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HEALTH & CONSUMERS DIRECTORATE-GENERAL

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**SUMMARY RECORD OF THE  
STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH  
HELD IN BRUSSELS ON 19 JUNE 2009**

**SECTION "TOXICOLOGICAL SAFETY OF THE FOOD CHAIN"**

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President : Mr M. FLUEH

All Member States were represented except Cyprus and Lithuania.

- 1. Exchange of views and possible opinion on a Regulation amending the annexes of Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs**

*(Document/SANCO/5907/2009)*

*(Legal basis : Regulation (EC) N°1935/2004, Right of scrutiny of the European Parliament)*

The draft measure was presented and minor editorial changes were agreed with Member States.

The Standing Committee gave a favourable opinion by qualified majority (2 Member States being absent).

- 2. Information on the EFSA re-evaluation of Benzophenone**

The opinion on the toxicological reassessment of Benzophenone was presented.

It was agreed that the discussion on Benzophenone and 4 Methybenzophenone will continue at working group level and, if necessary, the point may be re-discussed in a future meeting of the Committee.

- 3. Exchange of views on a request from Germany to apply the safeguard clause foreseen by Article 18 of Regulation (EC) No 1935/2004 to triclosan which is listed on the provisional list of additives established under article 4a of Directive 2002/72/EC**

Germany presented the measure transposing into national law Directive 2008/39/EC amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food. This measure integrates a

national ban on the use of Triclosan, a substance which is listed in the provisional list of additives established under article 4a of Directive 2002/72/EC. Germany considered that such measure had to be notified to the Commission under Article 18 of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, which deals with the adoption by Member States of safeguard measures temporarily suspending the application of Community provisions.

The Commission representative explained that substances listed on the provisional list of additives are not authorised at Community level for use in plastics materials and articles but Article 4a.4 of Directive 2002/72/EC provides that these may be used subject to national law.

Therefore, the responsible Commission service considers that the German measure does not need to be notified as a safeguard measure under Article 18 of Regulation (EC) No 1935/2004, as it does not aim at suspending any Community provision.

It was agreed that further discussions will continue bilaterally between the responsible Commission service and the German authorities.

**4. Exchange of views on a resolution voted by the Danish Parliament requesting to forbid the use of Bisphenol A in baby bottles**

Denmark informed on a resolution passed by the Danish Parliament on Friday 29 May 2009 that urges the Danish Government to ban the use of Bisphenol A in infant feeding bottles. It should also work at European level for a total ban of Bisphenol A. The Danish Government has not yet taken a decision on the follow-up of this resolution. Any follow-up will respect the procedure for national measures to be followed in the EU. 5 Member States reported that there had been discussions at national parliamentary level on measures on BPA. However, as the EFSA opinion indicates that current use of Bisphenol A in food contact materials is safe, no measures at national level are envisaged.

**5. Information about the recent cases of adulteration of food through illegal dyes**

The discussion focused on the recent cases of adulteration of safflower with Orange II and spice with butter yellow. It was agreed that, for the time being, the High Pressure Liquid Chromatography (HPLC) method should be considered appropriate to be used in routine for quantification of these dyes and the limit of quantification (LOQ) of 500 ppb should be retained as an action limit. In parallel, the European Commission has proposed the UK delegation to review its report drafted in 2006 related to the "illegal dyes analytical network" and possibly to consider whether a lower LOQ could be achievable in routine under currently used analytical method.

**6. Update of the outcome of the Expert Committee on Environmental and Industrial contaminants**

The Commission delegate presented a short summary on some items discussed in the last Expert Working group on Environmental and Industrial contaminants which took place on 15 June 2009. No comments were made on this presentation.

On cadmium, the Expert Committee discussed the follow-up to the recent scientific opinion of the European Food Safety Authority (EFSA). In its opinion, EFSA had derived a Tolerable Weekly Intake (TWI) of 2.5 µg/kg bodyweight (b.w.), which is about 3 times lower than the previous Provisional Tolerable Weekly Intake (PTWI) of 7 µg/kg bodyweight set by Joint FAO/WHO Expert Committee on Food Additives and Contaminants (JECFA) in 1988 and endorsed by the Scientific Committee on Food (SCF) in 1995. This means that the exposure of the average consumer is around or slightly above the TWI and that specific population groups (e.g. high consumers, vegetarians or children) could exceed the TWI by about 2-fold. The Expert Committee will review the current maximum levels and assess whether it is possible to lower some of them and/or whether there is a need for additional maximum levels for commodities currently not yet regulated. Some specific requests for increases of maximum levels were discussed, which were previously put on hold pending the outcome of the EFSA opinion. Member States felt that increases of cadmium maximum levels would be very difficult to justify given that the conclusions of the EFSA risk assessment point to a need for reducing exposure. A more in-depth discussion will take place in the next Expert Committee.

