Agro MilkWays HighWays Trilobes

EUROPEAN COMMISSION
Executive Agency for Small and Medium-sized Enterprises (EASME)
GRANT AGREEMENT 684937 — Agro Highway

MW 2016 10 AHW Report 13 List of Documents and Organizations

The overview of a number of refence documents and orgnizations which were studied

1. NL Information Transport van levensmiddelen
2. NL Veiligheid van levensmiddelen en diervoerders
3. NL/EU Voedselveiligheid EUR Lex
4. EU White Paper on Food Safety
5. EU Health and Food Safety; General Food Law
6. NL Ilent Gevaarlijke stoffen
7. Codex Alimentarius
8. NL Informatie blad 85; Microbiologische criteria voor levensmiddelen
9. NL Gevaarlijke stoffen; Marpol Tripartite
10. NL Bijlage Beslisboom; schematisch risico op uitgroei van micro-orgamismen
11. European Food Safety Authority
12. NL Hygienecode voor transport HACCP code
13. ATP UNECE Transport Divison
14. Marpol

1.

Nederlandse Voedsel- en Warenautoriteit
Ministerie van Economische Zaken

Informatieblad Transport van levensmiddelen, diervoeders en dierlijke bijproducten.

Nadere uitwerking van de Hygiënecode Transport Opslag en Distributie en de Hygiënecode Diervoedersector Wegtransport Diervoeders.

Opgesteld door de NVWA in samenwerking met TLN en EVO

19 november 2014

Inleiding

Op het transport van de productgroepen food, feed, dierlijke bijproducten en afgeleide producten hiervan zijn verschillende wettelijke eisen van toepassing. Met name voor bedrijven die twee of meer van deze productgroepen vervoeren kan dit tot verwarring leiden. Hieronder staat per productgroep aangegeven en toegelicht wat wettelijk is voorgeschreven en hoe vervoerders daaraan kunnen voldoen.

Overzicht

De (wettelijke) eisen zijn samengevat in onderstaand schema.

Food	Feed	Dierlijke bijproducten (DBP)
Betreft: grondstoffen, levensmiddelen en ingrediënten bestemd voor menselijke consumptie	Betreft: diervoeders (voedermiddelen, additieven, voormengsels, aanvullende en volledige diervoeders)	Betreft: producten van dierlijke oorsprong en afgeleide producten die niet (meer) voor menselijke consumptie zijn bestemd
NVWA-registratie aanmelding via NVWA: http://www.nvwa.nl/onderwerpen/regels-voor-ondernemers-eten-en-drinken/dossier/erkenningen-vergunningen-registraties/registratieformulier-levensmiddelenbedrijven	NVWA-registratie aanmelding via NVWA: http://www.nvwa.nl/onderwerpen/regels-voor-ondernemers-eten-en-drinken/dossier/erkenningen-vergunningen-registraties/registratieformulier-diervoederbedrijven	NVWA-registratie aanmelden via NVWA: http://www.nvwa.nl/onderwerpen/regels-voor-ondernemers-eten-en-drinken/dossier/erkenningen-vergunningen-registraties/registratie-verordening-dierlijke-bijproducten
Toepassen Hygiënecode Transport, opslag en distributie óf er dient middels een eigen HACCP-handboek te worden voldaan aan art. 4 en 5, en de bijlage II van Vo 852/2004	Toepassen Hygiënecode Wegtransport Diervoeders, via de GMP+ standaard B4 óf er dient middels een eigen HACCP-handboek te worden voldaan aan art. 6 en 7, en de bijlage II van Vo 183/2005	Geen Hygiënecode Eisen staan in Bijlage VIII bij Verordening (EG) nr. 142/2011 De belangrijkste eisen hierin zijn: - Vervoer DBP en afgeleide producten hiervan in gesloten nieuwe verpakkingen of lekvrije voertuigen; - Voertuigen moeten schoon en droog zijn voor gebruik en voor zover nodig na elk gebruik gereinigd, gespoeld en/of ontsmet, om versleping te voorkomen; - DBP en afgeleide producten hiervan bestemd voor de diervoederproductie moeten tijdens het vervoer op een geschikte temperatuur worden gehouden; - Tijdens het vervoer moeten DBP en afgeleide producten vergezeld gaan van een handelsdocument - De verzender en de vervoerder dienen tenminste 2 jaar een kopie te bewaren van het handelsdocument. De ontvanger bewaart het origineel tenminste 2 jaar. Voor een aantal DBP en afgeleide producten gelden specifieke voorschriften ten aanzien van bijv. temperatuur en etikettering. Bij vragen hierover kunt u contact opnemen met uw branche-organisatie.
Levensmiddelen in bulk in vloeibare-, gegranuleerde of poedervormige staat: - Containers/tanks mogen uitsluitend voor vervoer van levensmiddelen worden gebruikt. - Tekst op container/tank/ruimte: 'Alleen voor levensmiddelen'		Etiket op het wegtransportmiddel met daarop de categorie die wordt vervoerd en de specifieke tekst die bij het soort product hoort. Bij grensoverschrijdend vervoer van DBP tussen de lidstaten, zijn voor de etiketten op de verpakking of op het vervoermiddel voorgeschreven kleurcodes van toepassing: categorie 1 = zwart, categorie 2 = geel, categorie 3 = groen.
Er zijn geen specifieke modellen handelsdocumenten voor food voorgeschreven.	Er zijn geen specifieke modellen handelsdocumenten voor feed voorgeschreven. Wel dienen in geval van diervoeders in bulk de etiketteringseisen van Vo 767/2009 op het transportdocument te worden vermeld.	Bij vervoer naar andere landen binnen de Europese Unie moet een voorgeschreven model handelsdocument de partij vergezellen. Het model hiervan staat in Hoofdstuk III van Bijlage VIII van Verordening (EG) nr. 142/2011. Bij binnenlands vervoer is dit voorgeschreven handelsdocument niet noodzakelijk, maar kan een model document (b.v. een CMR) de partij vergezellen. Hierop moeten wel

		bepaalde gegevens zijn opgenomen: zie hiervoor Bijlage VIII, Hoofdstuk III, punt 6, f). De ontvanger bewaart het origineel, de verzender en transporteur bewaren elk een afschrift van het handelsdocument

