4. Strumenti per prevenzione e analisi

Prevenzione

Autocontrollo e HACCP

Autocontrollo in azienda

- In un'impresa alimentare, il responsabile del piano di autocontrollo deve
  - predisporre e
  - attuare il piano con l' attiva partecipazione della dirigenza e del personale avvalendosi, se del caso, di un supporto tecnico-scientifico esterno.
- Il piano deve essere applicabile e applicato,
- finalizzato a prevenire le cause di insorgenza di non conformità **prima** che si verifichino e
- deve prevedere le opportune azioni correttive per minimizzare i rischi quando, nonostante l'applicazione delle misure preventive, si verifichi una non-conformità.
- L'obiettivo principale è istituire un **sistema documentato** con cui l'impresa sia in grado di dimostrare di aver operato in modo da minimizzare il rischio. L'applicazione del sistema HACCP può risultare complessa soprattutto nei casi di piccole imprese

HACCP

- ampia gamma di imprese alimentari prese in considerazione dal Regolamento CE 852/2004 e
- grande varietà di prodotti alimentari e di procedure di produzione applicate agli alimenti,
  - → sono state redatte dalla Commissione Europea delle **Linee guida generali** sullo sviluppo e sull'applicazione delle procedure basate sui principi del sistema HACCP come documento diretto ad aiutare tutti coloro che intervengono nella catena della produzione alimentare.
- → Tali linee-guida si ispirano principalmente ai principi enunciati nel "Codex Alimentarius" CAC/RCP 1-1996, (rev. 4-2003) e forniscono indicazioni su un'applicazione semplificata delle prescrizioni in materia di HACCP in particolare nelle piccole imprese alimentari

La Commissione per il Codex Alimentarius

- creata nel 1963 da FAO e WHO
- per sviluppare standard alimentari, linee e guida e testi correlati quali codici di procedure all'interno del **Joint FAO/WHO Food Standards Programme**
- Scopi principali
  - proteggere la salute del consumatore,
  - assicurare pratiche per un commercio leale e
  - promuovere il coordinamento tra le diverse istituzioni mediante lo sviluppo di standard

Principi per elaborazione di un piano HACCP

- sono 7:
  - Identificare ogni pericolo da prevenire, eliminare o ridurre
  - Identificare i punti critici di controllo (CCP - Critical Control Points) nelle fasi in cui è possibile prevenire, eliminare o ridurre un rischio
  - Stabilire, per questi punti critici di controllo, i limiti critici che differenziano l'accettabilità dalla inaccettabilità
  - Stabilire e applicare procedure di sorveglianza efficaci nei punti critici di controllo
  - Stabilire azioni correttive se un punto critico non risulta sotto controllo (superamento dei limiti critici stabiliti)
  - Stabilire le procedure da applicare regolarmente per verificare l'effettivo funzionamento delle misure adottate
  - Predisporre documenti e registrazioni adeguati alla natura e alle dimensioni dell'impresa alimentare.
- La prima codifica normativa in Europa risale al 1993 con la Direttiva 43/93/CEE (recepita in Italia con il D. Lgs 26 maggio 1997 n. 155, ora abrogato). Questa normativa è stata sostituita dal Regolamento CE 178/2002 e dal Regolamento CE 852/2004

Autocontrollo in azienda

Per facilitare l'adozione di piani di autocontrollo adeguati vengono resi disponibili **Manuali di Corretta Prassi Igienica (Good Hygiene Practice o GHP)**

sono documenti orientativi voluti dalla normativa comunitaria ed utilizzabili come guida all'applicazione dei sistemi di autocontrollo

Manuali GHP - buona prassi igienica

- Sono valutati dal Ministero del Lavoro, della Salute e delle Politiche sociali con il supporto tecnico dell'Istituto Superiore di Sanità e devono risultare conformi alle disposizioni del Regolamento (CE) n. 852/2004.
- La procedura operativa standard interna, redatta ai sensi del Decreto Dirigenziale 15 maggio 2008, definisce le modalità per il processo di valutazione e validazione dei manuali di corretta prassi igienica e prevede:
  - trasmissione in via informatica alla casella dedicata ai manuali GHPManuals@sanita.it
  - invio dei manuali, in via informatica, a Regioni, Associazioni di categoria, Associazioni dei consumatori
  - riunione del Tavolo di lavoro interno per la valutazione e la successiva validazione dei manuali (tempi previsti 90 giorni)
  - invio comunicazione di validazione del manuale alla G.U. e copia alla Commissione Europea.

Manuali GHP validati dal Ministero

- Manuali validati fino al 1° settembre 2007
- Manuali validati con la nuova procedura
  - Manuale per il **settore della panificazione Industriale** (AIIPA - Associazione Italiana Industrie Prodotti Alimentari)
  - Manuale **per le imprese agricole** (CIA - Confederazione Italiana Agricoltori)
  - Manuale **per l'industria molitoria** (ITALMOPA - Associazione Industriali Mugnai d'Italia)
  - Manuale **per la rintracciabilità e l'igiene dei prodotti alimentari e dei mangimi** (COLDIRETTI - Confederazione Nazionale Coldiretti)
  - Manuale **per la distribuzione automatica di alimenti** (CONFIDA - Associazione italiana distribuzione automatica)
  - Manuale **per la distribuzione di acqua in boccioni** (CONFIDA - Associazione italiana distribuzione automatica)
  - Manuale **per la distribuzione di alimenti conservati in legame di temperatura** (CONFIDA - Associazione italiana distribuzione automatica)

  → vedi documento

Gestione dei rischi

- Prevenzione
- Controllo mediante applicazione di tecniche

Prevenzione/controllo dei rischi

- pratiche di coltivazione/allevamento
- pratiche di manipolazione/lavorazione
- trasporto
- stoccaggio
- confezionamento
- conservazione

Sicurezza

- chimica
- microbiologica
  - fattori biotici
  - prodotti di microrganismi
    - micotossine
    - amine biogene
    - antibiotico-resistenze

Sicurezza chimica

Additivi alimentari, qualsiasi sostanza aggiunta intenzionalmente ai prodotti alimentari per un fine tecnologico (Enzimi))

Aromi, composti usati per conferire odore e/o sapore agli alimenti. La legislazione comunitaria e nazionale definisce diversi tipi di aromi

I **contaminanti** sono sostanze **non aggiunte intenzionalmente** agli alimenti e la cui presenza può derivare dall' ambiente, dalla coltivazione e/o dal processo produttivo

I **contaminanti chimici** possono derivare sia da materie prime utilizzate per la produzione del prodotto alimentare, sia da diffusione e cessioni dei materiali di confezionamento o dagli impianti, sia da residui di pratiche agronomiche (pesticidi, fitofarmaci, antiparassitari ecc.), residui di pratiche zootecniche (anabolizzanti, ormoni ecc.) etc.

Oggetti/materiali destinati al contatto con alimenti (utensili da cucina, da tavola, recipienti, imballaggi etc.) sono soggetti a vigilanza da parte dell'autorità sanitaria

Residui di farmaci veterinari e sostanze proibite negli alimenti di origine animale, sostanze proibite possono essere anabolizzanti (inducono un incremento ponderale dell'animale) o farmaci (l'UE stabilisce un limite massimo) o contaminanti ambientali (metalli pesanti, composti organoclorurati etc.)

