EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 11 FEBRUARY 2015

(Section Toxicological Safety of the Food Chain)

CIRCABC Link: *https://circabc.europa.eu/w/browse/3548b628-fe6f-4ef2-9bf0-922f2dcfa676*

A.01 Ad hoc study in preparation of the development of a common methodology for gathering of information by the Member States on the consumption and use of food additives and flavourings in the European Union:

Member States are required to monitor the consumption and use of food additives and flavourings in accordance with the provisions of Regulations 1333/2008 on additives and 1334/2008 on flavourings.

The Commission will prepare guidance developing a common methodology for the Member States on these issues.

In 2001 the report (COM (2001) 542 final) Scientific Cooperation (SCOOP) Task addressed the difficulties in the estimation of the intakes of additives. EFSA has also indicated during the re-evaluation of additives its concern regarding the quality and quantity of data. The Commission's Food and Veterinary Office reported in 2012 that the monitoring of the consumption and use of food additives was not implemented in a number of Member States.

Against this background the Commission commissioned a study to be carried out during 2014 on
- the ways this is currently done by the different Member States, including a comparison among them
- identifying the needs in this respect by EFSA (in particular regarding the re-evaluation of additives or the evaluation of flavourings), and
- considering several options on how this monitoring could be done in the future.

The report was introduced by the contractant Arcadia international. There were several issues discussed such as
- which information could be requested to food business operators,
- the clarification of the precise meaning of monitoring in this context, the desirability of using of data from official control or RASFF,

- the consideration of a EU reference laboratory for certain additives or flavourings, and
- the uses of the different existing systems to estimate intake/exposure to additives and flavourings.

The report will be used as supporting documentation and will be discussed in detail in the working groups on additives and flavourings at their next meetings in order to start developing the guidance.

A.02 Follow-up to the scientific opinion from EFSA on the risks to public health related to the presence of perchlorate in food, in particular fruits and vegetables.

Following the discussions and conclusions at the previous meeting of the Committee on 28 November 2014 and the detailed discussions in the Expert Committee "Industrial and Environmental Contaminants" on 8 January 2015, the proposed revised levels as reference for intra-Union trade were presented. These levels were based upon available occurrence data obtained after September 2013. These levels are provisional awaiting the availability of more data on the occurrence of perchlorate in food.

As many requests for changing the proposed levels, supported with data, were presented by stakeholders and competent authorities to the Commission the days before the Committee, it was proposed to postpone the endorsement of the levels after a detailed discussion in the next meeting of the Expert Committee "Industrial and Environmental Contaminants", scheduled for 2 March 2015. Also the endorsement of the draft Commission Recommendation was postponed.

A.03 Common risk management measures as regards the presence of dioxins and PCBs in fish from the Baltic region.

Due to time constraints the point was only shortly discussed.

A.04 Endorsement of a guidance document for competent authorities for control of compliance with EU legislation on aflatoxins in food.

A guidance on the application of Article 9(4) of the Commission Implementing Regulation (EU) No 884/2014 of 13 August 2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) No 1152/2009 was presented and discussed.

In particular guidance on the following aspects was provided :

1) *"The competent authority at the Designated Point of Entry (DPE) shall authorise transfer of the consignment to a Designated Point of Import (DPI) after favourable completion of the documentary check"*

This authorisation for transfer of the consignment to a DPI for identity and physical check is given after the favourable completion of the documentary check in the DPE and on the condition that box I.20 of the Common Entry Document (CED) is correctly completed. Guidance on the correct completion of box I.20 is provided.

2) "The original certificate, results of sampling and analysis and the CED shall accompany the consignment during transfer. The competent authority of the DPE shall immediately inform the competent authority at the DPI of the sending of the consignment and the business operator has to inform the competent authority at the DPI of the arrival of the consignment at least one working day prior to the physical arrival of the consignment"

Several comments were made including the request to explicitly refer to the possibility to use of TRACES for exchange of information in case the DPE and DPI are both using the TRACES system for controls on food of non-animal origin.

The Commission indicated to propose at the next meeting of the Committee a revised text, taking into account the comments, for endorsement.

A.05 Exchange of views and discussion on possible ways forward as regards the Fusarium toxin contamination situation in the European maize harvest 2014.

