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 08 FEBRUARY 2017

(Section Toxicological Safety of the Food Chain)

CIRCABC Link: *https://circabc.europa.eu/w/browse/a5891803-ccea-4c39-ac15-9bfaf2ccc316*

A.01 Feedback and discussion on issues discussed in the Expert Committee Agricultural Contaminants and Expert Committee Industrial and Environmental contaminants (further details to follow).

* *Alternaria* toxins in food

Following EFSA's " Scientific Opinion on the risks for animal and public health related to the presence of *Alternaria* toxins in feed and food" (2011) and the EFSA report on " Dietary exposure assessment to *Alternaria* toxins in the European population" (2012), the estimated chronic dietary exposure to alternariol (AOH) and alternariol monomethyl ether (AME) and tenuozonic acid (TeA) exceeded the relevant Threshold of Toxicological Concern (TTC) value indicating a need for additional compound-specific toxicity data. The estimated chronic dietary exposure to tentoxin (TEN) are lower than the relevant TTC value and is therefore considered unlikely to be a human health concern.

The Committee agreed to the following follow-up :

a) there is a need to have compound specific toxicity data for AOH, AME and TeA to clarify the risk for human health.
b) it is appropriate to continue to submit the occurrence data to EFSA in the EFSA data submission format in line with the requirements of EFSA's Guidance on Standard Sample Description (SSD) for Food and Feed and the additional EFSA's specific reporting requirement.
c) awaiting the carrying out of the compound specific toxicity data, it is appropriate to consider the need to set maximum levels for *Alternaria* toxins of most concern in foods in which they can occur at high levels in order to ensure a high level of human health protection, in particular for vulnerable groups of the population.

* ergot sclerotia

The document "Method for the Determination and quantification of Ergot (*Claviceps purpurea* Tul.)" provides guidance for the control of ergot sclerotia in cereals to verify the compliance with the maximum level established in Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.

The sampling shall be performed in accordance with point B of Annex I to Commission Regulation (EC) No 401/2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.

The document does not replace the application of international standards for the determination of ergot in cereals such as EN 15587:2008+A1:2013 "Cereal and cereal products – Determination of Besatz in wheat, durum wheat, rye, triticale and feed barley".

No comments were raised as regards the document.

* aflatoxins in peanuts from US

An increase of non-compliance as regards the presence of aflatoxins in groundnuts from the US has been observed since mid-2016. The US authorities were informed thereof and commitments were made to remediate the situation. However it can be observed, after 6 months, that the situation has not improved.

Therefore it can be concluded that the conditions leading to the approval of the pre-export controls for peanuts from US as regards aflatoxins, provided by Regulation (EU) 949/2015 approving the pre-export checks carried out on certain food by certain third countries as regards the presence of certain mycotoxins, are no longer fulfilled.

Therefore the Commission services intend to submit at a next meeting a draft Regulation providing for the removal of groundnuts from the US from the list of approved pre-export checks. In the meantime, in accordance with Article 23, point 8 of Regulation (EC) No 882/2004 the reduced frequency provided for in Regulation (EU) 949/2015 does no longer apply.

In a second stage and in case the situation does not improve, it might be appropriate to consider to include peanuts from US in the Regulation (EU) 884/2014 for the control on aflatoxins to ensure a high level of human health protection.

* 3-MCPD, 3-MCPD fatty acid esters and glycidyl esters in certain foods

The health based guidance value (HBGV) established by Joint FAO/WHO Expert Committee on Food Additives (JECFA) for 3-monochloropropane diol (3-MCPD) and its fatty acid esters (Tolerable Daily Intake (TDI) of 4 µg/kg bw) at its 83rd meeting in November 2016 is different from the HBGV established by the EFSA Scientific Panel on Contaminants in the Food Chain (CONTAM) in its opinion adopted in March 2016 earlier this year (TDI of 0.8 µg/kg bw). The divergence is related to the dose-response modelling. While EFSA used the unrestricted model for the identification of the Benchmark Dose Lower Bound (BMDL), JECFA used the restricted model.

Also for glycidyl fatty acid esters the outcome of the assessment is divergent but less different with the JECFA outcome stricter than the EFSA outcome. While the CONTAM Panel stated that the data were unsuitable for deriving a Benchmark Dose Lower Bound (BMDL) and T25 was used (T25 of 10.2 mg/kg bw day and MOE's of 25000 or higher considered of low health concern), JECFA considered the same data as suitable to define a BMDL and consequently derived a BMDL10 (BMDL10 of 2.4 mg/kg and MOE of 10000 or higher considered of low health concern).

