



Regulation (EC) No 2073/2005 on Microbiological criteria for foodstuffs

CA 26.02.2008

Ari Hörman





Microbiological criteria

Main objectives

- To ensure a high level of human health protection
⇒ Reduction of human cases of foodborne diseases
- To verify the HACCP measures
- To harmonise microbiological criteria in the EU
⇒ Uniform rules within the EU and for the import





Codex Alimentarius 1997

A microbiological criterion for food

- defines the acceptability of a product or a food lot, based on the absence or presence, or number of micro-organisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume area or lot.



Establishment of Community criteria

Criteria should

- enhance food safety
- be feasible in practice
- Be based on the scientific risk assessment





Scientific opinions, e.g.

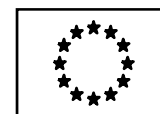
■ SCVPH opinions

(http://ec.europa.eu/food/fs/sc/oldcomm4/previous_en.html)

- *Listeria monocytogenes* 1999 (+ SCF 2000)
- *Vibrio vulnificus* and *V. parahaemolyticus* 2001
- Norwalk-like viruses 2002
- Gelatine 2002
- Verotoxigenic *E. coli* 2003
- *Salmonella* 2003
- Staphylococcal enterotoxins in milk products 2003

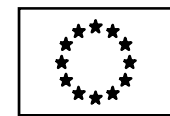
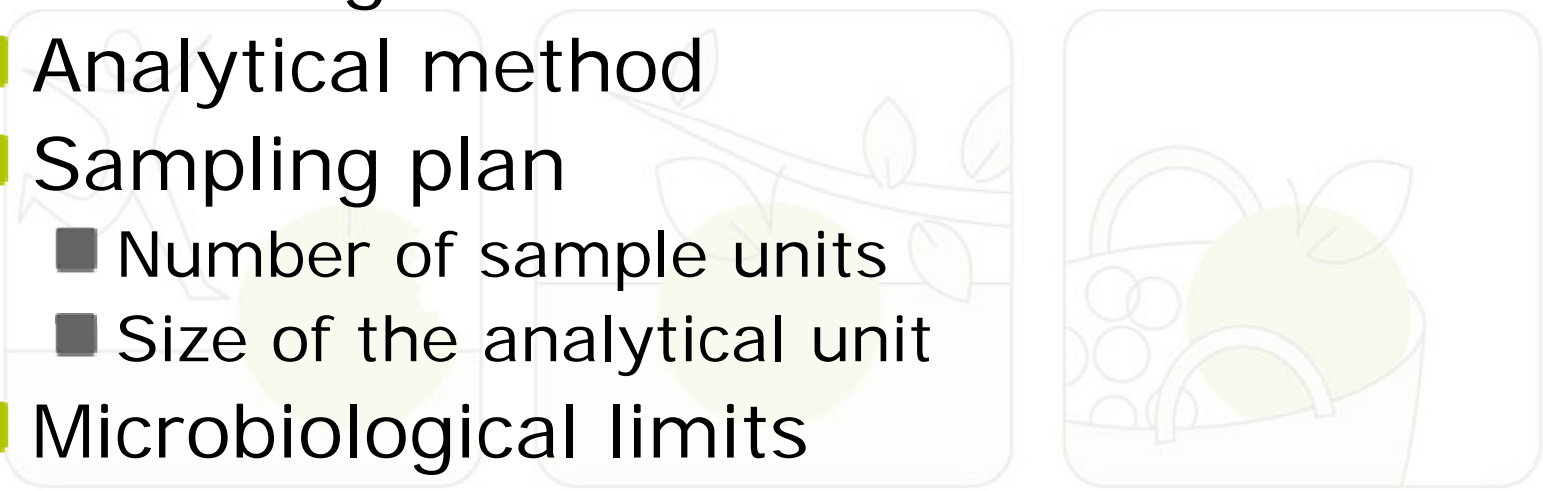
■ EFSA opinion (www.efsa.europa.eu)

- Microbiological risks in baby formulae and follow-on formulae 2004



Components of a microbiological criterion

- Micro-organism of concern
- Analytical method
- Sampling plan
 - Number of sample units
 - Size of the analytical unit
- Microbiological limits
- The foodstuff
- The point of the food chain where the limit applies
- Actions to be taken when unsatisfactory results





Commission Regulation (EC) No 2073/2005 microbiological criteria

Responsibility of FBOs

- To demonstrate the compliance with MC
 - Food safety criteria throughout the shelf-life
 - Durability, challenge studies (Annex II)
- To establish a sampling and testing scheme based on risk (HACCP)
- To respond in case of non-compliance
- To follow and assess trends





Commission Regulation (EC) No 2073/2005 microbiological criteria

Process hygiene criteria

- Indicate the acceptable functioning of production process
- Stage: during the process, not when placed on the market
- Actions when unsatisfactory results
 - = Corrective actions defined in HACCP programme
 - Improvement of production hygiene
 - Selection of raw materials