The weather conditions that preceded and accompanied the 2014 maize crop have been characterized by an unprecedented warm winter followed by an exceptionally wet spring and abundant rain in summer. This had two main consequences:

1. it has provided for a very large maize crop with record yields and
2. it has dramatically compromised its sanitary quality with an extremely high mycotoxins contamination.

The level of Fusarium toxins (deoxynivalenol, fumonisins and zearalenone) found in the raw maize crop is significantly high and very often above the maximum regulatory limits prescribed for mycotoxins presence in raw materials and food products. The occurrence of mycotoxins is extended to a large portion of the European territory (EU and non-EU countries) with a heterogeneous pattern that makes it very difficult to separate between qualities.

As a consequence, up to 60 % of the maize that was initially destined for the milling industry exceeds the regulatory levels for at least one mycotoxin.
Maize millers use maize varieties that have particular and essential quality characteristics. For these reasons, milling maize varieties are produced under supply chain contracts to respond to the needs of the maize milling industries. The reduced availability of milling maize in the EU related to exceeding regulatory limits for mycotoxins causes a supply problem.

Therefore a request for a temporary derogation was introduced by a major EU stakeholder organisation. As regards the possible consequences of such a temporary derogation for public health, reference is made to the scientific statement that EFSA delivered on the 22 May 2014 [1] .

Divergent views were expressed as regards this request for derogation. The Commission urged the Member States to continue to follow-up the situation in their country and indicated that a final decision as regards this request for derogation will be taken at the latest at the meeting of the Committee foreseen on 14 April 2015.
A delegation indicated that it would be important to perform investigations into possible causes, other than weather conditions, resulting in higher levels of Fusarium toxins in maize in order to determine mitigation measures, as the problem occurs now in two consecutive years (harvest 2013 and harvest 2014).

[1] EFSA (European Food Safety Authority), 2014. Evaluation of the increase of risk for public health related to a possible temporary derogation from the maximum level of deoxynivalenol, zearalenone and fumonisins for maize and maize products. EFSA Journal 2014;12(5):3699, 61 pp. doi:10.2903/j.efsa.2014.3699

Available at: http://www.efsa.europa.eu/en/efsajournal/doc/3699.pdf

A.06 Feedback on issues discussed in the Expert groups on contaminants and endorsement of the conclusions reached at the Expert Committee level.

1) Modified forms of the Fusarium toxins zearalenone, nivalenol, T-2 and HT-2 toxin and fumonisins. Follow-up to the Scientific Opinion.

The EFSA Panel on Contaminants in the Food Chain (CONTAM) adopted on 25 November 2014 Scientific Opinion on the risks for human and animal health related to the presence of modified forms of certain mycotoxins in food and feed [2] .

The CONTAM Panel considered it appropriate to assess human exposure to modified forms of the various toxins in addition to the parent compounds, because many modified forms are hydrolysed into the parent compounds or released from the matrix during digestion. For modified forms of zearalenone, nivalenol, T-2 and HT-2 toxins and fumonisins, 100 %, 30 %, 10 % and 60 % were added, respectively based on reports on the relative contribution of modified forms. In the absence of specific toxicity data, toxicity equal to the parent compounds was assumed for modified mycotoxins.
As regards deoxynivalenol, a separate scientific opinion is expected to be adopted by the EFSA CONTAM Panel in the second half of this year.

The follow-up was discussed at the Expert Committee “Agricultural contaminants” on 15 January 2015. Following conclusions were reached and are presented for comments at the Committee

a) EFSA to be requested to assess whether it is appropriate and feasible to set a group health based guidance value (in order of priority)

* for zearalenone and its modified forms identified in the opinion and to consider, if relevant, the appropriateness to use the parent compound as a marker for presence and toxicity of zearalenone and its modified forms.

* for fumonisin B1 and B2 and their modified forms identified in the opinion and to consider, if relevant, the appropriateness to use the parent compounds as a marker for presence and toxicity of fumonisin B1 and B2 and their modified forms.
* for nivalenol and its modified forms identified in the opinion and to consider, if relevant, the appropriateness to use the parent compound as a marker for presence and toxicity of nivalenol and its modified forms.
* for T-2 and HT-2 toxin and their modified forms identified in the opinion and to consider, if relevant, the appropriateness to use the parent compound as a marker for presence and toxicity of T-2 and HT-2 toxin and their modified forms.

b) To include in the work programme 2016 for the EURL for mycotoxins in feed and food the organisation of proficiency test with a multi-mycotoxin method of analysis for the analysis of a wide range of Fusarium toxins and their modified forms.
The Committee made no comments as regards this proposed follow-up.
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2) Hydrocyanic acid in apricot kernels.

