April 2018 Stakeholder update on rapidly developing policy on food contaminants

Mycotoxins and plant toxins

Ergot alkaloids

As mentioned in the December 2017 update, discussions have continued on setting maximum levels (MLs) for ergot alkaloids in cereal-based products. Taking into consideration the availability and sensitivity of analytical methods, it has been decided that initially, MLs will be discussed for milling products (barley, wheat, oats, spelt and rye). There has been some stakeholder feedback to the European Commission that the proposed MLs may not be achievable by some whole grain flours. However, as there is no legal definition for whole grain products, it is proving difficult to discuss this as a separate category. There is a possibility to have a more appropriate ML for bran and set this as a separate category. MLs would be lower-bound levels with an LOQ of 4 µg/kg (each individual alkaloid) for milling products.

Any further data on ergot alkaloids in bran would be useful to inform the discussions.

Ochratoxin A

The European Commission is planning to have a targeted consultation of European trade associations on possible MLs to be set for the following foods. These levels have been discussed between the Commission and Member States. However, it is important for the Commission to receive feedback on whether these levels are achievable based on good practice.

- dried fruit (except vine fruit) - 8 µg/kg
- sunflower seeds, pumpkin seeds, peanuts and processed products thereof - 10 µg/kg
- all tree nuts - 5 µg/kg
- herbs, tea and herbal infusions - 10 µg/kg
- spices in general and mixture of spices - 15 µg/kg (except Capsicum spp. which will have an ML of 20 µg/kg)
- foods containing liquorice placed on the market for the final consumer - 10 µg/kg
- Cocoa powder sold to the final consumer or as an ingredient in sweetened cocoa powder sold to the final consumer (drinking chocolate) - 2 µg/kg

Alternaria toxins

Alternaria toxins are mycotoxins produced by fungi that can contaminate cereals, oilseeds, fruits and vegetables. EFSA had carried out assessments for four of the known Alternaria toxins - alternariol (AOH), alternariol monomethyl ether (AME), tenuazonic acid (TeA) and tentoxin (TEN). Estimates of dietary exposures indicated that in the case of AOH, AME and TeA, levels

calculated using the threshold of toxicological concern (TTC) approach could be exceeded. Although there are no specific toxicity data for these mycotoxins, as a precaution, it is being considered whether to set MLs for the following categories that may constitute major contributors to dietary exposure:

- tomato purée
- tomato juice
- sunflower seeds
- tree nuts
- cereals grains and cereal derived products
- cereal based foods for infants and young children
- ready to eat soups (before reconstitution)
- the EURL will be requested to provide expert advice and input on the analytical methods and performance criteria.

Citrinin in red yeast rice supplements

There has been wide support for lowering the current ML of 2000 µg/kg to 500 µg/kg for food supplements based on rice fermented with red yeast Monascus purpureus.

Stakeholder forum on mycotoxins

The European Commission is organizing a stakeholder forum to discuss fusarium toxins as well as climatic effects on mycotoxin formation from 14-15 May 2018. Several scientific opinions have been published by EFSA on fusarium toxins, including their modified forms. Regulatory measures are in place for some fusarium toxins, including MLs and indicative levels. There is evidence to show that climatic conditions have a significant influence on the levels of fusarium toxins and it has been acknowledged that there is a need to also address issues relating to climate change and increased formation of mycotoxins.

Pyrrolizidine alkaloids in honey, tea, herbal infusions and food supplements
Following the European Food Safety Authority's (EFSA) conclusion that there is a possible concern for human health related to the exposure to pyrrolizidine alkaloids (PAs), discussions continue on appropriate risk management measures for their presence in food. Proposals include setting MLs or action levels for PAs in teas, herbal teas, plant-based food supplements and honey.

