ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD

PESTICIDES RESIDUES MAXIMUM RESIDUE LIMITS – POTENTIAL IMPACT ON FOOD SAFETY

- 1. The issue of changes to maximum residue limits (MRLs) for quaternary ammonium compounds (QACs), chlorate and biocidal actives which are used as disinfectants/sanitisers in the food industry was originally brought to ACMSF in October 2015. The Committee at its January 2016, January 2017 and January 2018 meetings have had discussions on these changes and the impact it might have on the food industry. Industry representatives present at the above meetings have expressed their concern about the changes. Records of the Committee and industry's views are attached at annex 1.
- 2. At the January 2018 ACMSF meeting members were informed that, as this issue is cross-cutting, a meeting was being planned between the Chairs of the ACMSF and the Expert Committee on Pesticide Residues in Food (PRiF) to consider the concerns both committees have on this subject and agree a possible way forward. The meeting (teleconference) took place on 18 April. Some of the points from the teleconference include:
 - Need for increased pace in addressing consumer safety concerns relating to changes to pesticides residue MRLs
 - Endorsement of the proposed joined-up approach to tackle the complexities that have been raised concerning the new rules on QACs and proposed changes for biocides and chlorate
 - Significance of both Committees having access to available data on this subject in order to be able to assess the effect of changes occurring in process hygiene control systems
 - Liaison with industry in defining the areas that are at risk
 - Asking industry to provide a clear picture of the areas of concern (see proposed questions below).
 - What are food businesses using if they have stopped using QACs?
 - In what food contexts are chlorine-based disinfectants used and what alternatives exist?
 - How are food businesses achieving an acceptable balance between microbiological and chemical safety i.e. what steps do they take to minimise residue levels without compromising microbiological safety?
 - What monitoring or additional information is necessary to ensure that changes in biocide usage do not increase the risk of food poisoning?

- 3. The aim is to put these questions to industry and the responses would be used to devise the next steps.
- 4. FSA's update on the issues relating to chlorate and biocides is at annex 2.

Secretariat May 2018

EXTRACT OF ACMSF MEETING MINUTES HELD IN OCTOBER 2015, JANUARY 2016, JANUARY 2017 AND JANUARY 2018

MINUTES OF THE EIGHTY-SIXTH MEETING OF THE ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD HELD ON 1 OCTOBER 2015

Changes to plant protection product maximum residue levels (MRLs): potential impact on food safety

The first time ACMSF's attention was drawn to the above issue was at its 1 October 2015 meeting (via an information paper¹). The Committee was informed about the changes to MRLs for two quaternary ammonium compounds (QACs) which are used as disinfectants/sanitisers in the food industry.

A member commented that the food industry has raised concerns that this may have implications for food hygiene and safety. Members agreed that it was timely to give this issue some thought now and revisit it at a future meeting. The Chair suggested that the Committee may have to set up a subgroup to carefully examine the areas of concern when this subject is formally brought to ACMSF.

Public Questions and Answers (members of the public that attend ACMSF)

The Chair invited observers to make any comments or ask any questions on the risk assessment work of the Committee.

Peter Littleton, Technical Director of Klenzan, a manufacturer of detergents used in catering and food processing environments, also a member of the Chilled Food Association's Biocides Working Group commented that there was great anxiety in the industry about the possible changes to plant protection product MRLs. He said there was a real risk to the microbiological integrity of food in catering and prepared food market where there were Listeria risks. There has been a drop in the sales of some QACs over the last year or so, with customers switching to other products because of a misunderstanding that QACs were banned. He highlighted various problems: some alternative disinfectants were unsuitable for food processing environments; there were restrictions because of Biocide Products Regulations; the cost of producing new biocides. He encouraged the Committee to engage with the Chilled Food Association and to raise the issue with EFSA because of the risk to the microbiological safety of food.

¹ https://acmsf.food.gov.uk/sites/default/files/acm_1197_changes%20to%20mrls.pdf

MINUTES OF THE EIGHTY-SEVENTH MEETING OF THE ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD HELD ON 29 JANUARY 2016

Changes to plant protection product MRLs: potential impact on food safety (update provided to the Committee at the 29 January 2016 meeting)

At the October 2015 meeting members had been alerted to changes to maximum residue levels (MRLs) for two quaternary ammonium compounds (QACs), chlorate and biocidal actives which are used as disinfectants/sanitisers in the food industry. The Chair invited Adekunle Adeoye to present paper ACM/1207² which gave further information about this issue (second time issue came to the Committee).

Mr Adeoye outlined the main issues. The first was that the new maximum residue levels now in place for QACs are set at much lower levels than would be considered necessary for food safety purposes. Both food industry and the FSA are concerned that food businesses, concerned about possible breaches of the new MRLs, could change their existing disinfection procedures to methods that are less effective.