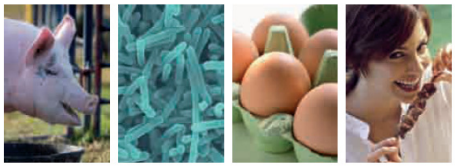
Residui di prodotti fitosanitari negli alimenti di origine vegetale. Al momento della loro immissione in commercio, i prodotti di origine vegetale non devono contenere residui di sostanze attive nei prodotti fitosanitari, superiori ai limiti massimi di residui stabiliti per legge

- → metodi di analisi alimenti per animali

Sicurezza microbiologica

- Rapporto EFSA sull'andamento e sulle fonti delle zoonosi e degli agenti zoonotici nell'Unione europea nel 2007
- Le zoonosi sono infezioni e malattie che possono essere trasmesse dagli animali agli esseri umani
- L'infezione può essere contratta direttamente dagli animali o attraverso l'ingestione di alimenti contaminati
- La gravità di tali malattie negli esseri umani può variare da sintomi leggeri ad affezioni potenzialmente letali
- Per scongiurare il rischio di zoonosi, è importante individuare quali animali e alimenti sono le principali fonti di infezione

Trends and Sources of Zoonoses and Zoonotic Agents in the European Union in 2007



January 2009

efsa European Food Safety Authority ecdc

Il report

articolato in 4 parti

- **1. Introduction**
- **2. Summary**
- **3. Information on specific zoonoses**
- **4. Materials and methods**
- **Appendix**

Rapporto EFSA

Informazioni da

- i 27 Stati membri
- Centro europeo per la prevenzione e il controllo delle malattie (ECDC)
- Anche quattro paesi che non fanno parte dell'Unione europea hanno contribuito alla relazione, raccogliendo informazioni sulle zoonosi
- Con l'aiuto del Centro di collaborazione per le zoonosi, l'Autorità europea per la sicurezza alimentare e il Centro europeo per la prevenzione e il controllo delle malattie hanno svolto un'**analisi congiunta di tutti i dati**
- riguarda dieci malattie

ECDC

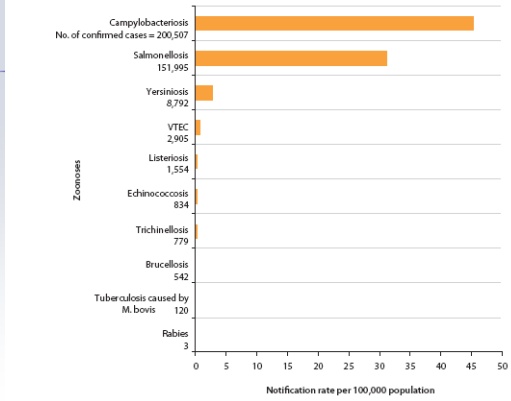
- Agenzia dell'UE (con base a Stoccolma, Svezia) istituita nel 2005
- Obiettivo: rafforzare le difese dell'Europa verso le malattie infettive
- Missione di ECDC:
  - identificare, determinare e comunicare tutti i pericoli per la salute umana, correnti ed emergenti
- Per raggiungere questo obiettivo ECDC collabora con tutte le istituzioni pubbliche nazionali europee e sviluppa, a livello comunitario, strategie di sorveglianza e allerta precoce
- ECDC si avvale del contributo di esperti in tutta Europa per sviluppare opinioni con forte base scientifica riguardo i rischi posti dalle malattie infettive, sia note che emergenti

- ***Monitoring and surveillance schemes*** *for most zoonotic agents covered in this report* ***are not harmonised between MSs****, and findings presented in this report must, therefore, be interpreted with care. The data presented may not necessarily derive from sampling plans that are statistically designed, and may not accurately represent the national situation regarding zoonoses.* ***Results are generally not directly comparable between MSs and sometimes not even between different years in one country***

Malattie zoonotiche più diffuse nel 2007

1. campilobatteriosi (200.507 casi denunciati e confermati) in crescita
2. salmonellosi (151.995 casi confermati) tendenza in decrescita

Figure SU1. | *The reported notification zoonoses rates in confirmed human cases in the EU, 2007*



Prodotti alimentari fonti di zoonosi

- *Campylobacter:* carne fresca di pollo; in media il 26% di tali campioni è risultato positivo, ma anche in esemplari vivi di bovini, suini e pollame.
- Le proporzioni denunciate dei campioni positivi di *Campylobacter* sono rimaste ad alti livelli, senza che si evidenziasse alcuna riduzione generale.

Prodotti alimentari fonti di zoonosi

La *Salmonella* è stata trovata più frequentemente nella carne fresca di pollo e maiale, con percentuali di campioni positivi che, in media, erano pari rispettivamente al 5,5% e all'1,1%, oltre a uova e, più raramente, prodotti lattiero-caseari, verdura e frutta.

Nella popolazione animale, la *Salmonella* è stata osservata con particolare frequenza nel pollame

Il 2007 è stato il primo anno in cui gli Stati membri hanno attuato i nuovi programmi di controllo della *Salmonella* sul pollame da riproduzione della specie *Gallus gallus* su base obbligatoria

Prodotti alimentari fonti di zoonosi

Listeriosi, 1.554 casi confermati registrati nel 2007

alto tasso di mortalità del 20% che ha colpito in particolar modo gli anziani

Livelli superiori ai limiti di sicurezza sono stati raramente riscontrati nei **cibi pronti**, mentre più spesso tali limiti sono stati superati nel **pesce affumicato** e in altri tipi di prodotti della pesca pronti per il consumo, seguiti da carni pronte e formaggi

Altre informazioni

Nel 2007, nell'Unione europea sono state segnalate in totale 2.905 infezioni confermate da *Escherichia coli* produttore di verocitotossina (VTEC),

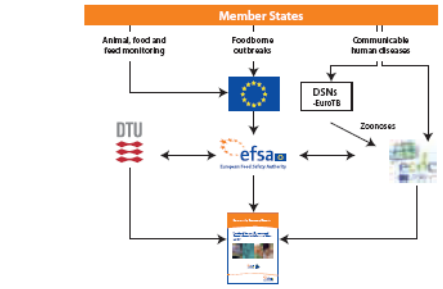
Fonti: principalmente nel bestiame e nella carne bovina. Questo batterio è stato individuato solo raramente nelle verdure

Yersinia, 8.792 casi di yersiniosi umana

il batterio è stato individuato nei maiali e nella carne di maiale

Due zoonosi parassitarie, la trichinellosi e l'echinococcosi, questi parassiti sono stati individuati soprattutto negli esemplari selvatici

Figure IN1. | *Scheme of the data flow for the Community Summary Report, 2007*



Note: Human data is collected by ECDC through The European Surveillance System (TESSy)

Zoonosi specifiche

- ***Salmonella***
  - Salmonellosis in humans
  - *Salmonella* in food
  - *Salmonella* in animals
  - General consideration
  - Discussion
- ***Campylobacter***
  - …
- ***Listeria***
- **Tuberculosis due to *Mycobacterium bovis***
- ***Brucella***
- **Rabies**
- **Verotoxigenic *Escherichia coli***
- ***Yersinia***
- ***Trichinella***
- ***Echinococcus***