Food

Verordening (EG) nr. 852/2004 regelt voor de productgroep food o.a. de levensmiddelenhygiëne en HACCP-verplichtingen. De verordening schrijft voor dat op wegtransportmiddelen voor bulkvervoer van levensmiddelen de tekst 'alleen voor levensmiddelen' is opgenomen. In de Verordening (EG) nr. 853/2004 staan specifieke voorschriften voor levensmiddelen van dierlijke oorsprong. HACCP staat voor Hazard Analysis Critical Control Points. In de verordening is vastgelegd dat de voedselveiligheid systematisch moet worden beheerst en geborgd . In de Hygiënecode Transport, Opslag en Distributie (TOD), ontwikkeld door TLN en EVO, zijn de HACCP-beginselen van de Verordeningen (EG) nr. 852/2004 en 853/2004 uitgewerkt. Aan de code ligt een branche-risicoanalyse ten grondslag en de code omvat uitsluitend de wettelijke HACCP- en hygiëneverplichtingen. Om te voldoen aan de wet kan worden volstaan met het aantoonbaar toepassen van de Hygiënecode TOD en de NVWA-registratie. Aanvullende mogelijkheden ten aanzien het organiseren en borgen van voedselveiligheid in uw bedrijf zijn het laten certificeren voor de Hygiënecode TOD of een eigen HACCP-handboek en HACCP-certificering.

Uitgangspunt voor Food:

Bij het bulkvervoer van vloeibare, gegranuleerde of poedervormige levensmiddelen (food) moet op de wegtransportmiddelen de tekst 'alleen voor levensmiddelen' zijn aangebracht en deze wegtransportmiddelen mogen niet voor vervoer van diervoeders (feed) of dierlijke bijproducten of andere stoffen (zoals chemicaliën) worden ingezet, ook niet na reiniging/ontsmetting van de laadruimte.

De volgende aanvullingen of uitzonderingen gelden hierop:

1. Een levensmiddel (zowel van plantaardige- als dierlijke oorsprong) mag in bulk met een vervoermiddel met tekst "alleen voor levensmiddelen" worden vervoerd naar een diervoederbedrijf. Let op: Dit geldt alleen voor levensmiddelen die ook zo naar levensmiddelenbedrijven vervoerd worden. Zijn levensmiddelen bijvoorbeeld om kwaliteitsredenen afgewaardeerd, en dus niet meer bedoeld als levensmiddel, dan is vervoer in een vervoermiddel met "alleen voor levensmiddelen" niet toegestaan.
2. Indien levensmiddelen van dierlijke oorsprong naar diervoederbedrijven worden vervoerd, dan dient ook aan de eisen van dierlijke bijproducten te worden voldaan.

Feed

De Verordening (EG) nr. 183/2005 is opgesteld tot vaststelling van voorschriften voor diervoederhygiëne. De Hygiënecode Wegtransport Diervoeders is 'vertaald' in de GMP+ standaard B4. Met het toepassen van de Hygiënecode Wegtransport Diervoeders, via de GMP+ standaard B4, én een NVWA-registratie of een PDV-registratie (Productschap

Diervoeders) voor de Verordening (EG) nr. 183/2005 voldoen vervoerders van diervoeders aan de wettelijke verplichtingen.

Bij het vervoer van diervoeders is het van belang dat het juiste reinigingsregime voor de verschillende ladingscategorieën (LR1 t/m LR 4) wordt toegepast.

Met ingang van 16 september 2012 is strengere regelgeving in werking getreden voor transport van (plantaardige)oliën en (meng)vetten voor de diervoedersector (zie Vo. 225/2012). De Bijlage II van Verordening (EG) nr. 183/2005 is hierop aangepast.

Dierlijke bijproducten (DBP) en afgeleide producten uit dierlijke bijproducten (AP)

De wettelijke eisen voor dierlijke bijproducten zijn geregeld in de Verordening (EG) nr. 1069/2009, de verordening (EG) nr. 142/2011, de Gezondheids- en Welzijnswet voor dieren, het Besluit dierlijke bijproducten en de Regeling dierlijke bijproducten 2011. Er zijn drie categorieën dierlijke bijproducten, waarmee in grote lijnen het volgende is toegestaan:

Categorie 1: moet als afval worden verwijderd; in Nederland wordt het materiaal eerst verwerkt tot vleesbeendermeel en vetten en daarna verwijderd door verbranding;

Categorie 2: mag worden verwijderd als afval, maar sommige producten mogen ook worden gebruikt in biogas- of composteerinstallaties of voor technische toepassing buiten de voedsel- en (dier)voederketen;

Categorie 3: mag onder bepaalde voorwaarden worden gebruikt voor de productie van voeder voor gezelschapsdieren, diervoeder en technische producten, maar kan ook worden gebruikt in biogas- of composteerinstallaties.

Bedrijven die iets met DBP of AP doen, zoals verwerken of transporteren, moeten bij de NVWA erkend of geregistreerd worden. In het algemeen geldt dat voor bedrijven die DBP en AP transporteren een registratie is vereist (dus geen erkenning). Op deze regel is één uitzondering: registratie is niet nodig wanneer een bedrijf al erkend is én met eigen transportmiddelen de eigen producten vervoert. B.v. een bedrijf dat erkend is voor de verwerking van slachtbijproducten haalt met eigen vervoermiddelen de slachtbijproducten op bij de slachterijen om bij hun eigen bedrijf verwerkt te worden.

Bij het vervoer van dierlijke bijproducten is vereist dat op het wegvervoermiddel of op de recipiënt een etiket is opgenomen met daarop de vermelding van de categorie dierlijke bijproducten én de specifieke vermelding die behoort bij het te vervoeren product. Zie hiervoor de lijst in Vo 142/2011, Bijlage VIII, Hoofdstuk II, onder identificatie.

b.v.

* 'Categorie 1' en de woorden 'uitsluitend geschikt voor verwijdering'
* 'Categorie 2' en de woorden 'niet voor dierlijke consumptie'
* 'Categorie 3' en de woorden 'niet voor menselijke consumptie'.

