Listeria monocytogenes Regulation

Best practice, background to EU Reg 2073/2005, future policy direction clues and consultation preparedness

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7/6/23
RSPH Conference
Listeria: legislation, the law and food practices
• Current Regs (2073/2005)
• What we know about potential proposals
• UK vs EU performance data
• Industry position
• What is needed
### L. monocytogenes EU Legislation

#### EU Microbiological Criteria for Foodstuffs 2073/2005

<table>
<thead>
<tr>
<th>Criterion number</th>
<th>Food category</th>
<th>Sampling plan</th>
<th>Limits</th>
<th>Analytical reference method</th>
<th>Stage where the criterion applies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2 (a and b)</td>
<td>Ready-to-eat foods able to support the growth of <em>L. monocytogenes</em>, other than those intended for infants and for special medical purposes</td>
<td>5 0</td>
<td>100 cfu/g: applies if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The FBO may fix intermediate limits during the process that must be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of shelf-life (footnote (5))</td>
<td>EN/ISO 11290-2</td>
<td>Products placed on the market during their shelf-life</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 0</td>
<td>Not detected in 25g: applies before products have left the immediate control of the producing FBO when he is NOT able to demonstrate to the satisfaction of the competent authority that the product will not exceed the limit of 100 cfu/g throughout the shelf life (footnote (7))</td>
<td>EN/ISO 11290-1</td>
<td>Before the food has left the immediate control of the food business operator, who has produced it</td>
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<tr>
<td>1.3</td>
<td>Ready-to-eat foods *unable to support the growth of <em>L. monocytogenes</em>, other than those intended for infants and for special medical purposes</td>
<td>5 0</td>
<td>100 cfu/g</td>
<td>EN/ISO 11290-2</td>
<td>Products placed on the market during their shelf-life</td>
</tr>
</tbody>
</table>

* Shelf life <5 days (P+4): food ‘automatically considered’ not to support growth (footnote 8). NB: P=0 (EU Lm Ref Lab Shelf Life Guidance)

** EU Reg 609/2013 on Food for Specific Groups (FSG), i.e. food for infants & young children (infant formula, follow-on formula and weaning foods), food for specific medical purposes, and total diet replacement for weight control. Limit of 0 cfu/g in 25g sample, n=10, c=0

About this initiative

Summary
This initiative aims to align EU rules with international 'Codex alimentarius' standards on the acceptable level of contamination by Listeria monocytogenes of certain categories of ready-to-eat food sold on the EU market.

The main objective is to protect consumers' health while facilitating official controls carried out by the competent authorities in EU countries.

Topic
Food safety

Type of act
Regulation

Committee
C20402

Draft act

Feedback: Upcoming

Type
Draft regulation

More about draft acts

Commission adoption

Feedback: Upcoming

Type
Regulation

More about adopted acts

Planned for
Fourth quarter 2021
EC-convened MS meeting Q3 2023?

Proposed 2023 EU Regs change(s):
Challenge testing to set shelf life?**, or ND before leaving control of the producing FBO or ND throughout life? … OR SOMETHING ELSE?

2003

EU REG 2007/2005
100 cfu/g max*
CFA food + envt test results database (>4m since 2004)

EU FBO guidance (DOP, EOL emphasis)

CCFH (Dec 2008): agreed on basis of epi data (EU/US) that 100/g gave acceptable level of protection of zero tolerance

Inconsistent FBO implementation/resourcing

Inconsistent commercial enforcement

European listeriosis rates increase beyond 2008 levels
June 2022 ECJ/Estonian fish court case: 1.2b interpretation: not applicable on market, but Art 14(8) 178/2002 applies

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CFA food + envt test results database (>4m since 2004)


FSA/CFA/BRC Lm & shelf life guidance (2010)

CODEX/EU 2008

LABS FOCUS ON CHALLENGE TESTING

EU FBO guidance (DOP, EOL emphasis)

EURL guidance: EC brief to focus on DOP/EOL data usage, but did not (challenge testing)

Campden Guideline 81 (Feb 2022) food challenge testing prioritised, 2073/2005 misinterpreted: WITHDRAWN

ISO 20976-1: 2019 food + feed challenge testing

EURL 3rd ed (Feb 2023) lab: shelf life testing competence (challenge + durability)