These will be based on the sum of 21 PAs commonly found in these food (the 17 PAs identified by EFSA - interermedine/lycopsamine, intermedine-N-oxide/lycopsamine-N-oxide, senecionine/senecivernine, senecionine-N-oxide/senecivernine-N-oxide, seneciphylline, seneciphylline-N-oxide, retrorsine, retrorsine-N-oxide, echimidine, echimidine-N-oxide, lasiocarpine, lasiocarpine-N-oxide, senkirkine as well as europine, europine-N-oxide, heliotrine and heliotrine-N-oxide). Lower bound levels will be considered (results below the Limit of Quantification (LOQ) will be counted as zero) and performance criteria will be specified (LOQs of 5 µg/ kg for honey, tea, herbs and spices and 10 µg/kg for oil based food supplements). Further advice and input on the latter will be obtained from the European Union Reference Laboratory (EURL).

Erucic acid

Following EFSA's assessment and ongoing discussions on reducing current MLs for erucic acid in oils and fats, the currently levels being considered are:

- vegetable oils and fats - 20 g/kg
- infant formulae and follow-on formulae - 4 g/kg
- mustard (whole weight) - 30 g/kg

*the maximum level refers to the level of erucic acid, calculated on the total level of fatty acids in food.

These will also be sent for a targeted consultation of EU stakeholders by European Commission. It has been acknowledged that some particular oils will not be able to achieve this ML. Therefore, stakeholders are requested to send evidence to the Commission in support of any requests for the exemption of specific oils and fats and justify their request and the use of the oil in food.

Tropane alkaloids

Following the publication of EFSA's dietary exposure assessment to tropane alkaloids, it was concluded that some population groups – especially infants, toddlers and children could exceed the safety guideline levels for atropine and scopolamine. High concentrations were reported for atropine and scopolamine in tea and herbal infusions, cereal bars and spices as well as some corn products. Therefore, regulatory measures could be considered for these categories as well.

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 now applies to food businesses (from 11 April 2018).

The Commission continues to work on high-level draft guidance for food business operators (FBOs) on the application of the legislation. The Commission also plans to undertake future awareness campaigns on acrylamide for both consumers and the food industry.

Discussions have started on which foods to include in a future monitoring recommendation for gathering data on acrylamide levels in foods not within the scope of the Regulation. Once agreed this will formally the repeal the existing Recommendation 2013/647. The Commission is also expecting to start discussions to consider whether MLs for acrylamide could potentially be set in the future for certain types of food.

Mercury and methylmercury in fish

Discussions are ongoing on possible revisions to the MLs for mercury in different fish species. There has been consideration of whether to increase the ML of 1 mg/kg for mercury in shark/swordfish to better reflect the levels of mercury found in such predatory fish. However, at this stage the Commission is minded to not increase the level. They are however considering reducing the level for some fish species to reflect levels encountered. The Commission is also considering including a provision in the future proposal requiring Member States (MS) to provide national consumption advice for fish with higher levels of mercury such as shark/swordfish. In the UK such advice has been available for some time. The future proposal will also include an ML for edible salt. The Commission is expecting to publish the proposal for 4 weeks of public comment in May with a possibility that it will be put to a vote at the next Standing Committee meeting in June.

3-monochloropropane diol - esters

EFSA updated its risk assessment on 3-monochloropropane diol and its fatty acid esters in early 2018. A revised tolerable daily intake of 2.0 mg/kg was established.

Discussions are in progress on the setting of MLs for 3-MCPDE mirroring those categories set for Glycidyl Esters (GE). A range of MLs are considered for:

- infant formula, oils and vegetable oils (2,500 to 3,000 mg/kg)
- baby foods and cereals (750 to 1,000 mg/kg)
- infant formula, follow-on formula and special food for children and infants (125 mg/kg).

Discussion on the ranges and the possible inclusion of fish oils will continue, as well as discussions on setting MLs for oils used and other foods which may have higher levels of MCPDE.

Perchlorate

Discussions will continue on setting MLs for perchlorate in various foods to replace the existing guidance levels for intracommunity trade. At the recent working group meeting the Commission noted that EFSA is examining some recent studies to see whether this would justify reopening the previous opinion. They expect to conclude this work by the summer.

Review of adaption to Regulation (EC) 333/2007
The Regulation on sampling and analysis needs to be updated to include acrylamide, MCPDE and GE. The Commission has not yet made a proposal for this but hopes to address this in the coming months.

Furan

Possible risk management approaches for furans and methyl furans in foods are also expected to be discussed at the next working group meeting.