



Listeria monocytogenes Regulation

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

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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

Criterion number	Food category	Sampling plan		Limits	Analytical reference method	Stage where the criterion applies
		n	c			
1.2 (a and b)	Ready-to-eat foods <u>able</u> to support the growth of <i>L. monocytogenes</i> , other than those intended for *infants and for special medical purposes	5	0	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))	EN/ISO 11290-2	Products placed on the market during their shelf-life
		5	0	Not detected in 25g: applies before products have left the immediate control of the producing FBO <u>when</u> he is NOT able to demonstrate to the satisfaction of the competent authority that the product will not exceed the limit of 100cfu/g throughout the shelf life (footnote (7))	EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it
1.3	Ready-to-eat foods <u>*unable</u> to support the growth of <i>L. monocytogenes</i> , other than those intended for **infants and for special medical purposes	5	0	100 cfu/g	EN/ISO 11290-2	Products placed on the market during their shelf-life

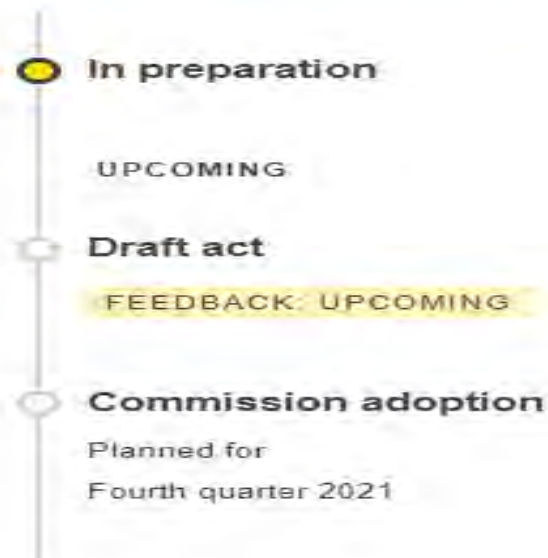
* Shelf life <5 days (P+4): food 'automatically considered' not to support growth (footnote 8). NB: P=0 (EU Lm Ref Lab Shelf Life Guidance)

** 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

Consolidated Reg <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02005R2073-20200308>

Listeria monocytogenes in ready-to-eat foods – update of safety criteria

Have your say > Published initiatives > Listeria monocytogenes in ready-to-eat foods – update of safety criteria



About this initiative

Summary	This initiative aims to align EU rules with international 'Codex alimentarius' standards on the acceptable level of contamination by <i>Listeria monocytogenes</i> 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](#)