The CONTAM Panel discussed in its meeting of 24-26/1/2017 in detail the scientific divergence identified in the assessment of 3-monochloropropanediol and glycidyl fatty acid esters with the JECFA. The CONTAM Panel agreed that it is appropriate to reopen its Scientific Opinion on the risks for human health related to the presence of 3- and 2-MCPD, and their fatty acid esters, and glycidyl fatty acid esters (EFSA-Q-2014-00535) to address the identified scientific divergence for the assessment of 3-MCPD and its fatty acid esters.

An exchange of views on the regulatory measures currently under discussion has taken place, following the decision from EFSA to re-open the opinion on 3-MCPD esters and glycidyl esters. The majority of the delegations which expressed a view were in favour to proceed with the envisaged measures on glycidyl esters in vegetable oils and fats and infant formula and follow-on formula and to await the outcome of the EFSA re-opening of the opinion before proceeding with the measures on 3-MCPD esters except eventually for infant formula and follow-on formula. The Commission indicated to reflect on the way forward taking into account the outcome of this exchange of views.

* Derogation applied by certain Member States as regards the maximum levels for polycyclic aromatic hydrocarbons (PAH) in traditionally smoked meat, meat products, fish and fishery products.

By Commission Regulation (EU) No 1327/2014, a derogation from the EU maximum levels for PAHs for local production and consumption of traditionally smoked meat and meat products and fish and fish products was granted to those Member States that had requested the derogation.

Member States which have been granted the derogation are required to continue to monitor the presence of PAHs in traditionally smoked meat and fish products and to implement good smoking practices where possible, within the limits of what is economically feasible and what is possible without losing typical organoleptic characteristics of those products.

The Regulation furthermore provides that the situation is re-assessed within 3 years from its application, i.e. before 1/9/2017 on the basis of all available data (monitoring data, feasibility of achieving lower levels) in view of determining a list of smoked meat and meat products and fish and fish products for which the derogation for local production and consumption shall be continued.

In view of this re-assessment of the situation, Member States are requested to provide by 3/3/2017 to the European Commission (preferably by email

Frans.Verstraete@ec.europa.eu) the monitoring results of the presence of PAHs in traditionally smoked products and provide the outcome of their programmes/investigations to implement good smoking practices where possible, within the limits of what is economically feasible and what is possible without losing typical organoleptic characteristics of those products.

In case of ongoing monitoring surveys and investigations Member States are requested to provide available information by 3/3/2017 and indicate the timeline for the availability of the remaining information.

It was furthermore confirmed that the Regulation does not provide that the derogation expires on 1/9/2017. The derogation therefore continues to apply after 1/9/2017 until new provisions reflecting the outcome of the abovementioned re-assessment are adopted.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EU) No 1333/2008 of the European Parliament and of the Council as regards the use of phosphoric acid- phosphates-di-tri-and polyphosphates (E 338-452) in certain meat preparations.

The Commission received an application from the Czech Republic for an extension of use of phosphates in certain meat preparations (*Bílá klobása, Vinná klobása, Sváteční klobása and Syrová klobása*) required for maintaining the physico-chemical state and to increase the binding capacity.

The use of phosphates is authorised in a wide variety of foods. Their safety was evaluated by the Scientific Committee for Food which established the Maximum Tolerable Daily Intake of 70 mg/kg body weight expressed as phosphorus. The extension of use is limited to a few specific products, therefore, it is not expected that it will have a significant impact on the overall exposure to phosphates.

Therefore, Annex II to Regulation (EC) No 1333/2008 should be amended accordingly.

Belgium made the following declaration for abstention :

Belgium is not opposed to the uses of additives in traditional products indicated in italics where they are very specific to the consumption habits and production in a particular Members state and well characterized in the guidance on food descriptors. The latter condition is not currently fulfilled. Belgium expresses concerns about the too extended use of food groups indicated in italics that may causes problems of interpretation and control, in particular when the description is used in other Member States. In view of protecting the traditional way of producing fresh sausages and to prevent the increase in intake of phosphates and to prevent the possible misleading of the consumer, Belgium does not support the authorization of uses of these additives in products in italics that are similar in many countries.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex III to Regulation (EU) No 1333/2008 of the European Parliament and of the Council as regards the use of butane (E 943a), isobutane (E 943b) and propane (E 944) in colour preparations.

The Commission received an application for authorisation of the use of butane (E 943a), isobutane (E 943b) and propane (E 944) as propellants in colour preparations of group II and group III, as defined in Part C of Annex II to Regulation (EC) No 1333/2008.