* voor mest geldt: "Categorie 2" en het woord "mest"

Daarnaast moet op de recipiënten, de etiketten of vervoermiddelen, tevens een kleurcodering zijn aangebracht: zwart, geel of groen. Zie hiervoor Hoofdstuk II in Bijlage VIII bij Verordening (EG) Nr. 142/2011.

Algemeen

Transporteurs hebben een meldplicht als ze constateren of vermoeden dat ze onveilige levensmiddelen of diervoeders vervoeren. Raadpleeg voor meer informatie hierover de NVWA-meldwijzer, http://www.nvwa.nl/onderwerpen/regels-voor-ondernemers-eten-en-drinken/dossier/melden-en-traceren/levensmiddel-of-diervoeder-melden

*) Voor informatie over de NVWA-registratie kunt u terecht op de website van de NVWA, via de link: http://www.nvwa.nl/onderwerpen/regels-voor-ondernemers-eten-en-drinken/dossier/erkenningen-vergunningen-registraties

2 Eur Lex Info Transport van Food, Feed, etc

Veiligheid van levensmiddelen en diervoeders

SAMENVATTING VAN:

Verordening (EG) nr. 178/2002 — algemene beginselen en voorschriften van de levensmiddelenwetgeving, tot oprichting van een Europese Autoriteit voor voedselveiligheid en tot vaststelling van procedures voor voedselveiligheidsaangelegenheden

SAMENVATTING

Deze verordening is bedoeld om de kwaliteit van levensmiddelen te waarborgen, ongeacht of deze voor menselijke of dierlijke consumptie zijn.

WAT DOET DEZE VERORDENING?

Deze verordening scherpt de voorschriften inzake de veiligheid van levensmiddelen en diervoeders in de EU aan. Ze voorziet ook in de oprichting van de Europese Autoriteit voor de voedselveiligheid (EFSA), die ondersteuning biedt voor de wetenschappelijke controle en evaluatie van levensmiddelen en diervoeders.

De verordening heeft geen betrekking op de primaire productie voor huishoudelijk gebruik of de behandeling van levensmiddelen thuis.

KERNPUNTEN

Levensmiddelen die gevaarlijk zijn voor de gezondheid of ongeschikt zijn voor consumptie mogen niet in de handel worden gebracht. De volgende factoren worden in aanmerking genomen:

— de normale omstandigheden van het gebruik van het levensmiddel door de consument;

— informatie die aan de consument wordt verstrekt;

— het kortetermijn- en/of langetermijneffect dat het levensmiddel heeft op de gezondheid;

— vermoedelijke cumulatieve toxische effecten;

— bijzondere gevoeligheden van een specifieke categorie consumenten, zoals kinderen.

Wanneer onveilige levensmiddelen of diervoeders deel uitmaken van een partij, wordt aangenomen dat die hele partij onveilig is.

Voedselwetgeving is van toepassing op **alle stadia van de voedselketen**, van de productie, de verwerking, het vervoer en de distributie tot aan de levering. Met name **moeten levensmiddelenbedrijven**:

— in alle stadia van de productie en de distributie de **traceerbaarheid** van levensmiddelen, diervoeders en voedselproducerende dieren garanderen,

— **levensmiddelen of diervoeders onmiddellijk uit de handel nemen** of de reeds geleverde producten **terugroepen** indien deze worden geacht schadelijk voor de gezondheid te zijn,

— **de bevoegde autoriteiten in kennis stellen**, alsmede consumenten indien nodig.

2. EUR LEX Transport

De EFSA biedt wetenschappelijke en technische ondersteuning aan de Europese Commissie en EU-landen op alle gebieden die van invloed zijn op voedselveiligheid. Ze is bovendien verantwoordelijk voor het coördineren van risicobeoordelingen, het identificeren van opkomende risico's en het adviseren over crisisbeheer.

Indien er naar aanleiding van een **gezondheidsrisicoanalyse** een risico wordt geïdentificeerd, kunnen EU-landen en de Commissie voorlopige voorzorgsmaatregelen goedkeuren die verenigbaar zijn met een hoog niveau van gezondheidsbescherming.

Het **systeem voor snelle waarschuwingen** (Rasff) waarbij EU-landen, de Commissie en de EFSA zijn betrokken, voorziet in de uitwisseling van informatie over:

— maatregelen waarbij het in de handel brengen of het terugroepen van levensmiddelen wordt beperkt;

— maatregelen die zijn getroffen om het gebruik van levensmiddelen te beheren;

— de afkeuring van een partij geïmporteerde levensmiddelen.

Deze informatie moet ook aan het algemene publiek worden beschikbaar gesteld indien dat van toepassing is.

Wanneer levensmiddelen of diervoeders een ernstig en onstuitbaar risico voor de gezondheid of het milieu vormen, kunnen de **beschermende noodmaatregelen** de opschorting van handel in of invoer van het product omvatten. Indien de Commissie geen actie onderneemt, kunnen EU-landen vergelijkbare maatregelen treffen.

De Commissie moet, samen met de EFSA en EU-landen, een **algemeen crisisibeheerplan** opstellen dat betrekking heeft op situaties waar de standaard beschermende noodmaatregelen ontoereikend zijn. Indien een dergelijk geval is geïdentificeerd, moet de Commissie onmiddellijk een **crisiseenheid** instellen om de opties voor de bescherming van de gezondheid van de mens te identificeren.

De EU beoogt tevens de bescherming van de consument tegen oneerlijke of misleidende praktijken in de levensmiddelenhandel, zoals vervalsing van levensmiddelen, en wil voorzien in een basis voor de consument zodat deze geïnformeerde keuzes over levensmiddelen kan maken.

VANAF WANNEER IS DE VERORDENING VAN TOEPASSING?

Deze richtlijn trad op 21 februari 2002 in werking.

BESLUIT

Verordening (EG) nr. 178/2002 van het Europees Parlement en de Raad van 28 januari 2002 tot vaststelling van de algemene beginselen en voorschriften van de levensmiddelenwetgeving, tot oprichting van een Europese Autoriteit voor voedselveiligheid en tot vaststelling van procedures voor voedselveiligheidsaangelegenheden (PB L 31 van 1.2.2002, blz. 1-24)

De achtereenvolgende wijzigingen in Verordening (EG) nr. 178/2002 werden in de basistekst opgenomen. Deze geconsolideerde versie is enkel van documentaire waarde.

