The Society of Food Hygiene and Technology

EU Microbiological Criteria Regulations 2073/2005 and Ready to Eat Foods' Shelf Life in Relation to L. *monocytogenes*

There are differences at European level regarding enforcement of the Microbiological Criteria Regulations which came into force in January 2006, however, many companies may still be unaware of the consequences of the new legislation, which simply sets criteria to be used as part of HACCP.

Microbiological Criteria Regulations

The European Union (EU) Microbiological Criteria for Foodstuffs Regulations (MCFR) were published on 22 December 2005 and came into force in January 2006[1]. The MCFR relate to the package of new EU hygiene regulations that also came into effect at that time, and to the General Food Law Regulation 178/2002.

There is nothing fundamentally new for a company applying HACCP (European Commission):

"The Regulations do not bring any new obligations or new administrative requirements for food businesses and do not cause additional costs for food businesses"[2]

What it's NOT about – myths

- **Increased sampling of foods even where HACCP is in place**
  - *NO! - no change proposed to current HACCP-based approaches*
  - *BUT specified sampling frequency for minced meat/preparations etc (1 product per site per week)*

- **I have to test every batch**
  - *NO! - frequency is HACCP-based except for minced meat/preparations* etc

1. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005R2073:EN:NOT
2. http://ec.europa.eu/food/food/biosafety/salmonella/discussion_paper_en.pdf

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- **5 samples need to be tested per batch (e.g. RTE foods)**
  - *NO! - compositing is allowed for between comparable lots*
- **Positive release is required**
  - *NO! – using functioning HACCP-based systems is required*
- **Challenge testing required to demonstrate safe shelf life**
  - *NO! - hierarchy of approaches is set out in the Regulation*
- **Testing emphasised over control – diverts resources**
  - *NO! – having functioning HACCP-based systems is the key legal requirement*
- **It all means extra work for labs**
  - *NO! – no change if sampling is already HACCP-driven*

Reduced emphasis on controls?

There is no reason for microbiological testing laboratories or test kit manufacturers to increase promotion of their wares to the industry under the general banner of: 'the MCFR requires testing'.

Enforcers in the UK have queried how much testing would constitute the minimum. However, the MCFR clearly states that food business operators must (with certain notable exceptions) determine the level of testing on the basis of HACCP for each product.

The EC does NOT intend that there will be any increased product testing where GMP (good manufacturing practice) and HACCP are in place and verification is carried out as it is now. However, in the case of minced meat/preparations the MCFR specifies the sampling frequency (one product per plant, per week). These

points need to be made clear to all parties, particularly in enforcement of the MCFR as different enforcement approaches are resulting across the EU (see Interpretation and Enforcement).

HACCP implementation is key, not testing, since testing is NOT a control (Food Standards Agency guidance for food business operators):

> **"It will not always be necessary to carry out microbiological testing to show compliance with the criteria. For example, routine monitoring of physical parameters associated with food safety management procedures (such as monitoring time/temperature profiles, pH, level of preservative and Aw) may provide adequate assurance that the criteria are being met."**[3]

The EC recognises the key point of principle that microbiological testing *per se* is not a control measure and in itself does not ensure food safety, whereas the implementation of GMP and HACCP do. Beyond periodic HACCP verification the only time that pathogen testing is required is during validation of a new process or in the case of a new material being used.

The EC has also stated that a company having implemented GMP, HACCP and supporting systems and following the shelf life assessment approach set out in Annex II of the MCFR is NOT expected to have to carry out *Listeria monocytogenes (Lm)* challenge testing.

The EC agrees that it is vital that the emphasis remains on control (GMP, HACCP) and that already scarce technical resources remain focused thereon in order to prevent many millions of Euros being spent unnecessarily on unwarranted escalated testing that will do nothing directly to improve food safety and will divert funds away from food safety measures such as GMP and HACCP implementation.