Appendix Table SA1. Surveillance systems on Salmonella *in feedingstuffs, 2007 (contd.)*

Process control	Compound feed			Comments
	Cattle	Pig	Poultry	
x	Each farm, processing plant and retailer are sampled at least twice per year			Official sampling is carried out according to Directive 1978/371/EC. Analysis method: ISO 6579:2002
-	x	x	x	
-	-	-	-	
-	-	-	-	
Targeted sampling				
-	Monitoring	Monitoring	Monitoring	
x	Self control systems based on requirements of legislation. Final products: risk-based official sampling			Official sampling is carried out according to Directive 1978/371/EC. Analysis method is Evine ISO 6579:2002 with some minor modifications
-	-	-	-	
-	Official monitoring, and own sampling			
-	-	-	-	
-	-	-	ISO 6571, ISO 6588	
-	-	-	-	
-	x	x	x	
-	Official control as well as HACCP or own check by the industry			
HACCP by the industry	Official and HACCP by the industry			Official sampling is carried out according to Directive 76/371/EEC. Analysis method: ISO 6579:2002
Official and self control	Official and self control	Official and self control	Official and self control	Analysis method: LST EN ISO 6579:2003 lt
-	-	-	-	
-	-	-	-	
-	Routine testing	-	-	
-	-	-	-	
-		-		
-	-	-	-	Official sampling according to Directive 1978/371/EC
Official target sampling and own check programme based on HACCP by the	Official target sampling and own check programme based on HACCP by the industry			

Appendix Table SA2. Salmonella *monitoring programmes in poultry breeders* (Gallus gallus)*, 2007*

Countries, running an approved monitoring or control programme[1,2] according to Directive 1992/117/EC; meeting at least the minimum sampling requirements set out by regulation (EC) No 2160/2003			
MS with approved surveillance programme (Decision 2006/759/EC)	24 MSs except MT, BG[3] and RO[3]		
Non-MS with approved surveillance programmes (ESA Decision No 364/07/COL)	NO		
MS with EU co-financing (Decision 2006/687/EC as amended by Decision 2007/851/EC	20 MSs except FI, LT, LU[4], MT, SI, SE, UK		
Countries with additional sampling (see Table SA3)	AT, DK, FR, NL, SE, UK		
Minimum requirement according to Regulation (EC) No 2160/2003			
Rearing period		**Production period**	
Day old chicks	Dead chickens / destroyed chickens Samples from the inside of the delivery boxes (internal lining/paper/crate material)	Every 2 weeks	dead chickens or meconium samples
4th week	faecal samples	Every 8 weeks	Official sampling instead of above mentioned sampling
2 weeks before moving	faecal samples		
Diagnostic methods used			
ISO 6579:2002	BE, CZ, EE, GR, IT, NO, PL, SK, SI, ES, NL, SE		
NMKL No 71:1999	SE		
Modified ISO 6579:2002	AT, DK, UK		
Annex D of ISO 6579(2002)	LV		
ISO 6579:2002 / Amendment 1:2007	FI		
AFNOR NF U 47 100 and 47 101	FR		

Appendix Table SA5. Salmonella monitoring programmes in laying hens (Gallus gallus) producing table eggs, 2007

Day old chicks		Rearing period		Production period	
Type of sample					
Samples from the inside of the delivery boxes (internal lining/paper/crate material)	CZ, DK, FR, LV, NO, PL, LT, SI[1]	Faecal samples/ Boot swabs	CZ[1], DK[1], EE[1], IE[1], FI, FR, LV, NO, NL, PL, SK, SE[1], SI[1], UK[1]	Faecal samples/ Boot swabs	AT[2], BE[1], CZ[1], DK, EE[1], IE, FI, FR, LV, NL[1], NO, PL, LT, SK, SE[1], ES, UK[8]
Dust samples	UK[6]	Dust samples	FR, UK[6]	Dust samples	FR, IE[1], UK[6]
Meconium	AT, EE, FR, PL, SK, SE, UK[6]	Blood samples	DK[1], NL[1]	Blood samples	NL[1]
Dead chickens	AT, CZ, DK, EE, GR, LV, SK, SI[1], SE, UK[1], LT			Egg samples	DK, UK[6]
Frequency of sampling					
Each delivery	DK, LV, SK, SI, UK	At 3 weeks	DK	Every 9 weeks	DK[3], LT
Every flock	CZ, FR, SE, LT, NO	At 4 weeks	CZ, SK, LT	Three times	DK[4], NO
Voluntary	PL	At 2 weeks before transfer	DK, EE, FI, FR, LV, LT, NO, PL, SE, SI, SK	At 25-30 and 50 weeks	LV, NO, SE[5]
		Max 21 days before transfer	NL	At 22-26 weeks and 8 weeks before slaughter	EE
		Monthly	IE	At 24, 40 and 55 weeks	FR
				Max 9 weeks before slaughter	NL
				Every 15-20 weeks, 2 weeks before slaughter	PL
				Every 2 weeks	SK
				Monthly	IE
				Every 12 weeks	AT, CZ
				At 22-26 weeks, after that every 15. week	SE[5]
				Every 15 weeks	FI
				3 weeks before	BE
				Max 9 weeks before slaughter	NL
				Every 15-20 weeks, 2 weeks before slaughter	PL
				Every 2 weeks	SK
				Monthly	IE
				Every 12 weeks	AT, CZ
				At 22-26 weeks, after that every 15. week	SE[5]
				Every 15 weeks	FI
				3 weeks before	BE
Diagnostic methods used through out the production					
ISO 6579 (2002)				AT, BE, CZ, EE, GR, IT, LV, NO, PL, SE, SK, SI, ES	
ISO 6579 (2002) / Amendment 1:2007				FI	
NMKL No 71:1999				SE	
AFNOR NF 47 100 and 47 101				FR	
The method described in the O.I.E. manual, 5th ed., 2004				SI	
Buffered Peptone water				PT	
Various bacteriological				DK, LT, UK	
No information				CY, DE, HU, IE, LU, MT	
Countries with no official sampling strategies, 2007					
				IT[7], PT[8], ES, UK	

Note: Monitoring is not compulsory by Directive 2003/99/EC
1. Number of samples depend on flock size
2. In Austria, sampling is voluntary
3. In Denmark, for eggs sold to authorised egg-packing stations
4. In Denmark, for eggs sold at farmyard sale or hobby poultry keeping
5. In Sweden, samples are collected from all holdings placing eggs on the market and holdings>200 layers not placing eggs on the market.
6. In the United Kingdom sampling is voluntary in 2007. All isolations of *Salmonella* must be reported
7. In Italy, a compulsory control programme is running in the Veneto region
8. In Portugal, a surveillance programme is running in one region (Beira Litoral)

