

Control Body's comments on the draft report received 02 May 2018

ANNEX CP_2017-6067

Comments to the findings of report ref. DG(SANTE)/2017-6067-MR of the audit carried out from 14 November 2017 to 24 November 2017 in order to evaluate the implementation of the organic production standards and control measures applied by a recognised Control Body operating in China

N°	Finding	Comment Proposed
28	For 2017, the risk assessment of operators certified at the beginning of the year resulted in the categorisation as high risk for 10.2 % of the operators. This led to the planning of additional inspections. Operators were also selected, based on the risk level, to be subject to unannounced inspections. In 2018, 28 % of the total number of inspections (annual and additional) was planned as unannounced.	The date indicated shall be 2017 and not 2018.
54	The audit team reviewed the 2016 and 2017 sampling programmes and noted that the total number of samples exceeded the minimum requirement set as at least equal to 5 % of the operators certified. In 2016, 468 samples were planned and 582 performed (additional sampling performed during investigations following suspicion or notifications and on new high risk clients or products). For 2017, the risk assessment led to the designation of 46% of operators for compulsory sampling at each visit and 33% for the completion of at least one sample per year.	The description of the sampling to perform is maybe not fully accurate. Concerning "46% of operators for compulsory sampling at each visit", the sampling is not compulsory at each visit but for at least one of the visit during the year. Concerning "33% for the completion of at least one sample per year", at least one sample must be done during the year for the defined products among all the operators certified for them.
55, 56 and 58	<p>At the time of the audit, 371 samples were already taken by the CB. A dedicated instruction describes the management of the samples and the analyses results.</p> <p>Of the 341 analyses results already received 34 presented non-compliances (four due to presence of genetically modified organisms, 29 with residues of pesticides and one case with both). All non-compliances were subject to investigations. For the cases closed, the conclusions were added in the client's file to allow follow up by inspectors.</p> <p>When a positive result is received, the investigations and impact on the certification decision are coordinated between the analysis officer and the certification officer. The operator concerned is informed of the analytical result and requested to investigate the origin of the contamination. As soon as the</p>	<p>The numbers of samples indicated take into consideration also counter-analysis performed. In fact, at the time of the audit, without counter-analysis the numbers were:</p> <ul style="list-style-type: none"> i. 364 samples already taken since 371 is including 7 counter-analysis. ii. 334 analysis results were received if we do not consider the 7 counter-analysis. iii. Among the 34 positive results recorded, 4 positive results were counter-analysis. So, in total 30 samples presented non-compliances: 3 due to presence of genetically modified organisms, 26 with residues of pesticides and 1 with both.

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ANNEX CP_2017-6067

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N°	Finding	Comment Proposed
	operator is notified by letter, products from the parcel, lot or operator concerned are blocked if above the action levels (no issuance of TC or Col). The audit team noted that for the 34 positive results recorded in 2017, although seven results were notified within the week of reception (and the related products blocked), the other cases were subject to slower reactions by the CB (four cases of information and blocking occurs within a two week period, seven within 1 month and for five samples actions were taken more than 50 days after reception of the analytical result).	
58	When a positive result is received, the investigations and impact on the certification decision are coordinated between the analysis officer and the certification officer. The operator concerned is informed of the analytical result and requested to investigate the origin of the contamination. As soon as the operator is notified by letter, products from the parcel, lot or operator concerned are blocked if above the action levels (no issuance of TC or Col). The audit team noted that for the 34 positive results recorded in 2017, although seven results were notified within the week of reception (and the related products locked), the other cases were subject to slower reactions by the CB (four cases of information and blocking occurs within a two week period, seven within 1 month and for five samples actions were taken more than 50 days after reception of the analytical result).	The information provided during the audit was inaccurate about "for five samples actions were taken more than 50 days after reception of the analytical result". Due to an internal filling mistake, the dates presented during the audit and registered in the monitoring tab were not the dates of notification to our operators but the dates of notification to the suppliers of our operators and the CB'S suppliers. The first notification to our operators was done prior to these dates and within one week after receiving the analysis results. The notification of the suppliers of our operators was done after our first investigations and so occurred more than 50 days later. Related evidences can be provided if necessary.
92	The CB consider non compliances to requirements such as these to be "minor issues": - Animal feeding: composition or origin of the raw materials. - Holding of animals: group holding, natural light or ventilation. - Farming: limit of maximum 170 kg of nitrogen per year and hectare, crops rotation or mapping of the plots. - Processors: checks at reception of the organic status of inputs, use of equipment suitable or food processing or mapping of the processing and storage facilities.	For the requirements concerning "Animal feeding: composition or origin of the raw materials", the related non-compliances are multiple and are not all considered as "minor issues". According to the severity of the non-compliance, it may also lead to "non-compliance" or "major non-compliance". A detailed list of the concerned non-compliances and their related sanction levels can be provided if necessary.