Butane, isobutane and propane can produce the necessary pressure to expel colour preparations from a spray in order to obtain an appropriate homogenous coverage of colours on foods.

The Scientific Committee for Food evaluated safety of propane, butane and isobutane and found such use acceptable subject to a residue limit in food of 1 mg/kg per substance.

Due to risk of ignition and the time needed to decrease the levels of propellants under the limit of 1 mg/kg it is appropriate to grant the authorisation for professional use only.

Therefore, Annex III to Regulation (EC) No 1333/2008 should be amended accordingly.

France made the following statement :

"*France regrets that the instructions of use, which would enable to respect the maximum limits for gases and group III colours, are not included in the draft*."

The United Kingdom made the following statement :

"*The UK considers it unnecessary to restrict the use of these colour sprays for 'professional use only'. This would unnecessarily preclude the use of these products for home bakers. There are not the same flammability issues that arise through the use of propellants with vegetable oil pan sprays which tend to be used near naked flames*."

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EU) No 1333/2008 of the European Parliament and of the Council as regards the use of nitrites (E 249 - 250) in golonka peklowana.

The Commission received an application from Poland for an extension of use of nitrites in the meat preparation *golonka peklowana* required for preserving effect and to achieve the desired colour, flavour and texture properties as expected by the consumers.

Nitrites are authorised for the use in meat products on a general basis, the use in meat preparations is restricted to certain traditional preparations and specific provisions are laid down for traditionally cured meat products. The application is limited to the specific meat preparation and therefore it is not expected that the extension will have a significant impact on the overall exposure to nitrites.

Therefore, Annex II to Regulation (EC) No 1333/2008 should be amended accordingly.

Belgium made the following declaration for abstention :

"*Belgium is not opposed to the uses of additives in traditional products indicated in italics where they are very specific to the consumption habits and production in a particular Members state and well characterized in the guidance document on food descriptors. The latter condition is not currently fulfilled. Belgium is not in favour of the authorization of nitrites in meat preparations and expresses concerns about the too extended use of food groups indicated in italics*."

Denmark made the following declaration for the vote against :

"*In accordance with Decision 2015/ 3526/EU concerning national provisions notified by Denmark on the addition of nitrite to certain meat products Denmark can maintain lower levels of nitrite in meat products. This is in accordance with the outcome of EFSA's risk assessment of nitrites added to meat products. However meat preparations are not covered by the decision and therefore the proposal concerning nitrites in meat preparations as proposed compromise food safety. We believe that further authorization regarding the use of nitrites in meat preparations should await the outcome of the evaluation of the use of nitrite which is expected in the near future. Therefore we voted against the proposal*."

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Regulation (EC) No 1881/2006 as regards maximum level of hydrocyanic acid in certain unprocessed whole, ground, milled, cracked, chopped apricot kernels.

The Scientific Panel on Contaminants in the Food Chain (CONTAM) of the European Food Safety Authority (EFSA) adopted a scientific opinion on acute health risks related to the presence of cyanogenic glycosides in raw apricot kernels and products derived from raw apricot kernels.

Amygdalin is the major cyanogenic glycoside present in unprocessed apricot kernels and is degraded to hydrocyanic acid (cyanide) by chewing. Cyanide is of high acute

toxicity in humans. An acute reference dose (ARfD) of 20 µg/kg bw was derived by the CONTAM Panel for assessing the risks associated with the presence of cyanogenic glycosides in unprocessed whole, ground, milled, cracked, chopped apricot kernels. Taking into account the reported levels of cyanogenic glycosides in unprocessed apricot kernels, the ARfD would be exceeded already by consumption of only a very few unprocessed apricot kernels.

It is therefore necessary for consumer protection to establish a maximum level of 20 mg/kg for the presence of hydrocyanic acid in unprocessed whole, ground, milled, cracked, chopped apricot kernels placed on the market for the final consumer.

Given the very fragmented market of unprocessed apricot kernels and the possible acute health risks for public health, it is necessary that it is guaranteed by the responsible operator that all unprocessed whole, ground, milled, cracked, chopped apricot kernels placed on the market for the final consumer complies with the maximum level.

Furthermore the Committee was informed that it is appropriate to consider the need to take regulatory measures as regards the presence of cyanogenic glycosides in foods other than unprocessed apricot kernels which are not yet regulated at EU level and to assess the appropriateness of existing maximum levels for hydrocyanic acid in food to provide a high level of human health protection. The Commission has addressed to EFSA a request to assess the applicability of the ARfD established for cyanogenic glycosides in unprocessed apricot kernels for other foods in which cyanogenic glycosides are present.

