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BY EMAIL TO nutritionlegislation@dhsc.gov.uk

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COMMENTS ON LIMITED TECHNICAL CONSULTATION: standardising the definition of pesticide residues in IFFOF and iFSMPs to a more detailed definition

The Food & Biocides Industry Group (FBIG) comprises some 20+ UK trade and professional organisations from the field to final food product, and the biocides industry, working together to secure recognition in law that it is not appropriate to apply pesticides MRLs to e.g. biocides used for disinfection (of water and equipment etc) that are not being used as Plant Protection Products. Contaminants legal instruments should instead be used, balancing risk, recognising the need for microbiological food safety assurance with potential traces in the diet.

In relation to the consultation we have the following comments:

14. Do you agree with the proposal to align the **definition of pesticide residue** laid down in **Commission Delegated Regulation (EU) 2016/127**, currently defined by using the terminology of **Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market**, with a detailed definition provided in **Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin**?

- No – disagree
- The Food & Biocide Industry Group wishes to draw attention to the fact that in carrying over this legislative amendment in response the recent EU amendment, DHSC would in fact be implementing legislation with a known inherent anomaly. The introduction of this definition as it currently stands will result in unintended consequences.

Commission Delegated Regulation (EU) 2016/127 requires that all pesticide residues, as defined currently by Regulation (EC) No 1107/2009, should not exceed 0.01mg/kg. Changing the definition of pesticides to that defined in Regulation (EC) No 396/2005 will result in a broadening of the substances which are impacted by this residue limit. Interpretation of this legislation, should the changes be introduced, would mean that many dual use or multisource substances which are not associated with Plant Protection products would be impacted. Based on the implementation of the proposed definition, for the following substances, compliance with the 0.01 mg/kg limit is requested:

- Chlorate
- Bromide
- Copper
- Phosphonate
- Sodium chloride
- Rapeseed oil

Presence of Multisource substances can be explained by the following:

- Natural occurrence e.g. copper, bromide
- Environmental contaminants e.g. mercury
- Use of these substances as biocides or carry over from ingredients that have been legally treated with biocides before e.g. drinking water

Illustrative example: Chlorate

Background

Chlorate ion (ClO₃⁻) is a well-known by-product of water chlorination with e.g. hypochlorite. The chlorination process is widely used at national level and recommended also at international level (WHO) to disinfect water for human and animal consumption. The presence of chlorate traces in potable water and on food commodities which are rinsed, sprayed, washed and cooled with potable water is therefore a consequence of water chlorination. The use of active chlorine in potable water is common practice worldwide by public water suppliers. The EFSA opinion on chlorate published in 2015 concludes that the presence of chlorate in food mainly arises from the use of chlorinated water for food processing and the disinfection of food-processing equipment.

Water Treatment

Disinfectants for water treatment play an essential role in the control of microbial, viral or parasitic pathogens and limit the occurrence of foodborne diseases. Almost every municipal water supply in the industrialized world has been treated with chlorine as a disinfectant since 1920. Chlorate, on the other hand, is a by-product resulting from the use of chlorine-based agents. In 2005, the WHO set a provisional guideline value of 0.7 mg/L for chlorate in potable water. In the UK, it has been proposed that chlorate in potable water should not exceed 0.25mg/l, however a 2020 Drinking Water Inspectorate (DWI) Report identified that 23.5% of water samples tested exceeded this value. Chlorination of UK water is also known to vary across the year and increase in summer months. Whilst also monitoring for excessive chlorine, the DWI annual drinking water report 2020 also identified cases of insufficient chlorine as a likely cause for microbiological contamination, highlighting the difficult balance to be achieved in this area.

Disinfecting of surfaces and equipment

Disinfectants such as chlorine are used on surfaces and equipment in food production to ensure microbiological safety and to prevent the contamination of food during the production process. Elimination of disinfectant residues from surfaces and equipment to avoid carry-over and to comply with extremely low limits is not always feasible and depends on the disinfectant agent and on the food commodity. Alternatives for disinfection are scarce or not well characterized in comparison to the current chlorine-based agents which have proven to be efficient in maintaining the high microbiological standards and requirements for nutrition products for infants and young as well as in the supply chain of the ingredients. Additionally, these chlorine-based agents are safe to handle in manufacturing plants.

