

DOSSIER CONCERNING THE REQUEST TO AMEND ANNEX VIII
Certain products and substances for use in production of processed organic food, yeast and yeast products

Commission Regulation (EC) No 889/2008

Articles 21 (2) of Council Regulation (EC) No 834/2007.

"Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in this paragraph should be amended, the Member State shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the MS."

1. General information on the request

Nature of the request	☐ Inclusion ☐ Deletion ☒ Change of disposition
Request introduced by	CR3-Kaffeeveredelung M. Hermsen GmbH Waterbergstr. 14 D-28237 Bremen Contact e-mail: qs@cr3-hermsen.com
Date	13.03.2018

Please indicate if the material provided is confidential

2. Requested inclusion/deletion/amendment

Name of additive / substance	Primary use/conditions
Sodium hydroxide is listed under Annex VIII Commission Regulation No. (EC) 889/2008 , section B: processing aids and other products, which may be used for processing of ingredients of agricultural origin from organic production. Conditions: Sugar(s) production Oil production from rape seed (Brassica spp)	Amendment: additional use as processing aid in the organic caffeine production (function: pH adjustment of the liquid extract)

3. Status

Authorization in general agriculture or food processing

Historic use Application:

- Peeling of fruits and vegetables
- Olive production
- Cacao production
- Jam production
- Production of pretzels
- Chinese and Japanese noodles
- Cleaning agent in the food industry

Regulatory status (EU, national, others) (including expiry dates of authorisation if applicable)

EU:

Sodium hydroxide is authorized to be used as a food additive (Group I additives, code E524) in all kind of foods without limit (quantum satis) in which group I additives are allowed. (Annex II of Regulation (EC) No 1333/2008)

USA:

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED)

PART 184 -- DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.1763 Sodium hydroxide.

(a) Sodium hydroxide (NaOH, CAS Reg. No. 1310-73-2) is also known as sodium hydrate, soda lye, caustic soda, white caustic, and lye. The empirical formula is NaOH. Sodium hydroxide is prepared commercially by the electrolysis of sodium chloride solution and also by reacting calcium hydroxide with sodium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(c) In accordance with 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a pH control agent as defined in 170.3(o)(23) of this chapter and as a processing aid as defined in 170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52444, Nov. 18, 1983]

Organic regulatory status (EU, Codex Alimentarius, USA, national, others);

EU:

- Sodium hydroxide is authorized as a food additive (code E524) for the production of organic “Laugengebäck” (pretzels) for the purpose of surface treatment (Commission Regulation No. (EC) 889/2008 , Annex VIII, section A)
- Sodium hydroxide is authorized as a processing aid for the organic Sugar(s) production and organic oil production from rape seed (Brassica spp). (Commission Regulation No. (EC) 889/2008 , Annex VIII, section B)

USA:

- Sodium hydroxide is authorized as a food additive and processing aid in organic food production with the exception of use in lye peeling of fruits and vegetables. (7 CFR § 205.605 b: Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labelled as “organic” or “made with organic (specified ingredients or food group(s)).”)

Private standards;

4. Identification¹

Identification of substance, terminology, synonyms

Chemical name(s)

Sodium hydroxide solution 50% food grade

Other names

Caustic soda, lye

Trade name

CAS code (Chemical Abstracts Systematic Names)

¹ To be filled in only when applicable

1310-73-2
Other code(s)
EINECS-Nr. 215-185-5

5. Aspects related to the relevance and priority of the request

Geographical relevance (Member States, regions, ...)
Socio-economic relevance (acreage, turnover, number of stakeholders affected, ...) The market for natural caffeine which is extracted from natural raw materials like green coffee beans is very small in comparison to the synthetic caffeine market. Natural caffeine is mainly used as an ingredient for beverages. As the demand for organic drinks and beverages is steadily growing, manufactures are demanding organic ingredients. In particular manufacturers can advertise and promote a product with 100% organic ingredients. In order to meet the demand of our customers, our company is establishing a process for the production of natural, organic caffeine.
Sectors affected Organic food and drink industry
Stakeholder engagement/consultation in dossier preparation
Market presence: availability (quantity / quality) and origin (local / imported) Actually the demand is exceeding the amount of natural organic caffeine on the world market.
Aspects of international harmonization / market distortion In the USA sodium hydroxide is authorized as a food additive and processing aid in organic food production (7 CFR § 205.605 b: Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labelled as “organic” or “made with organic (specified ingredients or food group(s)).”)
A (possible) authorization leads to amendment(s) in the respective Annex ²

² 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 the objectives, criteria and principles of the organic regulation. There is no need for amendment of the specific conditions of Annex ..."

Amendment of Annex VIII Commission Regulation No. (EC) 889/2008 , section B: processing aids and other products, which may be used for processing of ingredients of agricultural origin from organic production.

Other aspects justifying high priority:

- relevance for the development of a new organic production sector,
- addressing a new trend in consumer preferences/nutritional habits or new developments in food technology

6. Basic topological data (ADI level)

ADI level;

Not defined

Date of JECFA /SCF evaluation;

See annex:

- Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)
- EU risk assessment report for NaOH
- OECD SIDS Initial Assessment Report NaOH

Short summary;

No risk for the intended field of application.

7. Origin and production of the substance

Active ingredients;

Sodium hydroxide

Possible carriers;

Origin of raw materials (including aspects of mining/harvesting them),

Production method: Electrolysis of saline solution

8. Technology

Application in food and or during food processing;

It is intended to use sodium hydroxide in the organic caffeine production. The caffeine itself comes from the decaffeination of organic green coffee beans. The extracted raw caffeine is refined to pure food grade caffeine by subsequent processing steps. Sodium hydroxide is

needed for pH adjustment of the liquid extract prior to active carbon treatment and crystallisation steps. It is not present in the final product anymore.
Intended use; See above
Technological function in food; pH adjustment
Used in food products in general; yes

9. Consistency with objectives and principles of organic production

Please use the check list in part A of this Annex to indicate consistency with objectives and principles of organic production, as well as criteria and general rules, laid down in Council Regulation (EC) 834/2007 Title II and Title III as applicable.

