

ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD
DISCUSSION PAPER

Changes to plant protection product and biocide MRLs: potential impact on food safety

Issue

In October 2015 the Food Standards Agency (FSA) brought to the attention of the Committee the changes to maximum residue levels (MRLs) for two quaternary ammonium compounds (QACs) which are used as disinfectants/sanitiser in the food industry (paper ACM/1197 refers). These MRLs are established under the Plant Protection Product (PPP) Regulations, for which Defra is the UK lead and the Health and Safety Executive (HSE) the enforcement body. The MRLs are set at much lower levels than would be considered necessary for food safety purposes. It was highlighted that industry has raised concerns, shared by FSA, that this may have implications for food hygiene and safety because food businesses concerned about possible breaches of the new MRLs could change their existing disinfection procedures to methods that are less effective.

Another issue relating to MRLs for members' attention concerns chlorate. Use of chlorate as a herbicide was previously authorised under PPP Regulations but its use is now banned and a default limit of 0.01mg/kg consequently applies to all foods. However, because chlorate occurs as an impurity in chlorine-based disinfectants and is also a by-product of water treatment, there are many potential sources for chlorate in food and there have been numerous exceedances of the default MRL. By agreement with the European Commission, enforcement action is not being taken on these exceedances. Revised MRLs for chlorate are currently under discussion in Standing Committee. The food industry has raised concerns, shared by FSA, that if the new MRLs are too restrictive this could curtail the use of chlorine-based disinfectants throughout the food and water industry. This has the potential to impact on the microbiological safety of food if they are replaced by less effective products or procedures.

Finally, the use of other biocidal active substances is under review. In the case of biocidal actives that are already regulated under PPP regulations, a problem similar to that with QACs may arise, which could further restrict the availability of disinfection products. For single-use biocidal actives, new MRLs will be established under the Biocidal Products Regulations, for which HSE is the key government lead. The FSA is concerned that new MRLs may be set without sufficient regard to the need to maintain microbiological safety.

As a consequence of these issues, the food industry has undertaken to produce new guidance on hygiene and disinfection practices, which will be by a food and chemical industry stakeholder group coordinated by FSA and HSE.

In view of the issues raised above and the potential implications for food hygiene and safety, the FSA would like to Committee to consider these changes in relation to risk to the microbiological safety of food.

Background

QACs

1. Two types of QAC, didecyldimethylammonium chloride (DDAC) and benzalkonium chloride (BAC) are commonly used as disinfectants and sanitisers in food processing facilities because of their biocidal properties. These are also listed as Plant Protection Products (PPP) and therefore fall within the scope of EC Regulation 396/2005¹, irrespective of their actual function in food processing.
2. Residues of QACs were previously detected in a broad range of foods, notably prepared fruit and vegetables, above the default MRL of 0.01 mg/kg set out in Regulation 396/2005. In the absence of a concern for health, a temporary guideline level for QACs of 0.5 mg/kg was agreed by the European Commission in 2012.
3. This guideline level has now been replaced by a new MRL of 0.1 mg/kg through Commission Regulation 1119/2014. The new MRL applies from 12 August 2015 to all food produced after that date and at any stage of the food supply chain. The Health and Safety Executive (HSE), as regulator for plant protection products, has written to the industry stakeholders to outline its regulatory approach, which will include enforcement of the new MRLs at all stages up to retail². In addition, the FSA has written to local authorities to draw their attention to industry concerns about potential food safety risks associated with the new MRLs.
4. Many food manufacturers have chosen to no longer use QACs for disinfection/sanitisers as they are concerned about breaching the MRL. Alternative products are available to control microbial growth but there is an expense for manufacturers in switching products.
5. The food industry has warned that changes to disinfection and sanitisation practices in food processing facilities may lead to a compromise of microbiological food safety citing, for example, that rinsing food contact surfaces with potable water to remove biocidal residues could lead to an increased growth of *Listeria* spp. However, the industry has yet to provide firm evidence of such

¹ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1442336915087&uri=CELEX:02005R0396-20150116>

² Available at <http://www.pesticides.gov.uk/Resources/CRD/Migrated-Resources/Documents/L/Letter%20to%20QAC%20Stakeholders%20re%20enforcement%20of%20MRLs%20-%20Aug%202015.pdf>

risks and therefore there is no data currently available to share with the Committee.