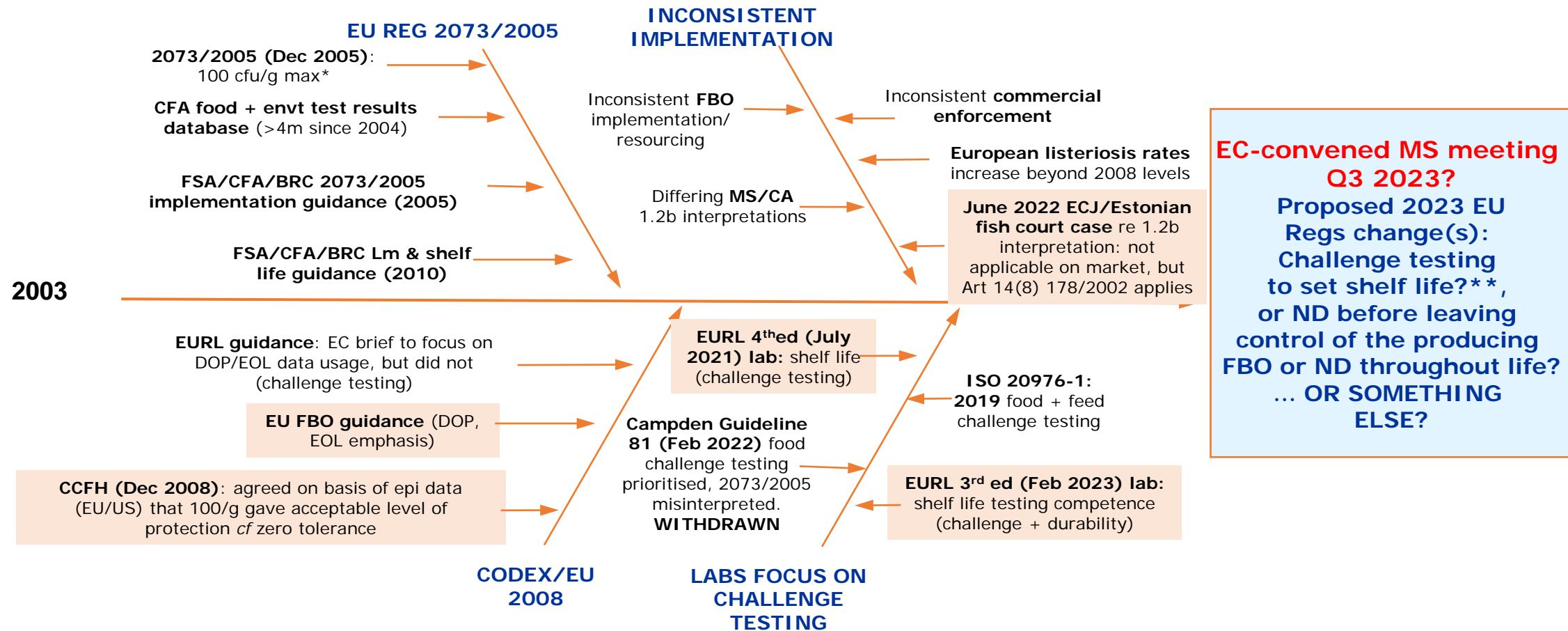
Commission adoption

Type
Regulation
[More about adopted acts](#)

Planned for
Fourth quarter 2021

5/5/21

EU Listeria legislation: Origins, Ethos & Direction



• With evidence of compliance throughout shelf life (criterion 1.2a), otherwise CA can specify not detected at point of production (criterion 1.2b)
 ** for RTE food supporting the growth of Lm

2021 EU27+EEA+EFTA Top 5 Foodborne Diseases Morbidity & Mortality

Disease	No. confirmed human cases	Hospitalisations				Deaths				Lm Fatality Rate <i>cf</i>
		Status available (%)	Number of reporting ‡countries	Reported hospitalised cases	Proportion hospitalised (%)	Outcome available (%)	No. reporting MS	Reported Deaths	Case Fatality (%)	
Campylobacteriosis	127,840	45,121	35.3	15	10,469	71.3	16	26	0.03	457
Salmonellosis	60,050	30,951	51.5	16	11,785	64.4	16	71	0.18	76
Yersiniosis	6,789	1,564	23.0	13	508	53.0	21	0	0	
STEC infections	6,084	2,133	35.1	17	901	71.8	20	18	0.41	33
Listeriosis	2,183	956	43.8	16	923	65.4	14	196	13.7	

- * 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

‡ Not all countries observed cases for all diseases

EXCLUDES UK

* EU One Health 2021 Zoonoses Report: <https://www.efsa.europa.eu/en/efsajournal/pub/7666>

** EU One Health 2020 Zoonoses Report, <https://www.efsa.europa.eu/sites/default/files/2021-12/6971.pdf>

*** EU One Health Zoonoses Report 2019. <https://www.efsa.europa.eu/en/efsajournal/pub/6406>

**** EU summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2017. <http://ecdc.europa.eu/sites/portal/files/documents/zoonoses-%20food-borne-outbreaks-surveillance-2017.pdf>

