without hormones. Without hormones, the production of caviar is possible. However, the use of hormones does increase capacity and profitability.

Origin of raw materials, methods of manufacture
Carp and sturgeon pituitary extracts are from natural origin.

Animal welfare issues
Fish are anesthetized using MS-222, before they are treated with hormones.

Reflections of the Group / Balancing of arguments in the light of organic farming principles
The request is in conflict with Art. 25i of Reg. 889/2008, which states "*The use of hormones and hormone derivate is prohibited*". The Group is concerned about other possible uses of hormones in other species, and does not want to set a precedent by recommending their use in sturgeons. Consumers are worried about the use of hormones in general, regardless of amounts or purpose.

Conclusions
The Group recommends not to allow the use of hormones for the production of caviar in sturgeons, nor for production of juveniles.

4.4 Specific rules for production of juveniles and their feed

Introduction, scope of this chapter
Larval rearing is one of the most critical stages for the successful propagation of any species and represents one of the major bottlenecks of the whole aquaculture process. Most fish larvae, particularly the marine ones, are very small (total length of approximately 3 – 4 mm) at first feeding and thus are sensitive to rearing environment and to feed quality. Furthermore, these small larvae require live plankton for their first feeding and thus hatcheries include facilities for plankton production (both phytoplankton and zooplankton), the actual larval rearing zone and also for weaning – nursery. The majority of the hatcheries have also brood stock facilities, although in some cases transported eggs are used to initiate a production cycle.
Note: in larviculture, the term 'food' is often used for live prey and 'feed' for formulated rations. In this report, however, the term 'feed' is used throughout.

4.4.1 Phytoplankton

Mass-production of phytoplankton
Phytoplankton is of major importance in the hatchery process, having a double role. It is used in the rotifer cultures either as feed or as enriching media and also as medium for improvement of the rearing environment of larvae. Its role for larval rearing includes antibacterial properties but also shading effect that improves larvae predation or as trigger for feeding behavior or physiological processes (Scott & Baynes 1979; Naas *et al.* 1992; Tamaru *et al.* 1993; Reitan *et al.* 1993; Cahu *et al.* 1998; Van der Meeren 1991).
In all cases, the cultures are started from selected strains followed by an upscale in production (increase in volume) and are based on three operations: (i) strain maintenance, (ii) pre-cultures and (iii) mass cultures. The mass culture is usually performed in plastic bags or more recently in photobioreactors at high cell density (Tredici & Materassi 1992; Pulz 2001).

Nutrients needed for mass-production of phytoplankton
Commercial nutrient solutions contain all necessary macro- and micronutrients, silicates and vitamins in easily soluble, mineral form (Vonshak, 1986; Smith et al., 1993; Lavens & Sorgeloos, 1996).
There is a potential conflict with the principles of organic production. In the organic production of terrestrial crops, it is an overall principle that plants must not be fertilized with easily soluble nutrients. Art. 4(b)(iii) of Reg. 834/2007 limits the use of fertilizers to '*low solubility* mineral fertilizers'. In the implementing rules, hydroponic production is prohibited (Art. 4 of Reg. 889/2008). It is clear that this principle was developed for terrestrial plants, and does not hold for aquatic production, i.e. phytoplankton, where the nutrients are only available in soluble form. In the case of vitamins and other substances, the same rules concerning GMO risk should apply as for feed of terrestrial animals.

Inputs and technologies needed
Carbon dioxide is regularly supplied for phytoplankton cultures (especially in reactors) as a nutrient source. In the context of greenhouse production, carbon dioxide has been previously discussed by the Group (see EGTOP report on greenhouse production).

Conclusions on phytoplankton
The Group sees no possibility for applying the overall principle of fertilization with low solubility fertilizers (as given in Art. 4(b)(iii) of Reg. 834/2007 and currently applied for

terrestrial plants) to phytoplankton. Also, the Group considers that it would be difficult to define production of 'organic phytoplankton' which would be sufficiently different from conventional phytoplankton to justify its existence as a separate, organically certified product.
In view of the necessity to use phytoplankton in hatchery, the Group recommends that, for the time being, the use of phytoplankton should be authorized without requiring organic certification. However, GMO strains of algae must not be allowed.

4.4.2 Zooplankton

Mass-production of zooplankton as live feed for larvae of marine fish
Two species of zooplankton are mass cultured due to their appropriate size and easiness of mass culture. These are (i) the rotifer *Brachionus sp.* and (ii) the nauplius of the branchiopod crustacean, *Artemia sp.* Rotifers are the initial prey for the majority of marine fish larvae and are later replaced by *Artemia sp.* during the larval rearing process. Appropriate methods have been developed also for the culture of some ciliate species and for some copepods (Lavens & Sorgeloos, 1996, Marcus 2005, A. Tandler pers. comm.).
Rotifers are an excellent first feed for fish larvae because of their small size and slow swimming speed, their habit of staying suspended in the water column and their ability to be cultured at high densities due to a high reproductive rate (Dhert et al., 2001). As with microalgae, there are many recognized techniques for culturing rotifers. Production may be extensive in large 50 to 150 m^3 tanks, or intensive in small tanks of 1.0 to 2.0 m^3. Culture methods are classified as either batch, semi-continuous, or continuous.

Nutrients needed for mass-production of rotifers
For the feeding of rotifers several products are used (sometimes in combination), such as baker's yeast, different algal species (locally produced or purchased as algal paste) and formulated feeds.

Artemia
Artemia sp. is collected as dehydrated embryos or cysts from salt lakes and salt works. It is used either as instar I nauplii (400-600 micro-meters) hatched from cysts or as instar II-III nauplii (800-1000 micro-meters), reared with specially enriched feed. Frequently, cysts are de-capsulated with hypochlorite prior to hatching, in order to allow both preliminary disinfection of prey and better hatching rates (Lavens & Sorgeloos, 1996). Recently, other methods are applied which do not require de-capsulation: *Artemia* cysts are coated with non-toxic ferro-magnetic material (SepArt). After hatching the cysts, drain or siphon the nauplii and unhatched cysts into a separator that contains a magnet. Thus, unhatched cysts are trapped by the magnet, while nauplii are ready to use. Hatching and culture is performed in columns with high aeration at temperatures of about 26 °C.

Omega-3 fatty acids enrichment
Rotifers and *Artemia* need to be enriched in highly unsaturated fatty acids (EPA and DHA) and vitamins (C and A) and this can be done with microalgae (local cultures, algal pastes or powders of *Thraustrochytrids* single cell products) as well as oil emulsions. Commercial products are made up with synthetic antioxidants and emulsifiers, and do not comply with organic standards.

Reflections of the Group / Balancing of arguments in the light of organic farming principles
Unlike phytoplankton, the Group sees the technical possibility of an organic production of zooplankton, which would differ from conventional zooplankton in several aspects. Rules for organic *production* would need to be based on: Use of organic yeast and other microorganisms

(e.g. *thraustrochytrids*), only natural antioxidants and emulsifiers. For organic *enrichment*, only antioxidants, emulsifiers and vitamins, as allowed for terrestrial animals, should be used.
There are no organic enrichment diets available at the moment, and the Group is not able to evaluate whether their production would be commercially viable. The economic feasibility should be explored and the sector encouraged to consider organic production of zooplankton. Meanwhile, the Group sees no other possibility than to allow the use of non-organic zooplankton until better alternatives have been developed.