Appendix Table SA14. Salmonella monitoring programmes in pigs, 2007

Breeding and multiplying herds – at farm		Fattening herds – at farm		Fattening herds – at slaughter	
Type of sample					
Blood samples	DK	Blood samples	BE[1]	Meat juice	DK[6], UK[7]
Faecal samples/ boot swabs	CZ, DK[4], EE[3], FI[3], NO, SE	Faecal samples/ boot swabs	AT, CZ, DK[4], EE[3], FI, NL, NO, SE[3]	Faecal samples/ boot swabs	CZ, DK[1]
Carcass/rectal swabs/litter/feed	SI	Carcass/rectal swabs/litter/feed	SI	Lymph nodes	FI, NO[1, 2], SE[1], SI
				Carcass swabs	BE, DK, NO[1,2], SE[1], EE
Frequency of sampling					
Monthly	DK, SI	Monthly	SI	Monthly	SI
Clinical suspicion	CZ, FI, SK, SI	Clinical suspicion	NO, SE, SK, SI	Clinical suspicion	CZ
Once a year – all elite herds	FI, NO, SE	Random samples	NL	Continuous, random samples	BE, DK, EE, FI, NO, SE
Twice a year - all sow herds	SE				
Diagnostic methods					
Modified ISO 6579 (2002)	AT, LT				
ISO 6579 (2002)	CZ, EE, FI, GR, NL, SI, SK				
Mix ELISA	DK, UK				
NMKL No 71:1999	FI, NO, SE				
Strategies in countries with no official sampling strategies, 2006					
No official monitoring	BE[8], CY, CZ, GR, IT[9], LV, PL, SK, LT, UK[7]				

Note: Monitoring is not compulsory by Directive 2003/99/EC
In this table priority is given to farm-based approaches; sample based approaches at slaughterhouse may be described in Table SA16

1. Number of samples depends on slaughterhouse capacity or farm capacity
2. In Norway, sows from multiplying herds are sampled in the same way as slaughter pigs at slaughter
3. In Finland and Estonia, all pigs sent to semen collection centres have to be examined for *Salmonella* with negative results
4. In Denmark, pen faecal sampling in control serological results from the blood samples (breeding and multiplying herds) and meat juice samples (fattening pigs) are too high
5. In Sweden, pen faecal samples herds are affiliated to voluntary heath control programmes
6. In Denmark, all herds producing more than 200 pigs for slaughter per year are monitored
7. In the United Kingdom, sampling is voluntary. All isolations of *Salmonella* must be reported
8. In Belgium, samples are collected as part of a monitoring programme for Aujeszky's disease
9. In Italy, a monitoring programme is running in the Veneto Region

Appendix Table CA1. Campylobacter monitoring, surveys and diagnostic methods used for humans animals and food, 2007

Country	Human Sample type	Diagnostic	*Gallus gallus* Sample type	Diagnostic
Austria	Faecal	Bacteriology	At slaughter: Caeca	Bacteriology, ISO 10272-1:2006/(E)
			Cattle and pig: Colon	Bacteriology (in cattle at first enrichment)
Belgium	-	-	At slaughter: Caeca	-
Bulgaria				
Cyprus	-	-	-	-
Czech Republic	-	-	At slaughter: cloacal swaps	ISO 10272:1997
Denmark	Faecal	Bacteriology	At slaughter: cloacal swaps	PCR
Estonia	Faecal	Bacteriology	At slaughter: Caeca	ISO 10272
Finland	-	Bacteriology	At slaughter: Caeca	NMKL 119:1990 w/no enrichment
France	Faecal	Bacteriology	At slaughter: Caeca	Multiplex PCR
Germany	-	-	At slaughter: Caeca	ISO 10272
Greece	-	-	-	-
Hungary	Faecal	Bacteriology	-	-
Ireland	-	-	Carcass	Bacteriology
Italy	-	-	At slaughter: Cloacal swaps (Veneto region)	Bacteriology
Latvia	-	-	At the farm before slaughter: cloacal swabs	OIE Manual chapter 2.10.8.B.1.
Lithaunia	-	Bacteriology	At slaughter: cloacal and neck skin	Bacteriology

Appendix Table LI1. Monitoring programmes and diagnostic methods for Listeria monocytogenes, *2007*

Country	Surveillance	Frequency and type of samples
Austria	No monitoring programme. Surveys by the local authorities	-
Belgium	Monitoring programme started in 2004	Fresh meat and final products sampled weekly
Bulgaria		
Cyprus	-	-
Czech Republic	Monitoring according to the Decree of the Ministry of Health No. 132/2004 Coll	-
Denmark	No monitoring programme Surveys by the local authorities	-
Estonia	No monitoring programme Surveys by the local authorities	Random sampling
Finland	Survey on vegetables	Random sampling
France	Monitoring programme on meat products	Random sampling
Germany	Monitoring, surveys and own-control	-
Greece	No monitoring programme Surveys by the local authorities	Routine and target sampling
Hungary	Monitoring milk products (EU requirements) based on Directive 92/46	-
Ireland	-	-
Italy	-	-
Latvia	No monitoring programme for animals	Random sampling

HACCP	Diagnostic method	Human diagnostic	Survey on cheeses from raw and thermised milk
yes	ISO 11290-1:1996 (E):1996,1998	Isolation of *L. monocytogenes* from blood, cerebral spinal fluid, vaginal swabs	-
-	Afnor validated VIDAS LMO2 followed by a chromogenic medium	-	-
-	-	-	-
yes	ISO 11290-1:1996 (E):1996,1998	-	yes
-	-	Bacteriology	yes
-	NMKL 136, 2004 ISO 11290-1:1996 (E):1996,1998	Isolation of *L. monocytogenes* from blood and cerebral spinal fluid	-
-	ISO 11290-1:1996 (E):1996,1998	Bacteriological culture	

Appendix Table RA1. Vaccination programmes for rabies in animals, 2007)

Country	Vaccination programmes in pets	Vaccination programmes in wildlife
Austria	Voluntary vaccination of pets	Since 1991, oral vaccines distributed to foxes twice a year. The programme is approved and co-financed by EU (Decision 2005/873/EC)
Bulgaria	Compulsory vaccination of dogs	-
Belgium	Compulsory vaccination of dogs and cats in the south and if staying at public campgrounds	Oral vaccines were distributed from 1989 to 2003
Cyprus	Compulsory vaccination of animals entering Cyprus	-
Czech Republic	Compulsory vaccination of carnivores in captivity	In 1989, oral vaccination of foxes in some districts. In 2003, the whole country is covered except for rabies free districts. Since 2004, vaccination twice a year by air in selected areas, mainly along the border with Poland and Slovakia. The programme is approved and will be co-financed by the EU (Decision 2005/873/EC)
Denmark	-	-
Estonia	Compulsory vaccination of dogs and cats	In autumn 2005 oral vaccination of wildlife in the northern part of the country. Since 2006 oral vaccines distributed to foxes twice a year by airplane. The programme is approved and co-financed by the EU (Decision 2005/873/EC)
Finland	Vaccination in dogs and cats are recommended	Since 1991, oral vaccines distributed to foxes and racoon dogs twice a year along the Russian border by flight. Since 2004, oral vaccines distributed to foxes twice a year. The programme is approved and co-financed by the EU (Decision 2005/873/EC)
France	-	-
Germany	Voluntary vaccination of pets, compulsory vaccination of animals used for hunting	Oral vaccines distributed to foxes twice a year in endemic areas. The programme is approved and co-financed by the EU (Decision 2005/873/EC)
Greece	Compulsory vaccination of dogs and cats	-
Hungary	Compulsory vaccination of dogs, voluntary vaccination of cats	Since 2004, oral vaccines distributed to foxes twice a year by flight. The programme started in 1997
Ireland	-	-
Italy	-	Oral vaccines distributed to foxes in the Region Friuli Venezia Giulia