In order to manage the potential risks of consumption of raw apricot kernels, Australia and New-Zealand have prepared a draft food regulatory measure to prohibit the sale of raw apricot kernels both unhulled (with skin) and hulled (without skin). This prohibition would also apply to any substance derived from raw apricot kernels (ground, milled, cracked, chopped) with an exemption for apricots containing raw apricot kernels, alcoholic beverages, oil, flavourings, stone fruit juices, marzipan, cakes, biscuits and confectionery.
There has been a number of poisoning incidences in both Australia and New Zealand following consumption of raw apricot kernels that contained high levels of hydrocyanic acid (HCN). This poses an ongoing risk for Australian and New Zealand consumers that need to be managed to avoid future poisoning incidences.

In the Expert Committee "Agricultural contaminants" on 15 January 2015 the presence of hydrocyanic acid in apricot kernels was acknowledged to be a potential acute health risk and therefore restrictive measures at EU level might also be appropriate. Therefore EFSA shall be requested to assess the acute health risk from the presence of hydrocyanic acid in apricot kernels and derived products.

[2] EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2014. Scientific Opinion on the risks for human and animal health related to the presence of modified forms of certain mycotoxins in food and feed. EFSA Journal 2014;12(12):3916, 107 pp. doi:10.2903/j.efsa.2014.3916

A.07 Exchange of views on the envisaged review of Commission Implementing Regulation (EU) 322/2014 imposing special conditions on the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station.

A specific ad hoc technical meeting was held on 19 January 2015 with the Member States on this issue. The Committee was informed of the information provided and the outcome of the discussions at that meeting.

At the technical meeting, more than 81 000 occurrence data on radioactivity in feed and food other than beef provided by the Japanese authorities concerning the fourth growing season after the accident were discussed in detail and the possible consequences this could have for the review of the measures.
The Committee was informed that the internal consultation on the review was still ongoing and that it was premature to propose concrete changes to the Commission Implementing Regulation (EU) 322/2014.
It was furthermore clarified that it is foreseen that Implementing Regulation (EU) 322/2014 has to be reviewed by 31 March 2014 but that the current measures continue to apply after that date if the review is not finalised.

A.08 Presentation of the Food and Veterinary Office (FVO) of the overview report on official controls on contaminants in food in the Member States, followed by a discussion.

The overview report was presented by a representative of the Food and Veterinary office (FVO) .

This report provides an overview of the outcome of a series of audits carried out by the Food and Veterinary Office in twelve Member States of the European Union (EU) between February 2012 and March 2014.
This was the first series of audits undertaken to Member States on official controls in place for contaminants in food of non-animal origin (FNAO). The objectives of the audits were to verify that the official controls for contaminants in FNAO are in accordance with the relevant provisions of Regulation (EC) No 882/2004, to evaluate the implementation of EU legislation in the area of food contaminants and to gather information about the results of investigations undertaken on food contaminants as specified in Commission Recommendations on certain food contaminants.
In most Member States visited, official controls covered all the contaminant groups listed in Regulation (EC) No 1881/2006 and some non-regulated contaminants listed in Commission Recommendations.
The requirements for designation of the Competent Authorities (CAs) responsible for official food controls, including food contaminant controls, were met. However, deficiencies in the cooperation between different CAs affected official controls at primary production level of FNAO. In general, the CAs was adequately resourced. A number of areas could be improved, notably in regard to the provision of specific training and procedures on contaminants controls and the provision of appropriate sampling equipment.
There were operational systems in place for food contaminant controls which included sampling and inspection programmes. The assessment of the reliability of food business operators' own-control systems (HACCP) in the course of official controls was, in general, unsatisfactory and such assessments were only rarely taken into account when planning the frequency of official controls. Furthermore, in some Member States, the general hygiene requirements for primary producers of FNAO laid down by Article 4(1) of Regulation (EC) No 852/2004 were inadequately or not at all controlled by the CAs. The risk-based sampling programmes were implemented as planned. Adequate enforcement measures were in place in the majority of Member States.