Conclusions on zooplankton
In the absence of better alternatives, the use of non-organic zooplankton should be allowed.

4.4.3 Production of larvae, post-larvae and juveniles

Introduction, scope of this chapter
A variety of hatchery techniques are available (Divanach & Kentouri, 1999), all sharing a common characteristic i.e. the use of plankton (phyto- and zooplankton) during the period of larval first feeding. The main classifications are based on the rearing density (intensive, semi-intensive, extensive) and the use of phytoplankton in the water (clear, green, pseudo-green) (Papandroulakis *et al.* 2002).
Independently from the applied method, there are three distinct phases during larval rearing: (i) egg hatching and autotrophic phase when larvae consume their yolk sac reserves, (ii) heterotrophic phase when larvae are fed on zooplankton, and (iii) the weaning to artificial diets. During these phases larvae complete their transformation to juveniles. Juveniles usually remain in the hatchery, for pre-growing, until reaching 2 – 5 g in weight. In cases where on-growing is performed in open sea conditions, the pre-growing period is extended until individuals reach a weight of 10-30g. During this period several procedures are commonly applied including grading, vaccination and quality control. This general scheme applies for both marine and freshwater larvae. A more detailed description of the applied techniques is presented in the following paragraphs

Intensive rearing systems for marine larvae
In intensive hatcheries, larvae are reared at high densities under controlled conditions and success is highly depending on the level of knowledge of the larvae's specific biological needs. Intensive rearing is characterized by high stocking densities, controlled conditions of water quality, light intensity, photo-phase and feeding. The most commonly applied method are (i) the 'clear water' technique (Coves & Gasset 1993; Papandroulakis 2000), with no use of phytoplankton in the rearing medium, (ii) the 'green water' technique that is based on the creation of optimum conditions for endogenous phytoplankton bloom of specific organisms in the larval tanks (Saroglia *et al.* 1989), and (iii) the so-called 'pseudo-green water' technology (Papandroulakis *et al.* 2002), which is based on the frequent addition of phytoplankton and zooplankton in the larval rearing tanks, where phytoplankton is not produced, nor bloom, but its concentration remains constant by daily addition. The pseudo-green method is applied during the most critical segment of the rearing process: at the beginning of larval rearing (until the 20^{th} to 30^{th} day post hatching), when the larvae are still extremely weak, sensitive to alterations in the rearing environment, easily stressed and difficult to feed. After this period, the 'clear water' methodology is applied.

Extensive and semi-intensive rearing systems for marine larvae

In extensive hatcheries, larvae are reared at low densities in large tanks or ponds under more natural conditions, feeding on endogenous blooms of wild marine zooplankton, but there is no industrial application due to the low productivity. As an intermediate approach between the intensive and extensive method, semi-intensive techniques, like the so called 'mesocosm technology' (Divanach & Kentouri 1999), have been developed and are applied for the rearing of several species. The actual form of the mesocosm technology was defined after studying the originally applied models of extensive rearing (Grice & Reeve 1982; Bever *et al.* 1985; Divanach 1985; Kentouri 1985; Lalli 1990). The most important characteristic of the infrastructure required is the size of the larval tanks which should range between 20 to 60 m^3. The conditions of rearing are independent from any climatic and/or seasonal changes. There is a partial control of the light conditions (intensity and photo-phase) and a minimal control of the temperature. The initial egg density in the mesocosm ranges from 4 to 7 eggs/l, depending on species, and should never exceed 20 eggs/l. Tanks are filled with natural seawater filtered mechanically, and wild plankton is thus introduced in the system offering a capacity for endogenous production. Phytoplankton is added daily to maintain the green medium for a period of 2 – 4 weeks after hatching. Exogenously produced enriched rotifers, enriched instar II *Artemia* sp. and artificial diet is added when required. The technology has been successfully used for the mass production of several species (Papandroulakis et al. 2004; Kentouri & Divanach 1983; Ben Khemis 1997; Koumoundouros et al. 1999; Papandroulakis et al. 2003; Papandroulakis et al. 2005). The mesocosm methodology results in high survival rates and low percentage of individuals with developmental abnormalities while, in general, larval growth performance is better than in the classical intensive systems. Similar semi intensive methods, like the above described, are also applied in different parts of the world, under different names such as 'large volume rearing' (Prestinicola et al 2013; Dhert et al., 1998) where the size of tanks, the rearing density and the presence of wild plankton are critical factors of the process. Recent studies (Prestinicola et al 2013) concluded that large volume rearing leads to a significant improvement of the morphological quality (i.e., lowered incidence of severe skeletal anomalies and meristic count variability) of gilthead seabream juveniles reared under semi-intensive conditions. Furthermore, there is evidence that the rearing conditions during the early life stages do have an impact on the behavioral response of sea bass during on-growing, and the individuals reared with the mesocosm method are more sensitive to human presence, presenting behavior closer to wild individuals (Papandroulakis et al., 2012).

Larval rearing of fresh water species (percid)

The larval rearing of pike-perch is very similar to that of marine fish larvae due to the size of the individuals at first feeding. The temperature is maintained constant at about 18 – 19 °C throughout the larval rearing phase, and gradually increased up to the time of transfer of juveniles to the on-growing tanks. The optimal temperature during on-growing is around 23 – 25 °C. Initial stocking density usually ranges between 20 and 50 larvae/l, but fish density must be reduced after the weaning phase. Feeding is based on live preys, similar to marine larvae, i.e. rotifers and *Artemia* nauplii. First feeding is composed of enriched rotifers (either the brackish water species *Brachionus plicatilis* or the freshwater species *B. calyciflorus*) or of small size *Artemia* nauplii (350-380 μm) for a period of 3 days. Afterwards, larvae are fed enriched *Artemia* nauplii (420-450 μm) (Lund, pers. comm.). At 25 – 30 days after hatching (body weight of 50 – 60 mg), the pikeperch are gradually weaned to appropriate dry feed, by replacing progressively the live prey with a high quality compound feed (300 – 500 μm) within 4-5 days.

Larval rearing of carp

Common carp are mainly omnivorous, with animal prey representing more than 75 % of the diet. A few days after hatching, the fish larvae feed mainly on small zooplankton, such as rotifers (not

enriched) and copepod nauplii. After a short period, however, they shift to larger organisms such as cladocerans and copepods (Dulic et al., 2011; Nunn et al., 2012) or, seldom, to non-enriched *Artemia* nauplii. This change occurs gradually, largely depending on the size of the fish mouth, that is also correlated with body size. The size at which individuals shift from planktivorous to benthivorous feeding habit, however, depends on many factors, such as the availability of planktonic and benthic food, as well as the ratio between both types of food. Crustaceans will form the main component of the feed until individuals reach 100 – 150 mm. The amount of zooplankton ingested increases with fish size. From the juvenile stage onward, carp is primarily a bottom feeder, and aquatic insects (mainly benthic larvae of chironomids) form the main component of the diet (Adamek, 2014, pers. comm).

Larval rearing of molluscs and crustaceans
Mollusc larvae and start-feeding shrimp larvae are filter feeders and consequently feed on phytoplankton, which should be produced following the above recommendations (see section 4.4.1). Later stages of shrimp (mysis and postlarval stage), and most other crustacean larvae are first fed on *Artemia* and later on microdiets, therefore recommendations of section 4.4.2 should be applied, especially considering enrichment on polyunsaturated fatty acids.
For mollusc rearing, low densities are commonly used. For crustaceans, stocking density has variable effects: shrimp postlarvae can be kept at higher densities, while this is not the case for prawns and even less for crab and lobster.

