June 2019 Stakeholder Update on Rapidly Developing Policy on Food Contaminants

Environmental and Industrial Contaminants

Acrylamide

Regulation (EU) 2017/2158 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food, has been in force since 11 April 2018. The publication of the EU Commission guidance for food business operators on the application of the legislation has been delayed but is due to be published by the Commission shortly. UK guidance is available, as is a toolbox developed by Food Drink Europe.

The Commission has started discussions on maximum levels for foods intended for Infants and young children and suggested acrylamide levels were put forward for a European Commission targeted EU stakeholder consultation in March.

Following a review of the responses and further discussions at working group the Commission is currently considering that maximum levels will be advanced for the following categories:

- Biscuits and rusks for infants and young children (possible maximum level: 150 μg/kg)
- Baby foods, processed cereal based foods for infants and young children excluding biscuits and rusks (possible maximum level: 50 μg/kg)

The maximum levels will apply to those as defined in Regulation (EU) 609/2013 on food intended for infants and young children.

The Commission is planning to finalise and vote on the proposal by the end of the year.

3-Monochloropropane-diol Esters (3-MCPD esters) and Glycidyl Esters (GE)

Discussions are concluding with regards to setting of maximum levels for 3-MCPD esters, progress had been made in recent working group meetings to take into account concerns surrounding extra virgin olive oil and virgin olive oil. The finalised agreement was to have split levels for 3-MCPD and 3-MCDPE's with the lower level of 1250 μ g/kg for named oils and an upper level of 2500 μ g/kg for other vegetable oils (including pomace olive oils), fish oils and oils from other marine organisms. These will be added to the levels already established in legislation for glycidyl esters, although some consequential changes to the glycidyl esters are expected to be made by way of this amendment, including extension of scope to all marine oils.

3-monochloropropanediol (3-MCPD)

- Hydrolysed vegetable protein 20 µg/kg
- Soy sauce 20 µg/kg

Glycidyl fatty acid esters expressed as glycidol

- Vegetable oils and fats, fish oil and oils from other marine organisms placed on the market for the final consumer or for use as an ingredient in food (with the exception of those destined for the production of baby food and processed cereal-based food for infants and young children) - 1000 μg/kg
- Vegetable oils and fats, fish oils and oil from other marine organisms destined for the production of baby food and processed cereal-based food for infants and young children -500 µg/kg
- Infant formula, follow-on formula and foods for special medical purposes intended for infants and young children (powder) and young-child formula - 75 µg/kg until 30 June 2019, 50 µg/kg from 1 July 2019
- Infant formula, follow-on formula and foods for special medical purposes intended for infants and young children (liquid) and young-child formula - 10.0 μg/kg until 30 June 2019, 6.0 μg/kg from 1 July 2019

Sum of Free 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD

The maximum level shall apply from 1 January 2021.

- Vegetable oils and fats, fish oils and oils from other marine organisms placed on the
 market for the final consumer or for use as an ingredient in food falling within the following
 categories, with the exception of those destined for the production of baby food and
 processed cereal-based food for infants and young children, and of virgin olive oils (as
 defined in part VIII of Regulation (EU) No 1308/2013):
 - oils and fats from coconut, maize, rapeseed, sunflower, soybean, palm kernel and olive oils (composed of refined olive oil and virgin olive oil) (as defined in part VIII of Regulation (EU) No 1308/2013) (and mixtures of oils and fats with oils and fats only from this category) - 1250 μg/kg
 - other vegetable oils (including pomace olive oils), fish oils and oils from other marine organisms and mixtures of oils and fats with oils and fats only from this category -2500 μg/kg
 - mixtures of oils and fats from the two above mentioned categories --- (level to be reviewed in view of lowering the maximum within 2 years from the date of application)
- Vegetable oils and fats, fish oil and oils from other marine organisms destined for the production of baby food and processed cereal-based food for infants and young children (when the product is a mixture of different oils and/or fats of the same or of different botanical origins, the maximum level applies to the mixture. The oils and fats used as ingredient for the mixture shall comply with the maximum level established for the oil and fat as above) 750 µg/kg
- Infant formula, follow-on formula and foods for special medical purposes intended for infants and young children (powder) and young-child formula - 125 µg/kg
- Infant formula, follow-on formula and foods for special medical purposes intended for infants and young children (liquid) and young-child formula (liquid) - 15 μg/kg

Notes

• "young-child formula" refers to milk-based drinks and similar protein-based products specifically processed/formulated and intended to satisfy the nutritional requirements of young children aged 1-3 years (Report from the Commission to the European Parliament and the Council on young child formulae (COM/2016/0169 final).

- For fish oil and oils from other marine organisms and young child formula, the maximum levels shall apply from 1 July 2020.
- The oils and fats used as ingredient for the mixture shall comply with the maximum level established for the oil and fat. Therefore, the level of the sum of free 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD in the mixture shall not exceed the level calculated according to Article 2 (c) of this Regulation. In case the quantitative composition is not known for the competent authority and the food business operator, not producing the mixture, , the level of the sum of free 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD in the mixture shall in any case not exceed 2500 µg/kg.