GERELATEERDE BESLUITEN

Verordening (EG) nr. 2230/2004 van de Commissie van 23 december 2004 houdende uitvoeringsbepalingen van Verordening (EG) nr. 178/2002 van het Europees Parlement en de

Raad voor wat betreft het netwerk van organisaties die werkzaam zijn op de gebieden die behoren tot de opdracht van de Europese Autoriteit voor voedselveiligheid (PB L 379 van 24.12.2004, blz. 64-67)

2004/478/EG: Besluit van de Commissie van 29 april 2004 betreffende de goedkeuring van een algemeen plan voor crisismanagement op het gebied van levensmiddelen en diervoeders (PB L 212 van 12.6.2004, blz.60-68)

Verordening (EG) nr. 854/2004 van het Europees Parlement en de Raad van 29 april 2004 houdende vaststelling van specifieke voorschriften voor de organisatie van de officiële controles van voor menselijke consumptie bestemde producten van dierlijke oorsprong (PB L 226 van 25.6.2004, blz. 83-127) Zie de geconsolideerde versie.

Laatste bijwerking 25.11.2015

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3.

Voedselveiligheid

Het beleid van de Europese Unie inzake voedselveiligheid is gericht op de bescherming van consumenten en tegelijkertijd op het garanderen van de goede werking van de interne markt. Het beleid trad in werking in 2003 en draait rond het concept van traceerbaarheid van zowel inputs (bijv. diervoeder) als outputs (bijv. primaire productie, verwerking, opslag, transport en detailhandelsverkopen).

De EU heeft normen bepaald waarmee de hygiëne van levensmiddelen, de gezondheid, het welzijn van dieren en de gezondheid van planten worden gegarandeerd, en waarmee de risico's van verontreiniging door externe stoffen, zoals pesticiden, worden voorkomen. In elke fase worden strenge controles uitgevoerd en geïmporteerde producten (bijv. vlees) van buiten de Unie moeten aan dezelfde normen voldoen en moeten dezelfde controles ondergaan als levensmiddelen die binnen de EU worden geproduceerd.

- Voedselveiligheid: algemene bepalingen
- Veterinaire controles, gezondheidsvoorschriften en levensmiddelenhygiëne
- Diervoeders
- Welzijn van dieren
- Diergezondheid
- Fytosanitaire controles
- Verontreiniging en milieufactoren
- Voedselveiligheid: internationale dimensie en uitbreiding
- Specifieke onderwerpen

4.

EXECUTIVE SUMMARY

Assuring that the EU has the highest standards of food safety is a key policy priority for the Commission. This White Paper reflects this priority. A radical new approach is proposed. This process is driven by the need to guarantee a high level of food safety.

European Food Authority

The establishment of an independent European Food Authority is considered by the Commission to be the most appropriate response to the need to guarantee a high level of food safety. This Authority would be entrusted with a number of key tasks embracing independent scientific advice on all aspects relating to food safety, operation of rapid alert systems, communication and dialogue with consumers on food safety and health issues as well as networking with national agencies and scientific bodies. The European Food Authority will provide the Commission with the necessary analysis. It will be the responsibility of the Commission to decide on the appropriate response to that analysis. A European Food Authority could be in place by 2002 once the necessary legislation is in place. Before finalising our proposals we are inviting all interested parties to let us have their views by end April. A definitive legislative proposal would then be brought forward by the Commission.

Food Safety Legislation

The setting up of the independent Authority is to be accompanied by a wide range of other measures to improve and bring coherence to the corpus of legislation covering all aspects of food products from "farm to table".

Already the Commission has identified a wide range of measures that are necessary to improve food safety standards. The White Paper sets out over 80 separate actions that are envisaged over the next few years.

There have been enormous developments in the past decades, both in the methods of food production and processing, and the controls required to ensure that acceptable safety standards are being met. It is clear that, in a number of areas, existing European legislation has to be brought up to date.

Following the Commission's Green Paper on food law (COM(97)176 final), and subsequent consultations, a new legal framework will be proposed. This will cover the whole of the food chain, including animal feed production, establish a high level of consumer health protection and clearly attribute primary responsibility for safe food production to industry, producers and suppliers. Appropriate official controls at both national and European level will be established. The ability to trace products through the whole food chain will be a key issue. The use of scientific advice will underpin Food Safety policy, whilst the precautionary principle will be used where appropriate. The ability to take rapid, effective, safeguard measures in response to health emergencies throughout the food chain will be an important element.

Proposals for the animal feed sector will ensure that only suitable materials are used in its manufacture, and that the use of additives is more effectively controlled. Certain food quality issues, including food additives and flavourings and health claims, will be addressed, whilst controls over novel foods will be improved.

The risks associated with the contamination of foods have been brought into sharp focus by the recent dioxin crisis. Steps will be taken to address those areas where the existing legislation in this sector needs to be improved to provide adequate protection.

Food Safety Controls

The experience of the Commission's own inspection service, which visits Member States on a regular basis, has shown that there are wide variations in the manner in which Community legislation is being implemented and enforced. This means that consumers cannot be sure of receiving the same level of protection across the Community, and makes it difficult for the effectiveness of national authority measures to be evaluated. It is proposed that, in co-operation with the Member States, a Community framework for the development and operation of national control systems will be developed. This would take account of existing best practices, and the experience of the Commission's inspection services. It will be based on agreed criteria for the performance of these systems, and lead to clear guidelines on their operation.

In support of Community-level controls, more rapid, easier-to-use, enforcement procedures in addition to existing infringement actions will be developed.

Controls on imports at the borders of the Community will be extended to cover all feed and foodstuffs, and action taken to improve co-ordination between inspection posts.

Consumer Information

If consumers are to be satisfied that the action proposed in White Paper is leading to a genuine improvement in Food Safety standards, they must be kept well informed. The Commission, together with the new European Food Authority, will promote a dialogue with consumers to encourage their involvement in the new Food Safety policy. At the same time, consumers need to be kept better informed of emerging Food Safety concerns, and of risks to certain groups from particular foods.

