Checklist to be used when assessing compliance with Commission Regulation EC (No) 2073/2005 on microbiological criteria for foodstuffs (as amended)

Supporting information relevant to each question is provided in Section 8 of FSAI's Guidance Note No. 27

QUESTION	ANSWER	COMMENT
Identifying relevant criteria		
1: Does the food business operator produce, manufacture or package foods for which there are relevant criteria in the Regulation?	☐ Yes ☐ No – **checklist doesn't apply to this food business operator**	
1 (a): Is this food business operator a caterer or retailer that only produces, manufactures or packages food that will be consumed within two days after production?	☐ Yes – **checklist doesn't apply to this food business operator** ☐ No	
1 (b): Is the food business operator a primary producer of live bivalve molluscs and live echinoderms, tunicates and gastropods?	☐ Yes – **checklist doesn't apply to this food business operator** ☐ No	
1 (c): Has the food business operator identified all food safety criteria that are relevant to the food they produce, manufacture or package? (Annex I, Chapter 1 of the Regulation)	☐ Yes ☐ No	
1 (d): Has the food business operator identified all process hygiene criteria that are relevant to the food they produce, manufacture or package? (Annex I, Chapter 2 of the Regulation)	☐ Yes ☐ No	
1 (e): Has the food business operator documented the relevant criteria as part of their HACCP-based procedures and good hygiene practice?	☐ Yes ☐ No	

QUESTION	ANSWER	COMMENT
2: Does the food business operator produce, manufacture or package ready-to-eat food?	☐ Yes ☐ No – **go to Q3**	
2 (a): Has the food business operator documented the ready-to-eat status of the food they produce, manufacture or package?	☐ Yes ☐ No	
2 (b): With respect to *L. monocytogenes*, has the food business operator determined and documented if the ready-to-eat food falls into food category 1.1, 1.2 or 1.3 in Annex I, Chapter 1 of the Regulation?	☐ Yes ☐ No	
Sampling and testing food		
3: Does the food business operator produce, manufacture or package food for which the Regulation sets a sampling frequency?	☐ Yes ☐ No – **go to Q4**	
3 (a): Does the food business operator take samples of food and test them according to the rules set in the Regulation?	☐ Yes – **go to Q4** ☐ No	
3 (b): Does the food business operator use a reduced frequency of sampling derogation?	☐ Yes ☐ No	
3 (c): Does the food business operator have evidence to back up their decision to use a reduced frequency of sampling derogation?	☐ Yes ☐ No	
3 (d): Can the food business operator show that their decision to use a reduced frequency of sampling derogation was authorised by the competent authority?	☐ Yes ☐ No	

QUESTION	ANSWER	COMMENT
4: Does the food business operator produce, manufacture or package food for which there is a relevant criterion, but for which the Regulation does not set a sampling frequency?	☐ Yes ☐ No – **go to Q5**	
4 (a): Has the food business operator conducted a risk assessment to decide if – and how often – they need to take samples of food and test them to check compliance with the relevant criteria?	☐ Yes ☐ No – **go to Q4d**	
4 (b): Has the food business operator documented this risk assessment?	☐ Yes ☐ No	
4 (c): Has the food business operator determined (based on their risk assessment) that they don't need to test food in order to check compliance with the relevant criteria?	☐ Yes ☐ No	
4 (d): Does the food business operator use means other than testing food to validate or verify that their HACCP-based procedures and good hygiene practice are working properly?	☐ Yes ☐ No	
5: Has the food business operator described and documented what constitutes a batch for each of their end-products?	☐ Yes ☐ No	

QUESTION	ANSWER	COMMENT
6: When testing food, does the food business operator collect and test the number of sample units (n) specified in the criterion's sampling plan?	☐ Yes ☐ No ☐ Food business operator doesn't test food to check compliance – **go to Q13**	
6 (a): Does the food business operator take these sample units from the same batch?	☐ Yes ☐ No	
6 (b): Does the food business operator ensure samples are representative of the batch and do not introduce sampling bias?	☐ Yes ☐ No	
6 (c): Does the laboratory provide a separate result record for each sample unit (n) tested?	☐ Yes ☐ No	
7: Was sufficient volume/ mass of food tested to check compliance with the criterion?	☐ Yes ☐ No	
8: Does the laboratory test samples using the analytical reference method specified in the Regulation?	☐ Yes ☐ No – **go to Q8b**	
8 (a): Does the laboratory use the most up-to-date version of the reference method?	☐ Yes ☐ No	
8 (b): Does the laboratory test the samples using an alternative method?	☐ Yes ☐ No – **go to Q9**	
8 (c): Was the alternative method validated against the most recent edition of the analytical reference method specified in the Regulation?	☐ Yes ☐ No	