One delegation was of the opinion that it was not appropriate to delete the recital referring to the need to consider the need to take regulatory measures as regards the presence of cyanogenic glycosides in foods other than unprocessed apricot kernels. The Commission explained that this was done for legal reasons as the recital does not relate to a provision in the enacting terms of the act.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation setting maximum levels for certain contaminants in food repealing Commission Regulation (EC) No 1881/2006.

Vote postponed

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of lactitol as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

The Commission representative presented the draft Implementing Decision authorising the placing on the market of lactitol as a novel food ingredient.

Vote taken: Favourable opinion.

C.01 Exchange of views of the Committee on a draft Commission Regulation on the application of codes of good practice to reduce the presence of acrylamide in food.

The outline of the envisaged regulatory measure on the application of codes of good practice to reduce the presence of acrylamide in food was presented.

* The envisaged regulatory measure is based upon the Food Hygiene Regulation (EC) 852/2004. The objective of the Food Hygiene Regulation is to ensure a high level of consumer protection with regard to food safety, including chemical hazards, through the application of food safety management measures to be applied by food business operators.

* The measure provides for a mandatory application by all concerned food business operators of mitigation measures to reduce the presence acrylamide in food. These mitigation measures contain clear obligations for the food business operators and are integrated as annex in the envisaged regulatory measure. The mitigation measures to be applied take into account and are proportionate to the size and the nature of the establishment, with the clear objective to achieve a reduction by setting strict levels to be used as a benchmark.

* Benchmark levels reflect the level which can be achieved on a consistent basis by applying mitigation measures to reduce the presence of acrylamide as low as reasonably achievable. The benchmark levels to be used to measure the efficacy of the applied mitigation measures are set at a strict level taking into account the most recent occurrence data from the EFSA database.

* Food business operators are obliged to monitor the effectiveness of the mitigation measures to reduce the presence of acrylamide by sampling and analysis of their production demonstrating that the levels of acrylamide are below the set benchmark levels.

* It is foreseen in a second phase to initiate the discussion on setting maximum levels for certain foods or food categories are placed on the market ready to eat. The discussion shall be started immediately after the adoption of and complementary to the regulatory measure obliging food business operators to apply mitigation measures.

* In addition to the regulatory measures, it is also important to raise awareness amongst consumers as a significant part of the exposure to acrylamide may come from home-cooking.

* On the basis of Article 14 of the General Food Law Regulation (EC) No 178/2002, foods can be withdrawn from the market if they are a risk for public health, e.g. containing a high level of acrylamide. Some weeks ago there has been a recall of a processed cereal based baby food from the market because of a too high level of acrylamide.

Furthermore it was indicated that it would be appropriate to monitor the presence of acrylamide in foodstuffs not covered by the mitigation measures and/or benchmark levels and in which, based on very few samples, significant levels of acrylamide was found in order to be able to assess the extent of the presence of acrylamide in these foodstuffs.

Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs shall be updated to include specific analytical performance criteria for the analysis of acrylamide in food. In the meantime the sampling provisions and the general analytical requirements are of application for the sampling of analysis of food for the presence of acrylamide.

Certain Member States expressed concern that the regulatory requirements/obligations could prevent innovation and that the proposed benchmark levels are too low. Furthermore it was mentioned that it is important that the opportunity shall be provided to discuss the regulatory measures in detail.

Member States expressed concern as regards the timeline and highlighted the need to not further delay the adoption of the envisaged measures obliging food business operators to apply mitigation measures to reduce the presence of acrylamide.

The Commission representative indicated that the obligatory mitigation measures referred to the Regulation reflect the "must do" mitigation measures referred to in the Codes of Practice developed by the industry and are therefore expected not to prevent innovation. Furthermore it was highlighted that the benchmark levels have to be strict in order to be an incentive for/to oblige food business operators to apply mitigation measures to reduce the levels of acrylamide in food as low as reasonably achievable. Maximum levels on the other hand has to take into account of the natural variations of acrylamide within a food category in order to avoid that certain speciality traditional products would have to disappear from the market.

As regards the timeline, the Commission confirmed that it is the intention of the Commission to submit the envisaged regulatory measure for opinion to the Committee later during this spring.

M.01 A.O.B.

A delegation indicated that it would be appropriate to receive the justification from a legal point of view for the approach of setting maximum levels of mercury in foodstuffs other than fish and fishery products and food supplements in the frame of Regulation (EC) 396/2005 on maximum residue levels of pesticides in or on food and feed instead of in the frame of Regulation (EEC) 315/93 on contaminants in food.