The issue of cadmium in crustaceans, in particular the definition of the portion of crabs to which the current cadmium maximum levels applies, was re-discussed taking into account the comments received in a previous Expert Committee in May 2009. As additional information is still expected, the issue will be taken up again. However, it was emphasised that a solution is urgently needed and that technical discussion should come to a close in September.

The Expert committee also discussed the follow-up to the EFSA risk assessment on polycyclic aromatic hydrocarbons (PAH). The EFSA opinion concluded that benzo(a)pyrene is not a suitable marker for the occurrence of PAH in food and that a system of 4 substances (PAH4<sup>1</sup>) or 8 substances (PAH8<sup>2</sup>) would be the most suitable indicators of PAH in food, with PAH8 not providing much added value compared to PAH4. Several options based on a system of PAH4 were presented and discussed. The discussion will be taken up in the next Expert Committee.

On acrylamide, the Expert Committee had a first exchange of views on the recently published acrylamide monitoring report prepared by EFSA. The report presents the first year's monitoring results collected in the framework of Commission Recommendation 2007/331/EC setting out a 3-year monitoring programme for acrylamide levels in food. The report shows that there is no clear and general trend towards lower levels. Therefore, most of the delegations who expressed their views were of the opinion that it would be time to consider further risk management measures. A more detailed discussion will take place at the next Expert meeting.

On ethylcarbamate, a first proposal for a recommendation relating to ethylcarbamate in stone fruit spirits and fruit marc spirits was discussed. The proposal combines a Code of Practice with a monitoring recommendation. Comments were received and will be considered for the next meeting.

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<sup>1</sup> Sum of Benzo[a]pyrene, Chrysene, Benz[a]anthracene, benzo[b]fluoranthene

<sup>2</sup> Sum of Benzo[a]pyrene, Chrysene, Benz[a]anthracene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[g,h,i]perylene, dibenz[a,h]anthracene and indeno[1,2,3-cd]pyrene

**7. Levels of zearalenone in wheat bran and high fibre breakfast cereals - harvest 2008 : discussion and agreement on risk management measures**

The European breakfast cereal Association (CEEREAL) requested a temporary increase of the maximum level of zearalenone in high fibre breakfast cereals from the current 50 µg/kg to 135 µg/kg due to the fact that since March/April 2009 serious supply problems are experienced for wheat bran from the harvest 2008 in the UK to be used in high fibre breakfast cereals.

Although there is currently no maximum level for zearalenone in wheat bran used as ingredient, the wheat bran for use in the high fibre breakfast cereals should not have a level higher than 75 µg/kg in order to enable high fibre breakfast cereal producers to comply with the current maximum level of 50 µg/kg for breakfast cereals other than maize-based breakfast cereals (the current maximum level of zearalenone in maize-based breakfast cereals is 100 µg/kg).

The Food Standards Agency (FSA) UK performed a risk assessment as the UK is the main producer and consumer of these high fibre breakfast cereals. It was confirmed by the DATEX – Data Collection and Exposure Unit from EFSA -that the consumption figures for breakfast cereals used in the FSA assessment are among the highest recorded in any EU Member State.

The assessment indicated that an increase of the maximum level of zearalenone in breakfast cereals to 135 µg/kg would not result in an unacceptable risk for the consumer. It was also indicated that as a more precautionary approach a level of 100 µg/kg could be considered.

Based on this a risk assessment and the information provided by CEEREAL, a level of 100 µg/kg of zearalenone in breakfast cereals, other than maize-based breakfast cereals and 125 µg/kg of zearalenone in bran to be used as ingredient in foodstuffs was discussed in the Expert Committee "Agricultural Contaminants" on 8 June 2009 in preparation of the discussion and possible endorsement at this meeting of the Standing Committee.

Therefore, the Committee was requested to endorse the approach whereby the level of 100 µg/kg of zearalenone in high fibre breakfast cereals other than maize based is recommended to be applied on a temporary basis (i.e. for high-fibre breakfast cereals produced before 31 October 2009).

In the meantime, EFSA could be requested to provide a scientific opinion before October 2009 on the effects on consumer health risk following a possible permanent increase of the maximum level for zearalenone from 50 µg/kg to 100 µg/kg in breakfast cereals (other than maize-based breakfast cereals).

