



Survey on Verification of Compliance with Commission Regulation (EC) No 2073/2005 (12NS1)

DECEMBER 2014

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SUMMARY

The aim of this survey was to verify that food business operators registered with the Health Service Executive (HSE) comply with the microbiological criteria set in Commission Regulation (EC) No 2073/2005, as amended. Food samples were collected from food establishments that were registered with the HSE and that manufactured, processed or prepared food for which there was a relevant criterion set in the Regulation. Foods were sampled and analysed following the sampling plans set in the Regulation. In total, 99% (459/462) of samples tested against the Regulation's food safety criteria were compliant but only 63% (90/143) of samples tested against process hygiene criteria complied with the Regulation.

A food safety criterion is used to assess the safety of food. Although the results of testing against food safety criteria were good, three (0.6%) samples did not comply with the Regulation: *Salmonella* Dublin was detected in one minced meat sample and *Listeria monocytogenes* was detected in one cooked ham sample and one coleslaw sample.

Process hygiene criteria are used to assess if the production process is functioning hygienically. Over one third (34%; 53/143) of samples tested against process hygiene criteria did not comply with the Regulation. Minced meat had the highest rate of unsatisfactory results: 83% (39/47) of samples tested for aerobic colony count (ACC) were unsatisfactory and 23% (13/57) of samples tested for *E. coli* were unsatisfactory.

Taking account of the results of this survey, food business operators that are registered with the HSE and which produce, manufacture or package ready-to-eat food should take measures to prevent ready-to-eat food becoming contaminated with *L. monocytogenes*. They should also prevent any subsequent growth of this pathogen in ready-to-eat foods by maintaining adequate temperature control and by setting an appropriate and safe shelf-life. Food business operators that manufacture minced meat at retail level (e.g. butcher shops and supermarkets) should review their procedures to ensure that their products comply with the process hygiene criteria set in Commission Regulation (EC) No 2073/2005, as amended. Although these food businesses are exempt from the requirements of Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, they could use this Regulation's technical rules for producing minced meat as a safeguard to improve compliance with the process hygiene criteria set in Commission Regulation (EC) No 2073/2005, as amended.

ACKNOWLEDGEMENTS

The Food Safety Authority of Ireland (FSAI) thanks those that participated in this survey: environmental health officers and the laboratory staff of the official food microbiology laboratories of HSE, the National *Listeria monocytogenes* Reference Laboratory (Backweston), and the *Salmonella*, *Shigella* and *Listeria* Reference Laboratory (Galway).

INTRODUCTION

Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs, as amended, sets microbiological criteria for certain combinations of foods and microorganisms (their toxins or metabolites). The types of foods for which criteria are set in the Regulation are broadly categorised as:

- Ready-to-eat foods
- Carcasses
- Fresh poultry meat
- Minced meat
- Meat preparations
- Meat products
- Mechanically separated meat
- Dairy products
- Egg products
- Live bivalve molluscs
- Fishery products
- Cooked crustaceans and molluscan shellfish
- Pre-cut fruit and vegetables (ready-to-eat)
- Sprouts and sprouted seeds
- Unpasteurised fruit and vegetable juices (ready-to-eat)

The Regulation aims to enhance food safety and facilitate fair trade by harmonising microbiological criteria that can be used to assess the acceptability of food. Two types of microbiological criteria are set in the Regulation: food safety criteria and process hygiene criteria.

Food safety criteria are used to assess the safety of food. These criteria apply to products placed on the market¹. If results of testing against food safety criteria are unsatisfactory, the batch of food² from which the sample came must be withdrawn or recalled from the market in accordance with Article 19 of Regulation (EC) No 178/2002. The food business operator must also investigate the cause of the unsatisfactory result and take measures to prevent its reoccurrence (see Appendix 1 of this report).

Process hygiene criteria are used to assess if the production process is operating hygienically. These criteria apply to food sampled during or at the end of the manufacturing process, and not to food placed on the market. If test results are unsatisfactory, the batch of food from which the sample came may be placed (or remain) on the market, but the food business operator must investigate the cause of the unsatisfactory result and take measures to prevent its reoccurrence (see Appendix 2 of this report).

¹ According to Regulation (EC) No 178/2002; 'placing on the market' means: 'the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves'

² Commission Regulation (EC) No 2073/2005, as amended, defines a 'batch' as 'a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one production period'



Food business operators' obligations

Food business operators are required to ensure that foodstuffs comply with the relevant microbiological criteria set in Commission Regulation (EC) No 2073/2005, as amended, by taking measures as part of their procedures based on HACCP³ principles together with implementing good hygiene practice (Article 3).

The Regulation has most impact on food business operators that produce, manufacture or package food for which criteria are set in the Regulation. Depending on the type of food produced, manufactured or packaged, the food business operator *may* need to:

1. Identify criteria in the Regulation that are relevant to the food they manufacture, package or produce
2. Test (where appropriate) the food they produce, manufacture or package to check it complies with the relevant criteria
3. Take the appropriate action if test results are unsatisfactory
4. Analyse trends in their test results and take action if they observe a trend towards unsatisfactory results
5. Conduct environmental monitoring
6. Label with the instruction to cook thoroughly, if they manufacture or package minced meat and meat preparations (made from species other than poultry) which are intended to be eaten cooked
7. Demonstrate the food complies with relevant criteria throughout its shelf-life

Competent authorities' obligations

Competent authorities, in accordance with Regulation (EC) No 882/2004, must verify food business operators' compliance with Commission Regulation (EC) No 2073/2005. Competent authorities can verify a food business operator's compliance in a number of ways including:

- a. Auditing their procedures based on HACCP and good hygiene practice
- b. Assessing their sampling and testing schemes
- c. Checking their laboratory test reports
- d. Assessing the adequacy of their corrective and preventive actions
- e. Inspection
- f. Monitoring
- g. Surveillance
- h. Taking official control samples of food for testing

The FSAI has published guidance for competent authorities on enforcing the Regulation (FSAI 2014a).