Chlorate

6. Chlorate (ClO_3^-) is a low-level by-product from the use of chlorine-based chemicals in the drinking water disinfection process. Sodium and calcium hypochlorite, chlorine dioxide and chlorine gas are often used for disinfection of drinking water. No maximum levels for chlorate in drinking water have been set in the European Union (EU) but the World Health Organisation (WHO) has established a guideline level for chlorate in drinking water of 0.7 mg/L. In the UK, the Drinking Water Inspectorate (DWI) applies a guideline level of 0.5 mg/L.
7. At the beginning of 2014, a German monitoring study found 20% of 600 food samples contained residues above the default MRL of 0.01 mg/kg with most of the exceedances being in fruits and root vegetables. Illegal use of chlorate as a herbicide is highly unlikely. Use of chlorine-treated water during washing and processing seems the most likely reason for the elevated levels.
8. The available data for chlorate in food was submitted to the European Food Safety Authority (EFSA) in 2014 by the Commission, with a request for a Scientific Opinion. The Opinion, which was published in June 2015, concluded that controls on chlorate levels in food would have a minimal effect in most age groups but that current levels of exposure were a potential concern for younger age groups with mild or moderate iodine deficiency. The critical effect for chronic exposure to chlorate is the inhibition of iodine uptake. Thus, there is a chemical safety risk associated with chlorate that needs to be managed.
9. The Commission tabled revised, higher MRLs at the residues section of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), but data from the UK and Germany among other Member States suggest that these would still often be breached. A concern is that, in trying to reduce chlorate levels in food, UK producers will stop using proven and effective chlorine-based disinfectants and sanitisers. Thus measures to manage the chemical safety risk associated with chlorate may lead to an increased risk of microbiological contamination and possible food poisoning. The Commission is aware of these potential consequences and now favours a more pragmatic approach. HSE and FSA are engaging with the food and biocide industries to keep them informed of developments, to seek data supporting the unavoidability of chlorate and to clarify the likely levels of occurrence in all types of food.
10. A timescale for resolution of the chlorate issue has not been fixed. However, there is some urgency because the default limit of 0.01 mg/kg is still legally applicable, although the Commission has left it to the discretion of individual Member States whether or not to enforce it. Chlorate will be discussed at the February meeting of the residues section of SCoPAFF with the earliest possible date for a vote on new MRLs in April. The Commission has also expressed its intention to go out to a wide stakeholder consultation but, again, there is no firm timetable.

Biocide MRLs

11. At present, biocidal active substances that already have a regulated use under PPP, Veterinary Medicine or other legislation relating to food (for example Additives or Food Contact Materials regulations) will continue to be controlled under those regulations. For example, for 'dual use' pesticides the MRLs established under PPP regulations will apply to the active substance whatever its actual use. This was the case for the QACs and similar problems to those encountered for the QACs are envisaged for any other PPP active substance that is used as a biocide.
12. In the case of biocidal active substances to which no other regulations apply ('single use' biocides), MRLs do not currently exist. There is a provision for these to be established under the Biocidal Product Regulation (BPR)³, although the BPR does not stipulate the process for setting the levels. The current thinking within the Commission is that the MRLs can be implemented under the procedure for contaminants in food (Regulation 315/93⁴). This approach is supported by the UK but is opposed by some Member States who favour following the PPP Regulations, which are likely to be much more stringent. The same Member States take the view that the starting principle should be that no detectable residue should be present. In any event, the process for establishing appropriate levels is currently under discussion.
13. The timescale for setting the new MRLs is longer than that for resolving the chlorate issue. The Commission hopes to reach agreement with Competent Authorities in March 2016 on an interim procedure to be followed to establish the MRLs. Those supporting the review of biocidal active substances must submit dossiers on the active substances in accordance with EU Regulation 1062/2014⁵ on the work programme for the systematic examination of all existing active substances contained in biocidal products. For the active substances for use in the product types identified as more prone to lead to the presence of residues in food or feed, dossiers should already have been submitted. Depending on the product type, assessments of the dossiers is scheduled to be completed by the end of 2015 or 2016, and preparation of the opinion on approval of the active substances is scheduled to begin no later than three months later.

³ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, available at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0528&from=EN>

⁴ Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food, available at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31993R0315&from=EN>

⁵ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council, available at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R1062&from=EN>

14. UK food production appears to differ to the rest of Europe, with a greater reliance on the use of disinfectant/sanitiser to control microbial contamination of food and food production facilities. This may be because the UK has a much larger chilled food manufacturing sector than the rest of Europe and as a result more stringent controls. It is possible, therefore, that other Member States have less concern about the implications of limiting biocide usage, although there are indications, at least from the most recent chlorate discussion at SCoPAFF, that a number now share the wider concerns that the UK has expressed about food poisoning risks.

Action

15. The Committee is invited to:

- a) identify the microbiological risks/consequences of the use of biocides in food production, including: -
- Overuse/underuse of biocides in food production (including disinfectants/sanitiser)
 - Limiting the number of biocides which can be used in food production (including disinfectants/sanitiser)
- Specifically to identify the risks associated with the presence of chlorate in food including: -
- how the restriction of disinfectants for which chlorate is a by-product would impact on microbiological safety
 - Toxicological evaluation of UK population exposure to chlorate from food and water sources
- To provide expert advice as necessary as the food and biocidal chemical industries work together with FSA to produce new guidance on disinfection and sanitation processes for food production
- In order to enable a full discussion of the above issues the Committee may wish to set up a working group to address these changes to MRLs for QACs and chlorate and the future MRLs for biocides. As the areas of concern goes beyond microbiological food safety membership of the suggested working group could be extended to relevant expertise from the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), Expert Committee on Pesticide Residues in Food (PRiF) and any other expertise needed on the proposed group.

Secretariat
January 2016