QUESTION	ANSWER	COMMENT
8 (d): If the alternative method was a rapid (proprietary) method, was it certified by a third party in accordance with the protocol set out in ISO 16140:2003 or other internationally accepted similar protocols?	☐ Yes ☐ No ☐ Not applicable	
8 (e): If using an alternative method other than those above (8c & 8d), was the method validated according to internationally accepted protocols?	☐ Yes ☐ No ☐ Not applicable – **go to Q9**	
8 (f): If using an alternative method other than those above (8c & 8d), was the method's use authorised by the competent authority (in conjunction with the FSAI and/or relevant reference laboratory, as necessary)?	☐ Yes ☐ No	
9: Does the food business operator interpret test results correctly?	☐ Yes ☐ No	
Taking action on unsatisfactory results		
10: Has the food business operator received unsatisfactory test results for a food safety criterion?	☐ Yes ☐ No – **go to Q11**	
10 (a): Did the food business operator **notify** the competent authority?	☐ Yes ☐ No	
10 (b): Had the batch of food reached the consumer?	☐ Yes ☐ No – **go to Q10d**	

QUESTION	ANSWER	COMMENT
10 (c): Did the food business operator **recall** the batch of food and: • Notify trade customers • Notify consumers • Remove the food from the distribution chain • Remove food from consumers (if necessary to protect public health)?	☐ Yes ☐ No	
10 (d): Did the food business operator withdraw the batch of food, and: • Notify trade customers • Remove the food from the distribution chain?	☐ Yes ☐ No	
10 (e): Did the food business operator take the corrective actions defined in their HACCP-based procedures?	☐ Yes ☐ No	
10 (f): Did the food business operator take any other actions necessary to protect the health of consumers?	☐ Yes ☐ No ☐ Not necessary	
10 (g): Did the food business operator take measures to find the cause of the unsatisfactory results?	☐ Yes ☐ No	
10 (h): Did the food business operator take measures to prevent the recurrence of the unacceptable microbiological contamination (e.g. modifications to the HACCP-based procedures or other food hygiene control measures in place)?	☐ Yes ☐ No	
10 (i): Did the food business operator reprocess the batch of food?	☐ Yes ☐ No – **go to Q10k**	

QUESTION	ANSWER	COMMENT
10 (j): Was the reprocessing treatment sufficient to eliminate the hazard of concern?	☐ Yes ☐ No	
10 (k): Did the food business operator use the batch of food for purposes other than for which it was originally intended?	☐ Yes ☐ No – **go to Q11**	
10 (l): Did the food business operator take into account their HACCP-based procedures and good hygiene practice when deciding on this alternative use?	☐ Yes ☐ No	
10 (m): Was the alternative use authorised by the competent authority?	☐ Yes ☐ No	
11: Has the food business operator received unsatisfactory test results for a process hygiene criterion?	☐ Yes ☐ No – **go to Q12**	
11 (a): Did the food business operator take actions laid down in Annex I, Chapter 2? (This specifies the action to take in case of unsatisfactory results for each process hygiene criterion)	☐ Yes ☐ No	
11 (b): Did the food business operator take the corrective actions defined in their HACCP-based procedures?	☐ Yes ☐ No	
11 (c): Did the food business operator take any other actions necessary to protect the health of consumers?	☐ Yes ☐ No ☐ Not necessary	
11 (d): Did the food business operator take measures to find the cause of the unsatisfactory results?	☐ Yes ☐ No	

QUESTION	ANSWER	COMMENT
11 (e): Did the food business operator take measures to prevent the recurrence of the unacceptable microbiological contamination, e.g. modifications to the HACCP-based procedures or other food hygiene control measures in place?	☐ Yes ☐ No	
Analysing trends in results		
12: Does the food business operator analyse trends in their test results?	☐ Yes ☐ No	
12 (a): Does/will the food business operator take timely appropriate actions to remedy the situation when they observe a trend towards unsatisfactory results in order to prevent microbiological risks occurring?	☐ Yes ☐ No	
Environmental monitoring		
13: Does the food business operator manufacture dried infant formulae or dried foods for special medical purposes intended for infants below six months which pose a *Cronobacter* spp. (*Enterobacter sakazakii*) risk?	☐ Yes ☐ No – **go to Q14**	
13 (a): Does the food business operator document their environmental sampling and testing programme? (Good practice)	☐ Yes ☐ No	