Perchlorate

Following discussions with regards to the setting of maximum levels for perchlorate following the targeted stakeholder consultation, the below levels are due to be finalised and put forward to vote at a future Standing Committee.

Performance criteria for testing of perchlorate will be added to the future amendments of Regulation (EC) 333/2007.

- Fruits and vegetables 0.05 mg/kg
 - o Cucurbitaceae and kale 0.10 mg/kg
 - o leaf vegetables and herbs 0.50 mg/kg
- Tea (Camellia sinensis), dried 0.75 mg/kg
- Herbal and fruit infusions, dried 0.75 mg/kg
- Infant formula, follow-on formula 0.01 mg/kg
- Baby food 0.02 mg/kg
- Processed cereal based food 0.01 mg/kg

Furan and methylfurans

The Commission proposed a draft Recommendation for monitoring of furan and methyfurans which has now been endorsed at Standing Committee and will be published in due course by the Commission.

The EURL have commenced a two-year programme for the development of methodology and validation in different foodstuffs for testing of furan and alkylfurans.

Cadmium

Following a review of data provided to EFSA, changes to some current maximum levels have been proposed along with suggesting inclusion of previously separate commodities in broader categories.

These are still initial discussions with additional interrogation of new data that becomes available to better inform the proposals.

Mineral Oil Hydrocarbons (MOH)

The reporting deadline for monitoring Recommendation on Mineral Oil Hydrocarbons has been extended with a new deadline set of 1st October 2019 as the sampling guidance has only recently been finalised and has been recently published.

Agricultural Contaminants

Ergot Alkaloids and Ergot Sclerotia

Following EU stakeholder consultation at the end of 2018 maximum levels for ergot alkaloids and ergot sclerotia were proposed. The discussions at working group have now concluded, and the resulting proposed levels can be seen in the table below. The levels for ergot alkaloids in wholemeal and rye milling products will be lowered in July 2022 if a data review to take place beforehand is favourable of the new lower levels. The maximum levels will apply to the sum of the following 12 alkaloids: ergometrine, ergosine, ergocornine, ergotamine, ergocristine, ergocryptine (?- and ?-form) and their respective -inine forms.

The proposal is expected to be presented to the Standing Committee for vote by the end of the year.

Ergot sclerotia

- Unprocessed cereals, with the exception of maize, rye and rice 0.2 g/kg
- Unprocessed rye 0.5 g/kg until 30 June.2022, 0.2 g/kg from 1 July 2022

Ergot alkaloids

- Milling products of barley, wheat, spelt, oats grains (with an ash content lower than 900mg/100g) - 100 μg/kg, 50 μg/kg from 1 July 2022
- Milling products of barley, wheat, spelt, oats (with an ash content equal or higher than 900mg/100g) - 150 μg/kg
- Barley, wheat, spelt and oats placed on the market for the final consumer 150 μg/kg
- Rye milling products and rye placed on the market for the final consumer 500 μg/kg until 30 June 2022, 250 μg/kg from 1 July 2022
- Processed cereal based food for infants and young children 20 μg/kg

Tropane Alkaloids

Maximum levels for tropane alkaloids in foods are currently being discussed at EU working group level. The levels will be for the sum of atropine and scopolamine for all product categories but cereal-based food for infants and children. The levels under discussion can be found below.

 Processed cereal-based foods and baby foods for infants and young children, containing millet, sorghum, buckwheat, maize or their derived products - 1.0 μg/kg Atropine, 1.0 μg/kg Scopolamine

The levels below are the sum of atropine and scopolamine.

- Unprocessed millet and sorghum 5 μg/kg
- Unprocessed maize with the exception of unprocessed maize intended to be processed by wet milling - 10 μg/kg
- Unprocessed buckwheat 10 μg/kg
- Millet and sorghum placed on the market for the final consumer, milling products of millet and sorghum 5 μg/kg
- Maize for popping, maize placed on the market for the final consumer, milling products of maize - 5 µg/kg
- Buckwheat placed on the market for the final consumer, milling products of buckwheat 10 µg/kg
- Herbal infusions (dried product) with the exception herbal infusions for infants and young children (dried product) - 25 μg/kg

- Herbal infusions (liquid) with the exception of herbal infusions for infants and young children (liquid product) - 0.2 μg/kg
- Herbal infusions for infants and young children (dried product) 5 μg/kg
- Herbal infusions for infants and young children (liquid product) 0.05 μg/kg

Pyrrolizidine Alkaloids

Levels for pyrrolizidine alkaloids in foods have been discussed for some time and the most recent proposal is presented in the table below. The transition period for the implementation of the new levels is still to be finalised but likely to be 2 years for food supplements and 1 year for the remaining categories. The 12 alkaloids known to co-elute with the 21 alkaloids to be regulated will be included in the levels until analytical methods can make the distinction possible. The proposal is expected to be presented to the standing committee for vote by the end of the year.