Secondly, the use of chlorate has now been banned and a default limit of 0.01mg/kg applies to all foods. However, because chlorate occurs as an impurity in chlorinebased disinfectants and is also a by-product of water treatment, there are many potential sources of chlorate in food and there have been numerous exceedances of the default MRL. Revised MRLs for chlorate are under discussion at the EU Standing Committee, but there are concerns on the impact of microbiological safety of food if less effective products start to be used. Chlorate will be discussed at the February meeting of the residues section of the Standing Committee (SCoPAFF) with the earliest possible date for a vote on new MRLs in April.

The third issue to bring to Members' attention was that the use of biocidal active substances is under review and new MRLs are to be established under the Biocidal Products Regulations. The FSA is concerned these may be set without sufficient regard to the need to maintain microbiological safety. The EU Commission hopes to reach agreement with Competent Authorities in March 2016 on an interim procedure to be followed to establish the MRLs.

Mr Adeoye highlighted a number of questions posed to the committee in the paper and asked for comments on the suggestion that a working group be set up to include wider expertise from the Committee on Toxicity (COT) and the Expert Committee on Pesticide Residues (PRiF) to enable a full discussion to take place.

Members commented as follows:

 from talking to the food industry it was clear that there was a great deal of concern about this issue as people are moving away from QACs and alternative products may be more costly. As the paper mentions, due to the large chilled food manufacturing sector, the UK seemed to be disproportionately affected by the changes.

² https://acmsf.food.gov.uk/sites/default/files/acm_1207_mrls.pdf

- Changes that were justified with regard to pesticides had had unintended consequences in the food industry where products are used for disinfection.
- Rinsing off any excess substances was not an option in a chilled food environment where there was a need to minimise the presence of water.
- The current situation could provide an opportunity for reinforcing the use of disinfectants in an appropriate, risked-based way.
- Any further work would need a good scoping process as the issues presented an enormous risk assessment task with many hazards and risks that are linked together.

In summing up, the Chair said there was agreement that this was an important subject and there was support for investigating it further but there was a need to include expertise from other Scientific Advisory Committees. It was acknowledged that it was potentially a huge task there was a need for careful scoping.

Mr Kyriakides, Prof McClure, Dr Barker, Dr Betts and Mrs Morris agreed to be part of a group to scope out how this work could be taken forward.

Public Questions and Answers (members of the public present at the meeting)

The Chair invited those observing to make any comments or ask questions on the risk assessment work of the committee. Peter Littleton, from Klenzan, commented that some of the alternatives to biocides are 3-8 times more expensive and there appears to be a trend away from using biocides. He said there was a huge problem because 80% of disinfectants that was used in food processing, including catering, were QAC-based. He reported that work was being done by chemical suppliers to collect data on volumes of disinfectants that could be going into the industry and to find out how much was being used as a general environmental spray and how much on food contact surfaces, to feed in to the FSA. He welcomed the idea of a working group and best practice guide.

Bridgette Clarke of Bakkavor also welcomed the proposed work on biocides and stressed the urgency as chemicals used in food production were already being changed and this brought with it the need for re-writing cleaning schedules and retraining of staff. She also pointed out that historically chlorine had been used to wash produce.

Gary McMahon, from Moy Park, reiterated that the problem with the change from chlorine based chemicals was urgent. Jo Head, an independent consultant asked what might be done in future to avoid unforeseen circumstances such as the MRL's issue. The Chair acknowledged that this was a challenge and there was a need to keep our ears to the ground as much as possible and to gather intelligence from all kinds of places in order to try not to be taken by surprise, but from time to time it was inevitable that things would emerge that had not been foreseen. A member of the Committee commented that when undertaking horizon scanning perhaps there was a need to look not just at newly emerging risks but also where old things might change. Bridgette Clarke said that there were often multiple risks involved in food factories, that were not just microbiological and it could be helpful when horizon scanning to include input from wider areas such as allergens and fraud. The Chair said she had suggested to the FSA's Chief Scientific Adviser that horizon scanning should be done across the Scientific Advisory Committees rather than working in silos. Peter Littleton mentioned that there were examples of large scale microbiological problems where disinfectants have not been involved, including one in Scotland where a chemical was described as biodegradable and this was misunderstood as meaning that it killed bugs. He said there were only about 4 chemicals that had a viable future for food processing environments and some of these do not have a good toxicological profile. Research had suggested that rinsing of food contact areas effectively to comply with the proposed MRLs would need to involve high pressure hot water which was not feasible in a chilled food environment.