Appendix Table RA2. Type of samples and diagnostic methods used when diagnosing rabies in humans and animals, 2007

Country	Humans		Animals	
	Type of sample	Diagnostic test	Type of sample	Diagnostic test
Austria	Liquor, smears from pharynx, swab from conjuntivae, biopsy at the nape of the neck and serum	FAT, immunohistochemistry, RT-PCR	Brain	Fluorescent antibody test (FAT), rabies tissue culture infection test (RIT-CIT). Mouse inoculation test (MIT)
Belgium	Blood, cerebrospinal fluid, saliva, *post mortem* brain tissue	Antigen detection, Virus isolation in neuroblastoma cells, RT-PCR, Virus isolation in mice, Rapid Fluorescent Focus Inhibition test RFFIT.	Brain	FAT, virus cultivation in neuroblast
Bulgaria	-	-		Direct immune-flourescent test (IFT)
Cyprus	-	-	Brain	Hellers stain
Czech Republic	-	-	Brain	FAT
Denmark	Blood samples, skin biopsy from neck	-	Brain	FAT, virus isolation
Estonia	-	-	Brain	FAT
Finland	-	Human: cultivation, serology, antigen-test, direct microscopy.	Brain	FAT, cell culture, RT-PCR
France	Cerebrospinal fluid, blood, saliva, if post mortem: brain tissue	PCR, FAT, immunohistochemistry, direct microscopy, RFFIT	Brain	FAT, cell culture, RT-PCR, MIT, FAVN
Germany	-	-	-	FAT, cell culture
Greece	-	-	-	-
Hungary	Cerebrospinal fluid, blood	In vivo from cornea imprint of the patient by immunofluorescence method, or determination of specific antibody titre of the blood or liquor by immunofluorescence method during the second week of the illness. Post mortem: detection of the Negri-body in the brain tissue, or the antigen by immunofluorescence method, or identification of the viral genetic material by PCR, or isolation of the virus in mouse.	-	-
Ireland	-	-	-	-
Italy	-	-	Brain	FAT

Appendix Table TR1. Diagnostic methods and monitoring programmes for Trichinella, *2007*

Country	Humans Diagnostic methods	Animals Diagnostic methods
Austria	Serology (ELISA), Western Blot	Regulation (EC) No 2075/2005
Belgium	Serology (ELISA), histopathology	Regulation (EC) No 2075/2005
Bulgaria		Compression method
Cyprus	EU recommendations	Directive 77/96/EC (digestion method)
Czech Republic	-	Pepsin digest method according to Regulation (EC) No 2075/2005
Denmark	Serology, histopathology	Pepsin digest method according to Regulation (EC) No 2075/2005
Estonia	Clinical symptoms, eosinophilia	Pepsin digest method according to Regulation (EC) No 2075/2005
Finland	Serology, histopathology	Regulation (EC) No 2075/2005
France	Serology, histopathology	Digestion method
Germany	Serology (ELISA), histopathology	Directive 77/96/EC (digestion or compression method) and PCR
Grece	-	Directive 77/96/EC (digestion or compression method)
Hungary	Serology (ELISA), histopathology, Western Blot	Pepsin digest method according to Regulation (EC) No 2075/2005
Ireland	-	Pepsin digest method according to Regulation (EC) No 2075/2006
Italy	-	Regulation (EC) No 2075/2005

In sintesi

- tecniche di **campionamento** e **analisi**
  - dipendono da alimento
  - da tipo di microrganismo
  - molto difficile unificare le trattazioni

Codex alimentarius

- http://www.codexalimentarius.net/download/standards/10141/CXG_050e.pdf
- linee guida per il campionamento

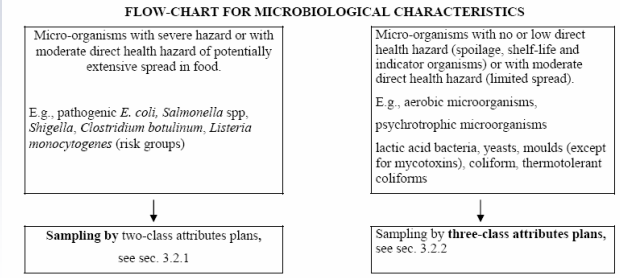
- **GENERAL GUIDELINES ON SAMPLING**
- particular Codex commodity standard

Struttura del documento

- **SECTION I. PURPOSE OF CODEX GUIDELINES ON SAMPLING**
- **SECTION 2. MAIN NOTIONS OF SAMPLING**
- **SECTION 3: THE SELECTION OF SAMPLING PLANS FOR SINGLE OR ISOLATED LOTS MOVING IN INTERNATIONAL TRADE**
- **SECTION 4. THE SELECTION OF SAMPLING PLANS FOR A CONTINUOUS SERIES OF LOTS FROM A SINGLE SOURCE**
- **SECTION 5. THE SELECTION OF SAMPLING PLANS FOR THE INSPECTION BY VARIABLES OF BULK MATERIALS: KNOWN STANDARD DEVIATION**
- **SECTION 6. REFERENCES**

- **SECTION I. PURPOSE OF CODEX GUIDELINES ON SAMPLING**
  - 1.1 PURPOSE
  - 1.2 TARGET AUDIENCE OF THE GUIDELINES
  - 1.3 USERS OF SAMPLING PLANS RECOMMENDED BY THE GUIDELINES
  - 1.4 SCOPE OF THE GUIDELINES
  - 1.5 RELATIONSHIP OF THE GUIDELINES WITH THE ISO GENERAL STANDARDS

- The sampling methods are intended for use as international methods designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to sampling and by diverging interpretation of results of analysis in relation to lots or consignments of foods, in the light of the relevant provision(s) of the applicable Codex standard.
- The present guidelines have been elaborated to facilitate the implementation of these goals by Codex Commodity Committees, governments and other users.



1.1 PURPOSE

- Sampling plans are required which ensure that fair and valid procedures are used when food is being controlled for compliance with a particular Codex commodity standard.
- Since numerous, yet often complex, sampling plans are available it is the purpose of these guidelines to help those responsible for sampling to select sampling plans that are appropriate for statistical inspections under specifications laid down by Codex standards.
- No sampling plan can ensure that every item in a lot conforms. These sampling plans are nevertheless useful for guaranteeing an acceptable quality level.
- These guidelines contain the elementary principles of statistical control at reception, which complete the basic recommendations laid down in the Preamble.

1.2 TARGET AUDIENCE OF THE GUIDELINES

- These Guidelines are above all aimed at Codex Commodity Committees which select from the plans recommended in sections 3, 4, and 5 those which at the time of the drafting of a commodity standard appear to them best suited for the inspection to be made. These Guidelines can also be used, if applicable, by governments in case of international trade disputes.
- The Codex commodity committees, Governments and other users should be provided with the competent technical experts needed for good use of these guidelines, including the selection of appropriate sampling plans.

1.3 USERS OF SAMPLING PLANS RECOMMENDED BY THE GUIDELINES

- The sampling plans described in these Guidelines may be implemented either by Governmental food control authorities, or by professionals themselves (self-inspection performed by producers and/or traders). In the latter case, these Guidelines enable the governmental authorities to check the appropriateness of the sampling plans implemented by the professionals.
- It is recommended that the different parties concerned with sampling come to an agreement on the implementation of the same sampling plan for the respective controls.