³ Hazard Analysis and Critical Control Point

AIM OF SURVEY

The aim of this survey was to verify that food business operators registered with the HSE comply with the microbiological criteria set in Commission Regulation (EC) No 2073/2005, as amended.

METHOD

The HSE assessed food business operators' compliance with microbiological criteria set in Commission Regulation (EC) No 2073/2005, as amended, through official control sampling and analysis of food, following the sampling plans set in the Regulation.

Sample collection

In September, October and November 2012, environmental health officers collected food samples from manufacturing, retail and catering establishments registered with the HSE. The types of food establishment from which samples were collected included bakeries, butcher shops, delicatessens, fruit and vegetable processors, hospitals, hotels, nursing homes, restaurants and supermarkets.

As the aim of this survey was to evaluate food business operators' compliance with microbiological criteria set in Commission Regulation (EC) No 2073/2005, as amended, only the following types of food were sampled:

1. Food for which a relevant microbiological criterion was set in the Regulation at the time the survey was being conducted⁴, and
2. Food that was manufactured, processed or prepared in the establishment from which the sample was taken

The following types of food were **excluded** from the survey:

1. Food for which no relevant criteria were set in the Regulation, and
2. Food that was manufactured, processed or prepared in a different establishment to that in which sampling was being carried out

For each criterion, the Regulation provides a sampling plan, which states the number of sample units 'n' that must be collected from a batch of food in order to make up one sample. For all food types collected in this survey, n=5.

Following the sampling plans in the Regulation, samples tested against process hygiene criteria were collected at the end of the manufacturing process. Samples tested against food safety criteria were collected in the same establishment in which they were manufactured, processed or prepared but only once they were placed on the market. On some occasions, samples for both process hygiene criteria and food safety criteria were taken from the same batch of food since in that particular establishment, there was very little difference between a product that has been placed on the market and the product which is at the end of the manufacturing process; for example, minced meat that was manufactured and immediately placed on display for sale.

⁴ At the time the survey was carried out, corrections and amendments to the Regulation up to and including Commission Regulation (EU) No 1086/2011 applied (Appendix 3)

Sample analysis and interpretation of results

Microbiological analysis was carried out in the seven official food microbiology laboratories of the HSE using the analytical reference method specified in the Regulation for each relevant criterion. Depending on the relevant food category, food samples were analysed for one or more of the following six parameters:

- ACC
- *E. coli*
- Enterobacteriaceae
- *L. monocytogenes* (detection)
- *L. monocytogenes* (enumeration)
- *Salmonella*

Each of the five sample units in a sample were analysed separately and results for the entire sample were interpreted in accordance with the Regulation. See Appendix 4 of this report for interpretation of food safety criteria results and Appendix 5 for the interpretation of process hygiene criteria results.

Statistical analysis

Fisher's exact test analysis was performed using SPSS Version 18.0. Significance was defined at the $p < 0.05$ level.

RESULTS AND DISCUSSION

In total, 99% (459/462) of food samples tested against food safety criteria and 63% (90/143) of food samples tested against process hygiene criteria complied with the relevant microbiological criteria set in Commission Regulation (EC) No 2073/2005, as amended.

Food safety criteria

The majority of food samples tested against food safety criteria were ready-to-eat foods (food category 1.2 or 1.3)⁵, followed by minced meat and meat preparations made from other species than poultry intended to be eaten cooked (food category 1.6) (Table 1). Three (0.6%) of these samples did not comply with food safety criteria:

1. One sample of **cooked ham** (food category 1.2): *L. monocytogenes* was detected in 1/5 sample units
2. One sample of **coleslaw** (food category 1.2): *L. monocytogenes* was detected in 2/5 sample units
3. One sample of **raw minced beef** (food category 1.6): *Salmonella* Dublin was detected in 3/5 sample units

For each unsatisfactory sample, environmental health officers informed the food business operator concerned and carried out follow-up investigations.

⁵ At the data analysis stage it was not possible to differentiate all ready-to-eat food samples into their relevant food category 1.2 (ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes) or food category 1.3 (ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes). Therefore, food category 1.2 and 1.3 results are combined in this report

Table 1: Results of testing against food safety criteria

Food category	Test	Number food samples analysed	Number satisfactory (%)	Number unsatisfactory (%)
1.2/1.3 Ready-to-eat foods ^(a) other than those intended for infants and for special medical purposes	<i>L. monocytogenes</i> (detection)	120	118 (98.3)	2 (1.7) ^(b)
1.2/1.3 Ready-to-eat foods ^(a) other than those intended for infants and for special medical purposes	<i>L. monocytogenes</i> (enumeration)	246	246 (100)	0 (0)
1.6 Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	<i>Salmonella</i>	68	67 (98.5)	1 (1.5) ^(c)
1.9 Meat products made from poultry meat intended to be eaten cooked	<i>Salmonella</i>	2	2 (100)	0 (0)
1.15 Ready-to-eat foods containing raw egg, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	<i>Salmonella</i>	5	5 (100)	0 (0)
1.19 Precut fruit and vegetables (ready-to-eat)	<i>Salmonella</i>	19	19 (100)	0 (0)
1.20 Unpasteurised fruit and vegetable juices (ready-to-eat)	<i>Salmonella</i>	2	2 (100)	0 (0)
	Total	462	459 (99.4)	3 (0.6)

^(a) Combined results for food category 1.2 (able to support *L. monocytogenes* growth) and food category 1.3 (unable to support *L. monocytogenes* growth). A number of food samples were tested using both the enumeration and detection tests

^(b) *L. monocytogenes* detected in 1/5 sample units of cooked ham and in 2/5 samples of coleslaw. Both products were food category 1.2 (able to support the growth of *L. monocytogenes*) and since neither food business operator had evidence to demonstrate that their product would not exceed the limit of 100 cfu/g throughout the shelf-life, absence of *L. monocytogenes* in 25g was required (see Table 2)

^(c) *Salmonella* Dublin was detected in 3/5 sample units of raw steak mince

Food Category 1.2

In total, 282 samples of ready-to-eat⁶ food were tested for *L. monocytogenes* by the detection method, the enumeration method, or both. The types of ready-to-eat food tested in this survey were broadly categorised as: prepared savoury dishes (59%), cooked meats (26%), pre-cut fruit and vegetables (8%), desserts (6%), orange juice (0.7%) and hard boiled eggs (0.4%).