MINUTES OF THE NINETIETH MEETING OF THE ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD HELD ON 26 JANUARY 2017

Changes to plant protection product and biocide MRLs: potential impact on food safety (update provided by the FSA)

Dr David Mortimer (FSA Food Policy) was invited to update the Committee on progress concerning several inter-related negotiations including the amendment of chlorate MRLs (first tabled by the Commission in 2015), the development of a procedure for setting biocide MRLs (under consideration since 2013) and finalisation of the legal definition for endocrine disrupting chemicals (EFSA opinion was published in 2013), all of which could impact on the availability and use of disinfection products for food and feed processes (third time Committee considered issue³). Dr Mortimer pointed out that the lead government departments on the above subjects were the Department of Environment, Food and Rural Affairs and the Health and Safety Executive.

ACMSF had been alerted to the issue of changes to MRLs for two quaternary ammonium compounds (QACs), which are used as disinfectants/sanitisers in the food industry, and about negotiations on chlorate (a contaminant in chlorine-based sanitisers) and biocidal actives at previous Committee meetings held October 2015 and January 2016. The Committee had agreed to the FSA's suggestion to setup a cross Scientific Advisory Committee working group to facilitate a full discussion, although this had been put on hold by the Agency in order to clarify the remit of the working group.

Concerning the new MRLs that came into force in late 2014 for QACs, members noted that the FSA has not received any reports from the food industry highlighting specific problems arising from restrictions in the use of QACs due to the low MRLs.

Dr Mortimer reported that the Commission's original proposal for revised chlorate MRLs had attracted a number of comments, notably that they were too low and too complex, but there was no consensus amongst Member States and the Commission had not come back with a fresh proposal. The Committee agreed with the FSA's concerns about the potential impacts on microbiological safety if the use of chlorine-based sanitisers were to be restricted, the difficulties in controlling chlorate levels in potable water used for processing and the possible high rate of non-compliance of a wide range of foods if MRLs were set at too low a level.

³ https://acmsf.food.gov.uk/sites/default/files/acm_1244_mrl.pdf

On the Interim Procedure for Setting Biocide MRLs which has been under consideration since 2013, the Committee noted that there have been several revisions to the Commission's proposed procedure. Dr Mortimer explained that, although the Commission favours a proportionate and risk-based approach with MRLs for active substances being established under contaminants regulations, a number of Member States prefer the hazard-based approach in line with that taken for pesticides.

Following the update the Committee observed that there is not yet a consensus among Member States on the proposal for revised chlorate MRLs, or on the process for setting biocide MRLs and that the EU proposals on criteria for endocrine disruptors are still under discussion. Members agreed with the FSA's concerns about the potential impacts on microbiological safety if the use of disinfection and sanitisation products were to be restricted through setting MRLs at too low a level or by a total ban on the use of certain active substances.

The Committee agreed to explore the availability of evidence in relation to microbiological food safety that can be employed by the FSA to underpin its position in its negotiation with other Member States and the European Commission. A few members (to be led by Dr Dan Tucker) were asked to meet together to suggest the types of data that would be available that might show that changes are occurring in process hygiene control systems. Members welcomed the opportunity to be involved in any forthcoming FSA stakeholder meeting on this subject, along with the Pesticide Residue in Food (PRIF) Expert Committee. The Committee requested further updates on this issue.

Response to above action

Following investigation, the members asked (Dan Tucker, Gwen Lowe and Heather Lawson) to consider what types of data could be available that might show that changes are occurring in process hygiene control systems recognised this was an impracticable exercise as they could not readily identify any data source that could be used for a comparison of different cleaning products. The members also questioned the validity of such a before and after comparison of industry routine data in a working environment that was not controlled scientifically. It was agreed that any data in relation to the above would potentially be difficult to interpret.

Public Questions and Answers (members of the public present at the meeting)

Kaarin Goodburn from the Chilled Food Association and the Food and Biocide Industry Group asked if Members of ACMSF could engage with European contacts on the issue of biocides as currently there was a greater focus on chemical rather than microbiological safety. She said there had been difficulty getting understanding of the issues amongst other Member States. She also asked if the ACMSF could ask the FSA, Defra and other appropriate government bodies to set out the UK's future regulatory options to protect food hygiene in the light of the UK's exit from the EU. The Chair said that it would be possible to find out what EFSA's BioHazard Panel was doing with regard to MRLs. It was suggested that PHE could raise the issue with ECDC because it was likely that sister organisations around Europe would have similar concerns. It was also mentioned that the issue was being discussed by ACNFP.

MINUTES OF THE NINETY-FIRST MEETING OF THE ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD HELD ON 25 JANUARY 2018

Matters arising

Changes to plant protection product and biocide maximum residue limits: potential impact on food safety (exploring the availability of evidence in relation to microbiological food safety that can be employed by the FSA to underpin its position in its negotiation with other Member States): it was noted that the investigation to consider what types of data could be available that might show that changes are occurring in process hygiene control systems produced no result.