- These Guidelines define at first in Section 2 general notions on food sampling, applicable in any situations, and then in Sections 3 to 5 cover certain situations of statistical food control, for whose certain sampling plans have been selected.
- The following sampling situations are covered: for the control of only homogeneous goods:
  - control of percentage of defective items by attributes or by variables, for goods in bulk or in individual items,
  - control of a mean content.
- These Guidelines do not cover the control of :
  - non-homogeneous goods;
  - for homogeneous goods, the cases where measurement error is not negligible compared to sampling error (see 2.4), as well as the control of a qualitative characteristic in a bulk material and;
  - they do not deal with double, multiple and sequential sampling plans, deemed too complex in the frame of these Guidelines

- **Detailed sampling procedures do not lie within the scope** of these general guidelines. If necessary, they should be established by the Codex commodity committees.
- These Guidelines are **applicable for control at reception**, and may not be applicable for control of endproducts and for process control during production.
- The following Table 1 summarises the situations covered by these Codex Guidelines and those, which are excluded**.** It also gives, where applicable, useful international references for some of the situations not covered by these Codex Guidelines.

TABLE 1 : GUIDE TO SELECTION OF SAMPLING PLANS FOR HOMOGENEOUS LOTS[3]

	Lots consisting of individualisable bulk material	Lots consisting of individual[4] items		
	Quantitative Measurements	Qualitative Measurements[5]	Quantitative Measurements	
Isolated lots	**Inspection by Variables of Bulk Materials for Percentage Non-conforming -Section 5.1** Example: check tank of milk for added water	**Inspection by Attributes for percentage non-conforming - Section 2.5.1.1** Example: inspection of pieces of fruit for defects **Microbiological inspection of product - Section 3.1, 3.2** **Example: testing uncooked vegetables for mesophilic aerobic micro-organisms.(see ICMSF standards)**	**Inspection by Variables for percentage non-conforming - Section 4.3.2 (s method)** Example: to check whether fat content of a skimmed milk powder complies with Codex limit	**Average Content – Sections 3.3 and 4.4** Example: to check that average weight of items in a lot complies with label declaration (see also ISO 2854-1976, 3494-1976)
Continuous series of lots	**Inspection by Variables of Bulk Materials for Percentage Non-conforming - Section 5.1** Example: check a tank of milk for added water	**Inspection by Attributes for percentage non-conforming - Section 2.5.1.1** Example: inspection of pieces of fruit for defects **Microbiological inspection of product - Section 3.1, 3.2** Example: testing uncooked vegetables for mesophilic aerobic micro-organisms (see ICMSF)	**Inspection by Variables for percentage non-conforming - Section 4.3.3 (σ method)** Example: to check whether fat content of a skimmed milk powder complies with Codex limit	**Average Content - Sections 3.3 and 4.4** Example: to check sodium content of a dietary food does not exceed prescribed level (See also ISO 2854-1974, 3494-1976)

[3] Assuming for quantitative measurements, that measurement error is negligible in relation to process variation (see Section 2.4)
[4] Or individualisable.
[5] Qualitative data includes quantitative data classified as attributes, for example with respect to a limit.

1.5 RELATIONSHIP OF THE GUIDELINES WITH THE ISO GENERAL STANDARDS

- In the cases of control situations dealt with by this document, the sampling shall only follow the rules of the sampling plans of this document, even if this document refers to the following ISO Standards for the details of the scientific and statistical background. In the cases of control situations not dealt with by this document, and if they are dealt with by a general ISO Standard (see below), the product Committee or the governments should refer to them, and define how to use them.

The ISO Standards are provided in the following:

- ISO 2854 : 1976(E) : Statistical interpretation of data – Techniques of estimation and tests relating to means and variances
- ISO 2859-0:1995(E): Sampling procedures for inspection by attributes - Part 0: Introduction to the ISO 2859 attribute sampling system
- ISO 2859-1:1999(E): Sampling procedures for inspection by attributes - Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection
- ISO 2859-2-1985(E): Sampling procedures for inspection by attributes - Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection
- ISO 3494:1976 : Statistical interpretation of data – Power of tests relating to means and variances
- ISO 3951:1989(E): Sampling procedures and charts for inspection by variables for percent nonconforming
- ISO 5725-1:1994 (E): Application of statistics
  - – Accuracy (trueness and precision) of measurement methods
  - and results – Part 1: General principles and definitions

… cnt'd

- ISO 7002:1986 (E) : Agricultural food products - Layout for a standard method of sampling a lot,
- ISO 8423:1991(E): Sequential sampling plans for inspection by variables for percent nonconforming (known standard deviation)
- ISO 8422:1991(E): Sequential sampling plans for inspection by attributes
- ISO/TR 8550:1994(E)): Guide for the selection of an acceptance sampling system, scheme or plan for inspection of discrete items in lots
- ISO 10725:2000(E): Acceptance sampling plans and procedures for the inspection of bulk material
- ISO/FDIS 11 648-1 : Statistical aspects of sampling from bulk materials – Part 1 : General principles
- ISO/DIS 14 560 : Acceptance sampling procedures by attributes – Specified quality levels in nonconforming items per million

The standards listed above were valid at the time of publication of these guidelines. However, since all standards are subject to revision, parties to agreements based upon these guidelines should ensure that the most recent editions of the standards are always applied

SECTION 2. MAIN NOTIONS OF SAMPLING

- 2.2 COMMONLY USED TERMS AND NOTIONS
  - 2.2.1 Lot
  - 2.2.2 Consignment
  - 2.2.3 Sample (representative sample)
  - 2.2.4 Sampling
  - 2.2.5 Total estimation error
  - 2.2.6 Sampling error
  - 2.2.7 Item or increment of individualisable goods
  - 2.2.8 Sampling plan
  - 2.2.9 The Characteristic
  - 2.2.10 Homogeneity
  - 2.2.11 Defects (Nonconformities) and Critical Nonconformities
  - 2.2.12 **Operating Characteristic Curve**
  - 2.2.13 Producers' risk and consumers' risk
  - 2.2.14 **The Acceptable Quality Level (AQL) and Limiting Quality (LQ) Level**
  - 2.2.15 Responsible Authority
  - 2.2.16 **Inspection Levels** and **Switching Rules**
  - 2.2.17 Acceptance Number
  - Lot Size and Sample Size

- 2.3 SAMPLING PROCEDURES
  - *2.3.2 Employment of Sampling Officers*
  - *2.3.3 Material to be Sampled*
  - *2.3.4 Representative sampling*
  - *2.3.5 Preparation of samples*
  - *2.3.6 Packaging and Transmission of Laboratory Samples*
  - *2.3.7 Sampling reports*
- 2.4 ESTIMATION ERRORS
- 2.5 TYPES OF SINGLE SAMPLING PLANS
  - *2.5.1 Single sampling plans for inspections of percent non-conforming items*
  - *2.5.2 Zero Acceptance Number Sampling Plans*
  - *2.5.3 Sampling plans for inspection of critical nonconformities*
- 2.6 COST OF SAMPLING

- **Operating Characteristic Curve**
- For a given sampling plan, an **Operating Characteristic (OC) curve** describes the probability of acceptance of a lot as a function of its actual quality. It relates the rate of defective items in lots (x-axis) with the probability of accepting these lots at control (y-axis). Section 4.1 develops the principle of such a curve and illustrates it with an example.