3. http://www.food.gov.uk/multimedia/pdfs/ecregguidmicrobiolcriteria.pdf

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Other aspects, such as the absence of any legal requirement to carry out *Lm* challenge testing, if not interpreted in line with the EC's intentions (i.e. it is NOT required where shelf life has been assessed), may cost the food industry millions of Euro. There therefore needs to be clarity, particularly in local implementation and enforcement, to ensure that gold plating of the MCFR is avoided in enforcement approaches.

Interpretation and enforcement

Due to differing legal systems in EU Member States, criteria can be viewed as being absolute in some countries and merely desirable targets in others. This problem of interpretation and enforcement of the legislation impacts on the competitiveness of industry in individual states, and can lead, for example, to more recalls being required in one Member State than another under equivalent microbiological circumstances.

The EC has developed guidance on Official Control aspects of the MCFR for Member States[4] and outline guidance for Food Business Operators (FBOs)[5] but has stated that it is for industry to develop its own guidelines under EU food hygiene legislation.

In the UK, this work was been led by the Chilled Food Association and BRC and involved a number of trade associations. Two sets of guidance developed by industry are available free of charge:

- Guidance on the Practical Implementation of the EC Regulation on Microbiological Criteria for Foodstuffs[6]
- Shelf life of ready to eat food in relation to *L. monocytogenes* - Guidance for food business operators[7]

4. http://ec.europa.eu/food/food/biosafety/salmonella/docs/shelflife_listeria_monocytogenes_en.pdf5.
5. http://ec.europa.eu/food/food/biosafety/salmonella/docs/guidoc_listeria_monocytogenes_en.pdf
6. http://www.chilledfood.org/Resources/Chilled%20Food%20Association/Public%20Resources/BRC_CFA_Micro_Criteria_Guidance_Ed_1.2.pdf
7. http://www.chilledfood.org/Resources/Chilled%20Food%20Association/Public%20Resources/Shelf%20life%20of%20RTE%20foods%20in%20relation%20to%20Lm%20FINAL%20v1.1.1%2023%203%2010.pdf

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Zero Tolerance?

The EC has stated that regarding *Listeria monocytogenes* for ready to eat (RTE) foods the objective is to keep levels below 100 cfu/g during the shelf life of food, 'according to scientific opinion'. The introduction of a potential zero tolerance policy in relation to *Lm* is a technically unachievable standard particularly where uncooked ingredients are used. However, if a product's shelf life has been determined in accordance with the approach set out in the Regulation and the level of 100 cfu/g will not be exceeded throughout the shelf life zero tolerance does not apply. Guidance as to how to demonstrate this is given in CFA/BRC guidance on implementation of the Regulations.

This implied zero tolerance approach, whilst intended to target companies which cannot substantiate the shelf lives given, is contrary to the views of the World Health Organization, CODEX, the EC's own Scientific Committee for Food and Scientific Committee for Veterinary Measures, the UK's Advisory Committee for the Microbiological Safety of Food and Health Protection Agency, which agreed that targeting the reduction of high levels of *Lm* is of the most significant health benefit.

Confusion between Ready to Eat & non-RTE foods?

If a product requires cooking prior to consumption or carries heating instructions, the food is not ready to eat and therefore no *Lm* criteria apply.

8. http://www.food.gov.uk/multimedia/pdfs/ecregguidmicrobiolcriteria.pdf

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Other Requirements

The MCFR introduced some other important concepts:
- Article 7(1) requires producers to find the cause of unsatisfactory results
- Article 7(2) requires conditional recall if food safety criteria are not met
- Article 9 requires trend analysis of test results and demands that if an adverse trend is identified it is remedied.

Implementing legislation (e.g. Food Hygiene (No.2)(England) Regulations 2005) brought in the requirements of Article 7 into local law. Note that exceeding the criteria is not an offence *per se*; not doing what is required by Article 7 **is** an offence.

Next steps

CFA/BRC guidance on the MCFR was published prior to the MCFR coming into force, to enable companies to be fully acquainted with their requirements.

FSA guidance to food business operators and implementing legislation has been published[8] and cross-references the CFA/BRC guidance.

A number of presentations on the Regulations are freely available on the CFA website: http://www.chilledfood.org/resources/presentations.

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