Paul Cook informed members that as this subject is cross cutting (with microbiological and chemical risk angles), a meeting had been proposed between the Chair of the Pesticides Residues in Food Committee and the ACMSF Acting Chair. A member requested for increased pace in the consideration of this subject because of the challenge these changes are presenting to industry from a microbiological food safety perspective. A member shared that recent material he had seen on this subject revealed that there was competition between chemical and microbiological risk and that chemical risk appears to have been given precedence. Members endorsed the proposed joined-up approach in tackling the complexities of the issues relating to these new and proposed additional rules.

Public Questions and Answers (members of the public present at the meeting)

Brigitte Clarke, from Bakkavor, stressed the urgency of the meeting between the pesticides residue committee (PRIF) and ACMSF because the industry had been talking about the issue for 2 years now and were finding it difficult to carry out various things in a factory setting such as trying to segregate allergens, and to prevent cross-contamination of meat species, because preservatives and other substances such as disinfectants could not now be used. The Chair said that her comment was valid and a number of members of the committee shared her concern. Dr Cook added that it was hoped that the meeting would soon take place and that it would be possible to provide an update at the next meeting.

Update from the FSA on Chlorate and Biocides

Issues

- 1. Some biocidal active substances may have their use restricted due to previous use as plant protection products
- 2. Regulation of chlorate as a former plant protection product may lead to restrictions on the use of chlorine-based disinfectants for food hygiene purposes
- 3. The forthcoming imposition of biocide MRLs may require food businesses to modify their disinfection and sanitisation procedures

Background

<u>Issue 1</u> has already been illustrated by the case of quaternary ammonium compounds (QACs), which are widely used by food businesses for disinfection, including the control of *Listeria*. Because the same QACs have been used in plant protection products, they fall under the pesticide residue regulations (396/2005) which apply a default maximum residue level (MRL) of 0.01 mg/kg to any non-approved plant protection use. This applies whatever the actual source. Much higher levels than 0.01 mg/kg were being found in a wide range of foods due to the biocidal uses of QACs during food production and it was agreed that the MRL should be raised, although it remained within the remit of the pesticide regulators. The MRL was revised to 0.1 mg/kg, which was still unnecessarily tight from a food safety viewpoint. Difficulties in achieving compliance led some food businesses to change to other disinfectants or disinfection processes. Nevertheless, QACs remain in use although non-compliances are still occasionally being picked up during routine monitoring by PRiF.

A concern now is that a similar problem may arise for other biocidal active substances that can also fall into the PPP category (dual or multiple use of active substances is not unusual – this can also extend to veterinary medicines) and therefore sustain the default MRL of 0.01 mg/kg. Any consequential limitations in the availability of biocidal actives may oblige food businesses to change existing, validated disinfection processes. Reductions in the pool of available actives could also increase the possibility of resistance.

<u>Issue 2</u> is of the most immediate concern. As originally with QACs, a default MRL of 0.01 applies to chlorate in any foodstuff because it was formerly used as a herbicide but is now banned. However, chlorate can arise from many sources including the use of chlorine-based disinfectants such as bleach, and chlorate is also commonly present in drinking water from chlorine-based wastewater treatment (with a current WHO guideline maximum level of 0.7 mg/ml). As a consequence, chlorate is often found in food well above the current MRL. Enforcement has been suspended while the MRL is being reviewed. In 2015, the Commission tabled a proposal for revised

MRLs based on occurrence data but the consensus in Standing Committee was that many of the proposed values were too low to be achievable for food businesses relying on chlorine-based products for disinfection and sanitisation, and overlooked the potential presence in potable water used for food production. The proposal was withdrawn pending the submission of further data. The Commission has now tabled a revised proposal that looks very similar to the original, with the same problems for food businesses foreseen. The Commission has indicated that the proposal will go out to consultation shortly. It is essential that concerns about the impact on microbiological safety are properly addressed so that a detailed and coordinated response can be provided to the consultation and we will need the assistance of ACMSF to achieve this.

<u>Issue 3</u> is a concern over the longer term and is included for information only. It is not a matter for PRiF as it relates only to biocidal actives that are not already covered under other legislation (such as pesticide, vet medicine or food contact material regulations). The Biocidal Products Regulation provides for the setting of MRLs for biocidal active substances in food, although no process is stipulated. A general approach has now been agreed, which will prioritise those where there is a perceived food safety concern. Food businesses will no longer be able to validate their disinfection processes using microbiological criteria alone, but will also need to demonstrate that they have optimised them to ensure that any biocidal active residues are minimised and certainly are below any applicable MRL. The food industry has produced guidance in relation to this and we will be needing feedback on its usage, performance, effectiveness and any problems encountered, a request that could be made through ACMSF.