EURL 4th ed (July 2021) lab: shelf life testing (challenge testing)

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Differing MS/CA 1.2b interpretations


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** for RTE food supporting the growth of Lm

• With evidence of compliance throughout shelf life (criterion 1.2a), otherwise CA can specify not detected at point of production (criterion 1.2b)

Updated 24/5/23
### 2021 EU27+EEA+EFTA Top 5 Foodborne Diseases Morbidity & Mortality


‡ Not all countries observed cases for all diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>No. confirmed human cases</th>
<th>Status available (%)</th>
<th>Number of reporting countries</th>
<th>Reported hospitalised cases</th>
<th>Proportion hospitalised (%)</th>
<th>Outcome available (%)</th>
<th>No. reporting MS</th>
<th>Reported Deaths</th>
<th>Case Fatality (%)</th>
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<td>Campylobacteriosis</td>
<td>127,840</td>
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<td>71.8</td>
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<td>65.4</td>
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<td>196</td>
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</table>

* 2020: Listeriosis death rate 260x Campylobacteriosis, 31x STEC
** 2019: Listeriosis death rate 586x Campylobacteriosis, 84x STEC
*** 2018: Listeriosis death rate 520x Campylobacteriosis, 71x STEC
**** 2017: Listeriosis death rate 345x Campylobacteriosis, 28x STEC
***** 2016: Listeriosis death rate 540x Campylobacteriosis, 60x STEC

EXCLUDES UK
<table>
<thead>
<tr>
<th>Country</th>
<th>2016 Cases</th>
<th>2017 Rate</th>
<th>2018 Cases</th>
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</tbody>
</table>
Evidence & Conclusions

• Epidemiology shows that 100/g limit drives sampling/monitoring, compliance with best practice and when enforced commercially achieves high levels of consumer protection
  • UK (and IE) listeriosis rates are consistently well below European (EU + EEA + EFTA) mean. Note ECDC/EFSA figures inc UK as EU MS to end 2019:

<table>
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<td>0.50</td>
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<td>0.42</td>
<td>0.49</td>
</tr>
</tbody>
</table>

• Day of Production (DOP) and End of Life (EOL) sampling, trending and analysis works as a means of demonstrating control and shelf life appropriateness

• Aggressive continuous environmental sampling to find *Listeria spp*, attacking with hygiene and is an effective strategy for factory hygiene control

• Current UK industry and EU hygiene, shelf life and microbiological rules are effective when implemented and enforced commercially

• High Care/Risk Area regimes are a demonstrably effective control strategy, i.e. application of GMP + HACCP
Distribution of European 2021 confirmed listeriosis cases by food, country

EU One Health 2021 Zoonoses Report:

UKHSA Oct 2022 report of 2020 data for England + Wales:
2 outbreaks. 124 cases total, 17 deaths (non-pregnancy). 20% of all cases were pregnancy-related, 34.8% of which resulted in stillbirth or miscarriage
## Examples of Major Fatal Listeriosis Outbreaks & Root Causes

<table>
<thead>
<tr>
<th>Country (year)</th>
<th>Outcomes and Root Causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK (1987-9)</td>
<td>&gt;17 dead, 200+ cases. Pâté imported from Belgium. Post-process hygiene</td>
</tr>
<tr>
<td>USA (1998-9)</td>
<td>17 dead, 4 miscarriages/stillbirths, 101 cases. Cooked meat. Contamination from air filtration unit maintenance</td>
</tr>
<tr>
<td>Canada (2008)</td>
<td>22 dead, 57 cases. CAD 27m. Cooked sliced meat. Dirty slicer. Post-process hygiene</td>
</tr>
<tr>
<td>Denmark (2014)</td>
<td>17 dead, 41 cases. Cooked meat (rullepølse). Post-process contamination</td>
</tr>
<tr>
<td>South Africa (2017-18)</td>
<td>216 dead, 1060 cases. Cooked RTE meat products. Post-process contamination</td>
</tr>
<tr>
<td>Netherlands, Belgium</td>
<td>3 dead, 21 cases. Cooked meat product. Post-process contamination</td>
</tr>
<tr>
<td>(2017-19)</td>
<td></td>
</tr>
<tr>
<td>Spain (2019)</td>
<td>3 dead, 7 miscarriages, 200+ cases. Cooked meat product. Post-process contamination</td>
</tr>
</tbody>
</table>