One sample of cooked ham and one sample of coleslaw were unsatisfactory. On receipt of the unsatisfactory results, environmental health officers informed the relevant food business operators and carried out follow-up investigations. As the shelf-life of both products had expired, and they were no longer on the market, a product withdrawal and recall was not required. However, the food business operators reviewed their HACCP-based procedures and made improvements to their production processes and hygiene.

The unsatisfactory ham and coleslaw samples both had a shelf-life of >5 days and fell into food category 1.2, for which the Regulation sets two limits: 100 cfu/g or absence in 25g (Table 2). Because food category 1.2 foods can support the growth of *L. monocytogenes*, the 100 cfu/g only applies if the manufacturer has demonstrated, to the satisfaction of the competent authority, that the product won't exceed the 100 cfu/g limit throughout the shelf-life. If the manufacturer can't demonstrate this, the absence in 25g limit applies before the food leaves their immediate control. As both the unsatisfactory samples were sampled when still under the manufacturer's immediate control, and because neither manufacturer had evidence to demonstrate that their product would not exceed 100 cfu/g *L. monocytogenes* throughout the shelf-life, the criterion requiring absence of *L. monocytogenes* in 25g applied to both samples. Both were deemed unsatisfactory because *L. monocytogenes* was detected in at least one of the five sample units of each sample (Table 1).

Because *L. monocytogenes* can become established in food processing establishments, food business operators must ensure that their cleaning and sanitisation procedures are effective to remove *L. monocytogenes*. This is particularly important for food processing equipment and food contact surfaces so that they do not contaminate ready-to-eat food with *L. monocytogenes*. Indeed, Commission Regulation (EC) No 2073/2005, as amended, requires that food business operators that manufacture ready-to-eat foods which may pose a *L. monocytogenes* risk for public health, sample the processing areas and equipment for *L. monocytogenes* as part of their sampling scheme. The FSAI's report on the control and management of *Listeria monocytogenes* contamination of food (FSAI 2005) provides information on sources of contamination and control measures for *L. monocytogenes* in food processing establishments. The European Commission has also produced guidance for food business operators on how to effectively sample their food processing environment and equipment for *L. monocytogenes* to verify that their cleaning and sanitation procedures are effective (EC 2012).

As *L. monocytogenes* can grow at refrigeration temperatures, foods which present the greatest *L. monocytogenes* risk are chilled, ready-to-eat foods with a long shelf-life. If the food business operators that produced the unsatisfactory coleslaw and ham had set a shorter shelf-life (<5 days) for their product, both would have fallen into food category 1.3 not food category 1.2. Food category 1.3 sets a legal limit for *L. monocytogenes* of 100 cfu/g. The results of *L. monocytogenes* enumeration testing carried out on the same samples of coleslaw and ham were <10 cfu/g. The FSAI's Guidance Note No.18 provides information for food business operators on setting a safe shelf-life for their products (FSAI 2014b). In addition, the European Commission has produced guidance on conducting shelf-life studies for ready-to-eat foods for food business operators (EC 2008) and for laboratories (EC 2014).

⁶ The Regulation defines 'ready-to-eat food' as 'food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern'

Table 2: The Regulation sets two *L. monocytogenes* limits for food category 1.2 foods

Food category	Microorganism	Sampling plan		Limits	Analytical reference method	Stage where the criterion applies
		n	c			
1.2 Ready-to-eat foods able to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes	<i>Listeria monocytogenes</i>	5	0	100 cfu/g ^(a)	EN/ISO 11290-2	Products placed on the market during their shelf-life
		5	0	Absence in 25g ^(b)	EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it

^(a) See footnote 5 in the Regulation "This criterion shall apply 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 operator 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."

^(b) See footnote 7 in the Regulation "This criterion shall apply to products before they have left the immediate control of the producing food business operator, 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."

Food Category 1.6

Regulation (EC) No 853/2004, as amended, defines:

- **Minced meat** as 'boned meat that has been minced into fragments and contains less than 1% salt'
- **Meat preparations** as 'fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat'

Examples of meat preparations commonly found on the Irish market include: raw beef burgers or meat balls; raw stuffed pork fillet; raw chicken wings marinated in barbeque sauce; raw pork stir-fry strips in Chinese sauce; raw sausages.

Of the 68 foods tested against food category 1.6, 54 (79%) were minced meat and 14 (21%) were meat preparations (13 sausage samples and one beef burger sample). The food safety criterion applicable to food category 1.6 requires absence of *Salmonella* in all five sample units. In one case, *Salmonella* was detected in 3/5 sample units of a sample of raw steak mince from a butcher shop⁷.

Follow-up investigations at the butcher shop were carried out by environmental health officers. The butcher, as required under Article 6 of the Regulation, had clearly informed consumers that the minced must be thoroughly cooked before consumption by way of point of sale notices in the shop. None of the implicated batch of mince was still on the market as its shelf-life had expired. However, the butcher placed recall notices in the shop in case consumers had purchased mince from the implicated batch and frozen it for use later. The butcher reviewed their HACCP-based procedures and good hygiene practice. Follow-up samples taken by environmental health officers and the butcher were satisfactory.