***** EU summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2016. EFSA Journal 2017. 10.2903/j.efsa.2017.5077

European Listeriosis Rates 2016-21

2016	Cases	Rate	2017	Cases	Rate	2018	Cases	Rate	2019	Cases	Rate	2020	Cases	Rate	2021	Cases	Rate
Spain	362	–	Spain	284	–	Estonia	27	2.05	Spain	505	–	Spain	191	–	Spain	224	–
Finland	67	1.22	Iceland	6	1.77	Finland	80	1.45	Estonia	21	1.59	Finland	94	1.7	Iceland	5	1.4
Belgium	104	0.92	Finland	89	1.62	Spain	370	0.89	Iceland	4	1.12	Slovenia	26	1.2	Finland	70	1.3
Germany	697	0.85	Denmark	58	1.01	Sweden	89	0.88	Sweden	113	1.1	Iceland	4	1.1	Denmark	62	1.1
Slovenia	15	0.73	Germany	726	0.88	Denmark	49	0.85	Denmark	61	1.05	Malta	5	0.97	Sweden	107	1
Denmark	40	0.7	Lux	5	0.85	Lux	5	0.83	Malta	5	1.01	Sweden	88	0.85	Slovenia	19	0.9
Sweden	68	0.69	Sweden	81	0.81	Germany	683	0.82	Slovenia	20	0.96	Denmark	44	0.76	Belgium	65	0.7
Estonia	9	0.68	Belgium	73	0.8	Belgium	74	0.81	Finland	50	0.91	Norway	37	0.69	France	435	0.64
Switz	50	0.6	NL	108	0.63	Latvia	15	0.78	Belgium	66	0.72	Switz	58	0.67	Germany	560	0.67
France	375	0.56	Slovenia	13	0.63	Lithuania	20	0.71	Germany	570	0.69	Germany	544	0.65	Lux	4	0.63
Austria	46	0.53	France	370	0.55	Portugal	64	0.62	NL	103	0.6	Lux	4	0.64	Latvia	10	0.53
NL	89	0.52	Switz	45	0.53	Switz	52	0.61	France	373	0.56	Belgium	54	0.59	NL	86	0.49
EU EFTA EEA	2,536	0.47	EU EFTA EEA	2,480	0.48	Iceland	2	0.57	Portugal	56	0.54	NL	90	0.52	EU27	2,183	0.49
Czech Rep	47	0.45	Portugal	42	0.41	France	338	0.51	Norway	27	0.51	France	334	0.5	EU27+EEA	2,268	0.44
Norway	19	0.37	Hungary	36	0.37	Slovenia	10	0.48	Lux	3	0.49	Austria	41	0.46	Austria	38	0.43
Lithuania	10	0.35	Austria	32	0.36	EU EFTA EEA	2,549	0.47	EU EFTA EEA	2,621	0.46	Portugal	47	0.46	Italy	241	0.41
Lux	2	0.35	Scotland	18	0.33	Norway	24	0.45	Austria	38	0.43	Latvia	8	0.42	Estonia	5	0.38
UK	201	0.31	Lithuania	9	0.32	Ireland	21	0.43	Switz	36	0.42	EU27 EFTA EEA	1,876	0.42	Switz	33	0.38
Scotland	16	0.3	Poland	116	0.31	NL	69	0.4	Hungary	39	0.4	Hungary	32	0.33	Norway	20	0.37
Italy	179	0.3	Estonia	4	0.3	Poland	128	0.34	Ireland	17	0.35	Italy	147	0.25	Hungary	35	0.36
Latvia	6	0.3	Norway	16	0.3	Austria	27	0.31	Italy	202	0.33	Eng+Wales	124	0.24	Poland	120	0.32
Portugal	31	0.3	Ireland	14	0.29	Slovakia	17	0.31	Slovakia	18	0.33	Scotland	13	0.24	Scotland	17	0.31
Ireland	13	0.28	Czech Rep	30	0.28	Czech Rep	31	0.29	Poland	121	0.32	Cyprus	2	0.23	Ireland	14	0.28
Poland	101	0.27	Italy	164	0.27	Italy	178	0.29	Latvia	6	0.31	Estonia	3	0.23	UK	184	0.27
Hungary	25	0.25	UK	160	0.24	Hungary	24	0.25	Czechia	27	0.25	UK	143	0.21	Lithuania	7	0.25
Malta	1	0.23	Slovakia	12	0.22	UK	168	0.25	UK	154	0.23	Greece	20	0.19	Slovakia	13	0.24
Greece	20	0.19	Croatia	8	0.19	Scotland	12	0.22	Lithuania	6	0.21	Poland	62	0.16	Czechia	24	0.22
Slovakia	10	0.18	Greece	20	0.19	Malta	1	0.21	Bulgaria	13	0.19	Czechia	16	0.15	Greece	21	0.2
Croatia	4	0.1	Bulgaria	13	0.18	Greece	19	0.18	Croatia	6	0.15	Slovakia	7	0.13	Croatia	8	0.2
Bulgaria	5	0.07	Latvia	3	0.15	Romania	28	0.14	Scotland	7	0.13	Croatia	5	0.12	Cyprus	1	0.11
Romania	9	0.05	Romania	10	0.05	Bulgaria	9	0.13	Cyprus	1	0.11	Ireland	6	0.12	Romania	11	0.06
Cyprus	0	0	Cyprus	0	0	Cyprus	1	0.12	Greece	10	0.09	Bulgaria	4	0.06	Bulgaria	3	0.04
Iceland	0	0	Malta	0	0	Croatia	4	0.1	Romania	17	0.09	Romania	2	0.01	Malta	0	0
												Lithuania	0	0	Liecht	0	0
														Portugal	0	0	