FBIG has published guidance on such usage¹, which has been adopted by the Global Food Safety Initiative².

Sodium Chlorate as a pesticide

Sodium chlorate was banned as a pesticide in the EU in 2008. As such, residues in infant formula (IF), follow-on formula (FOF) and Foods for specific medical purposes (FSMPs) do not arise from use as a pesticide and we have no evidence of unapproved or inappropriate use as a pesticide. As this new definition of pesticides includes substances which have previously been used as a pesticide, chlorate is technically required to comply with the 0.01mg/kg limit. However, chlorate is currently present in infant formula and a recent survey has shown chlorate to exist above 0.01mg/kg due to unavoidable causes.

Sodium Chlorate in IF/FOF

Chloride residues in IF and FOF can be accrued along various steps in the development of the final product. Chlorate residues may come from:

¹ 'Biocides in Cleaning and Disinfection — Working Document', Food & Biocides Industry Group (October 2016), <https://www.chilledfood.org/wp-content/uploads/2018/08/Biocides-Cleaning-and-Disinfection-working-document-industry-guidance-18-10-16-with-updated-best-practice-example-FBIG-logo-in-progress.pdf>.

² 'Chemicals in Food Hygiene, Volume 1: The optimal usage of cleaning agents, sanitisers and disinfectants to minimise the risk of traces in foods', GFSI. <https://mygfsi.com/wp-content/uploads/2019/09/Chemicals-in-Food-Hygiene-Volume-1.pdf>

Raw material producer: Processing water, including for cleaning and disinfection
Detergents/ disinfectants used for GMP purposes
Washing soy beans for soy IF/FO, in water which is chlorinated

Food Producer: Ingredient water (municipal/factory)
Processing water, including for cleaning and disinfection
Detergents/ disinfectants used for GMP purposes

Consumer: Water for reconstitution at home

In October 2016, relevant industry stakeholders developed a roadmap to reduce chlorate in foods for infants and young children and FSMPs. The objective of this roadmap was to reduce the levels of chlorate to the lowest achievable level. The achievement of a reduction in chlorate in the final product requires addressing the use of chlorinated water along each of the production steps. It must also be recognised that microbiological safety of foods for IYC must not be compromised.

At the outset in 2015, the level of chlorate in ready to consume IF, FOF and FSMPs was 1.24 mg/kg. With the mitigation efforts of the sectors, the level was reduced to 0.03 mg/kg by the end of 2020, however, mitigation measures across the sectors will not allow a reduction below 0.01 mg/kg. Further reduction will be very challenging mainly due to potable water in the IF FOF supply chain, and concentration factors in key ingredients. This is especially relevant in the case of FSMPs considering the technological issues that the suppliers are facing when the process needs pH adjusters (KOH, NaOH) in addition to potable water.

The HSE has previously acknowledge that it is not possible for food business operators to control residues in supplied or extracted water and the use of biocides during crop and food production is an essential microbiological safety measure, and the microbiological safety of food must not be compromised. We agree with this and are concerned that further reductions risk microbial contamination along the chain. This would be unacceptable from a human health perspective.

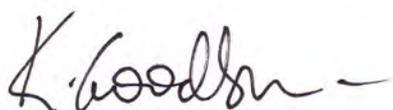
We would propose that the definition of a pesticide in Article 3 2. (c) of Regulation 396/2005 need to be changed to read:

‘pesticide residues’ means residues, including active substances, metabolites and/or breakdown or reaction products of active substances ~~currently or formerly~~ used in plant protection products as defined in Article 2, point 1 of Directive 91/414/EEC, which are present in or on the products covered by Annex I to this Regulation, ~~including in particular those which may arise as a result of use in plant protection, in veterinary medicine and as a biocide;~~

We therefore would disagree with introducing into UK IF/FOF legislation, an amendment with acknowledged flaws and failings.

We would be happy to discuss the issues with you, and provide further information as required.

Yours sincerely



KARIN GOODBURN MBE
Chair - FBIG