⁷ The results of testing against process hygiene criteria (ACC and *E. coli*, based on food category 2.1.6 'minced meat') on a sample (n=5) taken from the same production batch of mince were satisfactory

The *Salmonella* isolated from the three positive sample units was identified as *S. Dublin*, antigenic structure 9,12:g,p, by the National Salmonella, Shigella & Listeria Reference Laboratory (NSSLRL) at the National University of Ireland, Galway. The isolates were fully susceptible to all 15 antibiotics⁸ tested. In Ireland, *S. Dublin* is strongly associated with cattle. *S. Dublin*, with the same antigenic structure, was also isolated during a national survey of raw minced beef and raw beef burgers Ireland (FSAI 2013). In that survey, 0.1% (1/983) of single samples (n=1) collected from retail and catering establishments were positive for *Salmonella*.

Between January 2007 and the end of May 2014, the NSSLRL received 100 isolates of *S. Dublin*, antigenic structure 9,12:g,p. Of these, 46% were isolated from cattle sources and 41% were isolated from cases of human illness. All of the 41 human cases were likely to have been infected in Ireland, since none of the cases reported foreign travel in the period prior to falling ill. Although none of the cases were directly linked to eating beef, five cases reported contact with cows; for example they worked on a farm. In total however, *S. Dublin* causes only a small proportion of human salmonellosis cases in Ireland. Only 1.9% (6/319) of *Salmonella* isolates from human cases in 2012 were serotype Dublin, with the majority of human salmonellosis caused by *S. Typhimurium* (38.2%) or *S. Enteritidis* (17.6%), (HPSC, 2013). Again in 2013, *S. Dublin* accounted for a small proportion (3.5%) of the human salmonellosis cases in Ireland (NSSLRL 2014).

Process hygiene criteria

While 62% (89/143) of food samples tested against process hygiene were satisfactory and 0.1% (1/143) were acceptable, over one third (37%; 53/143) did not comply with the limits set in the Regulation and were classified as unsatisfactory (Table 3).

The majority of samples tested against process hygiene criteria were raw minced meat (food category 2.1.6) and meat preparations (food category 2.1.8). Raw meat can become contaminated with microorganisms, including pathogens, from the animal's intestinal tract and hide during slaughter and hide removal. The microbial contamination usually occurs on the exposed surface of whole cuts of meat, but when meat is minced, microorganisms that are on the surface of the meat become mixed throughout. A Canadian risk assessment for *E. coli* O157, demonstrated that, in terms of foodborne illness, it is 7,300 times riskier to consume minced beef than intact cuts of beef (Catford *et al*, 2013). This is why minced meat and beef burgers should be cooked thoroughly, but steaks or whole joints of beef may be cooked rare (FSAI 2014c).

Hygiene and temperature control during slaughter, cutting, boning and the preparation of minced meat and meat preparations is essential because there are no pathogen elimination steps during these processes. Regulation (EC) No 853/2004, as amended, sets specific rules for hygiene and temperature control at slaughter and during cutting and boning of carcasses, and for temperature control and age of meat used for producing minced meat and meat preparations. With respect to temperature control, Regulation (EC) No 853/2004, as amended, requires that the meat used to produce minced meat is no more than 7°C, and that immediately after production the minced meat must be chilled to an internal temperature of not more than 2°C, or frozen to an internal temperature of not more than -18°C, and that these temperatures must be maintained during storage and transport. However, food businesses that manufacture minced meat and meat preparations at retail level, such as butcher shops and supermarkets, are exempt from these rules. All minced meat and meat preparations tested in this survey were sampled from butcher shops or supermarkets.

⁸ Ampicillin, Chloramphenicol, Streptomycin, Sulphonamides, Tetracycline, Trimethoprim, Nalidixic acid, Ciprofloxacin, Ceftazidime, Gentamycin, Cefotaxime, Azithromycin, Tigecycline, Meropenem and Cefepime

Table 3: Results of testing against process hygiene criteria

Food category	Test	Number of food samples analysed	Number satisfactory (%)	Number acceptable (%)	Number unsatisfactory (%)
2.1.6: Minced meat	ACC	47	8 (17.0)	0 (0)	39 (83.0)
	<i>E. coli</i>	57	43 (75.4)	1 (1.8)	13 (22.8)
2.1.8: Meat preparations	<i>E. coli</i>	16	15 (93.8)	0 (0)	1 (6.3)
2.2.8: Ice-cream ^(a) and frozen dairy desserts	Enterobacteriaceae	2	2 (100)	0 (0)	0 (0)
2.3.1: Egg products	Enterobacteriaceae	1	1 (100)	0 (0)	0 (0)
2.5.1: Precut fruit and vegetables (ready-to-eat)	<i>E. coli</i>	18	18 (100)	0 (0)	0 (0)
2.5.2: Unpasteurised fruit and vegetable juices (ready-to-eat)	<i>E. coli</i>	2	2 (100)	0 (0)	0 (0)
Total		143	89 (62.2)	1 (0.7)	53 (37.1)

^(a) Only applies to ice-cream containing milk ingredients

Food Category 2.1.6

The highest unsatisfactory rate for process hygiene criteria was in minced meat (food category 2.1.6). 83% (39/47) of minced meat samples tested for ACC were unsatisfactory and 23% (13/57) minced meat samples tested for *E. coli* were unsatisfactory⁹. An Austrian study, which tested 179 samples (n=5) of minced meat (beef, pork or beef/pork mix) from 129 outlets of one supermarket chain against the process hygiene criteria, found that 31.3% (56 samples) were unsatisfactory for ACC and 4.5% (8 samples) were unsatisfactory for *E. coli* (Paulsen *et al* 2011). The higher rate of unsatisfactory results for ACC compared to *E. coli* in the current study suggests poor handling practices and temperature control as the *E. coli* test is used as an indicator of faecal contamination.