Control Body's comments on the draft report received 02 May 2018

ANNEX CP_2017-6067

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<i>N°</i>	<i>Finding</i>	<i>Comment Proposed</i>
	- PGs: absence of conflict of interest, adequate knowledge for the internal auditors or level of performance of internal control inspections at the adequate period.	

Control Body response to the report recommendations received 02 May 2018

ANNEX AP_2017-6067

Response of the Control Body to the recommendations of report ref. DG(SANTE)/2017-6067-MR of the audit carried out from 14 November 2017 to 24 November 2017 in order to evaluate the implementation of the organic production standards and control measures applied by a recognised Control Body operating in China

N°	Recommendation	Action Proposed by the Control Body
1	Ensure that inspection takes place at the defined and adequate moment as required by Articles 65 and 90 of Regulation (EC) No 889/2008. Recommendation is based on conclusion No 39 Associated findings: No 30 and 33	<p>Based on our internal procedures, sampling and audit periods are defined according to a risk assessment performed at the beginning of each year. Until now, the monitoring of the real audits period compared to the targeted one was only done for most risky operations.</p> <p>From July 2018, a dedicated procedure will be implemented and introduced to the concerned staff in order to:</p> <ul style="list-style-type: none"> i. Extend the monitoring by including the verification of audit and sampling periods for all operators. ii. In case of deviation observed, assess the risk and take appropriate actions on a case by case basis. <p>Concerning the finding about the internal inspections for PG members:</p> <ul style="list-style-type: none"> i. In case of a new applicant, initial audit will be realized once all internal inspections are performed. To do so, specific checks will be implemented during OMP review and before auditor assignment to ensure that all internal inspections are already performed. Eventual non-compliance to this prerequisite noticed during our on-site audit will lead to related decision. ii. In case of a renewal of certification, the completeness and efficiency of the internal inspections performance will be checked either based on: <ul style="list-style-type: none"> a. the current year if internal inspections are already finalized at the audit time, b. the previous year if internal inspections for the current year are not yet finalized at the audit time. In that case, progress of the current year internal inspections will also be verified. <p>The concerned staff will be trained on that topic for an implementation by the end of July 2018.</p>

Control Body response to the report recommendations received 02 May 2018

ANNEX AP_2017-6067

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N°	Recommendation	Action Proposed by the Control Body
2	Ensure that actions are taken immediately as required by Articles 91 of Regulation (EC) No 889/2008 to insure that only products in compliance with organic production rules are placed on the market. Recommendation is based on conclusion No 64 and 101 Associated findings: No 58, 59, 60 and 94	<p>For each of the different findings related to the recommendation, the following actions will be implemented:</p> <p>i. <u>Delay to notify operators in case of positive result:</u></p> <p>In case of positive result, a systematic notification is sent to the operator and, according to the risk assessed, appropriate blocking measures are implemented on products in order to prevent the setting in circulation of non-compliant products.</p> <p>However, there was no clear deadline defined in our procedure for this notification and the monitoring was incomplete.</p> <p>The procedure will be updated to specify a 5 days deadline to be met to notify the operator once a positive result is received. This deadline will then be followed up.</p> <p>The updated procedure will be introduced to the concerned staff and implemented by the end of June 2018.</p> <p>ii. <u>Variable duration of the investigation in case of positive result:</u></p> <p>As mentioned in point i., systematic notification is sent to the operator in case of positive result and blocking measures are implemented and maintained on products during the investigation period according to the risk assessed.</p> <p>The time expected to complete our investigation is already defined in our procedures. This time can be variable according to the situation faced. For instance, more time is necessary where multiple operations and/or CBs are involved or where the next suitable period for audit is later in the year.</p> <p>To avoid inappropriate delays and to ensure fulfilment of existing procedures, a close monitoring of the defined timelines will be implemented from August 2018. In case of a drift, immediate actions will</p>