Reflections of the Group / Balancing of arguments in the light of organic farming principles
For marine fish, there is evidence that juveniles produced with 'mesocosm' or 'large volume rearing' systems are more similar in behaviour and morphology to their wild counterparts. With respect to freshwater fish, molluscs and crustaceans, there is not enough experience with comparable rearing systems for drawing such conclusions.

Conclusions
The Group recommends that for larval rearing of marine fish species, methods such as the 'mesocosm' or 'large volume rearing' should be used. The specific requirements for these rearing systems include:

- An initial stocking density below 20 eggs or larvae/l.
- Larval rearing tank volume of minimum 20 m^3.
- Feeding of larvae on the natural plankton developing in the tank that is supplemented by externally produced phytoplankton and zooplankton.

With respect to the larval rearing of freshwater fish, molluscs and crustaceans, the Group cannot make specific recommendations at the moment, because of lack of scientifically based investigations.

4.4.4 Microbial control in hatchery

Introduction, scope of this chapter
As in any aquaculture operation, microbial control in hatcheries is essential and standard disinfection methods are applied for the facility and the equipment used. The list of substances in Annex VII covers the general requirements. Specific aspects are discussed below.

Disinfection of eggs
In some cases, fish eggs are disinfected. Disinfection of eggs is mandatory in salmonid species. In marine species, it is not frequently practised. The OIE manual recommends the use of

iodophors for egg disinfection (OIE 2012). Hydrogen peroxide is also used. For organic production, the Group recommends that no other substances than iodophors and hydrogen peroxide should be used for eggs disinfection.

Disinfection of zooplankton
Hydrogen peroxide is often used for disinfection of the live prey before administering the prey to the larvae. The range of substances authorized in Annex VII is sufficient, and there is no need for amendments.

Control of bacteria in hatcheries
The aquatic environment is more supportive to pathogenic bacteria, independently of their host, than the terrestrial environment and, consequently, pathogens can reach high densities around the animals, which then ingest them either with the feed or when they are drinking. As a consequence, culturing several species of aquatic animals (especially larval stages) in many cases suffers from highly unpredictable survival rates because of bacterial diseases (Verschuere et al., 2000). Independently from the species reared, no antibiotics are used in larval rearing, as larvae are in general very vulnerable and cannot tolerate the treatment. Hence, techniques to control pathogenic bacteria are paramount to the further development of the aquaculture sector.
In the review of Defoirdt et al. (2007) a critical evaluation is presented of alternative measures that have recently been developed to control disease caused by *V. harveyi* and closely related bacteria. Techniques discussed include phage therapy, the use of SCFAs and polyhydroxyalkanoates, quorum-sensing disruption, probiotics and 'green water' (see section 4.4.3 for explanation). Some of the techniques have only been studied recently and have only been tested in the laboratory (e.g. disruption of cell-to-cell communication), whereas others have a longer history, including farm trials (e.g. the application of probiotics). Each of the techniques has its advantages but also its limitations. In fact, none of them will probably be successful in all cases. Therefore, it is of importance to develop further all of these alternatives to construct a toolbox containing different sustainable measures. A good management strategy might then use different techniques in rotation to prevent resistance development. Alternatively, it might be valuable to determine which techniques are, and which are not, compatible with each other, to apply them together to maximize the chance of protecting the animals successfully.

Conclusions
Provided that the recommendations in chapter 4.5 are followed, the Group considers that the range of substances in Annex VII covers the general requirements for microbial control in hatcheries. However, alternative methods should be considered as soon as they become available for practical use.

4.4.5 Weaning procedure

Feed mixes
Feed mixes for weaning are different from those for on-growing. The Group thinks that their production in organic quality is technically possible. At the moment, the Group is not aware of any organic weaning diets which would comply with organic production rules. However, some manufacturers would be interested to produce such feeds, if there is sufficient demand.
The Group would welcome that feed companies develop organic diets for the early stages, in order to cover the specific requirements of the juveniles. During the weaning and the pre-growing phase, when dry feeds are used, the rules for organic aquaculture should be applied, both in terms of management and type of feed used.

4.5 Evaluation of substances for cleaning and disinfection

4.5.1 General comments on cleaning and disinfection

Use of substances in the presence of animals – experiences in Denmark
Currently, section 2.2 of Annex VII only includes limestone and dolomite as allowed for use in presence of aquatic animals. However, the possibility of using only these two substances is an urgent challenge for sustainable performance of the organic farming. Negotiations with the Danish authorities resulted in an amending specific authorization (DK, 2010) which allows the use of the following substances in Danish organic aquaculture:

- rock salt/ sea salt
- hydrogen peroxide
- sodium percarbonate
- mixture of hydrogen peroxide and peracetic acid
- calcium hydroxide (slaked lime)

Rock and sea salt, hydrogen peroxide, sodium percarbonate and mixtures of hydrogen peroxide and peracetic acid can be used in the presence of animals; slaked lime can be used prior to inlet to the ponds/tanks. At the time of authorization of these substances in 2010, research at DTU Aqua already had indicated positive results by using the substances as sanitizers in trout farming to keep sufficiently hygienic conditions/suppressed disease incidence. Research already carried out in recent years, and still ongoing, on these few substances has been shown to be efficient against pathogens, environmentally friendly and with no health risks for animals or humans (Pedersen et al., 2006; 2012; 2013). The above mentioned substances have proven to be useful in organic farming, as replacement for formaldehyde, chloramin-T and blue vitriol (copper sulphate). Indeed, organic farming is dependent on sanitizers for proper management and securing fish welfare, as farming in open systems increases the risk of infection with parasites, bacteria, viruses and fungi. Such substances were introduced in Danish aquaculture practice to improve environmental/labour conditions and to reduce possible negative environmental impact.

Use of substances in organic production
In this chapter, the Group evaluates the inclusion of substances in section 2 of Annex VII of the Reg. 889/2008.
The Group underlines that even for those substances which are *not* listed in Annex VII, the use is still possible with a veterinary prescription (see Art. 25t(2) of Reg. 889/2008).

Biocides legislation
The use of disinfectants is subject to Reg. 528/2012. This regulation distinguishes between various 'product-types' of biocides (see Annex V). Disinfectants used in aquaculture fall into product-type 3 'veterinary hygiene'. This category includes products for use in all animals (also terrestrial), and there is no specific sub-category for aquaculture.
Most of the substances discussed in this report have been in use for many years. Such substances are subject to the EU's biocide re-evaluation programme, which is still on-going. For the moment, only few substances have been re-evaluated as biocides. In particular, the public register of 'draft assessment reports' on the European Commission's website 'CIRCABC' does not yet contain any entries for product-type 3. For substances which were classified as 'existing active substances' in Reg. 1451/2007, national authorizations remain valid until the re-evaluation at EU level is completed.

Veterinary medicinal products legislation

Veterinary medicinal products are in the scope of Dir. 2001/82/EC. According to a guidance document[1], products for the control of external parasites of fish, used by adding the products to the water where fish swim, would normally be considered as veterinary medicinal products. However, the document admits in the absence of claims and in specific cases, they could also be considered as biocides. Finally, the document states that this advice is not legally binding, as only the Court of Justice can give an authoritative interpretation of existing Community law.