The ACC counts in minced meat ranged from 9.1×10^4 to 3.1×10^8 cfu/g (Table 4). An ACC count is unsatisfactory when $>5 \times 10^6$ cfu/g, or if more than two of the five sample units in a sample are in the acceptable range (5×10^5 to 5×10^6 cfu/g). A count $\leq 5 \times 10^5$ cfu/g is satisfactory. In the current study, the ACC counts for 42% of the 235 sample units tested were unsatisfactory.

⁹ Although food category 2.1.6 cites criteria for both ACC and *E. coli*, fewer samples of minced meat were tested for ACC than for *E. coli* because the ACC criterion does not apply to minced meat produced at retail level when the shelf-life of the product is less than 24 hours. See footnote 7 of Annex 1, Chapter 2, 2.1 Meat and products thereof, of the Regulation

Table 4: Range of ACC results for minced meat sample units (food category 2.1.6)

Result	Number of sample units ^(a)	Actual counts ranged from:
Satisfactory ≤5x10 ⁵ cfu/g	42 (18%)	9.1x10 ⁴ to 5.0x10 ⁵ cfu/g
Acceptable Between 5x10 ⁵ and 5x10 ⁶ cfu/g	94 (40%)	5.3x10 ⁵ to 4.9x10 ⁶ cfu/g
Unsatisfactory ^(b) >5x10 ⁶ cfu/g	99 (42%)	5.2x10 ⁶ to 3.1x10 ⁸ cfu/g

^(a) As 47 samples of minced meat were tested for ACC and n=5, this resulted in 235 (5x47) ACC test results

^(b) A sample is also categorised as unsatisfactory if more than 2/5 sample units have an ACC result in the acceptable range

The *E. coli* counts in minced meat ranged from <10 to 23,000 cfu/g (Table 5). An *E. coli* count is unsatisfactory if >500 cfu/g, or if more than two of the five sample units in a sample are in the acceptable range (50 to 500 cfu/g). A count of ≤50 cfu/g is satisfactory. In an Austrian study of minced meat at retail level, none of the 154 samples tested (88 in 2010 and 66 in 2011) exceeded the *E. coli* upper limit of 500 cfu/g, with most samples (93.3% in 2010 and 84.8% in 2011) having an *E. coli* count <50 cfu/g (Höck *et al*, 2012). In the current study, the upper limit of 500 cfu/g of *E. coli* was exceeded in 6% of the 285 sample units of minced meat tested.

Table 5: Range of *E. coli* results in minced meat (food category 2.1.6)

Result	Number of sample units ^(a)	Actual counts ranged from:
Satisfactory ≤50 cfu/g	223 (78%)	<10 to 50 cfu/g
Acceptable Between 50 and 500 cfu/g	45 (16%)	60 to 430 cfu/g
Unsatisfactory ^(b) >500 cfu/g	17 (6%)	920 to 23,000 cfu/g

^(a) As 57 samples of minced meat were tested for *E. coli* and n=5, this resulted in 285 (5x57) *E. coli* test results

^(b) A sample is also categorised as unsatisfactory if more than 2/5 sample units have an *E. coli* count in the acceptable range

When the results of testing minced meat for *E. coli* or ACC are unsatisfactory, food business operators are required to improve production hygiene and improve selection and/or origin of raw materials. The mincing process distributes microbial contamination from the outside cut surface of the meat throughout the minced meat, increases the meat's temperature and increases its surface area – all of which encourage microbial growth. The mincer may also be a significant source of contamination if it is not effectively cleaned between uses.

Although Regulation (EC) No 853/2004, as amended, sets rules for the hygienic production, temperature control and the age of meat used to prepare minced meat, this Regulation has an exemption for retail food businesses, including butcher shops and supermarkets, from which the samples in this survey were collected. However, the technical rules in the Regulation for the production of minced meat could be a useful safeguard for retail butchers to improve compliance of their minced meat with the process hygiene criteria.

With respect to temperature control at retail level, foods which require refrigeration must be stored and displayed at a temperature $\leq 5^{\circ}\text{C}$ (NSAI 2007). In the current study, compliance with this temperature requirement was good with 84% (26/31¹⁰) of minced meat samples tested for ACC and 85% (29/34¹¹) of minced meat samples tested for *E. coli* stored or displayed at a temperature $\leq 5^{\circ}\text{C}$ at the time the sample was collected. Five samples of minced meat were stored or displayed at a temperature $> 5^{\circ}\text{C}$ at the time the sample was collected – the storage/display temperatures were recorded as: 5.2, 5.4, 6.1 and 9.4 $^{\circ}\text{C}$. All five samples were unsatisfactory for ACC. The *E. coli* results were unsatisfactory for two of these samples, acceptable for one sample and satisfactory for two samples. There was no statistically significant¹² difference between the results of minced meat samples stored at $\leq 5^{\circ}\text{C}$ compared to those stored at $> 5^{\circ}\text{C}$. This is unsurprising since the samples which exceeded 5°C only slightly exceeded this temperature.

Food Category 2.1.8

Sixteen samples of meat preparations were tested for *E. coli*: 13 sausages samples, two meatball samples and one beef burger sample. The Regulation sets limits for *E. coli* in meat preparations, but not ACC. One meat preparation sample – raw sausage – was unsatisfactory (Table 3). A sample from the same production batch of sausages complied with the food safety criterion; i.e. *Salmonella* was not detected in any of the five sample units.