QUESTION	ANSWER	COMMENT
13 (b): Does the food business operator take samples of the processing areas and equipment to test for Enterobacteriaceae?	☐ Yes ☐ No	
13 (c): Has the food business operator determined a sampling frequency?	☐ Yes ☐ No	
13 (d): Does the food business operator take samples of the processing areas and equipment in accordance with ISO standard 18593?	☐ Yes ☐ No	
13 (e): Does the food business operator sample appropriate sites in the production facility?	☐ Yes ☐ No	
13 (f): Does the food business operator pre-determine and document the appropriate action to take in the case of unsatisfactory results?	☐ Yes ☐ No	
13 (g): Does the food business operator take appropriate action in the case of unsatisfactory results?	☐ Yes ☐ No	
13 (h): Does the food business operator monitor trends in their test results?	☐ Yes ☐ No	

QUESTION	ANSWER	COMMENT
Q14: Does the food business operator produce, manufacture or package ready-to-eat food which may pose a *L. monocytogenes* risk for public health?	☐ Yes ☐ No – **go to Q15**	
14 (a): Does the food business operator take samples from processing areas and equipment to test for *L. monocytogenes*?	☐ Yes ☐ No	
14 (b): Does the food business operator document their environmental sampling and testing programme? (Good practice)	☐ Yes ☐ No	
14 (c): Does the food business operator take samples from processing areas and equipment according to the EU Guidelines on sampling the food processing area and equipment for the detection of *Listeria monocytogenes*? (Best practice)	☐ Yes ☐ No	
14 (d): Does the food business operator take samples from the appropriate sites in the food processing environment?	☐ Yes ☐ No	
14 (e): Does the food business operator take samples at the appropriate time during production?	☐ Yes ☐ No	
14 (f): Does the food business operator use the appropriate sampling swab and sampling method?	☐ Yes ☐ No	
14 (g): Does the food business operator sample a large enough surface area?	☐ Yes ☐ No	

QUESTION	ANSWER	COMMENT
14 (h): Does the food business operator test samples for *L. monocytogenes* using EN ISO 11290-1 or valid alternative method according to Article 5 of the Regulation?	☐ Yes ☐ No	
14 (i): Has the food business operator determined a sampling frequency?	☐ Yes ☐ No	
14 (j): Has the food business operator pre-determined and documented the appropriate action to take if *L. monocytogenes* is detected?	☐ Yes ☐ No	
14 (k): Does/will the food business operator take appropriate action if *L. monocytogenes* is detected?	☐ Yes ☐ No	
14 (l): Does the food business operator monitor trends in their test results?	☐ Yes ☐ No	
Labelling		
15: Does the food business operator manufacture or package minced meat and meat preparations (made from species other than poultry) which are intended to be eaten cooked?	☐ Yes ☐ No – **go to Q16**	
15 (a): Has the food business operator clearly labelled the product to inform the consumer that the product must be thoroughly cooked before consumption?	☐ Yes ☐ No	

QUESTION	ANSWER	COMMENT
Compliance with relevant criteria throughout the shelf-life		
16: Has the food business operator set a shelf-life of the foods they produce, manufacture or pack?	☐ Yes ☐ No – **end of questionnaire**	
16 (a): Can the food business operator demonstrate that the food they produce, manufacture or package complies with the relevant criteria throughout its shelf-life?	☐ Yes ☐ No	
16 (b): Has the food business operator determined the physico-chemical characteristics of their product (such as pH, water activity, salt content, concentration of preservatives and type of packaging) taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf-life?	☐ Yes ☐ No ☐ Not necessary	
16 (c): Has the food business operator consulted available scientific literature and research data regarding the growth and survival characteristics of the microorganisms of concern?	☐ Yes ☐ No ☐ Not necessary	
16 (d): Has the food business operator conducted predictive mathematical modelling established for the food in question, using critical growth or survival factors for the microorganisms of concern in the product?	☐ Yes ☐ No ☐ Not necessary	

QUESTION	ANSWER	COMMENT
16 (e): Has the food business operator carried out tests (i.e. challenge studies) to investigate the ability of appropriately inoculated microorganisms of concern to grow or survive in the product under different reasonably foreseeable storage conditions?	☐ Yes ☐ No ☐ Not necessary	
16 (f): Has the food business operator carried out durability studies to evaluate the growth or survival of the microorganism of concern that may be present in the product during the shelf-life under reasonably foreseeable conditions of distribution, storage and use?	☐ Yes ☐ No ☐ Not necessary	