Conclusions on regulatory aspects

(1)The requests on disinfectants should not be postponed. Several member states have stated that the organic aquaculture sector urgently needs adaptations in the list of authorized disinfectants. In order to meet this need, the Group has decided to consider also substances for which no re-evaluation as biocides is available yet. This advice should be reconfirmed when the biocides re-evaluation is completed.

(2)It is not always simple to determine whether a given substance falls mainly under biocides legislation, veterinary medicinal products legislation or possibly some other legislation at EU and/or member state level. For these cases, the Group suggests to use a wording which clarifies that these substances must be used in compliance with general legislation, without anticipating association with any specific legislation (see proposals in section 4.6.2).

4.5.2 Tosylchloramide sodium (Chloramine T)

Introduction, scope of this chapter

The Group was asked whether tosylchloramide sodium can be used in the presence of aquaculture animals (inclusion in section 2.2 of Annex VII).

Tosylchloramide sodium is also known by several other names, such as 'chloramine T', 'N-chloro tosylamide' or 'N-chloro 4-methylbenzenesulfonamide, sodium salt'. It has the CAS number 127-65-1 (see glossary), and the molecular formula $C_7H_7ClNO_2S{\cdot}Na$ ($3H_2O$). Despite the similarly sounding name 'chloramine T', this substance should not be confused with 'chloramines', which are derivatives of ammonia by substitution of one, two or three hydrogen atoms with chlorine atoms.

Authorization in general aquaculture and in organic production

Tosylchloramide sodium was identified as an 'existing active substance' (Reg. 1451/2007). At the moment, no draft assessment report is available and it has not been approved for PT 3. Thus, national authorizations remain valid until the re-evaluation at EU level is completed. For some other uses of tosylchloramide sodium (PT 1, 6, 9, 10 and 11), approval was rejected. No MRL is set for tosylchloramide sodium in fin fish (Reg. 37/2010). In organic production, tosylchloramide sodium is currently not authorized.

Technological or physiological functionality for the intended use

Tosylchloramide sodium is a strong oxidizing agent. Its action is based on an irreversible destruction of microbial cell material. It is active against a wide range of micro-organisms,

[1] Doc-Biocides-2002/01 (Version 08.01.2008). Guidance document agreed between the Commission services and the competent authorities of the Member States for the Biocidal Products Directive 98/8/EC and for the Medicinal Products for Human Use Directive 2001/83/EC and the Veterinary Medicinal Products Directive 2001/82/EC. BORDERLINE BETWEEN DIRECTIVE 98/8/EC CONCERNING THE PLACING ON THE MARKET OF BIOCIDAL PRODUCTS, DIRECTIVE 2001/83/EC CONCERNING MEDICINAL PRODUCTS FOR HUMAN USE AND DIRECTIVE 2001/82/EC CONCERNING VETERINARY MEDICINAL PRODUCTS.

including tuberculosis, foot-and-mouth disease and avian influenza. It is used for disinfecting surfaces and tools in hospitals, laboratories, medical, dental and veterinary facilities.
In aquaculture, it can be used for disinfection of installations and tools, as well as for preventive or therapeutic treatments of bacterial gill disease (EMEA 2005). The dossier mentions disinfections of various equipments, egg disinfection at the hatchery, and control of White Spot Disease (*Ichthyophthirius multifiliis*) in on-growing fish.

Necessity for intended use, known alternatives
The dossier does not give sufficient evidence of the necessity for using tosylchloramide sodium. The dossier stresses the use against white spot disease. However, there are alternatives for treating this disease (e.g. salt water, hydrogen peroxide).

Origin of raw materials, methods of manufacture
Tosylchloramide sodium is a synthetic substance. It is manufactured from p-toluenesulfonamide and sodium hypochlorite.

Environmental issues, use of resources, recycling
No evaluation as a biocide is available yet. According to the dossier, tosylchloramide sodium fully degrades within a few hours to a few days, depending on the properties of the receiving water. The environmental fate of the resulting chlorine is not further explained. Tosylchloramide sodium does not accumulate in sediments or trophic chains.
According to Danish environmental legislation[2], the maximum limit for discharge of tosylchloramide sodium is 5.8 µg/l. This precludes the use of tosylchloramide in practical aquaculture.

Animal welfare issues
If used correctly, the Group has no concerns over its impact on animal welfare. On the contrary, the prevention or cure of gill disease or other diseases is beneficial for the welfare of fish.

Human health issues
No evaluation as a biocide is available yet. If used correctly, the Group has no concerns over human health effects.

Impact on food quality
No issue

Traditional use and precedents in organic production
Tosylchloramide sodium has no traditional use in EU organic production.

Authorised use in organic farming outside the EU / international harmonization of organic farming standards
At the moment, neither the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods (GL 32-1999, last amended 2013) nor the National Organic Program (USA) cover aquaculture. The NOP rules for livestock production do not allow the use of tosylchloramide sodium.

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[2] BEK nr 1022 af 25/08/2010 (Danish national consolidation act no. 1022 of 25/08/2010 'Consolidation act on environmental quality requirements for wetlands and requests to discharge of pollutants to water courses, lakes and the sea').

Reflections of the Group / Balancing of arguments in the light of organic farming principles
Tosylchloramide sodium is a synthetic substance. There are authorized alternatives in Annex VII, and veterinary treatments would be an additional option.

Conclusions
The Group concluded that the use of tosylchloramide sodium for disinfection is not in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. It should therefore not be included in Annex VII.

4.5.3 Hydrogen peroxide / sodium percarbonate

Introduction, scope of this chapter
Hydrogen peroxide is already authorized for use in the *absence* of aquaculture animals (section 2.1 of Annex VII). The Group was asked to evaluate whether it could also be used in the *presence* of aquaculture animals (section 2.2 of Annex VII). In addition, the dossier also requests the authorization of the 'powder form' (sodium percarbonate).
Hydrogen peroxide has the chemical formula H_2O_2. It is the simplest peroxide and a strong oxidizer. Sodium percarbonate is an adduct of sodium carbonate (Na_2CO_3) and hydrogen peroxide (H_2O_2), with the formula $2Na_2CO_3 \cdot 3H_2O_2$. Due to its content of hydrogen peroxide, it is also an oxidizing agent.
This chapter discusses mainly hydrogen peroxide. Sodium percarbonate is mentioned in some places.

Authorization in general aquaculture and in organic production
Hydrogen peroxide is authorized for disinfection under general legislation as 'existing substance'. It is also authorized as a veterinary treatment against sea lice in salmonids.
According to Danish national Consolidation Act no. 1671 (22. Dec. 2010), on Organic Food and Organic Aquaculture, Art. 7, § 14 the use of hydrogen peroxide is authorised for use in water in presence of aquaculture animals in Danish organic production (see chapter 4.5.1).