E. coli counts in meat preparations ranged from < 10 to 4,500 cfu/g (Table 6). Even though no sample unit had an *E. coli* count $> 5,000$ cfu/g (unsatisfactory); for one sausage sample the *E. coli* count in all five sample units was in the acceptable range¹³ (500-5,000 cfu/g) and so the overall sample was categorised as unsatisfactory as per the rules for interpreting test results set in the Regulation (see Appendix 5 of this report). It should be noted the *E. coli* limits for meat preparations are ten times less stringent than those for minced meat. Even so, the highest *E. coli* count for a meat preparation was of 4.5×10^3 cfu/g compared to the highest minced meat *E. coli* count of 2.3×10^4 cfu/g (Tables 5 and 6).

Table 6: Range of *E. coli* results in meat preparations (food category 2.1.8)

Result	Number of sample units ^(a)	Actual counts ranged from:
Satisfactory ≤ 500 cfu/g	75 (94%)	< 10 to 170 cfu/g
Acceptable Between 500 and 5,000 cfu/g	5 (6%)	1,000 to 4,500 cfu/g
Unsatisfactory ^(b) $> 5,000$ cfu/g	0	

^(a) As 16 samples of meat preparations were tested for *E. coli* and $n=5$, this resulted in 80 (5x16) *E. coli* test results

^(b) A sample is also categorised as unsatisfactory if more than 2/5 sample units have an *E. coli* count in the acceptable range – this occurred for the unsatisfactory sample mentioned in Table 3

As for minced meat, compliance with the requirement at retail level to store meat preparations at a temperature $\leq 5^{\circ}\text{C}$ was good, with 92% (12/13¹⁴) of the samples stored or displayed at a temperature $\leq 5^{\circ}\text{C}$ at the time they were collected. One meat preparation sample was unsatisfactory for *E. coli*, and this was stored or displayed at a temperature 3.4°C at the time the sample was collected.

¹⁰ Temperature was provided for 31/47 minced meat samples that were tested for ACC

¹¹ Temperature was provided for 34/57 minced meat samples that were tested for *E. coli*

¹² $p=0.56$ (ACC test); $p=0.19$ (*E. coli* test)

¹³ Actual counts were for the five sample units were: 1,000; 2,100; 2,300; 4,200 and 4,500 cfu/g

¹⁴ Temperature was provided for 13/16 meat preparation samples tested for *E. coli*. The temperature of one sample was recorded was 5.2°C

CONCLUSIONS

While the results of testing against food safety criteria were good, two samples of ready-to-eat food contained *Listeria monocytogenes*, and one sample of minced meat contained *Salmonella*. The process hygiene criteria for minced meat were poor. 83% of samples had unsatisfactory ACC levels and 23% had unsatisfactory *E. coli* levels.

RECOMMENDATIONS

Taking account of the results from this survey, it is recommended that:

Food business operators registered with the HSE that produce, manufacture or package ready-to-eat food should:

1. Take measures to prevent contamination of ready-to-eat foods with *Listeria monocytogenes*
2. Take measures to prevent the growth of *L. monocytogenes* in ready-to-eat foods
3. Set an appropriate and safe shelf-life for the ready-to-eat food they produce, manufacture or package

Food business operators registered with the HSE that manufacture minced meat at retail level (e.g. butchers shops, supermarkets):

1. Should review their procedures to ensure that the minced meat they manufacture complies with the process hygiene criteria set in Commission Regulation (EC) No 2073/2005, as amended
2. Although exempt from Regulation 853/2004, as amended, could use the technical rules set in this Regulation to ensure compliance of their minced meat with the process hygiene criteria set in Commission Regulation (EC) No 2073/2005, as amended

