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Report Name: Ukraine's MRLs for Microbiological Contaminants

Country: Ukraine

Post: Kyiv

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Report Highlights:

This report lists Maximum Residue Levels (MRLs) for microbiological contaminates in different food products. These requirements are adopted by Ministry of Health Care of Ukraine Order 548 and went into power in August of 2015. These requirements are applicable to all domestically produced and imported meat, seafood, egg, milk and dairy products, infant formula, pre-cut fruits and vegetables, sprouted seeds, unpasteurized fruit and vegetable juices.

The Ministry of Healthcare of Ukraine adopted Order No. 548 "On Approval of Microbiological Criteria for Establishing Food Safety Indicators" (link in Ukrainian) on July 19, 2012. These requirements largely mimic EU Commission Regulation (EC) No 2073/2005 adopted on 15 November 2005 on microbiological criteria for foodstuffs. The Order went into effect on August 20, 2015 and is compulsory for all domestically produced and imported food products. It covers a variety of meat, dairy, fish and egg products, vegetables, fruits and products thereof. A separate set of regulations establishes MRLs for non-biological contaminants. Post issued a GAIN report outlining Ukraine's MRLs for non-biological contaminants.

Criteria that differ from those established in EU Regulations are highlighted in red. Ukraine maintains its own salmonella requirements and separate (but not different from the EU) requirements for infant formula for children between six and twelve months of age. Ukraine also established criteria for the simultaneous testing for *Cronobacter spp.* and *Enterobacter sakazakii* in infant formula.

Copied norms of EU Regulation 2073/2005 are partially compliant with the Codex Alimentarius guidelines: "Principles for the establishment and application of microbiological criteria for foods CAC/GL 21 — 1997" and microbiological safety recommendations of the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) and the Scientific Committee on Food (SCF). The regulation also considered existing Codex specifications in respect to dried milk products, food for infants and children and the histamine criterion for certain fish and fish products.

U.S. exporters must be aware that Ukraine's single food safety competent authority – the State Service of Ukraine on Food Safety and Consumer Protection (SSUFSCP) may require, implicitly and/or explicitly, compliance of imported foodstuffs with provisions of Order 548. U.S. exporters are strongly advised to consult with their Ukrainian partners regarding compliance of imported products with the norms listed below.

GENERAL REQUREMTNTS of Order 548:

Order 548 lays down general food safety requirements, prohibiting the placement on the market of products deemed as unsafe. Importers (food business operators) have an obligation to withdraw unsafe food from the market. Importers are required to comply with microbiological criteria provided below. This should include testing against the values set for the criteria. The testing process includes the taking of samples, conducting analyses and the implementation of corrective actions, in accordance with Ukraine's food law and instructions provided by SSUFSCP.

The Order allows food business operators to decide on testing frequency, but testing should meet or exceed requirements (if established in CRITERIA for Safety of Food Products table) of Order 548. Market operators are encouraged to conduct risk assessments and adjust testing frequency accordingly. Importers must comply with import testing requirements established by the SSUFSCP at border crossing points.

CRITERIA
for Safety of Food Products

(Criteria that differ from those established by EU Commission Regulation (EC) No 2073/2005 are in red)

Category of Food Products	Microorganisms / their toxins and metabolites	Sampling Plan[1]		Allowed Limits[2]		Analytical Reference Method[3]	Stage where the criterion applies
		n	c	m	M		
1. Ready-to-eat foods for infants and ready-to-eat foods for special medical purposes[4]	*Listeria monocytogenes*	10	0	Absence in 25 g		EN / ISO 11290-1	Products placed on the market during their shelf-life
2. Ready-to-eat foods able to support the growth of L. monocytogenes, other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	5	0	100 cfu/g[5]		EN / ISO 11290-2[6]	Products placed on the market during their shelf-life
		5	0	Absence in 25 g[7]		EN / ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it
3. Ready-to-eat foods unable to support the growth of L. monocytogenes, other than those intended for infants and for special medical purposes[4,8]	*Listeria monocytogenes*	5	0	100 cfu/g		EN / ISO 11290-2[6]	Products placed on the market during their shelf-life
4. Minced meat and meat preparations intended to be eaten raw	*Salmonella*	5	0	Absence in 25 g		EN / ISO 6579	Products placed on the market during their shelf-life
5. Minced meat and meat preparations made from poultry meat intended to be eaten cooked	*Salmonella*	5	0	Absence in 25 g		EN / ISO 6579	Products placed on the market during their shelf-life

6. Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	*Salmonella*	5	0	Absence in 10 g	EN / ISO 6579	Products placed on the market during their shelf-life
7. Mechanically separated meat (MSM)[9]	*Salmonella*	5	0	Absence in 10 g	EN / ISO 6579	Products placed on the market during their shelf-life
8. Meat products intended to be eaten raw, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g	EN / ISO 6579	Products placed on the market during their shelf-life
9. Meat products made from poultry meat intended to be eaten cooked	*Salmonella*	5	0	Absence in 25 g	EN / ISO 6579	Products placed on the market during their shelf-life
10. Gelatin and collagen	*Salmonella*	5	0	Absence in 25 g	EN / ISO 6579	Products placed on the market during their shelf-life
11. Cheeses, butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation[10]	*Salmonella*	5	0	Absence in 25 g	EN / ISO 6579	Products placed on the market during their shelf-life
12. Milk powder and whey powder[10]	*Salmonella*	5	0	Absence in 25 g	EN / ISO 6579	Products placed on the market during their shelf-life
13. Ice cream[11], excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g	EN / ISO 6579	Products placed on the market during their shelf-life

14. Egg products, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g	EN / ISO 6579	Products placed on the market during their shelf-life
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	*Salmonella*	5	0	Absence in 25 g or ml	EN / ISO 6579	Products placed on the market during their shelf-life
16. Cooked crustaceans and molluscan shellfish	*Salmonella*	5	0	Absence in 25 g	EN / ISO 6579	Products placed on the market during their shelf-life
17. Live bivalve molluscs and live echinoderms, tunicates and gastropods	*Salmonella*	5	0	Absence in 25 g	EN / ISO 6579	Products placed on the market during their shelf-life
18. Sprouted seeds (ready-to-eat)[12]	*Salmonella*	5	0	Absence in 25 g	EN / ISO 6579	Products placed on the market during their shelf-life
19. Pre-cut fruit and vegetables (ready-to-eat)	*Salmonella*	5	0	Absence in 25 g	EN / ISO 6579	Products placed on the market during their shelf-life
20. Unpasteurized fruit and vegetable juices (ready-to-eat)	*Salmonella*	5	0	Absence in 25 g	EN / ISO 6579	Products placed on the market during their shelf-life
21. Cheeses, milk powder and whey powder, as referred to in the coagulase-positive staphylococci criteria in Paragraphs 2.3-2.5 and 2.7 of Section II of Annex 2 to these Criteria	Staphylococcal enterotoxins	5	0	Not detected in 25 g	European screening method of the CRL for Milk[13]	Products placed on the market during their shelf-life

22. Dried infant formula and dried dietary foods for special medical purposes intended for infants below six months of age	*Salmonella*	30	0	Absence in 25 g		EN / ISO 6579	Products placed on the market during their shelf-life
23. Dried infant formula and dried dietary foods for special medical purposes intended for infants above six months, but below one year of age	*Salmonella*	30	0	Absence in 25 g		EN / ISO 6579	Products placed on the market during their shelf-life
24. Dried infant formula and dried dietary foods for special medical purposes intended for infants below six months of age[14]	*Cronobacter spp. (Enterobacter sakazakii)*	30	0	Absence in 10 g		ISO / TS 22964	Products placed on the market during their shelf-life
25. Live bivalve mollusks and live echinoderms, tunicates and gastropods	*E. coli*[15]	1[16]	0	230 cells (Most probable number technique) in 100 g of flesh and intra-valvular liquid		ISO TS 16649-3	Products placed on the market during their shelf-life
26. Fishery products from fish species associated with a high amount of histidine[17]	Histamine	9[18]	2	100 m g/kg	200 m g/kg	High Performance Liquid Chromatography	Products placed on the market during their shelf-life
27. Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine[17]	Histamine	9	2	200 m g/kg	400 m g/kg	Products placed on the market during their shelf-life	Products placed on the market during their shelf-life
28. Raw poultry meat[19]	Salmonella typhimurium[20]	5	0	Absence in 25 g.		EN / ISO6579 (for	Products placed on the market during

	and Salmonella enteritidis				detection), Kaufman-White scheme (for serotype)	their shelf-life

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[1] n - number of units comprising the sample; c - number of sample units giving values over m or between m and M.

[2] For points 1.1-1.25 m=M.

[3] The most recent edition of the standard shall be used.

[4] Regular testing against the criterion is not useful under normal circumstances for the following ready-to-eat foods:

— those which have received heat treatment or other processing effective to eliminate L. monocytogenes, when recontamination is not possible after this treatment (e.g. products heat treated in their final package),

— fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds,

— bread, biscuits and similar products,

— bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products,

— sugar, honey and confectionery, including cocoa and chocolate products,

— live bivalve mollusks;

— salt intended for human consumption.

[5] This criterion 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 operator may fix intermediate limits during the process that should be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of the shelf-life.

[6] 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.

[7] This criterion applies 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.

[8] Products with pH ≤ 4,4 or active water (a_w)≤ 0,92, products with pH ≤ 5,0 and a_w ≤ 0,94, products with a shelf-life of less than five days are automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.

[9] This criterion applies to mechanically separated meat (MSM) produced with the techniques referred to in Paragraph 8.4 Section VIII of Microbiological Criteria.