Technological or physiological functionality for the intended use
Hydrogen peroxide has a wide range of uses as a bleaching agent and disinfectant in industry, medicine, dentistry and agriculture. Hydrogen peroxide is very effective against all kinds of pathogenic microorganisms (bacteria, fungi, parasites). In aquaculture, it can be used as a broad-spectrum disinfectant in all live stages of different species of fish and shellfish, including eggs. Hydrogen peroxide has various applications: in the *absence* of animals, it is used as a general disinfectant, as a water sanitizer, i.e. to lower bacterial loads and as part of biofilter maintenance in recirculated systems, and to reduce geosmine during depuration. In the *presence* of animals, it is used at the hatcheries and for on-growing for water treatment against the motile forms of one of the most common parasites of fish: *Ichtyobodo necator* (provoking direct mortality or major branchial injuries leading to bacterial infections) and *Ichthyophthirius multifiliis* (belonging the protozoa ciliates and provoking the White Spot Disease), on eggs and broodstock against *Saprolegnia*, to treat Amoebic Gill Disease in Salmonids and to disinfect zooplankton before feeding to marine larvae (see review by Yanong, 2014). Hydrogen peroxide is easy to use as a dip, flush or bath treatment and concentration can easily be monitored by use of test strips.
Sodium percarbonate is used to disinfect ponds in the absence of animals, and also together with water filtration to treat parasites (Heinecke and Buchmann 2009). It is also used for terminal disinfection and cleaning of systems. It increases pH and liberates hydrogen peroxide (Heinecke & Buchmann, 2009; Møller et al., 2010; Pedersen et al., 2006; Pedersen & Pedersen, 2012; Saez

& Bowser, 2001; Schmidt et al., 2006). Sodium percarbonate may also be used as emergency oxygen ('oxygen powder'), as it liberates O_2 during degradation.

Necessity for intended use, known alternatives
Hydrogen peroxide has been used in aquaculture as a substitute for other, less preferable, substances such as formaldehyde or tosamylchloramine sodium.

Origin of raw materials, methods of manufacture
Hydrogen peroxide is naturally produced in trace quantities by organisms (Schmidt et al., 2006), most notably by a respiratory burst as part of the immune response. The substance used for disinfection is manufactured synthetically, most frequently by the anthraquinone process.
Sodium percarbonate is produced industrially by reaction of sodium carbonate and hydrogen peroxide, followed by crystallization. The Group has no evidence for a natural occurrence of sodium percarbonate.

Environmental issues, use of resources, recycling
Hydrogen peroxide spontaneously dissociates in water producing dissolved oxygen and water. When discharged into the river system, it disappears in a few hours to a few days (half-life of about 5 days in continental aquatic environment). The more the water contains oxidizable matter the faster the dissolution (consumption by organic matter in the water column, sediment, macrophytes). It does not accumulate in the sediments or in the food chain.
Hydrogen peroxide has little or no chronic toxicity in the aquatic environment, due to its chemical properties. It is also produced naturally by aquatic ecosystems in low concentrations.
Regarding acute toxicity (exposure to hydrogen peroxide less than a few hours), the data is abundant for fish (cf. Schmidt et al., 2006). There is no risk of acute toxicity on the aquatic environment under normal conditions of handling.

Animal welfare issues
The Group has no concerns. On the contrary, it is desirable as water sanitizer.

Human health issues
As long as hydrogen peroxide and sodium percarbonate are used correctly, the Group has no concerns. Sodium percarbonate is easier for handling than hydrogen peroxide.

Impact on food quality
No concerns.

Traditional use and precedents in organic production
Hydrogen peroxide is already authorized for use in the *absence* of aquaculture animals. In at least one member state (Denmark) its use in the presence of animals is authorized (see chapter 4.5.1).

Authorised use in organic farming outside the EU / international harmonization of organic farming standards
At the moment, neither the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods (GL 32-1999, last amended 2013) nor the National Organic Program (USA) cover aquaculture. The NOP rules for livestock production allow the use of hydrogen peroxide 'as disinfectants, sanitizers and medical treatments as applicable', i.e. in the absence and in the presence of animals. Sodium percarbonate is not

allowed for livestock production, but it may be used as a pesticide, 'if the requirements of 205.206(e)[3] are met'.

Reflections of the Group / Balancing of arguments in the light of organic farming principles
Sodium percarbonate acts by releasing hydrogen peroxide as active substance. Nevertheless, hydrogen peroxide and sodium percarbonate are two separate, clearly defined substances. Sodium percarbonate would need to be listed explicitly in Annex VII, in order to be authorized.
Water treatment/sanitation and disinfection is part of good fish husbandry and health management in the aquaculture production. Hydrogen peroxide/sodium percarbonate is efficient against external fungi and parasites that cause heavy damages both at the hatchery and at the on-growing stages. Hydrogen peroxide/sodium percarbonate is easily degradable and considered as safe both regarding human health and environmental impact.

Conclusions
The Group concluded that the use of hydrogen peroxide and sodium percarbonate in the absence as well as in the presence of animals is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007.
The Group recommends to include both substances in Annex VII, in the 'basic list of substances for management of aquatic environments'. The concept of the 'basic list of substances for management of aquatic environments' is explained in detail in chapter 4.6.

4.5.4 Peracetic acid and peroctanoic acid

Introduction, scope of this chapter
Peracetic acid and peroctanoic acid are already authorized for use in the *absence* of aquaculture animals (section 2.1 of Annex VII). The Group was asked to evaluate whether they could also be used in the *presence* of aquaculture animals (section 2.2 of Annex VII). The simultaneous listing of these two acids can apparently be traced back to the existence of a commercial product containing these two active substances. The Group chose to carry out a general evaluation of these substances, not restricted to a particular commercial product.
Peracetic acid (also known as peroxyacetic acid, or PAA; CAS number: 79-21-0), is an organic compound with the formula CH_3COOOH. This organic peroxide is a highly corrosive, colourless liquid. It is frequently used as a disinfectant, also without peroctanoic acid.
Peroctanoic acid (also known as peroxyoctanoic acid; CAS number: 33734-57-5) has the formula $CH_3(CH_2)_6COOOH$. It is similar to peracetic acid, but has a longer hydrocarbon chain. This substance is not commonly used for disinfection. The only use that the Group is aware of is in the commercial product mentioned above, where it is a minor ingredient. The Group had very limited information on peroctanoic acid at disposal.
Authorization in general aquaculture and in organic production
Both for peracetic and peroctanoic acid, applications as PT 3 biocides are pending.
According to Danish national Consolidation Act no. 1671 (22. Dec. 2010), on Organic Food and Organic Aquaculture, Art. 7, § 14 the use of peracetic acid is authorised for use in water in presence of aquaculture animals in Danish organic production (see chapter 4.5.1).

Technological or physiological functionality for the intended use
When peracetic acid dissolves in water, it dissociates to hydrogen peroxide (which is also authorized; see chapter 4.5.3) and acetic acid. Peracetic acid is a very powerful oxidant; the

[3] reference to US law (‚National Organic Program')

oxidation potential outranges that of chlorine and chlorine dioxide. Peracetic acid is used in aquaculture as a sanitizer, similar to applications with hydrogen peroxide (see chapter 4.5.3 above) (Kitis, 2004; Meinelt et al., 2009; Pedersen et al., 2009; Pedersen et. al., 2013).
Based on structural analogy, the Group assumes that a similar reaction occurs when peroctanoic acid dissolves in water, again releasing hydrogen peroxide.

Necessity for intended use, known alternatives
Peracetic acid and peroctanoic acid have been used in aquaculture as a substitute for other, less preferable, substances such as formaldehyde or tosylchloramide sodium.

Origin of raw materials, methods of manufacture
Peracetic acid is a synthetic substance. It is produced by autoxidation of acetaldehyde. The Group could not ascertain the origin of peroctanoic acid, but assumes that this is also a synthetic substance.