Consumers have the right to expect information on food quality and constituents that is helpful and clearly presented, so that informed choices can be made. Proposals on the labelling of foods, building on existing rules, will be brought forward. The importance of a balanced diet, and its impact on health, will be presented to consumers.

International dimension

The Community is the world's largest importer/exporter of food products. The actions proposed in the White Paper will need to be effectively presented and explained to our trading partners. An active role for the Community in international bodies will be an important element in explaining European developments in Food Safety.

Conclusions

The implementation of all the measures proposed in the White Paper will enable Food Safety to be organised in a more co-ordinated and integrated manner with a view to achieving the highest possible level of health protection.

Legislation will be reviewed and amended as necessary in order to make it more coherent, comprehensive and up-to-date. Enforcement of this legislation at all levels will be promoted.

The Commission believes that the establishment of a new Authority, which will become the scientific point of reference for the whole Union, will contribute to a high level of consumer health protection, and consequently will help to restore and maintain consumer confidence.

The success of the measures proposed in this White Paper is intrinsically linked to the support of the European Parliament and the Council. Their implementation will depend on the commitment of the Member States. This White Paper also calls for strong involvement of the operators, who bear the prime responsibility for the daily application of the requirements for Food Safety.

Greater transparency at all levels of Food Safety policy is the thread running through the whole White Paper and will contribute fundamentally to enhancing consumer confidence in EU Food Safety policy.

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(b) surfaces in contact with food must be in a sound condition and be easy to clean and, where necessary, disinfect. This will require the use of smooth, washable, non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate;

(c) adequate provision must be made for the cleaning and, where necessary, disinfecting of work utensils and equipment;

(d) adequate provision must be made for the cleaning of foodstuffs;

(e) an adequate supply of hot and/or cold potable water must be available;

(f) adequate arrangements and/or facilities for the hygienic storage and disposal of hazardous and/or inedible substances and waste (whether liquid or solid) must be available;

(g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions must be available;

(h) foodstuffs must be so placed as to avoid, so far as is reasonably practicable, the risk of contamination.

IV

Transport

1. Conveyances and/or containers used for transporting foodstuffs must be kept clean and maintained in good repair and condition in order to protect foodstuffs from contamination and must, where necessary, be designed and constructed to permit adequate cleaning and/or disinfection.

2. Receptacles in vehicles and/or containers must not be used for transporting anything other than foodstuffs where this may result in contamination of foodstuffs.

   Bulk foodstuffs in liquid, granular or powder form must be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers must be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or must be marked 'for foodstuffs only'.

3. Where conveyances and/or containers are used for transporting anything in addition to foodstoffs or for transporting different foodstuffs at the same time, there must be effective separation of products, where necessary, to protect against the risk of contamination.

4. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there must be effective cleaning between loads to avoid the risk of contamination.

5. Foodstuffs in conveyances and/or containers must be so placed and protected as to minimize the risk of contamination.

6. Where necessary, conveyances and/or containers used for transporting foodstuffs, must be capable of maintaining foodstuffs at appropriate temperatures and, where necessary, designed to allow those temperatures to be monitored.

V

Equipment requirements

All articles, fittings and equipment with which food comes into contact shall be kept clean and:

(a) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimize any risk of contamination of the food;

(b) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept thoroughly cleaned and, where necessary, disinfected, sufficient for the purposes intended;

(c) be installed in such a manner as to allow adequate cleaning of the surrounding area.

Health and Food Safety

General Food Law

European citizens need to have access to safe and wholesome food of the highest standard.

A series of food incidents in late 1990s draw attention to the need to establish general principles and requirements concerning food and feed law **at Union level**. Accordingly, the European Commission developed an **integrated approach to food safety 'fromfarm to table'**, primarily set out in its **White Paper on Food Safety**. It covers all sectors of the food chain, including feed production, primary production, food processing, storage, transport and retail sale.

In 2002, the European Parliament and the Council adopted **Regulation (EC) No 178/2002**laying down the general principles and requirements of food law (**General Food Law Regulation**).

The General Food Law Regulation is the foundation of food and feed law. It sets outs an overarching and coherent framework for the development of food and feed legislation both at Union and national levels. To this end, it lays down general **principles**, **requirements** and **procedures** that underpin decision making in matters of food and feed safety, covering all stages of food and feed production and distribution.

It also sets up an independent agency responsible for scientific advice and support, the **European Food Safety Authority (EFSA).**

Moreover, it creates the main procedures and tools for the management of emergencies and crises as well as the **Rapid Alert System for Food and Feed (RASFF).**

The General Food Law Regulation ensures a **high level of protection of human life** and consumers' interests in relation to food, while ensuring the effective functioning of the internal market.

Last update: 18.10.2016

9.

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- Submenu

Gevaarlijke stoffenVloeibare gevaarlijke stoffen (IBC-code)

Het vervoer van vloeibare gevaarlijke en schadelijke stoffen in bulk in de zeevaart is geregeld in de International Bulk Chemical Code (IBC-code) van de International Maritime Organisation (IMO).

Sinds de publicatie van de 2007 editie van de IBC-Code zijn er verschillende wijzigingen c.q. aanvullingen door de IMO gepubliceerd in de IBC-Code Supplement – May 2014.

Het vervoer van de stoffen genoemd in MARPOL Annex II is gebonden aan de voorwaarden van hoofdstuk 17 of 18 van de IBC-code. Wanneer stoffen niet in hoofdstuk 17 of 19 van de IBC Code of in de door IMO jaarlijks gepubliceerde MEPC.2/Circ. worden vermeld mogen deze niet in bulk over zee vervoerd worden en dient eerst een overeenkomst (tripartite) tussen het verzendende land, vlaggenstaat van het schip en ontvangende land(en) te worden gesloten. De IBC-code kent geen classificatie volgens een UN-nummer.

Meer informatie

- IBC-Code Supplement - May 201424-10-2014 | PDF-document, 1266 kB
- Overeenkomst (tripartite)
- Voorwassen van tanks
- Vereiste documenten
- Cleaning additives
- Assessment of Bulk Liquid Chemicals

CONTENTS

CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS

CAC/RCP 57-2004

INTRODUCTION

Milk and milk products are a rich and convenient source of nutrients for people in many countries and international trade of milk-based commodities is significant. The purpose of this Code is to provide guidance to ensure the safety and suitability of milk and milk products to protect consumers' health and to facilitate trade. The Code satisfies the food hygiene provisions in the Codex Alimentarius *Procedural Manual* under "Relations Between Commodity Committees and General Committees" for use in the various dairy standards.