Also: EU frozen sweetcorn (2015-18) – not produced to RTE (High Care) standards but consumed uncooked by some
Focus on what actually makes food RTE

- **Manufacturer’s risk assessment & product design, i.e. HACCP plan:**
  - **Appropriate production controls** – validation + **ONGOING MONITORING**
    - Minimise potential for contamination by zoonotic organisms
  - **Hygienic preparation and packing** – validation + **ONGOING MONITORING**
    - Process (e.g. thermal)
    - Prevent re-/cross-contamination
  - **Limited shelf life** (NOTE: UK chilled prep food shelf lives third to half of usual Continental)
    - Ensure peak quality
    - Minimise opportunity for microbial growth
  - **Chilled distribution, sale and storage** (UK chill 5°C max to Retailers’ DCs – commercial requirement)
    - Minimise potential for microbial growth – domestic fridges run @ ~7°C (FSA project B13006)
  - **Appropriate usage instructions**

**Applies to B2B and B2C FBOs**

UK Supplier QA systems in major chilled FBOs assure supplier compliance
What Good Control Looks Like (UK Chill): Validation & Monitoring

- Regular environmental swabbing and food sampling
  - Target environmental sampling: try to find *Listeria spp* (inc Lm – must speciate), address with hygiene
  - RTE food components at intake (especially high risk)
  - Trend results (2073/2005) and act on adverse trends (hygiene)
- Environmental swabbing (presence/absence)
  - Validate cleaning method efficacy
  - Verify ongoing efficacy
- Food sampling
  - Day of Production (DOP) hygiene indicator
  - End of Life (EOL) shelf life appropriateness
What Good Looks Like - CFA Members’ Lm Database: Jan 2011-Dec 2022

RTE food prevalence
(1,050,585 samples):

~0.6% Lm at any point during shelf life, of which <0.01% present at quantifiable levels, i.e. >20 cfu/g LOQ (Note: 10/g is common LOQ used):
DOP: 97 quantifiable out of 822,204 samples
EOL: 50 quantifiable out of 228,381 samples

Production environment prevalence
(1,947,956 samples):

Food contact surfaces: ~0.3% Lm (~964k samples)
Non-Food contact surfaces: ~2.5% Lm (~984k samples)

All detections are investigated and addressed
## Listeria-related Guidance Already Available

<table>
<thead>
<tr>
<th>Author</th>
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<tr>
<td>Sainsbury’s Supermarkets</td>
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<td>Code of Practice for the Monitoring and Control of Listeria spp. In Sainsbury’s Brand Products. COP 19.</td>
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Key Messages Summary

1. **Challenge testing or zero tolerance/Not Detected in 25g should not be mandatory** where FBOs have data supporting the safety of their food and performance of their FSMS = ongoing and historical document of effectiveness of HACCP-based procedures.

   All MS reportedly support challenge testing so could fallback position be to support it for EFSA’s high risk foods, i.e. RTE fish, meat, dairy??

2. Instead of challenge testing place effort particularly on ensuring FBOs have sufficient resources to implement effective preventative actions including cleaning and monitoring factory hygiene and to undertake aggressive effective corrective actions if a suspect result is found.
3. We propose that **international** industry guidance is developed to set out effective environmental hygiene management monitoring data gathering and usage in triggering corrective actions. **DONE**

This would give much-needed detail to support GHP particularly for SMEs and for enforcement not only by CAs but also commercially, e.g. by FBOs buying RTE ingredients from suppliers and for final product retail customers.

4. Tech document drafted setting out implications of challenge testing and ND in 25g including environmental monitoring and management guidance

5. Enforcer and FBO training is needed to ensure understanding of the necessary controls and how to validate and verify their continual effective application

6. Tech document endorsed by UK industry (TAs, FBOs + BRC), Euro Chilled Food Fed, CLITRAVI (Euro meat products fed), Euro Smoked Salmon Assn, Euro Sprouted Seeds Assn

7. Need Non-UK industry, Eurocommerce, EU federation buy-in and action when proposals emerge from EC.
The centre of excellence for the chilled food industry

www.chilledfood.org

www.chillededucation.org

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