Control Body response to the report recommendations received 02 May 2018

ANNEX AP_2017-6067

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N°	Recommendation	Action Proposed by the Control Body
		<p>be implemented according to the reasons of the delay and the process will be sped up should it be necessary.</p> <p>The concerned staff will be trained by the end of July 2018.</p> <p>iii. <u>Time spent between the detection of irregularities and the final decisions:</u></p> <p>In the case of detection of a major non-compliance, we will clarify the following points in our procedures in order to reduce the time spent between the detection of irregularities and the actions taken to prevent the commercialisation of noncompliant products:</p> <ul style="list-style-type: none"> a. Which immediate decision to take until the process is completed to the final decision: for instance, reduction of certification of the products/plots with evidence of non-compliance and/or suspension of doubtful products. b. The timeline to be met at each step of the process before final decision is made. <p>The concerned staff will be trained on that topic before the end of July 2018 in order to implement the procedures and especially the deadlines to be met from August 2018.</p>
3	<p>Ensure that information and activities of the operators are correctly evaluated as required by Articles 63.2 of Regulation (EC) No 889/2008. Recommendation is based on conclusion No 79. Associated findings: No 73 and 74</p>	<p>As the evaluation of the OMP is already well detailed in our system, we have implemented/will implement the following training and monitoring measures:</p> <ul style="list-style-type: none"> i. From March to April 2018, the persons in charge of the verification of the OMP were trained on the content and purpose of the verification of the information included in the OMP as well as on their responsibilities. A practical case training was also provided to auditors and certification officers. ii. Before the end of July 2018, these trainings will be complemented by further detailed reminders to the concerned staff on: <ul style="list-style-type: none"> - the objective of the OMP in the whole process of certification, - its content and the main critical points,

Control Body response to the report recommendations received 02 May 2018

ANNEX AP_2017-6067

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		<ul style="list-style-type: none"> - how to evaluate its compliance before the audit, - how to record the conclusion of the evaluation, - how to use it during the audit and which related non-compliances to apply. <p>iii. From August 2018, a regular supervision of the evaluation of the OMP will be done to confirm the expected improvements or implement additional actions if necessary.</p> <p>Concerning the incomplete visit of the production and storage facilities, the following dedicated actions were or will be implemented:</p> <ul style="list-style-type: none"> i. On the 11th and 13th of April 2018, a "sharing experience" session was organised with all auditors on: <ul style="list-style-type: none"> - how to realize complete and consistent visits, - a review of the related European Commission audit findings, - a review of best practices. ii. Before the end of July 2018, a detail reminder will be sent to all auditors to support them on how to conduct a complete visit of the facilities in consistency with the assessed risk, to challenge and cross-check the activities described in the documents with the on-site observations. iii. For the three operations concerned by the findings, the points of vigilance will be highlighted in the auditors assignments in order to ensure the completeness of the next visits. iv. Starting August 2018, specific focus will be on this issue during the on-site supervision of auditors in order to ensure the good comprehension and application of this requirement.

Control Body response to the report recommendations received 02 May 2018

ANNEX AP_2017-6067

Response of the Control Body to the recommendations of report ref. DG(SANTE)/2017-6067-MR of the audit carried out from 14 November 2017 to 24 November 2017 in order to evaluate the implementation of the organic production standards and control measures applied by a recognised Control Body operating in China