10. Impact

Environment none
Animal health and welfare none
Human health none
Food quality and authenticity Will be improved

11. Other aspects

Various aspects, further remarks Sodium hydroxide is allowed as a food additive in the organic food production (Commission Regulation No. (EC) 889/2008 , Annex VIII, section A), which has a bigger impact on human nutrition as this would be the case if sodium hydroxide is used as a processing aid. Sodium hydroxide as a processing aid is not present in the final product anymore and does not have an influence on the human nutrition.
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12. References

13. Annexes

Annex A

CHECKLIST FOR CONSISTENCY

with objectives and principles of organic production with reference to specific articles in the organic regulation

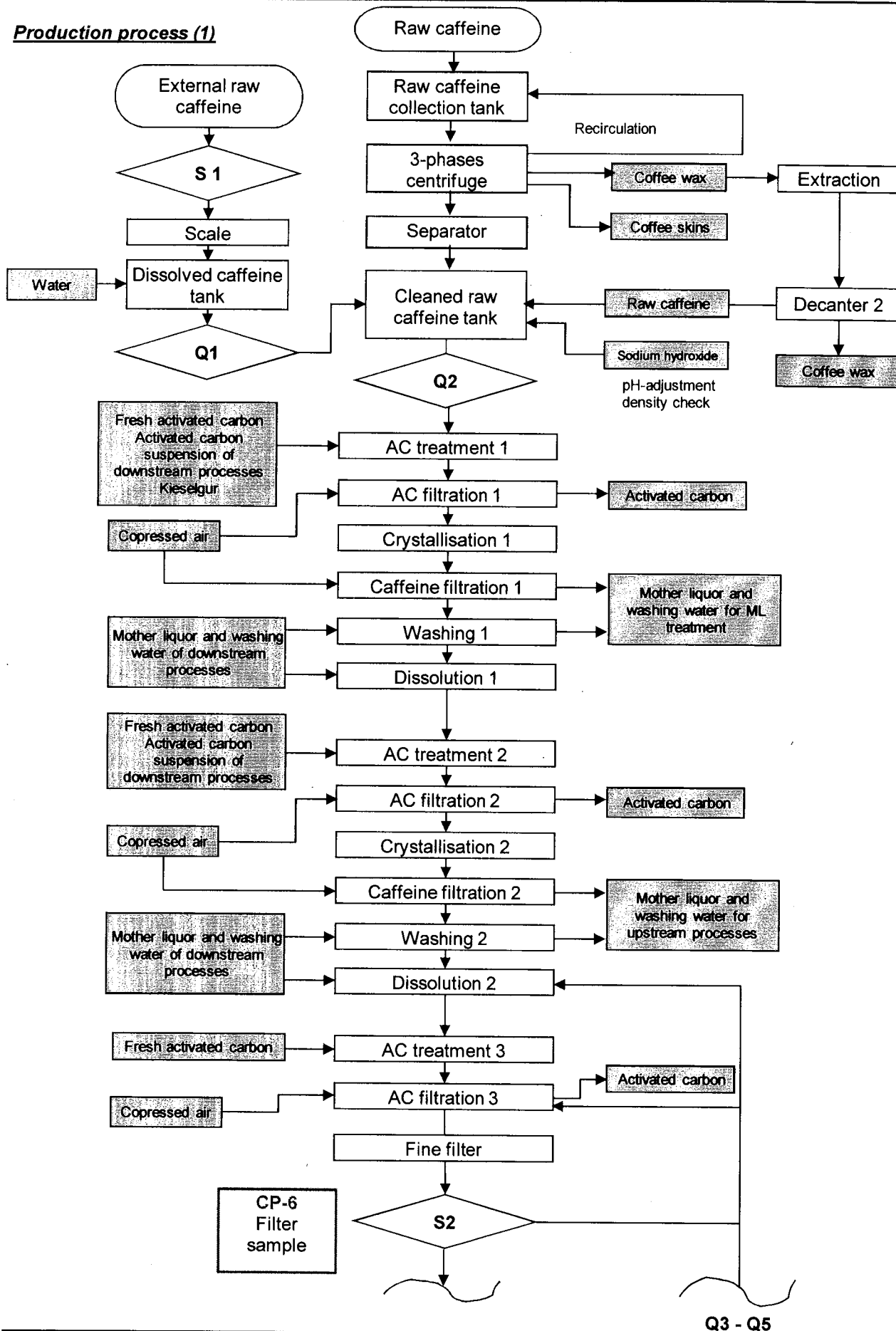
Criteria	Specific articles in Reg. 834/2007	Fulfilled? Yes / no / not applicable	Detailed qualification
Not a GMO and not produced from or by GMOs	Art. 9(1)	Yes	See product specification
Alternatives authorized are not available; (not available in sufficient quantities or qualities on the market/advantages and disadvantages	Art 21 (1) i)	Yes	
Only in case of essential technological need or for particular nutritional purposes; Without having recourse to them, it would be impossible to produce or preserve the food or to fulfil given dietary requirements	Art 6 (b) Art 21 (1) (ii)	Yes	Sodium hydroxide is essentially needed for pH adjustment.
The substances and processing methods do not misleading regarding the true nature of the product	Art 6 (c)	Yes	Sodium hydroxide is not present in the final product anymore
The products and substances are to be found in nature and may have undergone only mechanical, physical, biological, enzymatic or microbial processes. (natural or naturally-derived substances;)	Art 21 Art 4 (b) (ii)	No	Synthetic production of sodium hydroxide
Strict limitation of the use of chemically synthesized inputs to exceptional cases	Art 4 (c)(i) (ii) (iii)	Yes	

Aim at producing products of high quality.	Art 3 (a)	Yes	
Helps to produce a wide variety of foods that respond to consumers' demand	Art 3 (b)	Yes	
Others: please specify			

Flow chart caffeine refinement



Production process (1)

