# British Association for Chemical Specialities (BACS) and the Chilled Food Association (CFA) position paper on MRL setting under the Biocidal Products Regulation

## Background

Article 19(1)(e) of the Biocidal Product Regulation (EU) No 528/2012 requires that Maximum Residue Limits, where appropriate, have been established for active substances contained in a biocidal products.

The meaning of "where appropriate" has not been defined. There are concerns that these limits might be set in an inappropriate manner, at impractical levels and enforced at inappropriate tiers of the supply chain.

A potential for dual regulation exists due to Regulation 396/2005 controlling residues of pesticides in food commodities "...to be used to be used as fresh, processed and/or composite food or feed in or on which pesticide residues may be present.". Some biocides are also listed as controlled pesticides.

## Issues

There a number of questions and issues resulting from inappropriate setting of MRLs, as follows:

1. Certain biocidal actives are already present in food either as naturally occurring molecules, intentionally added ingredients or breakdown products from either of the above. Examples include organic acids, alcohols, hydrogen peroxide and sulphur dioxide. How can MRLs be practically set for these ingredients?
2. For those ingredients which naturally change from one chemical to another, at what point is the MRL enforceable? Examples include sugars fermenting into alcohol and alcohols oxidising into organic acids.
3. For "product in product" foods, what is to be enforced and who is liable? The BPR regulates the disinfectants used in the food industry, not the food itself. If the means of enforcement is by monitoring food for biocide residues, then who would be liable in the case of an assembled food which has gone through multiple processing steps? An example is pepperoni, cheese and tomato assembled to make a pizza. Each component will have been individually processed prior to the pizza being assembled. In each process the disinfectant may have been used correctly, and only a trace of biocide added to the food, but the accumulated residues from the multiple steps may have exceeded the MRL.

4. The enforcement of the Regulation is complicated by the fact that some components of assembled food are present in a form which brings them within scope of Regulation 396/2005. For example, lettuce in a sandwich would potentially be regulated by 396/2005, whilst the disinfectant used in the assembly of that sandwich would be regulated by the BPR. As herbs are listed on Annex 1 of 396/2005 and are used in a wide variety of products, it is possible that most processed foods would contain at least one component regulated under 396/2005. There is significant potential for dual regulation as at least two biocides (BAC and DDAC) are listed as actives under both regulations.
5. The rapid detection methods for biocidal active analysis are not currently available within the food and drink industry. Waiting for batch approval from 3rd party laboratories is neither practical nor desirable with short shelf life foods such as perishable produce. See Annex 1.
6. Validating existing practices to negate batch testing is only practicable where MRLs are set sufficiently above detectable threshold levels. The food and drinks industry makes such a significant variety of products, that validating each one to the limits of detection is not viable. Examples of minor changes which could potentially need re-validating are changing the thickness setting on sliced bread, switching a pepperoni pizza to a ham pizza, changing supplier of cheese. See Annex 2.
7. There may be trade restriction issues. Many foodstuffs originate from outside the EU.
8. Practices, food consumption patterns and the enforcement of food hygiene issues are performed locally within the EU Member States. These can conflict with a pan-European approach to regulation. For example, in some Member States there is a desire amongst enforcers to shorten disinfectant contact times, which will normally lead to greater concentrations of active substances used in the biocidal products. See Annex 5.

<u>Consequences</u>

1. Food safety may be adversely affected. Biocides are used to control pathogens**.** **I**nappropriate restrictions on biocide use may impact negatively on food poisoning outbreaks. See Annex 3.
2. Food waste may be adversely affected. Biocides also control environmental bacteria which are linked to food spoilage. Premature food spoilage results in higher levels of food waste.
3. Negative consumer perception from recalled food. Since real-time analysis of biocides is not possible on food production lines there is a danger of food being found to breach the MRL only once it is in the supply chain. Any such recall should be proportionate to the risk to the consumer.
4. Adverse effect on the biocides market. If one active has an MRL set at a level which does not accommodate the multiple stages of the food supply chain then may it lose favour in the marketplace. This restricts the actives available to the food industry to meet a variety of food hygiene needs. It can also adversely affect the suppliers of disinfectants operating in the downstream stages of the supply chain. This consequence is exacerbated by the potential for dual regulation (see Issue 4 and Recommendations 1, 2 & 3).This consequence is also of particular importance given the impending product freeze. See Annex 4.
5. Adverse effect on the food supply chain, particularly those stages handling produce which has already undergone one or more steps. Many businesses serving fresh produce or multi-

component produce are micro enterprises which simply have no way of analysing the residues in the varied products they offer. See also Annex 4.