Accredited laboratories for the testing of official samples had generally been designated, although, in a number of Member States, not all required National Reference Laboratories had been designated. A number of areas for improvement were identified concerning adherence to minimum sample quantity requirements and sample preparation. The thresholds for enforcement of the EU maximum levels for food contaminants varied between the Member States due to the varied approaches taken in presenting results of analysis with regard to recovery and the measurement of uncertainty.
This report identifies examples of good practice and includes a summary of the recommendations made to Member States.

A.09 Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs, adopted by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on 11 December 2014.

EFSA gave a presentation on its Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs, which was published on 21 January 2015. Member States thanked EFSA for the presentation and asked the Commission to act on the Opinion as a matter of importance. The Commission stated that it was in the process of evaluating the Opinion in full and is prioritising work on the follow up.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs.

The Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) of the European Food Safety Authority (EFSA) adopted an opinion on arsenic in food [3] on 12 October 2009. The scientific opinion identified high consumers of rice in Europe, such as certain ethnic groups, and children under three years of age as the most exposed to inorganic arsenic dietary exposure. Dietary exposure to inorganic arsenic for children under three years old, including from rice-based foods, is in general estimated to be about 2 to 3-fold that of adults.

The technical information on the need for a specific maximum level for parboiled milled rice is very recent. Therefore, it is foreseen that Member States should collect additional data before 1 January 2018 on the inorganic arsenic content of this commodity in order to confirm the need for a specific maximum level for this commodity and to reassess the maximum limit.
The occurrence data demonstrate that rice cakes and rice wafers can contain high levels of inorganic arsenic and as these commodities can make an important contribution to the dietary exposure of infants and young children, therefore, a specific maximum level for these commodities is envisaged.

Rice is an important ingredient in a broad variety of food for infants and young children and it is therefore appropriate to establish a specific maximum level for rice when used as an ingredient for the production of such food.

A few minor comments were made which have been taken into account.

[3] Scientific Opinion on Arsenic in Food. EFSA Journal 2009; 7(10):1351.

Vote taken: unanimous in favour.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards maximum levels of lead in foodstuffs.

The Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) of the European Food Safety Authority (EFSA) adopted an opinion on lead in food on 18 March 20104 [4]. Following the conclusions of the opinion, it is appropriate to reduce the dietary exposure to lead in food by lowering existing maximum levels and setting additional maximum levels for lead in relevant commodities.

Existing maximum levels for lead in infant formulae and follow-on formulae are proposed to be lowered and new maximum levels to be established for processed cereal-based foods and baby foods for infants and young children, food for special medical purposes for infants and young children and drinks, which are highly consumed by this vulnerable group of consumers.
New occurrence data show that specific higher maximum levels are no longer necessary for brassica other than leafy Brassica, fresh legumes, most of the berries and small fruits while existing maximum levels should be lowered for cephalopods, most fruiting vegetables, most fruit juices, wine and aromatised wine.
For salsify, compliance with current maximum levels is difficult. Since consumption of this commodity is low and effects on human exposure are negligible, it is appropriate to raise the maximum levels of lead for salsify.
Erratic findings of high levels of lead in honey have triggered enforcement actions by Member States at different levels of lead. It is therefore appropriate to establish a harmonised maximum level for lead in honey.
Legislation related to processed cereal-based foods, baby foods for infants and young children and dietary foods for special medical purposes and related to wines, sparkling and aromatised wines has been replaced necessitating changes to certain endnotes.

A few minor comments were made which have been taken into account;
The vote has been taken and the Committee expressed a favourable opinion by unanimity.

One delegation abstained as the delegation had doubts as regards the accurateness of the reference to the new legislation as regards wines, sparkling and aromatised wines and was not able to check it in time with their service competent in this matter.

[4] EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on Lead in Food. EFSA Journal 2010; 8(4):1570.

Vote taken: favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards removal from the Union List of certain flavouring substances.

The Union list of flavourings substances adopted in 2012 (Regulation 872/2012) contains some 2500 flavouring substances.

A number of substances were included in the list subject to the submission of additional data before specific deadlines. There were three different deadlines: 31/12/2012, 30/6/2013 and the 31/12/2013 for different substances.