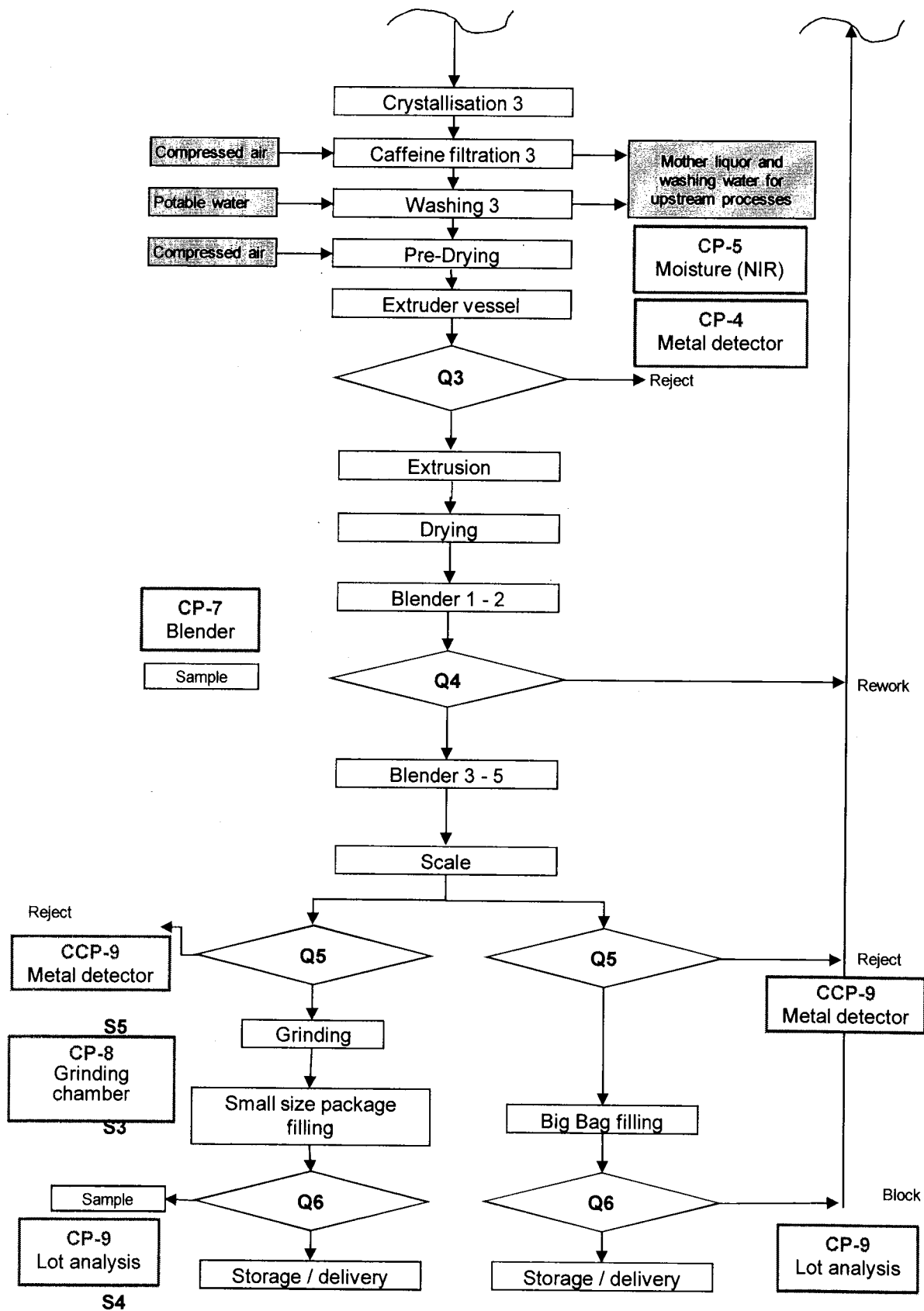


Q3 - Q5

Flow chart caffeine refinement



Production process (2)



This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization.

**WORLD HEALTH ORGANIZATION
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**FAO NUTRITION MEETINGS
REPORT SERIES**

No. 40

**SPECIFICATIONS FOR THE IDENTITY AND
PURITY OF FOOD ADDITIVES AND THEIR
TOXICOLOGICAL EVALUATION:
SOME ANTIMICROBIALS, ANTIOXIDANTS,
EMULSIFIERS, STABILIZERS,
FLOUR-TREATMENT AGENTS,
ACIDS, AND BASES**

**Ninth Report
of the Joint FAO/WHO Expert Committee
on Food Additives**

Rome, 13 - 20 December 1965



Published by
FAO and WHO



WORLD HEALTH ORGANIZATION

GENEVA

1966

JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES

Rome, 13-20 December 1965

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Dr G. Della Porta, Head, Section of Experimental Carcinogenesis, National Institute for the Study and Treatment of Tumours, Milan, Italy
Dr O. Garth Fitzhugh, Deputy Director, Division of Toxicological Evaluation, Food and Drug Administration, Washington, D.C., USA
Professor A. C. Frazer, Department of Medical Biochemistry and Pharmacology, University of Birmingham, England (*Rapporteur*)
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Professor Dr S. W. Souci, Director, German Research Institute for Food Chemistry, Munich, Germany
Professor R. Truhaut, Director, Laboratory of Toxicology and Industrial Hygiene, Faculty of Pharmacy, University of Paris, France (*Chairman*)

Observers invited by FAO :

- Dr U. Casoli,* Experimental Station for the Canned Food Industry, Parma, Italy
Mr D. F. Dodgen, Food Chemicals Codex, National Research Council, Washington, D.C., USA
Professor Dr Ir. M. J. L. Dols, Chairman of Codex Alimentarius Commission, Ministry of Agriculture, The Hague, Netherlands
Dr P. E. Johnson, Food Protection Committee, National Academy of Sciences — National Research Council, Washington, D.C., USA
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Mr G. O. Kermode, Officer in Charge, Joint FAO/WHO Food Standards Program, FAO, Rome, Italy

* Delegated by : The International Committee on Canned Food, Paris, France.

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Monographs containing specifications for identity and purity, biological data and toxicological evaluation will be issued later by FAO and WHO in separate documents entitled :

Specifications for the Identity and Purity of Food Additives and their Toxicological Evaluation : Some Antimicrobials and Antioxidants.

FAO Nutrition Meetings Report Series No. 40A

WHO/Food Add./66.29 (in preparation).

Specifications for the Identity and Purity of Food Additives and their Toxicological Evaluation : Some Flour-Treatment Agents.

FAO Nutrition Meetings Report Series No. 40B

WHO/Food Add./66.30 (in preparation).

Specifications for the Identity and Purity of Food Additives and their Toxicological Evaluation : Some Acids and Bases.

FAO Nutrition Meetings Report Series No. 40C

WHO/Food Add./66.31 (in preparation).

**SPECIFICATIONS
FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES
AND THEIR TOXICOLOGICAL EVALUATION :
SOME ANTIMICROBIALS, ANTIOXIDANTS,
EMULSIFIERS, STABILIZERS, FLOUR-TREATMENT
AGENTS, ACIDS AND BASES**

**Ninth Report of the Joint FAO/WHO Expert Committee
on Food Additives**

INTRODUCTION

A Joint FAO/WHO Expert Committee on Food Additives met in Rome from 13 to 20 December 1965. The meeting was opened by Dr M. Autret, Director, Nutrition Division, FAO. Dr O. E. Fischnich, Assistant Director-General, Technical Department, FAO, addressed the Committee on behalf of the Directors-General of the Food and Agriculture Organization of the United Nations and of the World Health Organization. Professor R. Truhaut and Professor J. F. Reith were unanimously elected Chairman and Vice-Chairman respectively. Professor A. C. Frazer agreed to serve as Rapporteur.

As a result of the recommendations of the Joint FAO/WHO Conference on Food Additives held in September 1955,¹ eight Joint FAO/WHO Expert Committees on Food Additives have met and issued the following reports : " General Principles Governing the Use of Food Additives : First Report ",² " Procedures for the Testing of Intentional Food Additives to Establish their Safety for Use : Second Report ",³ " Specifications for Identity and Purity of Food Additives (Antimicrobial Preservatives and Antioxidants) : Third Report ",⁴ " Specifications for Identity and Purity

¹ *FAO Nutrition Meetings Report Series*, 1956, No. 11 ; *Wld Hlth Org. techn. Rep. Ser.*, 1956, 107.

² *FAO Nutrition Meetings Report Series*, 1957, No. 15 ; *Wld Hlth Org. techn. Rep. Ser.*, 1957, 129.

³ *FAO Nutrition Meetings Report Series*, 1958, No. 17 ; *Wld Hlth Org. techn. Rep. Ser.*, 1958, 144.