All foods have the potential to cause food borne illness, and milk and milk products are no exception. Dairy animals may carry human pathogens. Such pathogens present in milk may increase the risk of causing food borne illness. Moreover, the milking procedure, subsequent pooling and the storage of milk carry the risks of further contamination from man or the environment or growth of inherent pathogens. Further, the composition of many milk products makes them good media for the outgrowth of pathogenic micro-organisms. Potential also exists for the contamination of milk with residues of veterinary drugs, pesticides and other chemical contaminants. Therefore, implementing the proper hygienic control of milk and milk products throughout the food chain is essential to ensure the safety and suitability of these foods for their intended use. It is the purpose of this Code to provide guidance to countries so that their appropriate level of public health protection for milk and milk products may be achieved. It is also the purpose of this code to prevent unhygienic practices and conditions in the production, processing, and handling of milk and milk products, as in many countries milk and milk products form a large portion of the diet of consumers especially infants, children, and pregnant and lactating women. This document is formatted in accordance with the *General Principles of Food Hygiene* (CAC/RCP 1-1969). This Code presents principles for the hygienic production and manufacture of milk and milk products and guidance on their application. This Code takes into consideration, to the extent possible, the various production and processing procedures as well as the differing characteristics of milk from various milking animals used by member countries. It focuses on acceptable food safety outcomes achieved through the use of one or more validated food safety control measures, rather than mandating specific processes for individual products.

Adopted in 2004. Amendment 2009.

1. OBJECTIVES

The objective of this Code is to apply the recommendations of the *Recommended Code of Practice: General Principles of Food Hygiene* to the particular case of milk and milk products. It also provides guidance on how to achieve the general requirements contained in the hygiene sections of the Codex commodity standards for milk products.

2. SCOPE AND USE OF THE DOCUMENT

2.1 Scope

This Code applies to the production, processing and handling of milk and milk products as defined in the *General Standard for the Use of Dairy Terms*[1](CODEX STAN 206-1999). Where milk products are referred to in the code it is understood that this term also includes composite milk products. The scope of this Code does not extend to the production of raw drinking milk.

This Code applies to products in international trade. It may also serve as a basis for national legislation.

2.2 Use of the document

The provisions of this document are supplemental to and must be used in conjunction with, the *General Principles of Food Hygiene* (CAC/RCP 1-1969).

This document consists of a series of principles, explanatory narratives and guidelines. Over-arching principles that are applicable to all phases of production, processing and handling of milk and milk products are given in Section 2.3.

Specific principles and their associated explanatory narratives and guidelines are given in the appropriate section.

Principles, shown in **bold text**, are a statement of the goal or objective that is to be achieved. *Explanatory narratives*, shown in *italicized text*, serve to explain the purpose of the stated principle. Guidelines for the application of the stated principle are shown in normal text.

The annexes are an integral part of this Code. They provide guidelines for different approaches to the application of the principles. The purpose of the guidelines contained in the annexes is to explain and illustrate how principles in the main body of this code may be met in practice. Thus, the *General Principles of Food Hygiene* (CAC/RCP 1-1969), the main body of this Code and its annexes must be used together to obtain complete guidance on the hygienic production of milk and milk products.

[1] This code applies to the milk and milk products obtained from all milking animals.

2.3 Overarching principles applying to the production, processing and handling of all milk and milk products

The following overarching principles apply to the production, processing and handling of all milk and milk products.

- **From raw material production to the point of consumption, dairy products produced under this Code should be subject to a combination of control measures, and these control measures should be shown to achieve the appropriate level of public health protection.**
- **Good hygienic practices should be applied throughout the food chain so that milk and milk products are safe and suitable for their intended use.** *No part of this Code should be used without consideration of what takes place in the chain of events prior to the particular measure being applied or what will take place subsequent to a particular step. The Code should only be used within the context of an understanding that there is a continuum of controls that are applied from production to consumption.*
- **Wherever appropriate, hygienic practices for milk and milk products should be implemented within the context of HACCP as described in the Annex to the *General Principles of Food Hygiene* (CAC/RCP 1-1969).** *This principle is presented with the recognition that there are limitations to the full application of HACCP principles at the primary production level. In the case where HACCP cannot be implemented at the farm level, good hygienic practices, good agricultural practices and good veterinary practices should be followed.*
- **Control measures should be validated as effective.** The overall effectiveness of the system of control measures should be subject to validation. Control measures or combinations thereof should be validated according to the prevalence of hazards in the milk used, taking into consideration the characteristics of the individual hazards(s) of concern and established Food Safety Objectives and/or related objectives and criteria. Guidance on validating control measures should be obtained from the *Guidelines for the Validation of Food Hygiene Control Measures* (CAC/GL 69-2008).

2.4 Relative roles of milk producers, manufacturers, distributors, retailers, transporters, consumers, and competent authorities

Although the responsibility lies with the manufacturer for ensuring that the foods manufactured are safe and suitable, there is a continuum of effective effort or controls needed by other parties, including milk producers, to assure the safety and suitability of milk products. It is important to recognize that distributors, competent authorities and consumers also have a role in ensuring the safety and suitability of milk and milk products.

The interrelationship and impact of one segment of the food chain on another segment is important to ensure that potential gaps in the continuum are dealt with through communication and interaction between the milk producer, the manufacturer, the distributor and the retailer. While it is principally the responsibility of the manufacturer to conduct the hazard analysis within the context of developing a control system based on HACCP and thus to identify and control hazards associated with the incoming raw materials, the milk producer should also have an understanding of the hazards associated with milk, so as to assist in minimizing their presence in the raw material.

To achieve an effective continuum, the various parties should pay attention, in particular, to the following responsibilities.