The scientific data to be submitted had been requested by EFSA in different earlier opinions.

The Regulation (EC) No 872/2012 indicates that where the necessary information is not provided by the time requested, the flavouring substance in question will be withdrawn from the Union list.

For the following five substances included in this measure: 1-methylnaphthalene [FL No. 01.014], furfuryl methyl ether [FL No. 13.052], difurfuryl sulphide [FL No. 13.056], difurfuryl ether [FL No. 13.061], and ethyl furfuryl ether [FL No. 13.123], the deadline for the submission of additional scientific data for these substances was established in Regulation 872/2012 at 31 December 2013.

No data on these five substances were submitted 9 months after the deadline. For one substance, as of February 2015, no data were submitted. In the case of the other four substances, two submissions were sent in January 2015 and November 2014. However there is no guarantee that these data would be sufficient for EFSA to conclude on the safety of the substances without asking for further data and clear the concerns expressed by EFSA when evaluating these substances.

In conclusion, there are currently today not sufficient scientific data backing the safety of these flavouring substances and the deadline established in 2012 for submitting scientific data has been missed by a year.

Therefore, it is appropriate to remove these substances from the Union list in accordance with the provisions of Regulation (EC) No 872/2012.

A transition period is foreseen.

Applicants can always submit new applications on these substances in accordance with the existing rules.

Statement by UK:

The UK considers that this action is disproportionate as industry have now provided data for four of the substances and there are no known safety concerns. This goes against the principle of better regulation as it will require significant reformulation costs to industry, but no benefits to consumers as there are no confirmed safety concerns for these substances.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the pre-export checks carried out on certain food by certain third countries as regards the presence of certain mycotoxins.

As the internal consultation within the Commission was not yet finalised, the vote has not been taken.
However, no major comments were noted as regards the provisions of the draft Commission Implementing Regulation.

Vote postponed

B.05 Exchange of views and possible opinion on a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in Katsuobushi (dried bonito) and certain canned smoked Baltic herring.

As the internal consultation within the Commission was not yet finalised, the vote has not been taken.
However, no major comments were noted as regards the provisions of the draft Commission Regulation.

Vote postponed

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards the maximum level of OTA in Capsicum sp.

As the internal consultation within the Commission was not yet finalised, the vote has not been taken.
However, no major comments were noted as regards the provisions of the draft Commission Regulation.

Vote postponed

C.01 Exchange of views of the Committee on a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards the setting of maximum levels for ergot sclerotia in cereal grains.

Due to time constraints the point was not discussed.

C.02 Exchange of views of the Committee on a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards the setting of maximum levels for tropane alkaloids in foods for infants and young children.

Due to time constraints the point was not discussed.

M.01 AOB

Application by Denmark of Article 114(4) TFEU in relation to Regulation (EC) No 1333/2008 regarding the use of nitrites in meat.

The Committee was informed that with reference to Article 114(4) TFEU, the Danish Government requested by letter of 25 November 2014 to the Commission, to maintain national provisions on the use of nitrite that differ from Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

Following the establishment of nitrite levels by Directive 2006/52/EC based on relevant opinions of the Scientific Committee on Food (SCF) and EFSA, the Kingdom of Denmark had requested to maintain own national provisions that are more stringent than those of Directive 2006/52/EC. Denmark considers that this lower amount is sufficient to protect against botulism and reduces the risk of formation of nitrosamines. By means of Commission Decisions 2008/448/EC and 2010/561/EU in accordance with Article 114(6) TFEU, the Commission approved these national measures first until 23 May 2010, later until 25 May 2015. During that period the Commission was required to monitor the situation in particular with regard to the control of botulism, the share of meat products covered by the 60 mg/kg limit in the overall consumption of meat products in Denmark, as well as imports of meat products from other Member States.

The conclusions of the desk study with the Member States on the implementation by the Member States of the EU rules on nitrites, the ad-hoc study as regards the use of nitrites by industry, the ongoing re-evaluation of nitrites by EFSA and the data reported by Denmark, will allow the Commission to review the maximum levels of nitrites as of 2016. Until these maximum levels have been reviewed, the Commission could agree that Denmark continues to maintain its more strict national levels about the use of nitrites for an additional period.

Member States were informed that the decision will be officially notified to their Permanent Representations in March 2015 with a request to provide comments within 30 days.