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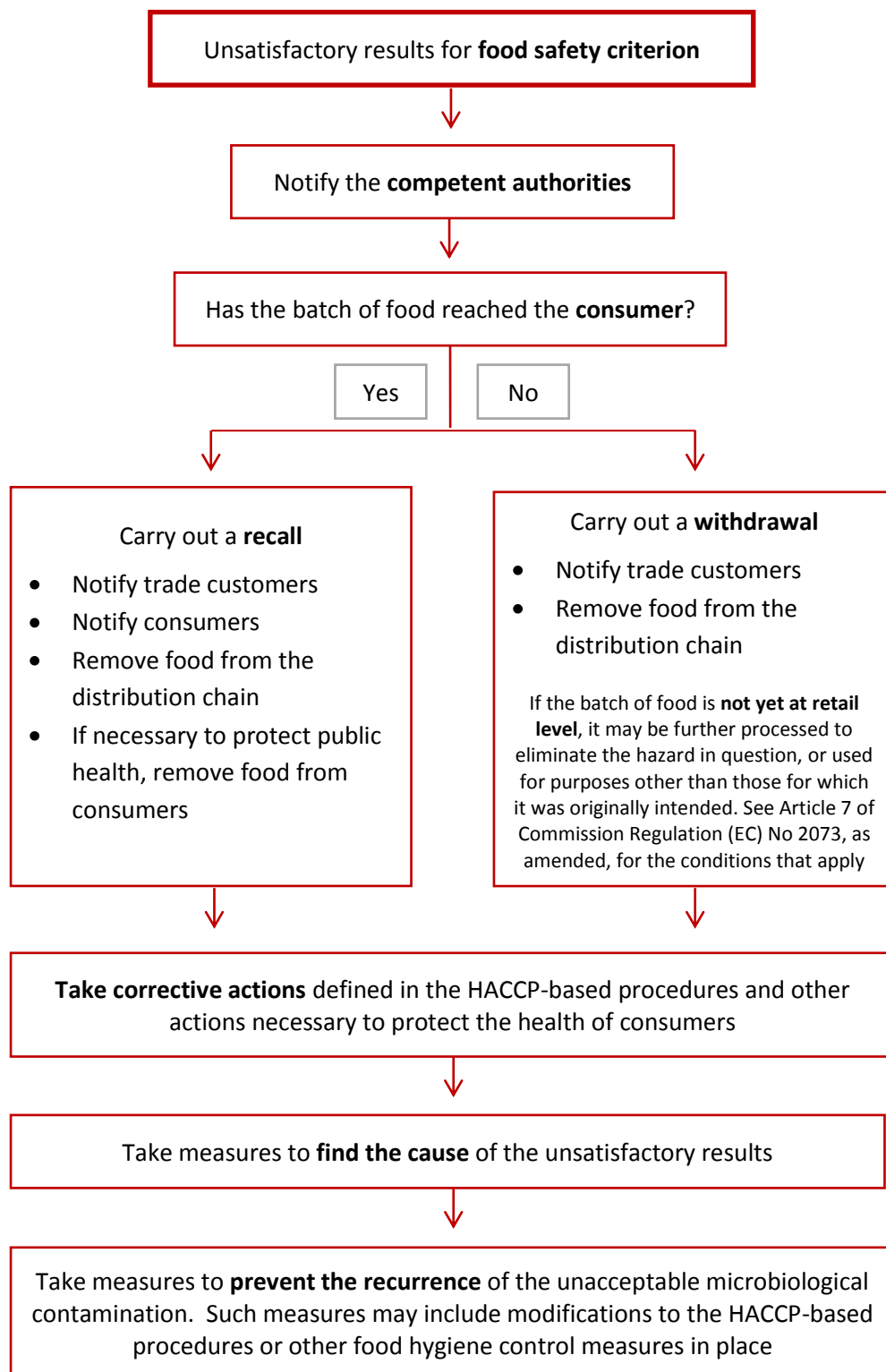
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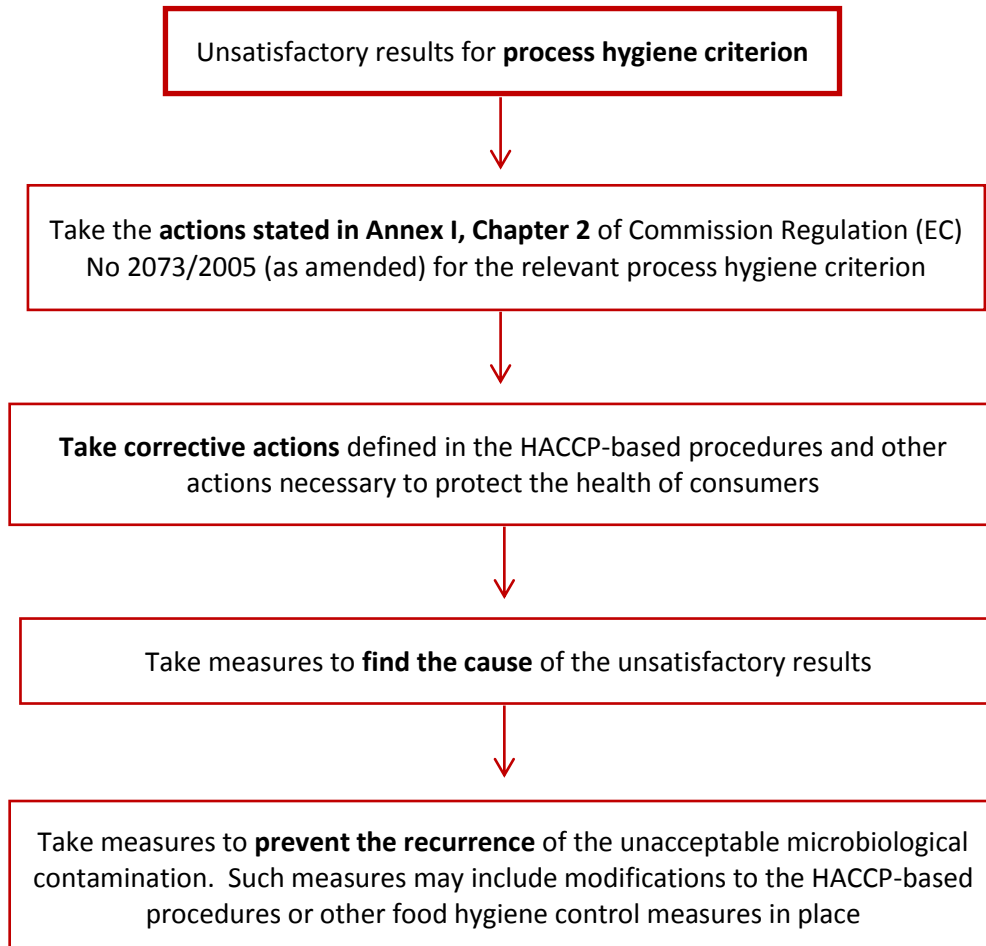
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APPENDIX 1: Action required by food business operator when food safety criteria results are unsatisfactory



APPENDIX 2: Action required by food business operator when process hygiene criteria results are unsatisfactory



APPENDIX 3: Amendments to Commission Regulation (EC) No 2073/2005

Since its publication in 2005, the Regulation has been corrected and amended on a number of occasions. At the time this survey was carried out, the corrections and amendments published up to September 2012 applied. These were:

1. Corrigendum (OJ L278, p32, 10/10/2006) to Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, p1, 22/12/2005)
2. Corrigendum (OJ L283, p62, 14/10/2006) to Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L338, p1, 22/12/05)
3. Commission Regulation (EC) No 1441/2007 (OJ L322, p12, 07/12/2007) of 5 December 2007
4. Commission Regulation (EC) No 365/2010 (OJ L107, p9, 29/04/2010) of 28th April 2010 as regards Enterobacteriaceae in pasteurised milk and other pasteurised liquid dairy products and *Listeria monocytogenes* in food grade salt
5. Commission Regulation (EU) No 1086/2011 (OJ L281, p7, 28/10/2011) of 27 October 2011 amending Annex II to Regulation (EC) No 2160/2003 and Annex I to Commission Regulation (EC) No 2073/2005 as regards *Salmonella* in fresh poultry meat