Environmental issues, use of resources, recycling
Peracetic acid is easily degradable as it reacts with organic matter (chemical oxidation) in the water, as well as on surfaces. Degradation products of peracetic acid are via acetic acid to acetate and CO_2 and H_2O as end products. Half-life at realistic dosage is typically below 1 hour in aquaculture systems. Moreover, peracetic acid trade products require only small application doses, thus limiting the environmental impact (Pedersen et al., 2009; Pedersen et al., 2013).
For peroctanoic acid, the Group assumes similar degradation, also finally leading to CO_2 and H_2O as end products.

Animal welfare issues
The Group has no concerns. On the contrary, the substances are desirable as water sanitizers.

Human health issues
As long as they are used correctly, the Group has no concerns.

Impact on food quality
No issue.

Traditional use and precedents in organic production
Peracetic acid and peroctanoic acid are already authorized for use in the *absence* of aquaculture animals. In Denmark, peracetic acid is also authorised for use in *presence* of aquaculture animals (see chapter 4.5.1).

Authorised use in organic farming outside the EU / international harmonization of organic farming standards
At the moment, neither the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods (GL 32-1999, last amended 2013) nor the National Organic Program (USA) cover aquaculture. The NOP rules for livestock production allow the use of peracetic acid for cleaning and disinfection in the absence of animals, while peroctanoic acid is not allowed.

Water treatment/sanitation and disinfection is part of good fish husbandry and health management in the aquaculture production. For peroctanoic acid, very limited information was available, so that the Group had to derive some informations from analogy with peracetic acid. However, the Group thinks that this can be justified by the similarity of these two substances, Peracetic acid and peroctanoic acid are efficient against bacteria and parasites that cause heavy damages both at the hatchery and at the on-growing stages. Both are easily degradable and will fully decay before discharge. They are considered as safe both regarding human health and environmental impact.

Conclusions
The Group concluded that the use of peracetic acid and peroctanoic acid in the absence as well as in the presence of animals is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007.
The Group recommends inclusion of both substances in Annex VII, in the 'basic list of substances for management of aquatic environments' (see chapter 4.6).

4.5.5 Hypochlorous acid produced from mixtures of potassium peroxomonosulphate and sodium chloride

Introduction, scope of this chapter
The Group was requested to evaluate the acceptability of a solid commercial product which releases hypochlorous acid in water. The request was accompanied by a comprehensive documentation from the manufacturer, but not with a member state dossier. The Group chose to carry out a general evaluation of the active substances involved, not restricted to the particular commercial product.
The product contains a mixture of common sea salt/rock salt (NaCl) with a strong oxidizing agent in solid form. The oxidizing agent is a triple salt consisting of the active constituent potassium peroxomonosulfate ($KHSO_5$), along with potassium hydrogen sulfate ($KHSO_4$) and potassium sulfate (K_2SO_4). When this mixture is added to water, chlorine (Cl_2) is formed.
Chlorine by nature reacts with water, and forms hypochlorous acid (HOCl) or the hypochlorite ion (OCl^-) and the hydrogen ion (H^+). Which form predominates depends on the pH of the water: under acidic conditions, hypochlorous acid predominates, while hypochlorite predominates under alkaline conditions. To stabilize the system and to achieve predominance of hypochlorous acid, an organic acid is added to the commercial product.
It is noteworthy that the hypochlorite ion is also formed when sodium hypochlorite or calcium hypochlorite (both included in section 2.1 of Annex VII) are dissolved in water.

Authorization in general aquaculture and in organic production
The production of hypochlorous acid from mixtures of potassium peroxomonosulphate and sodium chloride is considered as '*in-situ* generated biocidal active substance' (EC 2014) and falls under the scope of the new biocides legislation (Reg. 528/2012). For such substances, the deadline for making a declaration of intention to notify a precursor has just expired (EC 2013), and no decisions have been published yet.

Technological or physiological functionality for the intended use
Hypochlorous acid is a broad spectrum disinfectant, which is effective against a wide range of bacteria, viruses, fungi and mycoplasmas, including a range of plant, animal and human pathogens. It may be used in greenhouses, poultry, swine, equine and bovine production and in

aquaculture. In aquaculture, it is intended for disinfection of equipment, and it is commonly used in footbaths.
According to the dossier of the manufacturer, the biocidal activity of hypochlorous acid is greater than that of hypochlorite.

Necessity for intended use, known alternatives
Hypochlorous acid might be an important sanitizer, along with similar substances listed in Annex VII.

Origin of raw materials, methods of manufacture
The oxidizing agent potassium peroxomonosulfate is synthetically manufactured.

Environmental issues, use of resources, recycling
According to the dossier of the manufacturer, the environmental profile of hypochlorous acid is considered to be identical to hypochlorite, which is already listed in Annex VII.

Animal welfare issues
No issues identified.

Human health issues
According to the dossier of the manufacturer, hypochlorous acid produced in this way is expected to be safer than sodium hypochlorite. In this sense, the Group has no concerns, if such products are used correctly.

Impact on food quality
If used in the absence of animals, the Group has no concerns.

Traditional use and precedents in organic production
Sodium hypochlorite and calcium hypochlorite have been authorized in organic production for a number of years, and are included in section 1, as well as section 2.1 of Annex VII. In aqueous solution, they form the hypochlorite ion, which is transformed into hypochlorous acid under acidic conditions. Thus, the same active ingredient has been authorized before.

Authorised use in organic farming outside the EU / international harmonization of organic farming standards
At the moment, neither the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods (GL 32-1999, last amended 2013) nor the National Organic Program (USA) cover aquaculture. The NOP rules for livestock production do not allow the use of potassium peroxomonosulphate.

Reflections of the Group / Balancing of arguments in the light of organic farming principles
The substances used to generate hypochlorous acid are synthetic, but the same is true for sodium and calcium hypochlorite. Because the active ingredient hypochlorous acid is the same as for sodium hypochlorite and calcium hypochlorite, the use of such mixtures seems similarly acceptable to the Group. The safety of handling is an argument in favour of hypochlorous acid produced from mixtures of potassium peroxomonosulphate and sodium chloride. The availability of an additional disinfectant may create new options for disinfection in aquaculture. In the Group's opinion, sufficient disinfection is clearly preferable to the use of veterinary drugs.

Conclusions
The Group concluded that the use of hypochlorous acid produced from mixtures of potassium peroxomonosulphate and sodium chloride in the absence of animals is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. It should be included in Annex VII, along with sodium hypochlorite and calcium hypochlorite.

4.5.6 Sodium chloride (salt)

Introduction, scope of this chapter
Sodium chloride (NaCl) is commonly known as salt. It is already authorized for use in the *absence* of aquaculture animals (Annex VII). The Group was asked to evaluate whether it could also be used in the *presence* of aquaculture animals. The use of marine water can have the same effect as sodium chloride solutions on freshwater fish. On marine species, the use of freshwater can have the same effect.

Authorization in general aquaculture and in organic production
Some of the potential applications of sodium chloride in fish production clearly do not fall under the scope of biocide legislation.

Technological or physiological functionality for the intended use
Sodium chloride has many potential applications in fish production. It serves to reduce osmoregulatory stress during transport and handling, and to avoid methemoglobia (brown blood disease). In addition, it controls some parasites (protozoans on the gills and skin of fish) (Francis-Floyd 1993). Details of the use are given by Francis-Floyd (1993). Freshwater fish (together with their freshwater parasites) are exposed to solutions of sodium chloride or sea water. Dosage and treatment time must be adapted to the fish species and to the practical conditions. Similarly, marine fish (together with their marine parasites) can be exposed to freshwater. In both cases, the antiparasitic action is caused by the osmotic pressure.