⁴ These specifications were subsequently revised and published as *Specifications for identity and purity of food additives. Vol. I. Antimicrobial preservatives and antioxidants*, Rome, Food and Agriculture Organization of the United Nations, 1962.

of Food Additives (Food Colours) : Fourth Report",¹ "Evaluation of the Carcinogenic Hazards of Food Additives : Fifth Report",² "Evaluation of the Toxicity of a Number of Antimicrobials and Antioxidants : Sixth Report",³ "Specifications for the Identity and Purity of Food Additives and their Toxicological Evaluation: Emulsifiers, Stabilizers, Bleaching and Maturing Agents : Seventh Report",⁴ "Specifications for the Identity and Purity of Food Additives and their Toxicological Evaluation : Food Colours and Some Antimicrobials and Antioxidants : Eighth Report".⁵

This meeting was convened on recommendations made in the previous reports of the Joint FAO/WHO Expert Committee on Food Additives. Its terms of reference were to draw up specifications for and to make a toxicological evaluation of some food additives belonging to the classes of antimicrobials, antioxidants, emulsifiers, stabilizers and flour-treatment agents not considered at earlier meetings. The Committee was also asked to re-evaluate some food additives already considered and to review their specifications or toxicological evaluation in the light of new biological and chemical data.

Some acids and bases were also considered at this meeting at the request of the Second Joint FAO/WHO Conference on Food Additives.⁶

Relationship to the Codex Alimentarius Commission

The relationship between the Joint FAO/WHO Expert Committee on Food Additives and the Codex Alimentarius Commission will in future be of paramount importance for the functioning of the Expert Committee. The links between these bodies are described in Annex 4, and a flowsheet (Annex 5) is provided that depicts the stages involved in the submission of a food additive for assessment and its subsequent consideration and evaluation.

¹ These specifications were subsequently revised and published as *Specifications for identity and purity of food additives. Vol. II. Food Colours*, Rome, Food and Agriculture Organization of the United Nations, 1963.

² *FAO Nutrition Meetings Report Series*, 1961, No. 29; *Wld Hlth Org. techn. Rep. Ser.*, 1961, 220.

³ *FAO Nutrition Meetings Report Series*, 1962, No. 31; *Wld Hlth Org. techn. Rep. Ser.*, 1962, 228.

⁴ *FAO Nutrition Meetings Report Series*, 1964, No. 35; *Wld Hlth Org. techn. Rep. Ser.*, 1964, 281.

⁵ *FAO Nutrition Meetings Report Series*, 1965, No. 38; *Wld Hlth Org. techn. Rep. Ser.*, 1965, 309.

⁶ *FAO Nutrition Meetings Report Series*, 1963, No. 34; *Wld Hlth Org. techn. Rep. Ser.*, 1963, 264.

1. GENERAL CONSIDERATIONS

1.1 Principles

The Committee agreed to base its considerations on the general principles set out in the first, second, fifth and sixth reports.

1.2 Publication of experimental results

The Committee wished to re-emphasise the great value of publishing experimental results. Work that is published in the scientific literature is subject to scientific examination, criticism, refutation or confirmation. Unpublished reports, on the other hand, are not necessarily submitted to this scrutiny. For this reason, when considering scientific information, much greater weight will usually be given to published than to unpublished work. It is an accepted principle that the Joint FAO/WHO Expert Committee prefers published information as the basis for its decisions; only under exceptional circumstances will the Committee use unpublished information; confidential reports will not be considered. In the last year or two, a considerable amount of information on the biological effects of food additives has been published, and much of this work is referred to in this report.

1.3 Supply of information to FAO and WHO

The policy with regard to the supply of information to FAO and WHO is as follows.

Preference will always be given to the consideration of published work, copies of which should be submitted. If work can be submitted only in unpublished form, this must be submitted as an official document sponsored by a scientist of standing; these documents will be placed on file at WHO (toxicological data) or FAO (data on specifications) and will be available for consultation by any scientist who is entitled to use the facilities of FAO or WHO. Photostats or other copies of appropriate sections of these documents will be supplied to scientists on request, without further reference to the investigators or to those responsible for the original submission. Under no circumstances will confidential documents be accepted or consulted.

2. SPECIFICATIONS

2.1 Removal of substances from the agenda

Certain substances that had been included on the agenda did not appear to the Committee to be used to a significant extent as food additives and were not considered further. These were : the calcium and sodium salts of methyl, ethyl, propyl and butyl *p*-hydroxybenzoate, calcium benzoate, sodium sorbate, sodium dithionite, nitrofurazone, 2,4,5-trihydroxybutyrophenone, ethylcellulose and gluconic acid. In other cases, adequate chemical information on the substance was not available. Specifications were not prepared for these substances : namely, stearyl citrate, diacetyl-tartaric acid esters of monoglycerides and diglycerides, hydroxypropyl-methylcellulose, propylene glycol alginate, propylene glycol monostearate and tannic acids. Details are mentioned under the appropriate section, and consideration of these substances, as well as of brominated vegetable oils, was postponed.

2.2 Limitation of selenium content in sulfur dioxide and related substances

The Committee was asked to reduce the limits of selenium in sulfur dioxide and related compounds from 30 ppm to 10 ppm. Since no toxicological problems were involved, and since it was not known whether all manufacturers could achieve the revised limit or whether the available test would be effective in controlling the selenium content at the lower level, the Committee decided that the maximum permitted level of selenium in sulfur dioxide and related substances should remain at 30 ppm. However, it was recommended that enquiries should be instituted by FAO to find out whether a lower level might be adopted at a later date.

2.3 Formulation of food additives

A food additive may be marketed as a formulated preparation consisting of a mixture of the main ingredient with a vehicle and possibly other substances. The specifications elaborated by the Committee refer only to the main ingredient as a pure substance, with the exception of acetone peroxide, which is diluted with starch to control its explosive property. Formulation does not affect the toxicological evaluation, provided that the substances added are known to be acceptable and that they do not alter the absorption or metabolism of the food additive in such a way that the biological data are thereby invalidated.

3. BIOLOGICAL DATA

The Committee agreed that the monographs dealing with the evaluation of the biological data should be drafted along the lines adopted in the previous reports.

3.1 Biochemical and metabolic studies

The Committee emphasised the importance of metabolic and biochemical studies in the investigation of the biological effects of a food additive. It may be possible to dispense with elaborate long-term studies if it can be convincingly shown that the substance is not absorbed or is broken down completely before absorption into well-known substances that are generally recognized as having no deleterious action. In any case, a proper understanding of the changes that the food additive may undergo in the food, in the gastro-intestinal tract or in the body is necessary for the full interpretation of the biological and toxicological data.

3.2 Zones of acceptability

The Committee decided to retain the method of expressing the daily acceptable intake level that had been adopted in earlier reports and, in appropriate cases, to continue to divide the overall zone of acceptability into two parts: unconditional and conditional. It was felt that any failure to understand this system was not due to inadequate explanation in earlier reports. The method was discussed in detail in the seventh report.¹ The Committee did agree, however, that footnotes or other devices should be used to ensure that the meaning of unconditional and conditional zones of acceptability is made clear in any table summarizing the values agreed by the Committee, without the necessity for referring to the text.