Since the survey was carried out, the following three amendments have been published:

1. Commission Regulation (EU) No 209/2013 (OJ L69, p19, 12/03/2013) of 11 March 2013 amending Commission Regulation (EC) No 2073/2005 of 15 November 2005 as regards microbiological criteria for sprouts and the sampling rules for fresh poultry meat
2. Commission Regulation (EU) No 1019/2013 (OJ L282, p46, 24/10/2013) of 23 October 2013 amending Annex I to Regulation (EC) No 2073/2005 as regards histamine in fishery products
3. Commission Regulation (EU) No 217/2014 of 7 March 2014 amending Regulation (EC) No 2073/2005 as regards *Salmonella* in pig carcasses

It is likely that the Regulation will be reviewed, revised or supplemented in the future in order to take account of developments in science, technology and methodology, changes in prevalence and contamination levels, changes in the population of vulnerable consumers, as well as the possible outputs from risk assessments. Any future amendments to the Regulation will be published on the FSAI's website:

www.fsai.ie/legislation/food_legislation/hygiene_of_foodstuffs/microbiological_criteria.html

APPENDIX 4: Interpreting results of samples tested against food safety criteria

The results of testing against food safety criteria were interpreted in accordance with Commission Regulation (EC) No 2073/2005.

Food category	Microorganism	Satisfactory	Unsatisfactory
1.2: Ready-to-eat foods able to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes	<i>Listeria monocytogenes</i>	Not detected in 25g for all five sample units	Detected in 25g for at least one of the five sample units
1.3: Ready-to-eat foods unable to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes	<i>Listeria monocytogenes</i>	All five sample units are ≤ 100 cfu/g	>100 cfu/g for at least one sample unit
	<i>Listeria monocytogenes</i>	Not detected in 25g for all five sample units	Detected in 25g for at least one of the five sample units
1.6: Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	<i>Salmonella</i>	Not detected in 10g for all five sample units	Detected in 10g for at least one of the five sample units
1.9: Meat products made from poultry meat intended to be eaten cooked	<i>Salmonella</i>	Not detected in 25g for all five sample units	Detected in 25g for at least one of the five sample units
1.15: Ready-to-eat foods containing raw egg, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	<i>Salmonella</i>	Not detected in 25g or ml for all five sample units	Detected in 25g or ml for at least one of the five sample units
1.19: Precut fruit and vegetables (ready-to-eat)	<i>Salmonella</i>	Not detected in 25g for all five sample units	Detected in 25g for at least one of the five sample units
1.20: Unpasteurised fruit and vegetable juices (ready-to-eat)	<i>Salmonella</i>	Not detected in 25g for all five sample units	Detected in 25g for at least one of the five sample units

APPENDIX 5: Interpreting results of samples tested against process hygiene criteria

The results of testing against process hygiene criteria were interpreted in accordance with Commission Regulation (EC) No 2073/2005.

Food category	Microorganism	Satisfactory	Acceptable	Unsatisfactory
2.1.6: Minced meat	Aerobic colony count	All five sample units are $\leq 5 \times 10^5$ cfu/g	Maximum of two sample units are between 5×10^5 and 5×10^6 cfu/g with the remaining three sample units $\leq 5 \times 10^5$ cfu/g	At least one sample unit is $> 5 \times 10^6$ cfu/g or more than two sample units are between 5×10^5 and 5×10^6 cfu/g
	<i>E. coli</i>	All five sample units are ≤ 50 cfu/g	Maximum of two sample units are between 50 and 500 cfu/g with the remaining three sample units ≤ 50 cfu/g	At least one sample unit is > 500 cfu/g or more than two sample units are between 50 and 500 cfu/g
2.1.8: Meat preparations	<i>E. coli</i>	All five sample units are ≤ 500 cfu/g	Maximum of two sample units are between 500 and 5,000 cfu/g with the remaining three sample units ≤ 500 cfu/g	At least one sample unit is $> 5,000$ cfu/g or more than two sample units are between 500 and 5,000 cfu/g
2.2.8: Ice cream ^(a) and frozen dairy desserts	Enterobacteriaceae	All five sample units are ≤ 10 cfu/g	Maximum of two sample units are between 10 and 100 cfu/g with the remaining three sample units ≤ 10 cfu/g	At least one sample unit is > 100 cfu/g or more than two sample units are between ten and 100 cfu/g
2.3.1: Egg products	Enterobacteriaceae	All five sample units are ≤ 10 cfu/g or ml	Maximum of two sample units are between 10 and 100 cfu/g or ml, with the remaining three sample units ≤ 10 cfu/g or ml	At least one sample unit is > 100 cfu/g or ml, or more than two sample units are between ten and 100 cfu/g or ml
2.5.1: Precut fruit and vegetables (ready-to-eat)	<i>E. coli</i>	All five sample units are ≤ 100 cfu/g	Maximum of two sample units are between 100 and 1,000 cfu/g with the remaining three sample units ≤ 100 cfu/g	At least one sample unit is $> 1,000$ cfu/g or more than two sample units are between 100 and 1,000 cfu/g
2.5.2: Unpasteurised fruit and vegetable juices (ready-to-eat)	<i>E. coli</i>	All five sample units are ≤ 100 cfu/g	Maximum of two sample units are between 100 and 1,000 cfu/g with the remaining three sample units ≤ 100 cfu/g	At least one sample unit is $> 1,000$ cfu/g or more than two sample units are between 100 and 1,000 cfu/g

^(a) Only applies to ice-cream containing milk ingredients



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