Commission Regulation (EC) No 2073/2005 microbiological criteria

- Operator can choose frequency and method
 - based on risk
 - in the context of HACCP
- Fixed frequency of sampling
- Once weekly fortnightly sampling
- Reduced frequency for small establishments



Process hygiene criteria

Examples:

- *Salmonella*
 - Carcasses
- Aerobic colony count and Enterobacteriaceae
 - Carcasses
- *E. coli*
 - Minced meat, meat preparations, butter and cream made from raw milk, precut fruit and vegetables
- Coagulase positive staphylococci
 - Certain dairy products
- Enterobacteriaceae
 - Dried infant formulae





Food category	Micro-organisms	Sampling plan ¹		Limits ²		Analytical reference method ³	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.2.3 Cheeses made from raw milk	Coagulase-positive staphylococci	5	2	10 ⁴ cfu/g	10 ⁵ cfu/g	EN/ISO 6888-2	At the time during the manufacturing process when the number of staphylococci is expected to be highest	Improvements in production hygiene and selection of raw materials. If values >10 ⁵ cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins .





Commission Regulation (EC) No 2073/2005 microbiological criteria

Food safety criteria

- Defines the acceptability of the product/batch
- Stage: products placed on the market
- Actions when unsatisfactory results
 - Withdrawal or recall
 - Further processing (not yet at retail level)
 - Other corrective actions based on HACCP programme





Food safety criteria

- *Listeria monocytogenes*
 - All ready-to-eat foods
- *Salmonella*
 - Certain ready-to-eat foods
 - Minced meat, meat preparations, meat products
- Staphylococcal enterotoxins
 - Certain dairy products
- *E. sakazakii*
 - Dried infant formulae
- *E. coli*
 - Live bivalve molluscs
- Histamine
 - Fishery products from certain fish species





Target: Reduction of human listeriosis

- Although the disease is relatively rare, listeriosis is a significant public health concern
 - Clinical severity and high mortality (20-30%)
- 1048 listeriosis cases reported in the EU and Norway
(EU Zoonosis report 2003)



Food category	Micro-organisms / their toxins, metabolites	Sampling-plan ¹		Limits ²		Analytical reference method ³	Stage where the criterion applies
		n	c	m	M		
1.1 Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes ⁴	<i>Listeria monocytogenes</i>	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
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 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



Salmonella

Food safety criteria



- Strict criteria

- minced meat, meat preparations and meat products intended to be eaten raw and cooked