Recommendations

The CFA and BACS hold the following views, noting that adoption of the suggestions in points 2 and 3 would negate some of the concerns.

1. Urgent clarification is required on the scope and means of enforcement of both the PPP (396/2005) and the BPR (528/2012) in the case of foodstuffs and biocidal actives which potentially fall under both regulations. It is clear that the means are not available to the Foodservice industry and other sectors to ensure compliance with the PPP for components of composite foods which fall under the scope of Annex I of the PPP.
2. As a solution to Recommendation 1, it is suggested that an exemption under the PPP is applied for residues of biocidally active substances regulated under the BPR in processed and composite foods. Safety will still be assured because the ingredients going into those composite foods will continue to be regulated under the PPP. And the disinfectant used to make the composite product will be regulated under the BPR. But the dual regulation issue will be removed. As a worked example, lettuce would be regulated under the PPP until it becomes a component of a sandwich. At that point, residues of BPR regulated biocides in the lettuce would become exempt under the PPP. The disinfectant used in the process of assembling the sandwich would be regulated under the BPR. The assembler of the sandwich would be obliged to use the disinfectant in accordance with the instructions, which are regulated under the BPR.
3. It is also suggested that the enforcement of disinfectants under the BPR is not conducted by analysing food for biocide residues since those residues may have arisen in prior stages of the food supply chain and not be attributable to the business under inspection.
4. The future efficacy requirements for various product types need to agreed by the member state Competent Authorities responsible for food hygiene substantially before the product authorisation process under the BPR commences.
5. Safety is of paramount concern for the food industry. The risks to safety from biocidally active substances should be considered in tandem with the risks to safety from those pathogens the biocides are intended to control.
6. MRLs should only be set for those operations and actives where risk assessment demonstrates that their use may exceed an acceptable margin of safety. In particular, the CFA and BACS support the tiered approach proposed by Cefic.
7. Impact and risk assessments should be commissioned to adequately consider all the concerns raised in this paper before any MRLs are set.
8. Careful consideration should be given to the workability of any regime to ensure that no size or type of business is set at a significant disadvantage in complying with this legislation.

Annexes

**Annex 1 – Further detail on Issue 4, availability of test methods**

A survey amongst the CFA membership indicated there are 5 known contract laboratories available which can perform the testing for biocide residues.

The cost per test is in the region of £250 for a 24 hour turnaround, or £100 for a result in 10 days.

The equipment necessary to test QACs, the most common active used, is an LC/MS machine costing in the region of £200k. There are also substantial human resources and consumables necessary to operate the equipment.

Limits of Quantification vary. 0.01 mg/kg of QAC has been detected in some produce. But other products, particularly those with high fat or pigment, have not been validated at such low levels.

**Annex 2 – Further detail on Issue 5, composite foods and relationship between MRL and LOQ**

A hypothetical example on the problems caused by having a composite food whereby the MRL is set at a similar level to the LOQ.

Consider a pizza, each of the ingredients will contain different levels of biocide, say 0.01 mg/kg for the tomato puree, 0.07 for the dough and the cheese, 0.04 for the pepperoni. However, the tools might not be available to quantity these levels, analysis may simply show that they are all <0.1 mg/kg. Or, noting Annex 1, it may be that the dough is quantifiable but the biocides in the other components are not quantifiable because the nature of those components interferes with the test method.

The manufacturing process may also add 0.02mg/kg for a deep pan pizza or 0.04mg/kg for a thin crust (by virtue of it having the same surface area in contact with the disinfected food production line but only half the mass). Again, these contributions may not be detectable.

The assembled product may come to 0.09mg/kg and within the MRL.

However, changing the recipe, any supplier, the thickness of the pizza, a different production line etc. may inadvertently raise the level to 0.11mg/kg and above the MRL. It should be noted that the majority of ingredients are seasonal so changes in supplier, including country of origin, will happen frequently.

Even though in this example the figure of 0.11mg/kg should be above the LOQ (it is assumed that no MRL would be set below the LOQ), the equipment to measure the biocide residue to this level of accuracy may still not be widely available. Therefore testing each batch of pizza prior to release is not a viable option. For food producers to be able to comply with the MRL they would need to be able to quantify the contribution from each step and each potential supplier to identify the critical steps which make a significant contribution to the total biocide load. Therefore the tools which can detect biocide levels significantly below the MRL need to be widely available.

**Annex 3 – Further detail on Consequence 1, adverse effect on food hygiene**

With respect to pathogen contamination, the levels of Listeria monocytogenes are still of concern in the UK

http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Listeria/EpidemiologicalData/listeCaseReports19832010/

Listeria monocytogenes causes more deaths in the UK than any other food pathogen and is a target for reduction by the Food Standards Agency.