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4	Ensure that risks and means of prevention of cross contamination are correctly assessed to guarantee the respect of Article 26 of Regulation (EC) No 889/2008. Recommendation is based on conclusion No 80. Associated finding: No 75	<p>The assessment of risks and means of prevention of cross-contamination, especially in case of parallel production, is a part of the initial training of all auditors before their qualification. Then, this point is evaluated systematically during on-site supervision of auditors.</p> <p>i. <u>Finding about the cleaning of containers used for the collection and distribution of honey at the beekeeper level:</u></p> <p>The audit performed was an additional audit. Consequently, only part of the activity was planned to be audited and verification of cleaning measures was not included in the audit plan. In addition, the cleaning of the containers and the related record were done at the factory level which was not included in the plan and visited during this audit either.</p> <p>For these reasons, this topic was shortly discussed during the audit but not deeply verified and no cleaning record was available at the audited beekeeper level. Finally, we can confirm that this point was checked during the last annual audit of the factory and was compliant.</p> <p>ii. <u>Finding at the feed producer level about the cleaning procedure for the production line used for parallel production and about the common storage warehouses along with the conventional products without physical separation or adequate protection against dust contamination:</u></p> <p>As this issue was never raised during the on-site supervisions of the concerned auditor, we consider it as a punctual mistake. Before the end of June 2018 this auditor will be trained on cross-contamination and with a specific focus on cleaning and storage for feed processing. In addition, the point of vigilance will be highlighted in the auditor assignment in order to evaluate in detail all cross-contamination risks at the feed producer level during the next audit.</p> <p>iii. <u>Finding at the vegetable processor level about the insufficient separation in storage:</u></p>

Control Body response to the report recommendations received 02 May 2018

ANNEX AP_2017-6067

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		<p>During the audit, the risk of contamination was assessed by our auditor and he considered that the risk of airborne contamination could be managed with sufficient distance between organic and conventional products. As the European Commission auditor assessed the risk as higher and in order to ensure prevention of any cross-contamination, a complementary check of the airborne contamination risk will be performed during the next audit of the operator to confirm or not the necessity to cover organic products.</p> <p>In addition to the actions mentioned above, the following global actions were or will be implemented:</p> <ul style="list-style-type: none"> i. Several training were performed in January and April 2018 and an additional one will be performed before the end of July 2018 to all auditors on how to assess cross-contamination risks, on the means of prevention and their effectiveness, especially for dusty operations such as feed or dried powder processing. ii. Starting August 2018, specific focus will be on these issues during the on-site supervision of auditors in order to ensure the good comprehension and application of the requirements.
5	<p>Ensure that the CB respects the product scope of its recognition as listed in Annex IV of Regulation (EC) No 1235/2008 for the issuance of certification. Recommendation is based on conclusion No 87. Associated finding: No 85</p>	<p>The service of certification according to our Organic Standard is offered without any restriction of the countries and its eligibility conditions are not linked to our recognised scope of products listed in Annex IV of Regulation (EC) No 1235/2008. The eligibility of product exports to the European Union is, however, directly linked to the scope of products listed in Annex IV of Regulation (EC) No 1235/2008 we are recognised for.</p> <p>For these reasons, we certify products on countries and categories for which we are not listed in the Annex IV of Regulation (EC) No 1235/2008 provided that the operator doesn't export its certified products in Europe. No Certificate of Inspection (CoI) is issued in that case.</p> <p>Concerning the operator in Brunei certified for the product categories C and D while we are only recognised by European Commission for category C in that country, no CoI has ever been issued for that operator.</p>

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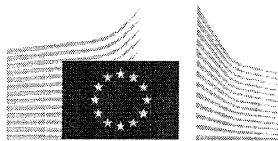
N°	Recommendation	Action Proposed by the Control Body
6	Ensure that operators committing recurrent and/or intentional infringements are subject to adequate and timely sanctions to prevent the marketing of products not in compliance with the organic production rules as required by Articles 92d of Regulation (EC) No 889/2008. Recommendation is based on conclusion No 101. Associated finding: No 95	<p>Our internal procedure related to operator with several sites under their certification will be clarified as follows:</p> <ul style="list-style-type: none"> i. Clear definition of responsibilities between the certification holder and its sites. ii. Specific verifications to be performed for such kind of complex organisation. iii. General mechanism to manage non-compliances at the certification holder and sites level. iv. Clear definition of consequences in case of recurrent and/or intentional breach of the organic production rules detected at a site level. v. Timelines to implement the different actions and decisions in case of major non-compliance (please also refer to our actions proposed on the recommendation n°2). <p>All concerned staff will be trained on that topic before the end of July 2018 in order to implement the procedure from August 2018.</p>
7	Ensure that responses to OFIS notifications are made in the allocated deadline as required by Article 15.4 of Regulation (EC) No 1235/2008. Recommendation is based on conclusion No 102. Associated findings: No 97 and 99	<p>In order to ensure that responses to OFIS notifications are made in the allocated deadline as required by Article 15.4 of Regulation (EC) No 1235/2008, the following actions were implemented:</p> <ul style="list-style-type: none"> i. Since the beginning of year 2017, clear timeline objectives have been implemented to fulfil the deadlines of reply concerning the irregularities and to prioritize these issues. ii. Since June 2017, the objective is to provide a first reply on OFIS within 30 days regardless of the status of the investigation. This first answer allows to confirm the admissibility of the irregularity and includes the first measures taken such as the ongoing investigation or blocking measure and the results already obtained at that moment. This objective has also been specified in our current procedure of management of OFIS notification. iii. During the year 2017, a re-organisation of the tasks and responsibilities linked to the management of irregularities has been implemented: focal point (called Analysis officer) has been identified to handle and follow-up irregularities and positive results.