In previous reports, acceptable daily intake has usually been expressed as milligrams of the substance in question per kilogram of body weight. There are, however, certain food additives that are more appropriately limited in terms of levels of treatment; for example, flour-treatment agents. There are also certain additives that are common components of food or normal body constituents; in such cases it is unreasonable to set specific limits. The appropriate method of expressing acceptable levels of use must be decided in each case.

¹ *Wld Hlth Org. techn. Rep. Ser.*, 1964, 281, 10.

3.3 Grouping of related food additives

As a number of food additives are closely related chemically and toxicologically, the Committee adopted a system of grouping of food additives. The acceptable daily intake level is expected to cover all the specified members of the group that may be included in the diet. In some cases, a given food additive may be related to two groups, in which case the level in the diet must not exceed the maximum acceptable level for either group. The problem is not as complicated as it may appear at first sight, since many of the substances in a group of additives are likely to be used as alternatives to each other.

3.4 Request for further work

Previous monographs have often listed further work that seemed to be desirable. However, it is only in relatively few cases that the studies requested have been done, although in some cases the work may be urgently needed in the interests of the consumer. The Committee therefore agreed to request, in the monographs, only work that is urgently needed in the interests of safety. All other suggestions for further work that may seem desirable, but not so urgently needed, will be included under the heading "Comments on experimental studies reported". The Committee draws the attention of manufacturers and users of food additives to the fact that, in future, if a statement about further work being required is included in a monograph, this matter should be given urgent attention. If the additive in question is one that is already in use, its continued use will be supported by the Committee only if the further work required has been carried out and the results justify continuance of the use of the additive. If no action is taken to provide the further evidence that is required, it will be assumed that neither the manufacturers nor the users are interested in continuing the use of the additive. In this case, the Committee may well decide to recommend the prohibition of its use. If the food additive is a new substance not yet in use and if further work has been required, a conditional intake level may be established for a limited period to allow the results of this additional work to be submitted and studied.

3.5 References

Authors who have submitted papers relevant to a given monograph but who are not mentioned in it may rest assured that their work has been consulted. In the interest of brevity, however, the bibliographies of some monographs may be restricted to the more recent or more extensive investigations in the field in question. The pioneering achievements of the earlier workers in these fields are fully appreciated.

4. COMMENTS ON SUBSTANCES ON THE AGENDA

4.1 Antimicrobials and antioxidants

The monographs on these food additives will appear in a publication to be entitled "Specifications for the Identity and Purity of Food Additives and their Toxicological Evaluation: Some Antimicrobials and Antioxidants"¹ and the recommended acceptable daily intakes are summarized in Annex 1.

The biological data on butyl *p*-hydroxybenzoate were insufficient to allow an evaluation to be made. Specifications for this substance were drawn up.

It was not possible to establish satisfactory specifications for the calcium and sodium salts of the methyl, ethyl, propyl and butyl esters of *p*-hydroxybenzoic acid.

No information was available on the use of calcium benzoate and sodium dithionite in food technology. Sodium sorbate was considered to be too unstable for satisfactory use in food. For these various reasons further study of these substances was postponed.

Because nitrofurazone is used in human therapeutics and for toxicological reasons the Committee considered that its use as a direct additive to food is highly undesirable and recommended that it should not be used for this purpose. It was understood that its use as a food additive was likely to be terminated by the end of 1965. No further consideration was therefore given to this substance.

There was no objection to the use of the calcium disodium salt of ethylenediaminetetra-acetic acid (EDTA), but the Committee considered that the use of the disodium salt, which will chelate calcium, requires careful control. There is no objection to its use in food provided that the amount added is accurately assessed and corresponds to the amount of calcium to be chelated. The end-product in the food will then be calcium disodium EDTA; an excessive amount of disodium EDTA in food would be highly undesirable.

The Committee agreed to the use of hydrogen peroxide in milk only as an emergency measure in those places where other methods of microbiological control, such as pasteurization, are not available; the treatment of milk with hydrogen peroxide may be justified if the alternatives are no milk or infected milk. The Committee strongly recommended that every effort should be made to find other methods of milk treatment to deal with problems of this nature. The Committee also understood that hydrogen

¹ *FAO Nutrition Meetings Report Series*, No. 40A; WHO/Food Add./66.29 (in preparation).

peroxide is used as a food additive for other special purposes in some countries. Provided that these special uses do not contravene the general principle that a food additive must not be used to mislead the consumer as to the nature and quality of food,¹ it is suggested that they receive consideration by a future meeting of the Committee.

A specification was elaborated for potassium metabisulfite. This substance contributes to the total dietary intake of sulfur dioxide, which should not exceed that recommended in the sixth report.²

Specifications, toxicological evaluation and acceptable daily intake levels for potassium benzoate, propionic acid and calcium and potassium sorbate will appear in the monographs.

Diethyl pyrocarbonate has been studied in detail from the biochemical and metabolic aspects, and the end-products of its breakdown, as well as products of interaction with constituents of beverages, are substances that are acceptable at the concentrations present and in the quantities likely to be consumed. It was considered advisable to recommend a maximum level of treatment of beverages rather than an acceptable daily intake.

Sufficient information was not available to allow for the establishment of a specification for stearyl citrate, which is an antioxidant synergist. Although the toxicological work on this substance was done some years ago, it was done thoroughly. The Committee did not suggest that the use of stearyl citrate should be discontinued, but did require that a satisfactory specification for its use should be sent to FAO as soon as possible and preferably before the next meeting (October 1966). Long-term studies using modern techniques were considered desirable, but the Committee did not insist on these studies as an urgent requirement.

The Committee understood that 2,4,5-trihydroxybutyrophenone is no longer marketed as a food additive and it was therefore given no further consideration.

4.2 Emulsifiers and stabilizers

Diacetyltartaric acid esters of mono- and di-glycerides had been thoroughly studied from a biochemical and metabolic standpoint. It was clear that complete hydrolysis of these substances occurred, giving rise to acetic acid, tartaric acid, and mono- and di-glycerides. All these substances occur in the diet in amounts in excess of those that might arise from the use of the mixed esters as a food additive. The Committee agreed that the use of this additive could be accepted without limitation. Unfortunately, no

¹ *FAO Nutrition Meetings Report Series*, 1957, No. 15; *Wld Hlth Org. techn. Rep. Ser.*, 1957, 129, 5.

² *FAO Nutrition Meetings Report Series*, 1962, No. 31; *Wld Hlth Org. techn. Rep. Ser.*, 1962, 228, 96.

specification could be elaborated because of lack of an assay method. The Committee stressed the importance of supplying to FAO all the information required for the elaboration of specifications at the same time that the biological data are sent to WHO (see flowsheet, Annex 5). It is hoped that this substance can be further considered at the next meeting of the committee (in October 1966).

The use of brominated vegetable oils presents a problem. These brominated oils are used to adjust the density of essential oil contained in certain beverages and to produce a clouding effect. The quantity of brominated oils used is likely to be small. Nevertheless, large quantities of beverages may be consumed over long periods of time, and no evidence was available on the possible accumulation of the brominated fatty acids in the body lipids, with subsequent release of bromine. The Committee was unable to evaluate brominated oils, since evidence from appropriate long-term studies, with special reference to possible cumulative effects, was not available. The results of such studies should be submitted to WHO if the use of brominated oils as food additives is to be continued.