Necessity for intended use, known alternatives
With respect to its use for reducing stress during transport and handling, there are no alternatives. With respect to its effect on parasites, alternatives exist, but sodium chloride is preferable, because it is natural.
Freshwater is currently one of the treatments of choice for Amoebic Gill Disease, which is caused by *Neoparamoeba perurans,* a parasome. It has no toxicity issues and dosage is easier to manage than with hydrogen peroxide.

Origin of raw materials, methods of manufacture
Sodium chloride is a natural substance of mineral origin. It is obtained either from sea water, or from mineral deposits.

Environmental issues, use of resources, recycling
The Group is not aware of sodium chloride accumulation in free flowing water systems as an environmental concern. Note that in terrestrial cropping systems, salinisation is a major concern and needs to be avoided (see EGTOP report on greenhouse production).

Animal welfare issues
Stress reduction during transport is beneficial. If properly used, the Group has no concerns.

Human health issues
The Group has no concerns.

Impact on food quality
The Group has no concerns.

Traditional use and precedents in organic production
The use of sodium chloride is already authorized in the *absence* of aquaculture animals (section 2.1 of Annex VII). In addition, sodium chloride is authorized as a fertilizer (Annex I), as feed material (Annex V) in food processing (Art. 27.1.e) and for seaweed dehydration (Art 29a.1).

Authorised use in organic farming outside the EU / international harmonization of organic farming standards
At the moment, neither the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods (GL 32-1999, last amended 2013) nor the National Organic Program (USA) cover aquaculture. The NOP rules for livestock production allow the use as feed, for health care and on management tools and production aides. However, it may not contain synthetic anti-caking agents or other prohibited substances.

Reflections of the Group / Balancing of arguments in the light of organic farming principles
From the mode of action, the Group considers such treatments as management practices rather than as disinfection. Not only sodium chloride should be authorized, but also treatment with marine water and freshwater (as explained above).

Conclusions
The Group concluded that the use of marine water and freshwater is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007.
The Group recommends:

1. to include sodium chloride in the basic list of substance in Annex VII, and
2. to amend Art. 25s(6) as follows: "For biological control of ectoparasites preference shall be given to the use of cleaner fish, and to the use of freshwater, marine water and sodium chloride solutions".

4.5.7 Slaked lime

Introduction, scope of this chapter
Calcium *hydroxide* ($Ca(OH)_2$) is traditionally called 'slaked lime'. It is obtained when calcium oxide is mixed with water. Calcium *oxide* (CaO) is also known as 'quicklime' or 'burnt lime'. The terminology in Annex VII is inconsistent: In section 1, both lime and 'quicklime' are mentioned (but the same substance is meant). In section 2.1, it is incorrectly referred to as 'lime' (a term which connotes various calcium-containing inorganic materials, such as carbonates, oxides and hydroxides of calcium).
The Group was asked (1) to clarify whether slaked lime can be used in the absence of aquaculture animals (as a consequence of the listing of quicklime in section 2.1), and (2) whether slaked lime can be used in the presence of aquaculture animals (listing in section 2.2). No dossier was submitted to support these requests.

Authorization in general aquaculture and in organic production

Both for calcium hydroxide and calcium oxide, dossiers for biocide PT 3 are currently being examined. The Group could not verify whether all applications of quicklime and slaked lime will fall under biocides legislation.

Technological or physiological functionality for the intended use
Following harvest, ponds are normally cleaned (as far as possible) and dried out for one or two weeks, to kill unwanted organisms including parasites, diseases and their vectors. Particularly in ponds, the bottom is often also limed. The method is described by OIE (2012), Boyd (2012) and Tonguthai (2000). Quicklime attacks any organism by desiccation/dehydration. In addition, both quicklime and slaked lime will raise the pH to 11 – 12, which also kills unwanted organisms. Quicklime is more effective than slaked lime.
In aquaculture, both recreational and commercial ponds are often fertilized to improve fish production. In ponds built on acidic soils and filled with fresh water of low mineral content, much of the phosphorus added in fertilizers becomes tightly bound in pond sediment where it is not available to support phytoplankton growth. Proper liming can improve phosphorus availability and greatly enhance pond productivity.

Necessity for intended use, known alternatives
Slaked lime is used for disinfection of ponds, i.e. drying out to get rid of viruses or other serious pathogens. For practical reasons, slaked lime or quicklime are ideal for this purpose. As the Group has no concerns over the use of these substances (see below), they are preferable to other chemical disinfectants. Liming helps to reduce the period of fallowing.
Slaked lime has also a use for water conditioning. It is used to remove solid iron compounds ('red ochre'; Fe_2O_3). In waters with a high content of ferric hydroxide, the use of slaked lime is essential, in order to avoid high mortality of the fish due to accumulation of ochre in the gills. It can also be used to remove aluminium compounds from the inlet water, where this is necessary. Such treatments take place prior to inlet to the ponds/tanks. Hence, in the Group's opinion, such uses can be classified as a use in the *absence* of animals.

Origin of raw materials, methods of manufacture
Calcium oxide is usually made by thermal decomposition of calcium carbonate (materials such as limestone or seashells) ('calcination'). It does not occur in nature.
Calcium hydroxide is obtained by mixing calcium oxide with water. In nature, calcium hydroxide occurs in the form of the mineral 'portlandite'.

Environmental issues, use of resources, recycling
Upon contact with water, calcium oxide is transformed to calcium hydroxide. By reaction with carbon dioxide from the air, this is transformed to calcium carbonate, and pH falls to 8.5 or less within a few days (Boyd 2012). The Group has no environmental concerns.

Animal welfare issues
The Group has no concerns.

Human health issues
Quicklime is caustic, and can burn the skin and cause serious eye injury (Boyd 2012). It reacts violently with water, so that particles may shoot-out, which presents a special risk for the eyes. Slaked lime is also caustic, but less hazardous. When proper precautions are taken (wearing of personal protective equipment), both substances can be used safely.

Impact on food quality
No issues identified.

Traditional use and precedents in organic production
Quicklime is already authorized for use in the absence of animals. According to Danish national Consolidation Act no. 1671 (22. Dec. 2010), on Organic Food and Organic Aquaculture, Art. 7, § 14 the use of slaked lime is authorised in Danish organic production for use 'in presence of aquaculture animals' (i.e. prior to inlet, see chapter 4.5.1). Shellfish may be treated with a lime solution to control competing fouling organisms (Art. 25p(2) of Reg. 889/2008). The Group assumes that 'lime solution' refers to aqueous solutions of slaked lime.

Authorised use in organic farming outside the EU / international harmonization of organic farming standards
At the moment, neither the Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods (GL 32-1999, last amended 2013) nor the National Organic Program (USA) cover aquaculture. The NOP rules for livestock production allow the use of 'hydrated lime' (=slaked lime) for health care, against external parasites and on management tools and production aides. It may be used as a topical disinfectant and external pest control. It may only be used in organic livestock production, 'if the requirements of 205.238 are met'.

Reflections of the Group / Balancing of arguments in the light of organic farming principles
Quicklime and slaked lime are two well-defined, separate substances. Slaked lime needs to be listed separately, in order to be used. In comparison to the already authorized quicklime, the properties of slaked lime can be summarized as follows:

- less effective than quicklime;
- environmental impact similar or better than for quicklime;
- safety for the user clearly better than for quicklime.