- Producers should ensure that good agricultural, hygienic and animal husbandry practices are employed at the farm level. These practices should be adapted, as appropriate, to any specific safety-related needs specified and communicated by the manufacturer.
- Manufacturers should utilize good manufacturing and good hygienic practices, especially those presented in this Code. Any needs for additional measures with regard to controlling hazards during primary production should be effectively communicated to suppliers to enable the milk producer to adapt their operations to meet them. Likewise, the manufacturer may have to implement controls or adapt their manufacturing processes based on the ability of the milk producer to minimize or prevent hazards associated with the milk. Such additional needs should be supported by an adequate hazard analysis and should, where appropriate, take into consideration technological limitations during processing, and/or market demands.
- Distributors, transporters and retailers should assure that milk and milk products under their control are handled and stored properly and according to the manufacturer's instructions.
- Consumers should accept the responsibility of ensuring that milk and milk products in their possession are handled and stored properly and according to the manufacturer's instructions.
- In order to effectively implement this Code, competent authorities should have in place legislative framework (e.g., acts, regulations, guidelines and requirements), an adequate infrastructure and properly trained inspectors and personnel. For food import and export control systems, reference should be made to the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997). Control programmes should focus on auditing relevant documentation that shows that each participant along the chain has met their individual responsibilities to ensure that the end products meet established food safety objectives and/or related objectives and criteria.

It is important that clear communications and interactions exist between all parties to help assure good practices are employed, that problems are identified and resolved in an expeditious manner, and that the integrity of the entire food chain is maintained.

2.5 Definitions

Definitions contained in the *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999) are incorporated into this document by reference. Definitions relevant to a particular annex (e.g., heat treatment definitions) will be contained in the relevant annex.

Avoid – To keep away from, to the extent reasonably practicable. This term will be used when it is possible, in theory, to have no contamination or to constrain a particular practice.

Control measure – Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.[2]

Food safety objective[3]

Minimize – To reduce the likelihood of occurrence or the consequence of an unavoidable situation such as microbiological growth.

Process criteria[4] – The process control parameters (e.g. time, temperature) applied at a processing step.

Raw milk – Milk (as defined in the *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999)) which has not been heated beyond 40°C or undergone any treatment that has an equivalent effect.

Shelf life – The period during which the product maintains its microbiological safety and suitability at a specified storage temperature and, where appropriate, specified storage and handling conditions.

Validation[5]

2.6 Suitability

Food Suitability as defined in the *General Principles of Food Hygiene* (CAC/RCP 1-1969) is: "Assurance that food is acceptable for human consumption according to its intended use".

For the purposes of this Code, Suitability includes:

- The concept of wholesomeness and soundness.
- Only matters relating to hygiene. Matters relating to grade, commercial quality or compliance to standards of identity are not included.

Additionally:

- Suitability of milk and milk products may be achieved by observing good hygienic practice as outlined in the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and specified in detail in this Code. The use of a management system based on HACCP principles is an effective way of ensuring suitability and demonstrating that suitability is achieved.

[2] For purposes of this Code, a control measure encompasses any action or activity used to eliminate a hazard or reduce it to an acceptable level. In addition the term refers to any action or activity taken to reduce the likelihood of the occurrence of a hazard in milk or milk products. Thus, control measures include both process controls such as heating, cooling, acidification, etc., as well as other activities such as general hygiene and pest control programmes, etc.

[3] *Procedural Manual*, Codex Alimentarius Commission.

[4] This term is defined in *Guidelines for the Validation of Food Hygiene Control Measures* (CAC/GL 69-2008).

[5] This term is defined in *Guidelines for the Validation of Food Hygiene Control Measures* (CAC/GL 69-2008).

- Milk and milk products may not be suitable if the milk or milk product, for example:
  - Is damaged, deteriorated or perished to an extent that makes the milk or milk product unfit for its reasonable intended use; or
  - Contains any damaged, deteriorated or spoiled substance that makes the milk or milk product unfit for its reasonable intended use; or
  - Contains a biological or chemical agent, or other matter or substance, that is foreign to the nature of the food and that makes the milk or milk product unfit for its reasonable intended use.
- The "intended use" is the purpose for which the product is specifically stated or could reasonably be presumed to be intended having regard to its nature, packaging, presentation and identification.

3. PRIMARY PRODUCTION

These principles and guidelines supplement those contained in Section 3 of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and the general principles presented in Section 2.3 above. Details on specific approaches to the production of milk are given in Annex I of this Code.

PRINCIPLES APPLYING TO THE PRIMARY PRODUCTION OF MILK

Milk should not contain any contaminant at a level that jeopardizes the appropriate level of public health protection, when presented to the consumer.

Because of the important influence of primary production activities on the safety of milk products, potential microbiological contamination from all sources should be minimized to the greatest extent practicable at this phase of production. It is recognized that microbiological hazards can be introduced both from the farm environment and from the milking animals themselves. Appropriate animal husbandry practices should be respected and care should be taken to assure that proper health of the milking animals is maintained. Further, lack of good agricultural, animal feeding and veterinary practices and inadequate general hygiene of milking personnel and equipment and inappropriate milking methods may lead to unacceptable levels of contamination with chemical residues and other contaminants during primary production.

Contamination of milk from animal and environmental sources during primary production should be minimized.

Note: A contaminant is "any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability" (General Principles of Food Hygiene *(CAC/RCP 1-1969)).*

The microbial load of milk should be as low as achievable, using good milk production practices, taking into account the technological requirements for subsequent processing.
Measures should be implemented at the primary production level to reduce the initial load of pathogenic micro-organisms and micro-organisms affecting safety and suitability to the extent possible to provide for a greater margin of safety and/ or to prepare the milk in a way that permits the application of microbiological control measures of lesser stringency than might otherwise be needed to assure product safety and suitability.

USE OF THIS SECTION
Guidelines for applying the principles in this section are contained in Annex I. The guidelines are intended to result in raw material that is acceptable for further processing and that will ultimately result in the level of protection required for the particular finished milk product.

Annex I provides details of the general approach that should be used for the primary production of milk intended for further processing of an unspecified nature. Additional provisions to be used in the production of milk intended for the manufacture raw milk products are identified in relevant sections of the annex. Flexibility in the application of certain aspects of the primary production of milk for small holder dairy farms is also provided for. Milk produced according to the provisions of this section should be subjected to the application of control measures described in Annex II.