Ethylcellulose is a packaging material and not a food additive. It was therefore not considered.

Hydroxypropylmethylcellulose has been investigated extensively. However, there appears to be some doubt as to whether the various substances that have been studied toxicologically were identical. The Committee recommended that the specifications for the different forms should be effectively correlated; no evaluation can be made until this has been done.

Sufficient information was not available to allow a specification for the propylene glycol esters of alginic acid to be elaborated.

No satisfactory information, either chemical or toxicological, was available on tannic acids. Further study of these substances was therefore postponed. The Committee appreciated the complexity of the problem but considered that the information required on tannic acids should be provided as soon as possible.

The additive "propylene glycol monostearate and palmitate" was considered, but no specifications were prepared because of lack of appropriate chemical information.

4.3 Flour-treatment agents

The monographs on these substances will appear in a publication entitled "Specifications for the Identity and Purity of Food Additives and their Toxicological Evaluation: Some Flour-Treatment Agents";¹ some information is given in summary form in Annex 2.

¹ *FAO Nutrition Meetings Report Series*, No. 40B; WHO/Food Add./66.30 (in preparation).

Differences in rate of oxidation may have considerable importance in bread technology and may even have some relevance to labour utilization. It is for this reason that some new agents are being brought forward for consideration that are much more rapid in action than those at present available. Such a rapidly acting agent is of particular value in the modern methods of bread-making that do not involve bulk fermentation. Since the main toxicological and nutritional considerations are concerned with treated flour rather than with the food additive itself, the Committee followed the procedure adopted in the seventh report for benzyl peroxide, chlorine dioxide, and potassium bromate¹ and recommended levels of flour treatment for this group of additives instead of setting an acceptable level of daily intake.

Specifications are essential before any evaluation of the biological data is possible. In the case of chlorine and nitrogen oxides, satisfactory specifications were not available to the Committee. However, both these additives have been used for the treatment of flour for many years. The Committee understood that the use of nitrogen oxides has greatly declined in recent times. Lack of adequate information prevented the Committee from advising the prohibition of the use of nitrogen oxides in flour treatment at this time. If their use is to be continued, however, further information would be required on the possible formation of nitrosamines and the effect of long-term ingestion of bread made with flour treated at various levels with nitrogen oxides. The Committee recommended that urgent action be taken to obtain information about possible nitrosamine formation so that this substance could be reconsidered at the next meeting (October 1966). The Committee also stated that the results of long-term studies as indicated should be made available to it by the end of 1969.

The Committee understood that chlorine is used for the treatment of flour for special purposes, such as cake and biscuit manufacture. Since the amount of chlorine-treated flour involved is probably not more than a small proportion of total flour consumption, the Committee did not recommend the prohibition of the use of chlorine for flour treatment at this time. Nevertheless, if chlorine treatment of flour is to continue, long-term studies using appropriate products made from flour treated with chlorine at various levels will be needed. The results of these studies should be submitted to WHO as soon as possible and, in any case, not later than the end of 1969. When these biological studies are done, it will, of course, be necessary to have adequate specifications for the gases used in flour treatment.

A specification was prepared for acetone peroxides, but no adequate biological information was available. Since the residues from acetone

¹ *FAO Nutrition Meetings Report Series*, 1964, No. 35; *Wld Hlth Org. techn. Rep. Ser.*, 1964, 281, 155, 159, 164.

peroxides are likely to be different from those from other peroxides, it was not possible to predict what biological effects they might produce. The biological evaluation of this substance was therefore postponed.

Biological information on calcium peroxides and calcium stearyl-2-lactylate was also inadequate, and further study of these additives was postponed.

Consideration was given to the use of potassium or calcium iodate as a flour-treatment agent. At the level of treatment proposed, it seemed likely that a considerable increase in the daily iodine intake would result. Although 10 ppm of iodide or iodate is the level that is commonly used for iodized table salt, there is a great difference between the daily intake of table salt and the daily intake of bread. While there may be some differences of opinion about the possible hazards of increasing the daily iodine intake to perhaps five or ten times the level usually recommended (100-200 $\mu\text{g/day}$), the Committee considered that the use as a food additive for the treatment of a staple, such as flour, of a substance having such physiological significance and potency as iodate is highly undesirable. The Committee therefore recommended that iodates should not be used for flour treatment.

Although ammonium and potassium persulfates have a long history of use, there are insufficient toxicological data for an acceptable treatment level for flour to be estimated.

Specifications, toxicological evaluation and acceptable levels of flour treatment for azodicarbonamide and stearyl tartrate can be found in the monographs.

4.4 Acids and bases

The monographs on these substances will appear in a publication entitled "Specifications for the Identity and Purity of Food Additives and their Toxicological Evaluation: Some Acids and Bases";¹ a summary of the information is given in Annex 3.

A group of acids that are well-known substances involved in intermediary metabolism was discussed. Included were acetic, lactic and malic acids. Propionic acid (see section 4.1) might also have been conveniently added to this list. It was agreed that no limit need be prescribed for any of these acids when used as food additives, on the assumption that only reasonable quantities of them are likely to be used. The following points were, however, considered to be relevant to the food-additive use of these acids.

¹ *FAO Nutrition Meetings Report Series*, No. 40C; WHO/Food Add./66.31 (in preparation).

As far as acetic acid is concerned, its acid taste is likely to be a safeguard against its ingestion in excessive quantities.

Fumaric acid has been shown to cause testicular damage in animals when administered in high dosage, especially if given parenterally. However, this observation was not regarded as pertinent when fumaric acid is used only in small quantities as a flavouring agent.

Both lactic and malic acids may occur in the D(−) form as well as in the L(+) form. In small infants, it has been shown that the enzyme responsible for converting the D(−) to the L(+) form is relatively deficient; consequently D(−) lactic acid may be toxic in early infancy. The Committee recommended that D(−) lactic acid should not be added to the diet of very young infants, and that, for adults, the use of the D(−) forms of lactic and malic acids should be restricted, as indicated in Annex 3 of the present report and in the monographs. In the case of malic acid, there is also the danger of contamination with maleic acid, which is a toxic substance. The Committee recommends that the maleic acid content of malic acid should not exceed 0.05%.

No details were available on the use of gluconic acid as a food additive, and it was not further considered.

Hydrochloric acid is not regarded as a toxic substance in the concentrations that are used in food technology. A specification for hydrochloric acid is included in the monograph as a safeguard against toxic impurities.

The specification, toxicological evaluation and acceptable daily intake of adipic acid are given in the monograph on this substance.

Monocalcium phosphate is used in flour. The Committee had no objection to its use, provided that this is taken into account in assessing the overall dietary load of calcium and phosphate; a limit for the latter has been recommended.