Slaked lime has various uses in aquaculture (see above). Some of these uses take place in the absence of animals (e.g. disinfection of dried ponds, treatment of water prior to inlet into the rearing units), while others take place in the presence of animals (e.g. treatment of shellfish). The Group supports all these use of slaked lime. In section 4.6.2, the Group suggests a new structure for Annex VII, which avoids the need for distinction between application in the presence or absence of animals.

Conclusions
The Group concluded that the use of slaked lime is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007.
In Annex VII, the entry 'lime' should be replaced by 'quicklime (calcium oxide) and slaked lime (calcium hydroxide)'.

4.5.8 Reconfirmation of advice from 2008

Introduction, scope of this chapter
The Group was asked to reconfirm the advice on various substances given in 2008 by an ad-hoc expert group. Due to time constraints, the Group could not make full evaluations, but indicates in which areas clarifications are most needed. The Group underlines that this preliminary advice should not be used for final decisions on these substances.

Humic acids
Humic acids are natural substances. Manufacturers claim that they improve water quality and/or reduce the susceptibility of fish towards pests and diseases. Clarifications are needed in the following areas:

- exact uses
- authorization under general legislation
- necessity and alternatives.

Iodophors
The Group sees a need for disinfection of eggs, and possibly also a limited use for equipment in aquaculture facilities and footbaths. The evaluation as a biocide is pending. Clarifications are needed in the following areas:

- necessity and alternatives for disinfection of equipment in aquaculture facilities

Potassium permanganate
Potassium permanganate is rather toxic. Clarifications are needed in the following areas:

- toxicity
- environmental impact
- authorization under general legislation
- necessity and alternatives

Formalin
Formalin (formaldehyde) is carcinogenic. It is still widely used in some countries. In Annex VII, it is listed only for terrestrial animals, and not for aquaculture. Even if formalin is not in the current aquaculture mandate, it has been previously questioned by the Group (see EGTOP report on poultry). Clarifications are needed in the following areas:

- toxicity
- authorization under general legislation
- necessity and alternatives

4.6 Proposals for regulation of cleaning and disinfection in Annex VII

4.6.1 Rationale for establishment of a 'basic list of substances for management of aquatic environments'

Introduction
Typically, synthetic disinfectants can be used only in the absence of aquaculture animals, while synthetic veterinary substances are used in the presence of aquaculture animals. This distinction is reflected by different general legislation (biocides vs. veterinary medical substances), and it is currently also reflected by two separate sections in Annex VII (section 2.1 vs. 2.2).
However, some of the substances used in organic aquaculture have an 'atypical' mode of action and do not fit well into this distinction. In some cases (e.g. seawater, sodium chloride), the use falls under different legislation (or perhaps none), depending on the intended purpose of the use. In order to avoid further complications at the level of organic legislation, the Group considers that a different way of listing in Annex VII would be prefereable. The listing concentrates on those requirements which are important from the point of view of organic principles, and leaves flexibility with respect to general legislation.

Careful evaluation of uses
The Group underlines the need for a careful evaluation of all uses of chemical substances in aquaculture. Such evaluations are already carried out in the framework of general legislation. They concern the active substance and/or the commercial product, and they take place at EU and/or member state level. A careful evaluation must take into account the substance, dosage and treatment time, as well as the fish species, the parasite or pathogen, and possibly the environment or management system.
The current distinction between section 2.1 and 2.2 is over-simplified and cannot deal with such complex interactions. There is no guarantee that a substance listed in section 2.2 can be safely used in the presence of aquaculture animals, unless there would be precise indications regarding fish species, dosage, treatment time and environmental factors. Such a level of detail would be impractical to handle in Reg. 889/2008, and it would also duplicate product authorization/registration at EU and member state level.

Proposal for establishment of a 'basic list'
The Group considers that for a few non-controversial substances, the organic regulation should not make restrictions regarding their use. This does *not* mean that these substances can be used in whatever way an operator wishes. It simply means that the organic regulation makes no *additional* requirement on top of those made by general legislation and product authorization.
Such an approach has been suggested previously by the Group for selected food additives ('basic tool box'; see EGTOP report on organic food), for disinfectants ('basic toolbox'; see EGTOP report on greenhouse production) and for plant protection products ('basic list of active substances'; see EGTOP report on plant protection products II). In analogy, the Group suggests to call this section 'basic list of substances for management of aquatic environments'.
The proposal is limited to non-controversial substances (as shown under point 2.1 of section 4.6.2 below) for which no concerns have been raised in the organic sector; for all other substances (e.g. iodophors), the Group fully supports the current practice of specifying uses in Annex VII.
With respect to *non-controversial substances*, the Group points out the following arguments:

- Even for substances where no specifications are given in Annex II, the use must follow the specifications laid down by general legislation/product authorization.

- With respect to organic farming principles, there is no added value in repeating these specifications.
- For the EU authorization process, these specifications represent an extra burden, because use categories must regularly be updated (for examples, see the evaluations of sodium chloride and a few other substances here).
- For organic aquaculture, these specifications unnecessarily delay the adoption of newly approved uses.

4.6.2 Proposed new structure of Annex VII, section 2

As explained above, the Group recommends to create as a first section within Annex VII a 'basic list of substances for management of aquatic environments'. This necessitates a rearrangement of the sections within Annex VII. If all recommendations in chapter 4.5 are followed, section 2 of Annex VII would look as follows (new text is underlined):

2. Substances for use in aquaculture and seaweed production referred to in Article 6e(2), 25s(2) and 29a.

2.1 Basic list of substances for management of aquatic environments
Substances may be used for all purposes authorized under general legislation

- sodium chloride
- quicklime (calcium oxide), slaked lime (calcium hydroxide)
- hydrogen peroxide, sodium percarbonate*
- organic acids (acetic acid, lactic acid, citric acid)
- humic acid
- peroxyacetic acid
- peracetic and peroctanoic acids
- limestone (calcium carbonate), dolomite

2.2 Substances for cleaning and disinfection of equipment and facilities, in the absence of aquaculture animals
Substances may be used for all purposes in the absence of aquaculture animals authorized under general legislation

- ozone
- sodium hypochlorite, calcium hypochlorite,
- mixtures of potassium peroxomonosulphate and sodium chloride producing hypochlorous acid*
- caustic soda
- alcohol
- potassium permanganate
- iodophores

2.3 Substances for limited use in aquatic environments
Substances may be used for very limited purposes indicated here

- iodophores (for disinfection of eggs)
- tea seed cake made of natural camelia seed (use restricted to shrimp production)
- copper sulphate; only until 31 December 2015

* new substances, for which inclusion is proposed in this report (chapter 4.5).

5. LIST OF ABBREVIATIONS / GLOSSARY

Annex VII	Annex VII to Regulation 889/2008
CAS number	CAS numbers are unique numerical identifiers assigned by Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature. CAS numbers are given in this report, because many of the substances discussed here have multiple colloquial names.
MIST	minimal invasive surgical technique
MRL	maximum residue level (see Reg. 396/2005)
On-growing	rearing of aquaculture animals from the juvenile stage to harvest size.
PT	product type. European biocides legislation distinguishes 22 types of biocidal products (see Reg. 528/2012, Annex V). Product-type 3 (disinfectants for veterinary hygiene) is of particular relevance in the context of this report.
RAS	Recirculation Aquaculture System
The Group	The Expert Group for Technical Advice on Organic Production (EGTOP)

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