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		<p>iv. A close monitoring of deadlines is performed since the beginning of 2018.</p> <p>These actions will allow to gain efficiency and reduce delays, but their effects were not fully visible during the European Commission audit as they were mainly launched in 2017. This year improvements have been observed in delays since, for all of the 19 OFIS notifications received (7 notifications for China), first answers were provided before the deadline of 30 days and the average time used to answer was of 12 days (16 days for China).</p> <p>We would also like to bring to your attention that even if a clear and suitable management of OFIS notification is now in place, the total duration of management can still exceed the 30 days due to causes not directly under our control. The different situations generally leading to this issue are:</p> <ul style="list-style-type: none">i. OFIS notification is not sufficiently documented to allow us to identify the concerned lot, to start investigation and to exclude contamination in Europe: additional information are expected.ii. When other CBs investigations are necessary, time can strongly increase until the final results of their investigations is fed back to us.iii. When an additional on-site audit needs to be performed, time increases when it is necessary to wait for the suitable period of audit.



EUROPÄISCHE KOMMISSION
GENERALDIREKTION GESUNDHEIT UND LEBENSMITTELSICHERHEIT

Gesundheits- und Lebensmittelaudits und Analysen

DG(SANTE)/2017-6067 – RS

AUSZUG AUS DEM BERICHT DER GD GESUNDHEIT UND LEBENSMITTELSICHERHEIT

ÜBER EIN AUDIT

14. - 24. NOVEMBER 2017

**BEWERTUNG DER ANWENDUNG DER STANDARDS FÜR DIE ÖKOLOGISCHE/BIOLOGISCHE
ERZEUGUNG UND DER KONTROLLMAßNAHMEN DURCH EINE ANERKANNTE KONTROLLSTELLE
IN CHINA**

HINWEIS: DIES IST – IN DEUTSCHER ÜBERSETZUNG – EIN AUSZUG AUS DEM BERICHT ÜBER DAS OBEN GENANNT E AUDIT.

VERBINDLICH IST NUR

DIE LANGFASSUNG DES ORIGINALBERICHTS (DG(SANTE)/2017-6067).

ZUSAMMENFASSUNG

Dieser Bericht enthält die Ergebnisse eines Audits, das die GD Gesundheit und Lebensmittelsicherheit vom 14. bis zum 24. November 2017 durchgeführt hat, um die Anwendung der Standards für die ökologische/biologische Erzeugung und die Durchführung der Kontrollmaßnahmen durch eine anerkannte Kontrollstelle in China zu bewerten.

Die Kontrollstelle ist gut organisiert und verfügt über qualifiziertes Personal, das durch ein gut entwickeltes Dokumenten- und Computersystem unterstützt wird. Die gemäß den Verordnungen und Akkreditierungsstandards vorgeschriebenen Kontrollen werden in der Regel zufriedenstellend durchgeführt und die Zielvorgaben bezüglich des Mindestprozentsatzes an Kontrollen und Analysen weitgehend erfüllt.