After extensive discussion, a large majority of delegations at the Standing Committee endorsed and agreed to the approach as outlined in the note, enclosed as annex to the summary report of this meeting. Upon request, the Commission confirmed to formally inform the competent authorities of the Member States of this agreement. The breakfast cereal industry should furthermore do efforts to diversify their sources of supply in order to enable them to better cope with acute shortages of supply and to avoid similar situations in the future.

**8. Alignment of EU maximum levels for aflatoxins to Codex decisions and related provisions : discussion**

The discussion on this point was postponed.

**9. Review of Commission Decision 2008/798/EC of 14 October 2008 imposing special conditions governing the import of products containing milk or milk products originating in or consigned from China, and repealing Commission Decision 2008/757/EC : discussion and agreement on review**

Commission Decision 2008/798/EC as amended by Decision 2008/921/EC currently prohibits the import into the EU of products containing milk, milk products, soya or soya products intended for the particular nutritional use of infants and young children originating from China. In addition, it foresees that Member States shall carry out tests, including laboratory analysis, on all consignments of ammonium bicarbonate intended for food and feed and of feed and food containing milk, milk products, soya or soya products originating from China.

Since January 2009, the number of Rapid Alert System for Food and Feed (RASFF) notifications on melamine in these products submitted to a 100% test regime originating from China has significantly dropped. In the last four months, only 9 out of the approximate 1200 consignments tested at import of these products originating from China were found to contain levels of melamine > 2.5 mg/kg (action level) and at levels significantly lower than the levels of melamine found in October –November 2008.

On 1<sup>st</sup> June 2009, the Chinese authorities (General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)) provided the Commission with a report on the measures the Chinese authorities have taken to address the melamine contamination problem and on the results achieved. The report outlines in detail the measures taken immediately after the central authorities in China were made aware of the melamine contamination incident, the controls performed and the measures taken to guarantee the safety and quality of Chinese food products on the long term.

As regards the guarantees for the safety of future exports of food and in particular the absence of unacceptable levels of melamine, reference is made to the Food Safety Law adopted by the China's National People's Congress (NPC) on 28 February 2009 and which entered into force on 1 June 2009. This law clearly outlines the responsibilities of the food producers to ensure the food safety and defines the responsibilities of all food safety related departments in the Chinese government. The law also contains detailed provisions concerning food safety standards, food inspection and supervision, export and import on food, investigation of major incidents of food safety and legal liability.

Following the abovementioned facts, following amendments to the current provisions of Commission Decision 2008/798/EC were proposed:

- To keep the suspension of import of products containing milk, milk products, soya or soya products intended for the particular nutritional use of infants and young children.
- Reduce the level of testing of the consignments of ammonium bicarbonate intended for food and feed and of feed and food containing milk, milk

products, soya or soya products originating from China from 100 to 20% in order to monitor the effectiveness of the control measures applied in China.

- To maintain the random checks by MS prior to importing feed and food products with a high protein content.
- To maintain the other provisions as regards designated control points, costs to be borne by the operator responsible and prior notification.
- To review the situation within six months.

The Committee welcomed these proposed amendments. The Commission indicated to draft the legal text providing for these amendments and to present it for opinion at one of the forthcoming meetings of the Standing Committee for the food Chain and Animal Health.

#### **10. Food Irradiation : update of lists of approved facilities in the EU, national authorisations and competent authorities**

The Czech Republic informed the Commission of a change in their national list of approved irradiation facilities: one facility has been closed and another one was approved. The adapted list is presented for information with request to all MS to check the coordinates of the facilities in their own country. The Czech Republic also signalled the existence of national authorisations that hadn't been published yet. The adapted list of national authorisations is presented for information. All amendments to both lists should be notified prior to 31 July 2009. At the same time, MS are asked to check whether all coordinates of their national authorities are still correct. If amendments are needed, they should be forwarded to the Commission also by 31 July 2009 in order to update the list.

MS are informed that EFSA is progressing with the request to provide an updated and general opinion on risks linked to food irradiation. Depending on the outcome of this opinion, different policy options will be explored. Pending smaller amendments to the food irradiation legislation will be introduced at the same moment.

Finally, MS are reminded that it has been agreed that they send in their contribution for the 2008 EU food irradiation report prior to 1st July 2009.