- Herbal infusions Rooibos, Anise; Lemon balm, Chamomile, thyme, peppermint, Lemon verbena (dried product) - 400 μg/kg
- Other herbal infusions (dried product) 200 μg/kg
- Tea (Camellia sinensis) and flavoured tea (Camellia sinensis) (dried product) 150 μg/kg
- Tea (Camellia sinensis) and herbal infusions for infants and young children (dried product) - 75 μg/kg
- Tea (Camellia sinensis) and herbal infusions for infants and young children (liquid) 1.0 µg/kg
- Food supplements containing herbal ingredients 400 μg/kg
- Pollen based food supplements, pollen and pollen products 500 μg/kg
- Dried herbs 400 μg/kg
 - borage, lovage, marjoram and oregano (dried) 1000 μg/kg
 - borage (fresh, frozen) 750 μg/kg
- Cumin seeds (seed spice) 400 μg/kg

Opium Alkaloids

There are continued discussions on the setting of maximum levels for morphine and codeine in poppy seeds and bakery products containing poppy seeds. It is proposed to set a level of 20 mg/kg for the sum of the two alkaloids in poppy seeds placed on the market for the final consumer. Additionally, levels of 1.5 mg/kg for breads and 2.0 mg/kg for fine bakery wares (biscuits, rusks and crackers) are being discussed.

Alternaria Toxins

Following the EFSA evaluation a need for further data has been identified before looking at the establishment of maximum levels. The European Commission is therefore proposing a monitoring recommendation to gather more data alongside indicative levels to trigger investigation of possible causes where these levels are breached. The current proposed indicative levels for alternariol, alternariol monomethyl ether and tenuazonic acid in different foods are shown in the table below. The recommendation will be presented at a future Standing Committee for endorsement before being published in the Official Journal. Interested parties are encouraged to collect data and submit to EFSA to inform future discussions.

Food	, , , , ,	Alternariol monomethyl ether (μg/kg)
Processed tomato products	10	5
Paprika powder	-	-
Sesame seeds	30	30

Food	Alternariol (ΑΟΗ) (μg/kg)	Alternariol monomethyl ether (µg/kg)
Sunflower seeds	30	30
Sunflower oil	10	10
Tree nuts	-	-
Dried figs	-	-
Cereal based foods for infants and young children	5	5

Deoxynivalenol (DON) and Modified forms & T2 and HT-2

Discussions have commenced on reviewing of the current maximum levels for deoxynivalenol (DON), 3-Ac-DON and DON-3-Glucoside. Discussions have also commenced at working group for T2 and HT2 toxin and the setting of maximum levels based upon EFSA scientific opinion. The industry is invited to submit any available data to the European Commission and EFSA as soon as they become available.

Erucic Acid and Hydrocyanic Acid

The discussions on erucic acid have concluded at working group and the proposal was presented at Standing Committee on 27 June 2019 for vote. The vote was favourable and the new levels will be as seen below.

Erucic acid, including erucic acid bound in fat

- Vegetable oils and fats placed on the market for the final consumer or for use as an ingredient in food, with the exception of camelina oil, mustard oil and borage oil - 20.0 g/kg
- Camelina oil, mustard oil (with acceptance from the competent authority, the maximum level does not apply to mustard oil locally produced and consumed) and borage oil - 50.0 g/kg
- Mustard (condiment) 35.0 g/kg

Hydrocyanic acid, including hydrocyanic acid bound in cyanogenic glycosides

 Unprocessed whole, ground, milled, cracked, chopped apricot kernels placed on the market for the final consumer - 20.0 mg/kg

Enniatins

The <u>EFSA opinion on enniatins</u> was published in 2014 without identifying any risks to health due to lack of data. New information is now becoming available on the levels of enniatins found in cereals in northern European countries and the EU Commission is revisiting the subject. The industry is invited to submit any data if available.

Persistent Organic Pollutants (POP's)

Dioxins and Dioxin-like PCBs

EFSA published an updated Scientific Opinion on the risk for animal and human health related to the presence of dioxins and dioxin?like PCBs in feed and food on 20 November 2018. <u>EFSA</u> proposes reducing the current Tolerable Daily Intake (TDI) of 2 picograms per kilogram body

weight to a Tolerable Weekly Intake (TWI) at the same level i.e. a seven-fold reduction. This is based on new epidemiological data on the effects of dioxins on the development of male adolescents. There remains considerable uncertainty around a number of aspects of the scientific evidence, notably the toxicity equivalency factors (TEFs) assigned to the dioxin-like PCBs including PCB 127, which is a major contributor to dietary exposure. It is likely that there will be a review of existing Maximum Levels for dioxins in food but this will not be finalized until there has been a comprehensive review of the TEF system by the World Health Organization (WHO) and until a full risk-benefit analysis of fish consumption has been completed.

Perfluorooctane sulphonate & perfluorooctanoic acid (PFOS/PFOA)

EFSA published a new Scientific Opinion on the Risk to human health related to the presence of per?uorooctane sulfonic acid and per?uorooctanoic acid in food on 13 December 2018. <u>EFSA proposes substantial reductions to health based guidance values</u> from the existing TDIs for PFOS and PFOA. However, there is considerable uncertainty over the scientific basis for the new values and they are therefore being regarded as provisional until the EFSA review of other perfluorinated compounds is completed, probably by the end of 2019. In the meantime, controls on levels of PFOS/PFOA in food are not envisaged.