The bases used in food technology are required for pH adjustment. The amounts and concentrations used are not likely to have any toxicological significance. The Committee placed no restriction on the food-additive use of the bases listed, provided that the contribution made to the dietary load of sodium, potassium, calcium and magnesium is assessed and considered to be acceptable.

4.5 Re-evaluation

The Committee was asked to re-evaluate a number of substances. The decisions are given in Annex 1. Details on these substances will appear in a publication to be entitled "Specifications for the Identity and Purity of Food Additives and their Toxicological Evaluation: Some Antimicrobials

and Antioxidants".¹ Successive Joint FAO/WHO Expert Committees on Food Additives have considered and reconsidered many additives belonging to these two categories. A table will be included in the above-mentioned publication indicating in which document the specification for and toxicological evaluation or re-evaluation of each substance can be found.

In the case of butylated hydroxytoluene (BHT), there was an excellent response to the request, in the sixth report,² for additional information, and a large amount of further published evidence became available to the Committee. After consideration of these data, the Committee recommended that BHT should be treated similarly to butylated hydroxyanisole (BHA), and that the acceptable daily intake already approved for BHA should now apply to both BHA and BHT, which should be considered together as a food-additive group.

A considerable amount of further work is being done on hexamethylenetetramine, and it is understood that much of this will be completed by the end of 1966 or thereabouts. The Committee recommended that no further action should be taken with regard to the food-additive use of hexamethylenetetramine until this further information is available. The Committee will evaluate this substance as soon as possible.

It was suggested that sorbitol might be accepted without an indication of an acceptable daily intake. The Committee agreed with this suggestion. The earlier decision recorded in the seventh report³ is revised accordingly.

Further evidence was presented on sulfur dioxide and sulfites and the Committee was asked to re-examine the limits proposed in the sixth report.⁴ The Committee studied this further information and recommended that the limits proposed in the sixth report should remain unchanged. The details of this new information are given in the monograph.

In accordance with the principle of grouping chemically and toxicologically related food additives (p. 10), the following substances were considered and grouped with related substances:

- (a) methyl, ethyl and propyl *p*-hydroxybenzoates
- (b) the calcium, potassium and sodium salts of propionic acid
- (c) sorbic acid
- (d) sulfur dioxide, sodium sulfite, sodium metabisulfite and sodium hydrogen sulfite.

¹ *FAO Nutrition Meetings Report Series*, No. 40A; WHO/Food Add./66.29 (in preparation).

² *Wld Hlth Org. techn. Rep. Ser.*, 1962, 228, 45.

³ *Wld Hlth Org. techn. Rep. Ser.*, 1964, 281, 101.

⁴ *Wld Hlth Org. techn. Rep., Ser.* 1962, 228, 96.

5. RECOMMENDATIONS TO FAO AND WHO

The second Joint FAO/WHO Conference on Food Additives recommended that the Joint FAO/WHO Expert Committee on Food Additives should serve as the advisory body to the Codex Alimentarius Commission on matters relating to specifications and toxicological evaluation of food additives. It is essential that the Committee meets annually in order that it may keep up with the progress made, through the said Commission, in the Food Standards Program. So that the criteria used for setting acceptable daily intakes may be reviewed in the light of new scientific knowledge at such meetings, WHO should further consider convening, as soon as possible, an additional meeting to discuss procedures for investigating food contaminants and intentional food additives in order to establish their safety to the consumer.

6. RECOMMENDATIONS TO THE CODEX COMMITTEE ON FOOD ADDITIVES

The Joint FAO/WHO Expert Committee on Food Additives would like the Codex Committee on Food Additives to consider, when establishing lists of food additives for consideration by future Joint Committees, whether they could recommend substances belonging to the same group(s) of food additives rather than substances belonging to a number of different groups. The group(s) recommended for consideration should, if possible, contain all the substances belonging to it (or them). This would greatly facilitate the work of the Joint FAO/WHO Expert Committee on Food Additives.

Furthermore, each additive recommended by the Codex Committee for consideration should be accompanied by data on the technological justification and the levels of use in the foods to which it is added. If an additive is recommended, it is assumed that biological data have already been sent to WHO and information from which a chemical specification can be elaborated has been sent to FAO.

Annex 1

**ACCEPTABLE DAILY INTAKES FOR MAN
OF SOME ANTIMICROBIALS AND ANTIOXIDANTS**

Compounds considered	Specifications available	Over-all daily intake zone ^a (mg/kg body-weight)		
		Unconditional	Conditional	
Benzoic acid	Yes	0-5 ^b	5-10 ^b	
Sodium benzoate	Yes			
Potassium benzoate	Yes			
Methyl <i>p</i> -hydroxybenzoate	Yes	0-2 ^c	2-7 ^c	
Ethyl <i>p</i> -hydroxybenzoate	Yes			
Propyl <i>p</i> -hydroxybenzoate	Yes			
Butyl <i>p</i> -hydroxybenzoate	Yes	Decision postponed (p. 11)		
Butylated hydroxyanisole	Yes	0-0.5 ^d	0.5-2.0 ^d	
Butylated hydroxytoluene	Yes			
Disodium EDTA	Yes	0-1.25 ^e	1.25-2.5 ^e	
Calcium disodium EDTA	Yes			
Hexamethylenetetramine	No	Decision postponed (p. 17)		
Hydrogen peroxide	Yes	Decision postponed (p. 11)		
Calcium propionate	Yes	0-10 ^f	10-20 ^f	
Potassium propionate	No			
Sodium propionate	Yes			
Propionic acid	Yes	0-12.5 ^g	12.5-25 ^g	
Calcium sorbate	Yes			
Potassium sorbate	Yes			
Sorbic acid	Yes	Not limited		
Sorbitol	Yes			
Sulfur dioxide	Yes	0-0.35 ^h	0.35-1.5 ^h	
Sodium sulfite	Yes			
Sodium metabisulfite	Yes			
Potassium metabisulfite	Yes			
Sodium hydrogen sulfite	Yes			
Antimicrobial for certain beverages				
Diethyl pyrocarbonate	Yes	0-300 (p. 12)		

^a The first part of the acceptable daily intake zone has been termed the unconditional zone of acceptability, and this represents levels of use that are effective technologically, at least for some purposes, and can be safely employed without further expert advice. The second part consists of a conditional zone of acceptability and represents levels of use that can be employed safely but at which it is thought desirable that some degree of expert supervision and advice should be readily available.

^b As sum of benzoic acid and sodium and potassium benzoate (calculated as benzoic acid).

^c As sum of methyl, ethyl and propyl esters of *p*-hydroxybenzoic acid.

^d As sum of butylated hydroxytoluene and butylated hydroxyanisole.

^e As calcium disodium EDTA. The use of disodium EDTA is recommended only for accurately chelating calcium.

^f As sum of propionic acid and calcium, sodium and potassium propionate (calculated as propionic acid).

^g As sum of sorbic acid and calcium and potassium sorbate (calculated as sorbic acid).

^h As sum of sulfur dioxide, sodium sulfite, sodium and potassium metabisulfite and sodium hydrogen sulfite (calculated as SO₂).