- Raw

Absence in **25 g**

n=5, c=0

- Cooked

Absence in **10 g**

n=5, c=0



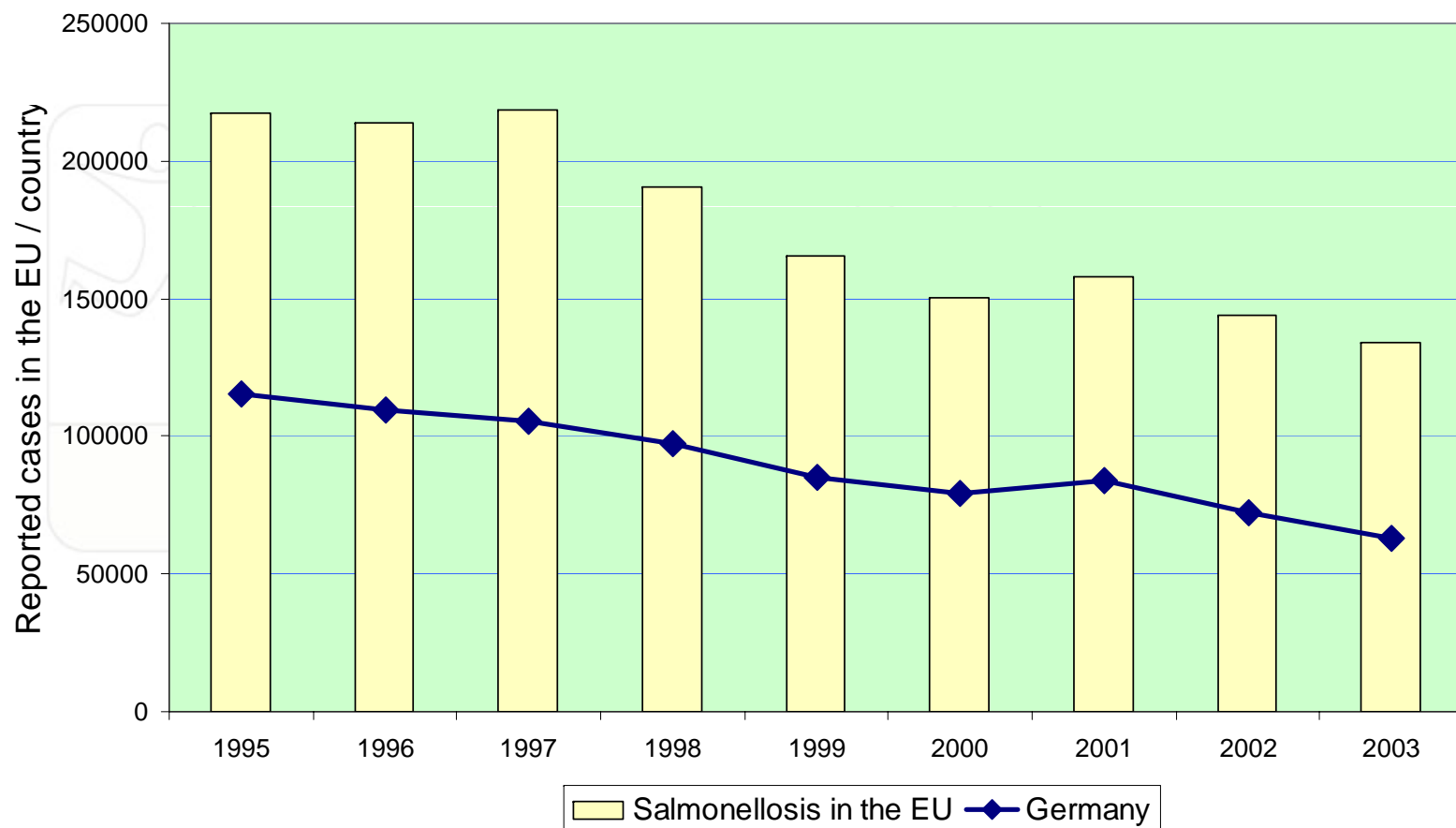


Target: Reduction of human salmonellosis

- Approximately 150 000 salmonellosis cases notified annually in EU and Norway
(EU Zoonosis report 2003)
- The estimated annual cost of foodborne salmonellosis 560-2840 *MEUR* in the EU
- An expectation would be a decrease in salmonellosis cases by 50%
 - Implementation of the new food hygiene and zoonosis legislation and microbiological criteria.



Trend in human salmonellosis





Food Safety Criteria for fish products

1.16	Cooked crustaceans and molluscan shellfish	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.17	Live bivalve molluscs and live echinoderms, tunicates and gastropods	<i>Salmonella</i>	5	0	Absence in 25g		EN/ISO 6579	Products placed on the market during their shelf-life
1.25	Live bivalve molluscs and live echinoderms, tunicates and gastropods	<i>E. coli</i> ¹⁵	1 ⁽¹⁶⁾	0	230 MPN / 100g of flesh and intra-valvular liquid		ISO TS 16649-3	Products placed on the market during their shelf-life
1.26	Fishery products from fish species associated with a high amount of histidine ¹⁷	Histamine	9 ⁽¹⁸⁾	2	100 mg/kg	200 mg/kg	HPLC ¹⁹	Products placed on the market during their shelf-life
1.27	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 mg/kg	400 mg/kg	HPLC ¹⁹	Products placed on the market during their shelf-life



Food Safety Criteria for Vegetables and Fruits

1.18	Sprouted seeds (ready-to-eat) ¹²	<i>Salmonella</i>	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.19	Precut fruit and vegetables (ready-to-eat)	<i>Salmonella</i>	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.20	Unpasteurised fruit and vegetable juices (ready-to-eat)	<i>Salmonella</i>	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life





National criteria

- Regulation (EC) No 2073/2005 harmonised the microbiological food safety and process hygiene criteria for foodstuffs in EU. From practical point of view this Regulation means that:
 - MSs cannot have other (national) microbiological food safety criteria.
 - However, Member States may have other or stricter national microbiological process hygiene criteria. These process hygiene criteria are applicable, by the definition, only during processing of the food in the particular Member State. These process hygiene criteria may not be used when product is on the market neither may they have impact on the import or intra-community trade.





Last amendments on Microcriteria

- Commission Regulation (EC) No 2073/2005 on microbiological criteria was amended by Regulation (EC) 1441/2007 of 5 December 2007.
 - Criteria on Enterobacteriaceae and *Salmonella* in dried follow-on formulae and *Bacillus cereus* in dried infant formulae
 - The reference method for the staphylococcal enterotoxin detection
 - Specifies the *Salmonella* sampling rules for carcasses of cattle, pig, sheep, goats and horses.





- Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs, Official Journal L 338, 22.12.2005, p. 1-26
- Regulation (EC) No 1441/2007 of 5 December 2007 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs, Official Journal L 322, 7.12.2007, p. 12-29
- GUIDANCE DOCUMENT on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs (http://ec.europa.eu/food/food/controls/foodfeed/sampling_testing.pdf)

Thank you