UK 2020 data: Food Security Report 2021. UK, Eng+Wales from UKHSA Oct 2022 & May 2023. Scotland from FSS. 2021 provisional

Sentinel system coverage: Belgium: 2016-21 80% pop Spain: 2016-21 no info

Switz incs Liechtenstein data to 2020

EU One Health 2021

Zoonoses Report:

<https://www.efsa.europa.eu/en/efsajournal/pub/7666>

Non-EU rates:

South Africa: 1.84 (2017-18)

USA: 0.24

Australia : 0.3 (2013)

NZ: 0.6

US rates:

[cdc.gov/listeria/technical.html](https://www.cdc.gov/listeria/technical.html)

Australia:

<https://www.health.vic.gov.au/infectious-diseases/listeriosis#public-health-significance-and-occurrence-of-listeriosis>

www.foodstandards.gov.au/publications/Documents/Listeria

%20monocytogenes.pdf

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:

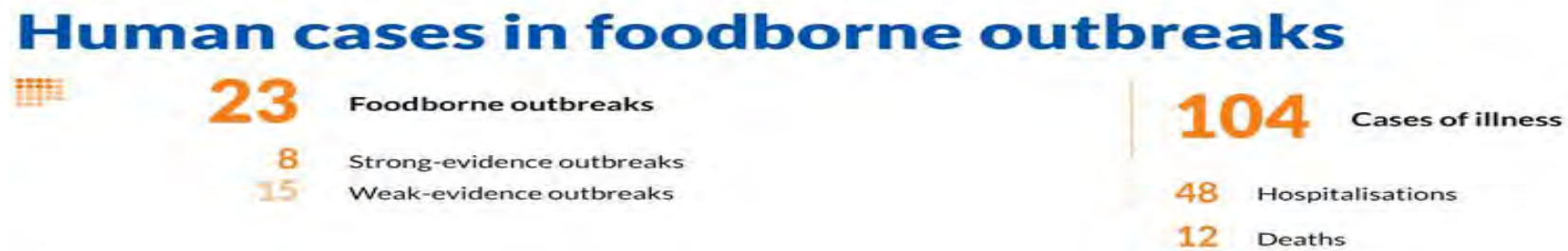
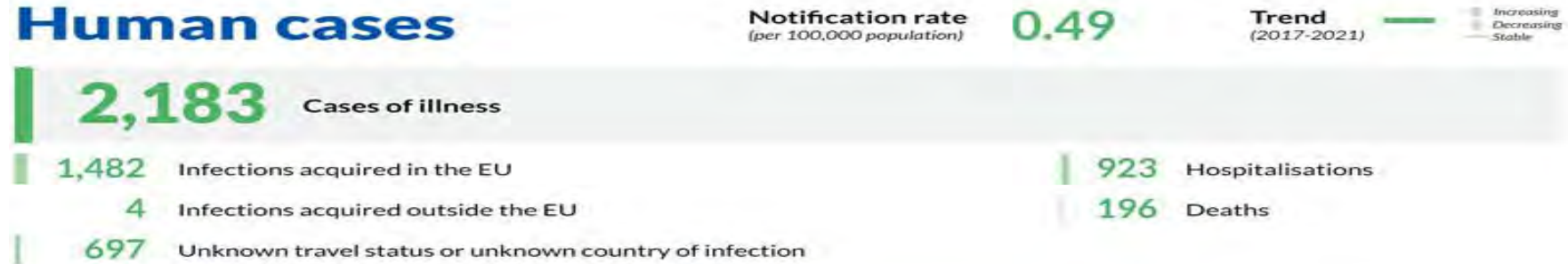
Rate Per 100k	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Europe inc UK	0.37	0.33	0.41	0.44	0.52	0.46	0.48	0.48	0.47	0.46		
UK	0.28	0.26	0.29	0.30	0.31	0.29	0.31	0.24	0.25	0.23	0.22	0.27
Europe exc UK	0.39	0.34	0.43	0.46	0.56	0.49	0.50	0.52	0.50	0.49	0.42	0.49