Allerdings bestehen einige Mängel bei der Ermittlung von Kontaminierungsrisiken aus benachbarten oder parallelen konventionellen Anbautätigkeiten sowie bei der Validierung von Mitteln zu ihrer Prävention. Auch das Fehlen klarer Mechanismen im Sanktionskatalog zum Vorgehen bei eindeutigen Verstößen gegen die projektbezogenen Regeln für ökologische/biologische Erzeugung und insbesondere bei vorsätzlichen Verstößen wurde festgestellt.

In dem Bericht wird der Kontrollstelle empfohlen, wie die festgestellten Mängel behoben und die Kontrollmaßnahmen besser umgesetzt werden können.

EMPFEHLUNGEN

<i>Nr.</i>	<i>Empfehlung</i>
<i>1.</i>	<p>Es sollte sichergestellt werden, dass die Inspektionsbesuche zu einem gemäß den Artikeln 65 und 90 der Verordnung (EG) Nr. 889/2008 festgelegten und angemessenen Zeitpunkt stattfinden.</p> <p><i>Empfehlung auf Grundlage der Schlussfolgerung 39</i></p> <p><i>Damit zusammenhängende Feststellungen: 30 und 33</i></p>
<i>2.</i>	<p>Es sollte sichergestellt werden, dass gemäß Artikel 91 der Verordnung (EG) Nr. 889/2008 unverzüglich Maßnahmen ergriffen werden, um dafür zu sorgen, dass nur Erzeugnisse, die den Vorschriften für ökologische/biologische Produktion genügen, in Verkehr gebracht werden.</p> <p><i>Empfehlung auf Grundlage der Schlussfolgerungen 64 und 101</i></p> <p><i>Damit zusammenhängende Feststellungen: 58, 59, 60 und 94</i></p>
<i>3.</i>	<p>Es sollte sichergestellt werden, dass die Informationen und Tätigkeiten der Unternehmer gemäß Artikel 63 Absatz 2 der Verordnung (EG) Nr. 889/2008 korrekt bewertet werden.</p> <p><i>Empfehlung auf Grundlage der Schlussfolgerung 79</i></p> <p><i>Damit zusammenhängende Feststellungen: 73 und 74</i></p>
<i>4.</i>	<p>Es sollte sichergestellt werden, dass die Risiken einer Kreuzkontamination und die Vorsorgemaßnahmen zu ihrer Vermeidung korrekt bewertet werden, um die Einhaltung von Artikel 26 der Verordnung (EG) Nr. 889/2008 zu gewährleisten.</p> <p><i>Empfehlung auf Grundlage der Schlussfolgerung 80</i></p> <p><i>Damit zusammenhängende Feststellung 75</i></p>
<i>5.</i>	<p>Es sollte sichergestellt werden, dass die Kontrollstellen bei der Ausstellung von Bescheinigungen die in ihrer Anerkennung gemäß Anhang IV der Verordnung (EG) Nr. 1235/2008 aufgeführten Erzeugniskategorien beachten.</p> <p><i>Empfehlung auf Grundlage der Schlussfolgerung 87</i></p> <p><i>Damit zusammenhängende Feststellung 85</i></p>
<i>6.</i>	<p>Es sollte sichergestellt werden, dass gemäß Artikel 92d der Verordnung (EG) Nr. 889/2008 bei Unternehmern, die wiederkehrende und/oder vorsätzliche Verstöße begangen haben, angemessene und zeitnahe Sanktionen angewendet werden, um zu verhindern, dass Erzeugnisse, die nicht den Vorschriften für eine ökologische/biologische Produktion genügen, in Verkehr gebracht werden.</p> <p><i>Empfehlung auf Grundlage der Schlussfolgerung 101</i></p>

	<i>Damit zusammenhängende Feststellung 95</i>
7.	<p>Es sollte sichergestellt werden, dass die Reaktionen auf OFIS-Meldungen innerhalb den in Artikel 15 Absatz 4 der Verordnung (EG) Nr. 1235/2008 festgelegten Frist erfolgen.</p> <p><i>Empfehlung auf Grundlage der Schlussfolgerung 102</i></p> <p><i>Damit zusammenhängende Feststellungen: 97 und 99</i></p>

Die Stellungnahme der zuständigen Behörde zu den Empfehlungen ist abrufbar unter:

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2017-6067