#### **11. A.O.B.**

##### **a) Recommendation to increase controls as regards aflatoxins and ochratoxin A on the import of paprika from Peru**

An inspection mission was carried out from 16 to 26 March 2009 to Peru, on the basis of the volume of imports of food of plant origin to the EU (according to EUROSTAT, Peru exported some 16,000 tonnes of dried fruits of genus Capsicum to the EU in 2008) and following the number of RASFF notifications. There were 9 RASFF notifications for the presence of unacceptable levels of mycotoxins, in particular ochratoxin A and to a lesser extent aflatoxins, in this product originating from Peru in 2007, but no notifications in 2008 and 2009.

During the inspection mission the following deficiencies (not exhaustive) were found:

- No legislation is in place as regards sampling procedures, analysis and maximum limits for mycotoxins in spices;
- General good agriculture practices are implemented in all the producers visited However, no specific requirements with regard to mycotoxin control are included;
- Lack of official control on the presence of aflatoxins and ochratoxin A

Following the findings of this inspection mission the Commission representative recommended the competent authorities of the Member States to increase the level of control of aflatoxins and ochratoxin A in paprika originating from Peru and to take the appropriate measures in case of non-compliance with the at EU level established maximum level for aflatoxins and/or in case of non-compliance with article 14(1) of the Regulation (EC) No 178/2002 (General Food Law) as regards ochratoxin A.

The Committee raised no comments or objections as regards this recommendation and therefore this recommendation is endorsed.

**b) Ochratoxin A (OTA) maximum levels in liquorice and spices – Outcome of the discussions at the Expert Committee on 8 June 2009**

The Committee was informed of the outcome of the discussion on the setting of maximum levels for OTA in liquorice (root and extract) and spices. The Committee raised no objections as regards the approach to set immediately a level for OTA in spices at a level of 30 µg/kg for the protection of public health and to avoid entering into the market of very highly contaminated paprika, with a lower level (15 µg/kg) to be set in a few years time after the implementation of good practices in the main production areas of the world. However the opinion was expressed that it is appropriate not to fix yet a specific date for the application of the lower level.

The Commission representative indicated to reflect on this but was of the opinion that the foreseen provisions must contain a strong incentive for the application of good practices to avoid and/or reduce the presence of ochratoxin A in spices, in particular paprika.

Michael FLUEH,  
Head of Unit (signed)

**THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL  
HEALTH**

**Section "Toxicological safety of the Food Chain"**

**19 June 2009**

**Subject: High levels of zearalenone in wheat bran and consequently resulting in possibly non compliant results in high bran breakfast cereals**

CEEREAL (the European Breakfast Cereal Association) requests a temporary increase of the level of zearalenone in high-fibre breakfast cereals from currently 50 µg/kg to 135 µg/kg due to the fact that since March/April serious supply problems are experienced for wheat bran from the harvest 2008 to be used in high fibre breakfast cereals.

Although no maximum level for wheat bran used as ingredient has been established, the wheat bran for use in the high fibre breakfast cereals should not have a level of higher than 75 µg/kg in order to enable high fibre breakfast cereal producers to comply with the current maximum level of 50 µg/kg for breakfast cereals other than maize based breakfast cereals.

The Food Standards Agency (FSA) UK performed a risk assessment following this request for the application of a higher maximum level of 135 µg/kg zearalenone in breakfast cereals. The assessment concluded that there is unlikely to be a health risk from the increase of the zearalenone limit to 135 µg/kg for the 2008 harvest for high-fibre breakfast cereals. However, as a more precautionary approach, in particular as regards toddlers, a maximum level of 100 µg/kg should be considered.

It was confirmed by the DATEX Unit from EFSA that the consumption figures for breakfast cereals used in the FSA assessment are among the highest recorded in any EU Member State.

Based on this assessment and the information provided by CEEREAL and to ensure the supply and availability of high-fibre breakfast cereals, given their beneficial health effects, **it is recommended to the Member States to apply on a temporary basis for a limited period of time (i.e. high-fibre breakfast cereals with production date before 31 October 2009) a level of 100 µg/kg of zearalenone for high-fibre breakfast cereals other than maize based breakfast cereals (the current maximum level of zearalenone in maize-based breakfast cereals is 100 µg/kg).**

Although no maximum level for wheat bran used as ingredient has been established, the wheat bran for use in the high fibre breakfast cereals should not have a level of higher than 125 µg/kg in order to enable high fibre breakfast cereal producers to comply with the proposed temporary level of 100 µg/kg for high fibre breakfast cereals other than maize based breakfast cereals

In the meantime, EFSA is requested to provide a scientific opinion on the effects on consumer health risk, following a possible permanent increase of the maximum level for zearalenone from 50 µg/kg to 100 µg/kg in breakfast cereals.