Annex 2

ACCEPTABLE TREATMENT LEVELS FOR SOME
FLOUR-TREATMENT AGENTS

Compounds considered	Specifications available	Acceptable levels of treatment (in parts per million)
Chlorine	No	No level set (p. 14)
Nitrogen oxides	No	No level set (p. 14)
Acetone peroxides	Yes	No level set (p. 14)
Calcium peroxides	Yes	No level set (p. 15)
Calcium iodate	Yes ^a	Use not recommended (p. 15)
Potassium iodate	Yes ^a	Use not recommended (p. 15)
Ammonium persulfate	Yes	No level set (p. 15)
Potassium persulfate	Yes	No level set (p. 15)
Azodicarbonamide	Yes	0-45
Stearyl tartrate	Yes	0-500
Calcium stearyl-2-lactylate	Yes	No level set (p. 15)

^a Identification tests only.

Annex 3

ACCEPTABLE DAILY INTAKES FOR MAN
OF SOME ACIDS AND BASES

Compounds considered	Specification available	Over-all daily intake zone ^a (mg/kg body-weight)	
		Unconditional	Conditional
Acids			
Acetic acid	Yes	Not limited	0-5
Adipic acid	Yes		
Calcium phosphate, monobasic	Yes	Not limited ^b	6-10
Fumaric acid	Yes	0-6	
Hydrochloric acid	Yes	Not limited	
DL-Lactic acid	Yes		0-100 ^c
DL-Malic acid	Yes		0-100 ^d
Bases			
Carbonates of ammonium, calcium, magnesium, potassium and sodium	Yes	Not limited ^e	(p. 16)
Hydrogen carbonates of ammonium, potassium and sodium	Yes		
Hydroxides of ammonium, calcium, magnesium, potassium and sodium	Yes		
Oxides of calcium and magnesium	Yes		

^a The first part of the acceptable daily intake zone has been termed the unconditional zone of acceptability and this represents levels of use that are effective technologically, at least for some purposes, and can be safely employed without further expert advice. The second part consists of a conditional zone of acceptability and represents levels of use that can be employed safely, but at which it is thought desirable that some degree of expert supervision and advice should be readily available.

^b Subject to limits of phosphorus load given in the seventh report (*Wld Hlth Org. techn. Rep. Ser.*, 1964, 281, 31).

^c Refers to content of D(—)-lactic acid.

^d Refers to content of D(—)-malic acid. (See also p. 16.)

^e Provided that use is in accordance with good manufacturing practice.

Annex 4

**RELATIONSHIP BETWEEN THE JOINT FAO/WHO EXPERT
COMMITTEE ON FOOD ADDITIVES AND THE CODEX
ALIMENTARIUS COMMISSION**

The Joint FAO/WHO Expert Committee on Food Additives consists of scientists who are chosen because of their knowledge and experience in the field under discussion ; they act as independent experts, and their decisions are based on scientific considerations alone. The FAO/WHO Codex Alimentarius Commission¹ consists of representatives of the governments of member countries ; they have a direct link with governments and with governmental agencies. The ultimate objective of the FAO/WHO Food Standards Program is to obtain agreement by governments, through the Codex Alimentarius Commission, on the acceptability and usage of food and food additives in order to ensure the safety of the consumer and to facilitate international trade. The FAO/WHO Expert Committee on Food Additives has been working for more than ten years on the elaboration of specifications for important food additives and on the evaluation of biological information on the effects of these food additives, leading to recommendations about safe usage. The Codex Alimentarius Commission and its subsidiary bodies, which have been in existence since 1963, have now become regular parts of FAO and WHO. This development is welcome, since it should greatly assist in the implementation of the scientific advice that has been put forward in the reports of the FAO/WHO Expert Committee. The Codex Alimentarius Commission has established a Codex Committee on Food Additives, which is the responsibility of the Netherlands Government and is under the Chairmanship of Professor M. J. L. Dols, who is also the current Chairman of the Codex Alimentarius Commission. This Codex Committee on Food Additives will apply the recommendations of the FAO/WHO Expert Committee to the practical problems of food and nutrition in the various member countries. Thus, the Codex Committee will examine such problems as the effects of using the appropriate food additives in different food commodities, technological problems concerned with the production of food or the use of food additives in accordance with the recommendations of the FAO/WHO Expert Committee, the total load of individual food additives or food-additive groups and the problems that may arise nationally

¹ Codex Alimentarius Commission (1965) *Report of the Third Session ...*, Rome (Alinorm 65/30).

as a result of disagreement of a dietary or legal nature. When the Codex Committee on Food Additives has reached decisions with regard to the application of this information to food production and to nutrition, these decisions regarding specific tolerances for particular foods will be communicated to the appropriate Codex Commodity Committee, and in due time the information will be included in the appropriate food standards published by the Codex Alimentarius Commission. The Codex Alimentarius is also expected to contain the main details about each food additive, and these will be based on the information supplied by the FAO/WHO Expert Committee. This procedure for the handling of these matters has been approved by both FAO and WHO and it has already come into operation.

The FAO/WHO Expert Committee will continue to elaborate specifications, to evaluate biological data and to make recommendations about the acceptable daily intakes for man. This information will be published in reports as previously, but it will also be transmitted to the Codex Committee on Food Additives for their attention.

In the past, it has proved difficult to select the food additives most deserving of consideration by the Expert Committee. Sometimes substances have been included on the agenda for which there appeared to be little demand or for which chemical and biological information was inadequate; at other times, important new additives that had been extensively studied scientifically did not appear on the agenda. The introduction of the Codex Committee on Food Additives, with its direct association with governments and governmental agencies in each of the member countries and through them, presumably, with the chemical and food industries in these countries, should make it easier to determine which food additives require consideration by the FAO/WHO Expert Committee. It will, however, be necessary to ensure that there is adequate publicity about the activities of FAO and WHO in the field of food standards and the safe use of food additives, that sufficient contact with the chemical and food industries in member countries is achieved and maintained, and that adequate notice is given to those concerned with the introduction of a new additive to ensure that full information is made available at the appropriate time, preferably in the form of published papers. The FAO/WHO Expert Committee has already reported on a considerable number of the more important food additives. This is fortunate, as it makes it possible for the Codex Committee on Food Additives to proceed with the application of the recommendations contained in the FAO/WHO Expert Committee's reports. However, there are still many food additives that require consideration by the FAO/WHO Expert Committee, further new food additives will be introduced, and new uses will be found for existing additives; for these and other reasons re-evaluation is likely to be requested quite frequently.

Thus, the FAO/WHO Expert Committee still has a great deal of work to do, and this situation is likely to continue for many years. In all its future deliberations, it will be of great importance that the closest possible liaison be maintained between the FAO/WHO Expert Committee and the Codex Committee on Food Additives ; frequent exchange of information in both directions is essential for the effective working of the procedure adopted.

Annex 5

FLOW DIAGRAM FOR INTERNATIONAL ACCEPTANCE OF FOOD ADDITIVES