Acceptable Quality Level (AQL)

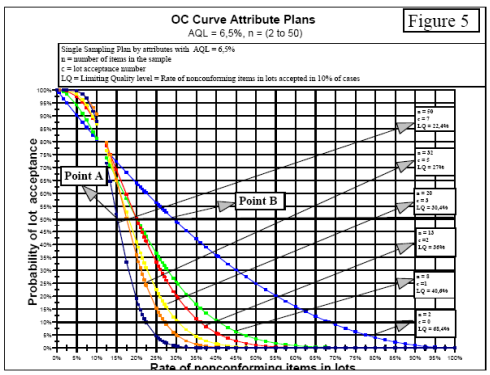
- The inspection of a lot using either an attributes or variables sampling plan will allow a decision to be made on the quality of the lot.
- *The **Acceptable Quality Level** (AQL) for a given sampling plan is the rate of non-conforming items at which a lot will be rejected with a low probability, usually 5 %.*
- The **Acceptable Quality Level** (AQL) is used as an indexing criterion applied to *a continuous series of lots* which corresponds to a maximum rate of acceptable defective items in lots (or the maximum number of defective items per hundred items). This is a quality goal fixed by the profession. This does not mean that all the lots having a rate of defective items greater than the AQL will be rejected at the control, but this means that the higher the rate of defective items exceeds the AQL, the greater is the probability of rejection of a lot.

AQL

- For any given sample size, the lower the AQL, the greater the protection for the consumer against accepting lots with high defective rates, and the greater the requirement for the producer to conform with sufficiently high quality requirements. Any value for AQL should be realistic in practice and be economically viable. If necessary, the value of AQL should take into account safety aspects.
- It should be recognised that the selection of a value for the AQL depends on the specific characteristic considered and of its relevance (economic or other) for the standard in its whole. A risk analysis may be undertaken to assess the possibility and severity of negative impacts on public health caused, for example, by the presence in food products of additives, contaminants, residues, toxins or pathogenic micro-organisms.
- **The characteristics which may be linked to critical defects** (for example to sanitary risks) **shall be associated with a low AQL** (i.e. 0,1 % to 0,65 %) whereas the compositional characteristics such as the fat or water content, etc may be associated with a higher AQL (e.g., 2,5 % or 6,5 % are values often used for milk products).
- **The AQL is used as an indexing device in the tables of the Standards ISO** 2859-1, ISO 3951 and in some tables of ISO 8422 and ISO 8423
- The AQL is particular producers' risk.

*Limiting Quality (**LQ**) Level*

- The **Limiting Quality** (LQ) for a given sampling plan is the rate of non-conforming items at which a lot will be accepted with a low probability, usually 10 %.
- The **Limiting Quality** (LQ) is applied when *a lot is considered in isolation*. It is a quality level (expressed, for example, as percentage nonconforming items in the lot) which corresponds to a specified and relatively low probability of acceptance of a lot having a rate of defective items of LQ. Generally, the LQ corresponds to the rate of defective items of lots accepted after control in 10 % of the cases.
- LQ is an indexing device used in ISO 2859-2 (where it is recommended that the LQ is set at least three times the desired AQL, in order to ensure that lots of acceptable quality have a reasonable probability of acceptance).
- The LQ is generally very low when the plans aim at the control of food safety criteria. It is often higher when the plans aim at the control of quality criteria.
- The LQ is a particular consumers' risk



Examples of sampling plans covering frequent inspection situations using AQL = 0,65 % or 2,5 % or 6,5 % are presented in 4.2.2.1 to 4.2.2.3.

Inspection Levels

- The **inspection level** *relates the sample size to the lot size and hence to the discrimination afforded between 'good' and 'poor' quality*. For example, Tables I and I-A of ISO 2859-1:1989 (E) and ISO 3951:1989 (E) respectively provide seven and five inspection levels. For a given AQL the lower the inspection level number the greater is the risk of accepting poor quality lots.
- The inspection level should be set by the '*responsible authority*'. *Unless otherwise specified, the normal (II) inspection level shall be used.* Reduced (I) level or tightened (III) level should be used when less or more discrimination, respectively, is required. Level II affords less than double the sample size of Level I, Level III gives about one and a half times the sample size of Level II. The 'special' levels (S-1 to S-4) should be used where relatively small sample sizes are required and large sampling risks can and/or must be tolerated.

Switching rules

- A sampling scheme involves 'switching' between normal, tightened and reduced inspection sampling plans.
- ...
- Normal inspection is designed to protect the producer against having a high proportion of lots rejected when the quality of the product is better than the AQL. However, if two out of any five (or fewer) successive lots are not accepted, then tightened inspection must be introduced. On the other hand, if production quality is consistently better than the AQL, sampling costs may be reduced (at the discretion of the responsible authority) by the introduction of reduced-inspection sampling plans.

SECTION 3.

THE SELECTION OF SAMPLING PLANS FOR SINGLE OR ISOLATED LOTS MOVING IN INTERNATIONAL TRADE

- 3.1 SAMPLING PROCEDURES FOR INSPECTION BY ATTRIBUTES: SAMPLING PLANS INDEXED BY LIMITING QUALITY (LQ) FOR ISOLATED LOT INSPECTION
  - *3.1.1 Procedure A: Producer and consumer regard lot in isolation*
  - *3.1.2 Procedure B: Producer regards lot as one of a continuing series: Consumer regards lot in isolation*
- 3.2 TWO AND THREE CLASS ATTRIBUTES PLANS FOR MICROBIOLOGICAL ASSESSMENT
  - *3.2.1 Two-class Attributes Plans*
  - *3.2.2 Three-class Attributes Plans*
  - *The Application of Two and Three-class Attributes Plans*
- 3.3 SINGLE SAMPLING PLANS FOR AVERAGE CONTROL (STANDARD DEVIATION UNKNOWN)

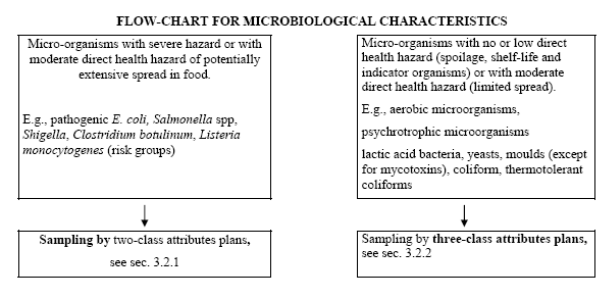
SECTION 4.