- **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:
<https://www.efsa.europa.eu/en/efsajournal/pub/7666>

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



Foodborne outbreaks



N of outbreaks

1	Austria
0	Belgium
0	Bulgaria
0	Croatia
0	Cyprus
0	Czechia
5	Denmark
0	Estonia
2	Finland
3	France
4	Germany
0	Greece
0	Hungary
0	Ireland
1	Italy
0	Latvia
0	Lithuania
0	Luxembourg
0	Malta
2	Netherlands
0	Poland
0	Portugal
0	Romania
0	Slovakia
0	Slovenia
0	Spain
4	Sweden
1	UK (N. Ireland)

N of outbreaks per 100,000 population*

AT	0.011
BE	0
BG	0
HR	0
CY	0
CZ	0
DK	0.086
EE	0
FI	0.036
FR	0.004
DE	0.005
EL	0
HU	0
IE	0
IT	0.002
LV	0
LT	0
LU	0
MT	0
NL	0.011
PL	0
PT	0
RO	0
SK	0
SI	0
ES	0
SE	0.039
XI	0.053



N of outbreak cases per 100,000 population

AT	0.056
BE	0
BG	0
HR	0
CY	0
CZ	0
DK	0.651
EE	0
FI	0.108
FR	0.009
DE	0.018
EL	0
HU	0
IE	0
IT	0.003
LV	0
LT	0
LU	0
MT	0
NL	0.052
PL	0
PT	0
RO	0
SK	0
SI	0
ES	0
SE	0.125
XI	0.525



* Differences among countries shall be interpreted with caution as this indicator depends on several factors including the type of outbreaks under surveillance and does not necessarily reflect the level of food safety in each country.

Examples of Major Fatal Listeriosis Outbreaks & Root Causes

Country (year)	Outcomes and Root Causes
UK (1987-9)	>17 dead, 200+ cases. Pâté imported from Belgium. Post-process hygiene
France (1992)	92 dead, 272 cases. Jellied pork tongue. Post-process hygiene
USA (1998-9)	17 dead, 4 miscarriages/stillbirths, 101 cases. Cooked meat. Contamination from air filtration unit maintenance
Canada (2008)	22 dead, 57 cases. CAD 27m. Cooked sliced meat. Dirty slicer. Post-process hygiene
Denmark (2014)	17 dead, 41 cases. Cooked meat (rullepølse). Post-process contamination
South Africa (2017-18)	216 dead, 1060 cases. Cooked RTE meat products. Post-process contamination
Netherlands, Belgium (2017-19)	3 dead, 21 cases. Cooked meat product. Post-process contamination
Spain (2019)	3 dead, 7 miscarriages, 200+ cases. Cooked meat product. Post-process contamination

