

**SUBMISSION FROM THE FOOD & BIOCIDES INDUSTRY GROUP ON EU DDAC PROPOSALS**  
**10 September 2022**



[www.chilledfood.org/FBIG](http://www.chilledfood.org/FBIG)

**DRAFT EC REGULATION (SANTE/10090/2022 REV. 5 [...] (2022)) AMENDING ANNEXES II, III, IV AND V TO REGULATION (EC) NO 396/2005 AS REGARDS MRLS FOR BENZALKONIUM CHLORIDE (BAC) AND DIDECYLDIMETHYLAMMONIUM CHLORIDE (DDAC) IN OR ON CERTAIN PRODUCTS**

The Food and Biocides Industry Group (FBIG) is a group of some 20 UK trade and professional organisations from the entire food chain working together to secure:

1. Continued ability for Food Business Operators (FBOs) to responsibly use effective hygiene biocides
2. A rational basis for the regulation of biocides
3. Recognition of FBOs' need to be able to protect hygiene for public health
4. A full risk assessment of impacts of the EU's biocide regulation review on hygiene including water
5. Regulation of non-pesticide use of hygiene biocides under contaminants legislation and not that relating to Plant Protection Products (PPP), e.g. EU Regulation 396/2005
6. No 'gold plating', e.g. going beyond scope of legislation applying to end products (foods) not listed in 396/2005
7. Clear enforcement guidance and rationale

These new EU proposals to halve the current 0.1mg/kg MRL for products of plant origin for DDAC are a continuation of its inappropriate approach to applying PPP law to hygiene biocides.

We have worked for almost a decade seeking that the EU address this misapplication of legislation to hygiene biocides. We have developed a range of practice guidance on hygiene biocide traces for industry from farm to final food, which is freely available from [www.chilledfood.org/FBIG](http://www.chilledfood.org/FBIG) and replicated internationally in GFSI guidance<sup>1</sup>.

The EU's legislative approach is an inherent anomaly as it means that the use of DDAC as hygiene biocides will be impacted, potentially challenging microbial food safety as the use of these substances is as hygiene biocides on surfaces. Although the importance of protecting food and water safety for public health has been recognised by the European Commission (Regulation 2020/749) non-PPP use of hygiene biocides should fall under contaminants legislation.

We would also highlight that the definition of a pesticide in Article 3 2. (c) of EU Regulation 396/2005 needs 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;~~*

That the EU is not however currently proposing to also reduce the temporary MRL for DDAC for products of animal origin reflects their outward appreciation of the vital role hygiene biocides have in assuring food safety.

Hygiene biocides such as DDAC are used on surfaces and equipment in food production to ensure microbiological safety and to prevent the contamination of food during the production process. DDAC and other quaternary ammonium compounds are extremely low toxicity to humans<sup>2</sup>, highly effective (e.g. versus *Listeria monocytogenes*) and affordable

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<sup>1</sup> Chemicals in Food Hygiene. Volume 1: The optimal usage of cleaning agents, sanitisers and disinfectants to minimise the risk of traces in foods. GFSI

Chemicals in Food Hygiene. Volume 2: Cleaning agents, sanitisers and disinfectants in food businesses: detection of traces and human risk assessment processes, GFSI

<sup>2</sup> Human health hazard assessment of quaternary ammonium compounds: Didecyl dimethyl ammonium chloride and alkyl (C12–C16) dimethyl benzyl ammonium chloride. Luz, A., DeLeo, P, Pechacek, N, Freemantle, M. doi.org/10.1016/j.yrtph.2020.104717

compared with alternatives. Elimination of disinfectant traces (not residues since they are not used as PPPs) 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 or notably more expensive in comparison to the current agents which have proven to be efficient in maintaining the high microbiological standards and requirements for foods as well as in the supply chain of the ingredients. In addition, these agents are safe to handle in manufacturing plants.

Both the European Commission and the UK Health & Safety Executive have previously acknowledged that it is not possible for FBOs to control traces of hygiene biocides in supplied raw materials, that their use during food production is an essential microbiological safety measure, and that 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 therefore disagree with the introduction of amended legislation, which is an amendment with acknowledged flaws and failings, and a technical barrier to trade.

**FOOD & BIOCIDES INDUSTRY GROUP**

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