What is positive is that the rate of listeria related deaths has stabilized in the UK and is now considered to be under control in spite of such a demand for ready to eat food (see Annex 8 explaining why Ready-To-Eat food poses challenges to food hygiene). In mainland Europe however, it is believed that there has been a rise of listeria related contaminations.

http://www.efsa.europa.eu/en/efsajournal/pub/3547.htm

http://wwwnc.cdc.gov/eid/article/14/5/07-1395_article.htm

http://www.foodprotection.org/events/european-symposia/09Berlin/Leclercq2.pdf

This relative discrepancy in the UK having one of the best safety records for listerioris whilst having a disproportionately large market for ready to eat food can in part be explained by the differing hygiene practices in the UK.

In the UK, the most commonly used biocides (DDAC and BAC) are not rinsed off surfaces. This is for 2 key reasons: firstly, DDAC and BAC residues provide a protection against subsequent cross contaminated by pathogenic or spoilage microorganisms. Secondly, there is often insufficient time for the process lines to dry prior to production commencing, bear in mind that in chilled factories surfaces do not dry quickly. In addition, many utensils are cleaned and soaked in DDAC or BAC to preserve their low microbial surface count prior to subsequent reuse. Automated cleaning and disinfection systems, e.g. tray washers, crate washers, also may have a disinfectant application as the last sanitation stage, which is not rinsed off

In the EU the trend is more towards rinsing equipment after disinfection. The rinse would undoubtedly lower the residues of biocides in food (although not necessarily have a material effect on the risk arising from those residues). However, there is a concern that implementing EU rinsing practices in the UK would raise cases of listeriosis not only to the EU average, but possibly higher due to the disproportionately high ratio of ready to eat food in the UK.

**Annex 4 – Further information on Consequences 4 & 5, the effect on the market**

It is not yet known how MRLs will be set and at what tier of the industry they will be enforced. The steps involved in the food chain could include the following:

- Primary food production e.g. farming, abattoirs, packaging of single good such as milk.
- Secondary processing e.g. cheese, tomato puree, bread etc.
- Assembly or production of multi-component products e.g. pizza, ready meals
- Retail of fresh produce, e.g. butchers, grocers, bakers, delicatessens, supermarket counters
- Foodservice e.g. canteens, takeaways, retail of baked goods, sandwich shops, restaurants. Often referred to as HORECA – Hotels, Restaurants and Caterers.

50% of food is sold through the Foodservice sector. There is a degree of geographical variation – Mediterranean countries tend to eat out to a greater extent than Northern European countries.

It is probable that the same biocidal active will be used at several stages of the supply chain. If the MRL is set at a level which is sufficient to cover the needs of only one of the higher stages in the supply chain then products containing that active would potentially not be able to be used in the lower tiers.

The BPR requires that companies make a significant investment in their products (>£100k). It is possible that after making this investment in a safe, efficacious product that the active chosen becomes unusable in the lower tiers of the supply chain due to the MRL being set at a level which only covers uses in the higher tiers.

In addition, the BPR creates effectively a 3 year product freeze at the date the approval of the active substance. In practice, this freeze is probably around 4 years since it takes a considerable amount of time to put together a product dossier to make an application.

It is conceivable that a large food service chain (e.g. fast food, sandwiches, supermarket cheese counter) could conduct a number of tests on a selection of the foods they served. It is also conceivable that after analysis such a chain would require the disinfectant being used in their stores to contain a different active to the primary steps in the food processing, to ensure the accumulated load of disinfectant stays below the MRL. In this case the manufacturer of the food service disinfectant will lose the investment made in supporting that product through the application process. But in addition, that manufacturer will also not be in a position to place an alternative product on the market for a number of years because of the restrictions in placing new products on the market during the dossier evaluation process. In effect, they could be frozen out of the market through no fault of their own.

In the same example, whilst it is conceivable that the large food service chains can conduct a number of tests, it is inconceivable that a local sandwich shop, delicatessen, ice cream van, cafe etc. could perform any meaningful level of testing. In this case, a large proportion of the food being served to consumers will be sold through an outlet which is unable to verify the residues in the food. Even the larger chains will at best be able to conduct a few checks and face the same complexity issues highlighted in Annex 2.

**Annex 5 – Further information on member state activity**

In the UK the Environmental Health Officers (EHOs) are implementing guidance from the Food Standards Agency (FSA) regarding which disinfectants can be used in catering environments. In most cases they implement the guidance as intended, in other cases the EHOs require products with shorter contact times based on modified EN 1276 test data. Currently, EN 13697 is not compulsory.