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

Author	Year	Title	Web link
ANSES, EURL	2012	Guidelines on sampling the food processing area and equipment for the detection of Lm. Version 3.	https://eurl-listeria.anses.fr/en/system/files/LIS-Cr-201213D1.pdf
BRCGS	2022	Global Standard - Food Safety. Issue 9.	https://www.brcgs.com/store/global-standard-food-safety-(issue-9)/p-12187
CFA	2008	Listeria Management Guidance	
	2016	Micro Testing & Interpretation (2 nd ed)	https://www.chilledfood.org/wp-content/uploads/2015/08/CFA_Micro_testing_interpretation_2nd_ed.pdf
CFA, BRC, FSA	2010	Shelf life of RTE food in relation to Lm - Guidance for FBOs	https://www.chilledfood.org/wp-content/uploads/2015/08/Shelf-life-of-RTE-foods-in-relation-to-Lm-FINAL-v1.1.1-23-3-10-with-worked-examples.pdf
CFA/BRC, (FSA)	2006	Guidance on the Practical Implementation of the EC Reg on Micro Criteria for Foodstuffs (ed 1.2)	https://www.chilledfood.org/wp-content/uploads/2015/07/BRC_CFA_Micro_Criteria_Guidance_Ed_1.2.pdf
CODEX Alimentarius Commission	2009	Guidelines on the Application of General Principles of Food Hygiene to the Control of Lm in Foods CAC/GL 61 – 2007	http://www.fao.org/input/download/standards/10740/CXG_061e.pdf
European Chilled Food Federation	2006	Recommendations for the Production of Prepackaged Chilled Food. 2 nd edition.	https://www.ecff.net/wp-content/uploads/2018/10/ECFF_Recommendations_2nd_ed_18_12_06.pdf
EC	2013	Commission Staff Working Document: Guidance document on Lm shelf-life studies for RTE foods, under Reg (EC) No. 2073/2005 of 15/11/05 on micro criteria for foodstuffs. (for FBOs)	https://ec.europa.eu/food/document/download/44257174-bf8c-4214-a60d-6790a7ca4109_en_(POOL/G4/2013/11510/11510-EN.doc)
Food & Biocides Industry Group	2016	Biocides in Cleaning and Disinfection	https://www.chilledfood.org/wp-content/uploads/2018/08/Biocides-Cleaning-and-Disinfection-working-document-industry-guidance-18-10-16-with-updated-best-practice-example-FBIG-logo-in-progress.pdf
FSAI	2005	Control & Management of Lm Contamination of Food. ISBN 1-904465-29-3.	https://www.fsai.ie/workarea/downloadasset.aspx?id=1234
FSS	2014	Safe Smoked Fish Tool (2022 revision)	https://safesmokedfish.foodstandards.gov.scot/assessment/3049
Profel	2020	Hygiene guidelines for the control of Lm in the production of quick-frozen vegetables.	https://profel-europe.eu/library/files/PROFEL_Listeria_mono_guidelines_November2020.pdf
Ruokavirasto	2020	Elintarvikkeiden mikrobiologiset vaatimukset komission asetuksen (EY) No 2073/2005 soveltaminen sekä yleisiä ohjeita elintarvikkeiden mikrobiologisista tutkimuksista - Ohje elintarvikealan toimijoille. Ohje 4095/04.02.00.01/2020/4	https://www.ruokavirasto.fi/globalassets/tietoa-meista/asiointi/oppaat-ja-lomakkeet/yritykset/elintarvikeala/elintarvikealan-oppaat/elintarvikkeiden-mikrobiologiset-vaatimukset_4095_04_02_00_01_2020_4_liitteet-yhdistetty.pdf
Sainsbury's Supermarkets		Code of Practice for the Monitoring and Control of Listeria spp. In Sainsbury's Brand Products. COP 19.	
USA FSIS	2014	Compliance Guideline: Controlling Lm in Post-lethality Exposed RTE Meat and Poultry Products.	https://www.fsis.usda.gov/sites/default/files/import/Controlling-Lm-RTE-Guideline.pdf

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.**

Key Messages Summary

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.**



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