- **THE SELECTION OF SAMPLING PLANS FOR A CONTINUOUS SERIES OF LOTS FROM A SINGLE SOURCE**
  - 4.1 PRESENTATION OF SECTION 4
  - 4.2 SINGLE SAMPLING PLANS RECOMMENDED FOR INSPECTION OF DEFECTIVE PERCENTAGE BY ATTRIBUTES (FROM ISO 2859-1 : 1989)
    - *4.2.1 General*
    - *4.2.2 Recommended plans by attributes*
  - 4.3 SINGLE SAMPLING PLANS FOR INSPECTION BY VARIABLES FOR PER CENT NONCONFORMING
    - *4.3.1 General*
    - *4.3.2 Recommended sampling plans by variables : s method*
    - TABLE 14: VARIABLE SAMPLING PLANS WITH UNKNOWN STANDARD DEVIATION
    - *4.3.3 Recommended sampling plans by variables: σ-method*
    - TABLE 17. VARIABLE SAMPLING PLANS WITH KNOWN STANDARD DEVIATION
    - *4.3.4 Rules and procedures of switching between inspection levels*
  - 4.4 SINGLE SAMPLING PLANS FOR AVERAGE CONTROL
    - *4.4.1 Unknown standard deviation*
    - *4.4.2 Known standard deviation*

SECTION 5.

- THE SELECTION OF SAMPLING PLANS FOR THE INSPECTION BY VARIABLES OF BULK MATERIALS: KNOWN STANDARD DEVIATION
  - 5.1 GENERAL
  - 5.2 STANDARDISED SAMPLING PROCEDURES FOR THE INSPECTION OF INDIVIDUAL LOTS

SECTION 3.



1. Micro-organisms in Foods. 2. Sampling for microbiological analysis: Principles and specific applications; International Commission on Microbiological Specifications for Foods, ICMSF, 1986, ISBN 0-632-015 67-5.

- When choosing a plan one must consider:
  (i) the type and seriousness of hazards implied by the microorganisms;
  (ii) the conditions under which the food is expected to be handled and consumed after sampling

Two class attributes plans

- Two-class attributes plans provide a simple means of inspection *where the sampling plan is defined by two values, n and c.*
- The value of n defines the sample size in terms of the number of items;
- and the value c denotes the maximum number of nonconforming items permitted in the sample.
- When undertaking a microbiological assessment, a maximum concentration of micro-organisms permitted in any item is denoted by m; any item contaminated at a concentration greater than m is considered to be nonconforming.

Two class attributes plans

- For a given value of c, the stringency (probability of rejection) of the plan will increase as n increases.
- Similarly, for a given value of n, the stringency will increase as c decreases. The equation of the OC (Operating Characteristic) of such plans is the following

$$P_A = P[x \le c] = \sum_{i=0}^{i=c} C_n^i p^i (1-p)^{n-i}$$

Where :

P_A = Probability to accept the lot

p = Defective rate in the lot, ie lots for whose the concentration of micro-organisms is greater than m

i and x are whole discrete variables, varying between 0 and c

$$C_n^i = \frac{n!}{i!(n-i)!}$$

The application of a two-class attributes plan

can be summarized as follows

- **1. Set the value of m, n and c**
- **2. Collect the sample with n items**
- **3. Inspect each item in the sample**
- 4. **Accept the lot if: number of defective items ≤ c**

EXAMPLE

Inspection of the presence of *Salmonella* in fresh vegetables

Description of an ICMSF plan :

- n = 5 = number of items of 25 g in the sample
- m = maximum content admitted in *Salmonella* per item = 0 CFU in 25 g
- c = 0 = maximum number of items of the sample where the concentration x in *Salmonella* is higher than m (ie *Salmonella* is detected).

The lot is accepted if no item in the sample shows a presence of *Salmonella*. The lot is rejected in the opposite case

Result of the inspection:

The results of the detections in the sample are the following:

- x1 = *Salmonella* detected
- x2 = 0
- x3 = 0
- x4 = 0
- x5 = 0

There is one item where *Salmonella* was detected (ie whose concentration in *Salmonella* is greater than m), the lot is therefore rejected.

Three class attribute plans

Three class attributes plans are defined by the values n, c, m and M (see below); and are applied to situations where the *quality of the product can be divided into three attribute classes* depending upon the concentration of micro-organisms within the sample:

- unacceptable quality, with a concentration of micro-organisms above the value, M (which must not be exceeded by any items in the sample).
- good quality, where the concentration must not exceed the value, m.
- marginally acceptable quality. Marginal items have a concentration which exceeds m, but which is less than M (such concentrations are undesirable but some can be accepted, the maximum number acceptable being denoted by c).

Three class attribute plans

- The value m is the concentration of the micro-organism which is acceptable and attainable in the food under inspection, as reflected by Good Commercial Practice (GCP).
- For 3-class plans, m will be assigned a nonzero value.
- The value M is a hazardous or unacceptable level of contamination caused by poor hygienic practice, including improper storage.

Three class attribute plans

- There are several approaches to choosing the value of M:
  - (i) as a 'utility' (spoilage or shelf-life) index, relating levels of contamination to detectable spoilage (odour, flavour) or to an unacceptably short shelf-life;
  - (ii) as a general hygiene indicator, relating levels of the indicator contaminant to a clearly unacceptable condition of hygiene;
  - (iii) as a health hazard, relating contamination levels to illness. A variety of data may be used for this purpose including, for example, epidemiological, experimental animal feeding and human feeding data

Three class attribute plans

- The values m and M may be independent of each other.
- The choice of values for n and c varies with the desired stringency (probability of rejection). For stringent 'cases', n is high and c is low; for lenient 'cases' n is low and c is high.
- The choice of n is usually a compromise between what is an ideal probability of assurance of consumer safety and the work load the laboratory can handle.
- If the concentration of micro-organisms in any item of the sample is greater than M, the lot is directly rejected.

equation of the OC curve

$$P_a = \sum_{i=0}^{i=c} C_n^i \left(\frac{P_m}{100}\right)^i \left(\frac{100 - P_d - P_m}{100}\right)^{n-i}$$

- where
- P*a* is the probability of acceptance of a lot containing:
  - a given percentage of defective items (P*d*) (a defective item having a concentration in microorganisms greater than M), i.e. lots for whose the concentration in micro-organisms is greater than M), and
  - a given percentage of marginally acceptable items (P*m*) (a marginally acceptable item having a concentration in micro-organisms between m and M) ;
- n is the number of items in the sample
- c is the maximum number allowed of marginal items.

Application of a three-class attributes sampling plan

may be summarized as follows :

- **Set the values of m, M, n ,c**
- **Collect the sample with n items**
- **Inspect each item in the sample**
- **Accept the lot if: number of marginally defective items (i.e. a concentration of micro-organisms between m and M) ≤ c**
- **Immediately reject the lot if the concentration of micro-organisms in any item > M and/or the number of marginally defective items > c**

Example

Inspection of the concentration of mesophilic aerobic micro-organisms in fresh vegetable

- Description of an ICSMF plan :
  - n = 5 = the number of items in the sample
  - m = 10^6 CFU/g
  - M = 5 * 10^7 CFU/g
  - c = 2 = the maximum number allowed of items in the sample whose concentration in mesophilic aerobic micro-organisms lies between m and M
- The lot is accepted if no item shows a concentration greater than M and if the maximum number of items in the sample whose concentration lies between m and M, is at most egal to c.

Result of the inspection

- The measures of concentration in the sample are the following :
  - x1 = 2* 10^7
  - x2 = 2* 10^6
  - x3 = 2* 10^7
  - x4 = 2* 10^6
  - x5 = 2* 10^6
- There are 5 items of the sample whose concentration in mesophilic aerobic micro-organisms lies between m and M, this figure is greater than c and the lot is rejected.