[10] Excluding products where the manufacturer can demonstrate to the satisfaction of the competent authorities that, due to the ripening time and a_w of the product where appropriate, there is no salmonella risk.

[11] Only ice cream containing milk ingredients.

[12] Preliminary testing of the batch of seeds before starting the sprouting process or the sampling to be carried out at the stage where the highest probability of finding Salmonella is expected.

[13] European Community Metrological Laboratory for coagulative staphylococci. European screening method for detection of staphylococcal enterotoxins in milk and dairy products

[14] Parallel studies *in Enterobacteriaceae* and *E. sakazakii* is performed only if no correlation has been established between these micro-organisms at the individual processing facility. If there are *Enterobacteriaceae* in any of the investigated product samples from a facility, the batch must be examined for *E. sakazakii* to establish correlation between *Enterobacteriaceae* and *E. sakazakii*.

[15] E. coli is used here as an indicator of fecal contamination.

[16] A pooled sample comprising a minimum of 10 individual animals.

[17] Particularly fish species of the families: *Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scombresosidae*.

[18] Single samples may be taken at the retail level. In such cases the provision that the whole batch should be deemed unsafe, shall not apply.

[19] This criterion applies to fresh meat from herds of *Galus galus* for breeding, laying hens, broilers and herds of turkeys for breeding and fattening.

[20] In the case of single-phase Salmonella typhimurium - only 1,4, [5], 12: i:

Interpretation of the Test Results

1. The limits given refer to each sample unit tested, excluding live bivalve molluscs and live echinoderms, tunicates and gastropods in relation to testing E. coli, where the limit refers to a pooled sample.
2. The test results demonstrate the microbiological quality of the batch tested.
3. L. monocytogenes in ready-to-eat foods intended for infants and for special medical purposes:
   satisfactory, if all the values observed indicate the absence of the bacterium,
   unsatisfactory, if the presence of the bacterium is detected in any of the sample units.
4. L. monocytogenes in ready-to-eat foods able to support the growth of L. monocytogenes before the food has left the immediate control of the producing food business operator when they are not able to demonstrate that the product will not exceed the limit of 100 cfu/g throughout the shelf-life:—
   satisfactory, if all the values observed indicate the absence of the bacterium,
   unsatisfactory, if the presence of the bacterium is detected in any of the sample units.
5. L. monocytogenes in other ready-to-eat foods and E. coli in live bivalve molluscs:
   satisfactory, if all the values observed are ≤ the limit,
   unsatisfactory, if any of the values are > the limit.
6. Salmonella in different food categories:
   satisfactory, if all the values observed indicate the absence of the bacterium,
   unsatisfactory, if the presence of the bacterium is detected in any of the sample units.
7. Staphylococcal enterotoxins in dairy products:
   satisfactory, if in all the sample units the enterotoxins are not detected,
   unsatisfactory, if the enterotoxins are detected in any of the sample units.
8. Enterobacter sakazakii in dried infant formula and dried dietary foods for special medical purposes intended for infants below 6 months of age:
   satisfactory, if all the values observed indicate the absence of the bacterium,
   unsatisfactory, if the presence of the bacterium is detected in any of the sample units.
9. Histamine in fish products from fish species associated with a high amount of histamine:
   satisfactory, if the following requirements are fulfilled:
   the mean value observed is ≤ m
   a maximum of c/n values observed are between m and M
   no values observed exceed the limit of M,
   unsatisfactory, if the mean value observed exceeds m or more than c/n values are between m and M or one or more of the values observed are >M.

Similar to EU Commission Regulation (EC) No 2073/2005 adopted on 15 November 2005 on microbiological criteria for foodstuffs Ukrainian norms contain Production Process Hygiene Criteria for the following food processing establishments:

- Meat and Products – Norms are identical to Directive 2073/2005;
- Milk and Dairy Products - Norms are identical to Directive 2073/2005 with the exception of *Enterobacteriaceae* for pasteurized milk and fluid dairy products and *Enterobacteriaceae* and *Bacillus cereus* in infant formula for infants of different ages;
- Egg Products – Norms are identical to Directive 2073/2005; and
- Fish Products - Norms are identical to Directive 2073/2005.

Attention! Although at this point Ukraine does not require products imported from the United States to be in compliance with the Production Process Hygiene Criteria, proposed import regulations may require that products imported from the United States be in compliance with those requirements in the future. FAS Kyiv will monitor these developments.

Important Note: Prior to the adoption of Order 548, import MRLs were established by Ukrainian Veterinary Department Order #16, 1998 (amended in 2004). Provisions of Order 548 prevail for all listed indicators. Although FAS Kyiv has no information about enforcement of Order #16; technically, all indicators that are not listed in Order 548, but listed in Order #16 remain binding.

FAS GAIN Report UP1105 - Mandatory Veterinary Testing Requirements lists all provisions of Order 16. A U.S. exporter is advised to clear additional MRLs of Order #16 with their Ukrainian importer.

Attachments:

No Attachments.