Some inspectors are producing their own register of 'approved' products which they believe meet the FSA guidance.

http://www.disinfectant-info.co.uk/

It is not known how the guidance will be revised in light of the BPR efficacy requirements. It is not known if short contact times for EN 13697 will also be 'in practice' enforced by EHOs irrespective of the FSA guidance. It is also not known if efficacy against other types of pathogen, such as yeasts, fungi and viruses will also become compulsory. And it is not known what requirements, both official and 'in practice' operate or are planned in other member states

A significant concern is that at the point that the last biocidal active substance has a decision made on its inclusion in the Approved Active Substances List of the BPR, the manufacturer of the formulated product has approximately 2 years in which to submit a dossier supporting his product. The dossier covers both efficacy and also in-depth risk assessments for both human and environmental safety and must go through a regulatory approval process which can also take a significant amount of time, estimated around 3 years. At the point the dossier starts to be compiled the formulation is effectively frozen for a number of years, in practice around 4 years is anticipated.

Therefore if the FSA or the EHOs were to introduce new requirements which are not aligned with the BPR guidance today then the manufacturers would not have the flexibility to update their products and comply.

The problem does not only apply to food area disinfectants. Other product types are commonly in use in the food manufacturing and service industries which are available in biocidal variants. Examples include hand soaps and washing up liquids. It is not known whether use of these products, and to what standard of efficacy, will become compulsory in practice.

As a general rule, higher efficacy requirements leads to greater use of biocides, which then have the potential to become present in trace amounts in the food. The issues of biocide residue and future efficacy requirement need to be resolved before the BPR authorisation program for disinfectants begins.

**Annex 6 – About BACS**

The British Association for Chemical Specialities (BACS) is a UK-based trade association which represents companies operating in the speciality chemicals sector of the chemicals supply chain.

BACS has around 120 members, including multi-national chemical companies, small and medium sized enterprises (SMEs) and sole traders. Member companies include manufacturers of speciality chemical ingredients, fine chemicals, performance chemicals for industrial and consumer use and process aids for industrial applications, together with formulators, distributors, retailers and service companies. Service companies include regulatory affairs consultancies, contract research organisations, providers of analytical and testing facilities, toll manufacturers and companies providing, in addition to chemicals, equipment and technical support. Most members are UK-based but this is not a condition of membership

**Annex 7 – About the CFA**

CFA was formed in 1989 to establish, continuously improve and promote best hygienic practice standards in the production of retailed chilled prepared food. CFA represents many of the leading names in UK chilled prepared food production, predominantly supplying the retail trade.

- Develop and promote common standards of safety and quality in the production and distribution of chilled prepared foods
- Represent the key interests of manufacturers of chilled prepared foods in their formal dealings on major issues with regulatory bodies and with other relevant groups
- Safeguard the industry as a whole by providing a common view and voice
- Co-ordinate with organisations and other groups having related interests
- Promote a favourable environment for the marketing of chilled prepared foods in the long term

**Annex 8 – About the UK Chilled Food market**

Currently, member companies of the CFA produce more than 7,000 different chilled prepared foods, mostly every day, such as:

Recipe Dishes/ready meals
Meal Accompaniments
Fresh Pasta
Chilled Pizza
Delicatessen Products (e.g. samosas)
Prepared Vegetables
Salad
Dressed Salads
Dressings
Dips
Sushi
Chilled Soups

Chilled Sauces
Pies, Flans and Quiches
Sandwiches
Sandwich Fillings
Desserts
Prepared Fruit
Fresh Juice

All of these foods need to be kept chilled to meet their shelf lives.

Around 2/3rds of the EU chilled food market is in the UK.

The UK chilled food sector is unique because UK chilled foods are:

1. Unpreserved - hygiene and safety is critical, assured by:-

    - HACCP from farm to fork
    - Traceability of raw materials
    - Temperature control
    - Short shelf life

2. Generally multicomponent, e.g. pizzas, sandwiches, ready meals, soups, salads

3. Prepared:-

    - Ready to eat
    - Ready to reheat
    - Ready to cook

4. Made to order:-

    - JIT (just in time) systems - short production runs
    - Often made on the day of delivery to retailers
    - Made of seasonal raw materials, but production is year-round so we use pan-global sources meeting UK standards

5. >95% retailer own label foods - manufacturers have exceptionally close partnerships with retailers

The lack of preservation and the assembly of large numbers of ingredients make chilled and ready to eat food a higher risk to food safety.