3.1 Environmental hygiene
Water and other environmental factors should be managed in a way that minimizes the potential for the transmission, directly or indirectly, of hazards into the milk.
Contaminated water, and for example pests (such as insects and rodents), chemicals and the internal and external environments where the animals are housed and milked, may contaminate feed, equipment or milking animals leading to the introduction of hazards into milk.

Water used in primary production operations should be suitable for its intended purpose and should not contribute to the introduction of hazards in milk.

3.2 Hygienic production of milk

3.2.1 Areas and premises for milk production
Areas including premises used for the production of milk should be designed, situated, maintained and, to the extent practicable, used in a manner that minimizes the introduction of hazards into milk.
Improperly protected and maintained premises for the holding and milking of dairy animals have been shown to contribute to the contamination of milk.

3.2.2 Animal health
The health status of milking animals and herds should be managed in a manner that addresses the hazards of concern for human health.
Milk should come from animals in good health so that, considering the end use, it does not adversely affect the safety and suitability of the end product.
It is important to prevent the spread of zoonotic diseases among animals and from animals (including milking animals) to milk. Milk and milk products produced from milk obtained from certain diseased animals has been known to be neither safe nor suitable for human consumption.
Maintenance of healthy milking animals has been shown to reduce the likelihood that human pathogens will be introduced into the milk via the mammary gland or from the faeces.

3.2.3 General hygienic practice

3.2.3.1 Feeding
With consideration given to the end use of the milk, forage and feed for lactating animals should not introduce, directly or indirectly, contaminants into milk in amounts that present an unacceptable health risk to the consumer or adversely affect the suitability of milk or milk products.
It has been shown that improper procurement, manufacturing and handling of animal feed can result in the introduction of pathogens and spoilage organisms to milking animals and the introduction of chemical hazards such as pesticide residues, mycotoxins and of other contaminants which can affect the safety and suitability of milk or milk products.

3.2.3.2 Pest control
Pests should be controlled, and in a way that does not result in unacceptable levels of residues, such as pesticides, in the milk.
Pests such as insects and rodents are known vectors for the introduction of human and animal diseases into the production environment. Improper application of pest control chemicals used to control these pests may introduce chemical hazards into the production environment.

3.2.3.3 Veterinary drugs
Animals should only be treated with veterinary drugs authorized by the competent authority for the specific use and in a manner that will not adversely impact on the safety and suitability of the milk, including adherence to the withdrawal period specified.
Milk from animals that have been treated with veterinary drugs that can be transferred to milk should be discarded appropriately until the withdrawal period specified for the particular veterinary drug has been achieved.

Residues of veterinary drugs in milk should not exceed levels that would present an unacceptable risk to the consumer.
The improper use of veterinary drugs has been shown to result in potentially harmful residues in milk and milk products, and may affect the suitability of milk intended for the manufacture of cultured products.

3.2.4 Hygienic milking

Milking should be carried out in such a manner that minimizes contamination of the milk being produced.

Effective hygienic practice during milking is an important element of the system of controls necessary to produce safe and suitable milk and milk products. Failure to maintain adequate sanitation and employee practices has been shown to contribute to the contamination of milk with undesirable or pathogenic micro-organisms or chemical or physical hazards.

3.3 Handling, storage and transport of milk

With consideration given to the end use of the milk, handling, storage and transport of milk should be conducted in a manner that will avoid contamination and minimize any increase in the microbiological load of milk.

Proper handling, storage and transport of milk are important elements of the system of controls necessary to produce safe and suitable milk and milk products. Contact with unsanitary equipment and foreign materials are known causes of milk contamination. Temperature abuse is known to increase the microbiological load of milk.

3.3.1 Milking equipment

Milking equipment should be designed, constructed, installed, maintained and used in a manner that will avoid the introduction of contaminants into milk.

Milking equipment is normally designed and constructed according to recognized standards that avoid the introduction of contaminants into milk. Equipment selected for installation on dairy farms should meet recognized design and construction standards. Recognized guidelines also exist for the proper use, cleaning and maintenance of milking equipment; such guidelines should be followed to avoid transfer of disease between animals through milking equipment and to help ensure obtaining milk that is safe and suitable.

Milking equipment should be operated in a manner that will avoid damage to udder and teats and that will avoid the transfer of disease between animals through the milking equipment.

It is important to prevent any damage to udder and teats by milking equipment since such damage can lead to infections and consequently adversely affect the safety and suitability of milk and milk products.

3.3.2 Storage equipment

Milk storage tanks and cans should be designed, constructed, maintained and used in a manner that will avoid the introduction of contaminants into milk and minimize the growth of micro-organisms in milk.

3.3.3 Premises for, and storage of, milk and milking-related equipment

Premises for the storage of milk and milking-related equipment should be situated, designed, constructed, maintained and used in a manner that avoids the introduction of contaminants into milk.

Whenever milk is stored, it should be stored in a manner that avoids the introduction of contaminants into milk and in a manner that minimizes the growth of micro-organisms.

3.3.4 Collection, transport and delivery procedures and equipment

This section also covers the activities of personnel involved in the transport of milk.

Milk should be collected, transported and delivered without undue delay, and in a manner that avoids the introduction of contaminants into milk and minimizes the growth of micro-organisms in the milk.

Note: See Section 10 for provisions on the training of personnel involved in the collection, transport and delivery of milk.

Milk transport tankers and cans should be designed, constructed, maintained and used in a manner that will avoid the introduction of contaminants into milk and minimize the growth of micro-organisms in milk.

3.4 Documentation and record keeping

Records should be kept, as necessary, to enhance the ability to verify the effectiveness of the control systems.

4. ESTABLISHMENT: DESIGN AND FACILITIES

These principles and guidelines are supplemental to those contained in Section 4 of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and to the general principles presented in Section 2.3 above.

4.1 Equipment

Equipment should be designed and installed such that as far as possible dead ends or dead spots in milk pipelines do not occur.

Where dead ends or dead spots occur, special procedures should ensure they are effectively cleaned or otherwise do not permit a safety hazard to occur.

5. CONTROL OF OPERATION

These principles and guidelines are supplemental to those contained in Section 5 of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) (including the Annex on *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application)* and to the overarching principles presented in Section 2.3 above.

USE OF THIS SECTION

This section contains principles for the control of operation that are intended to be applied in such a manner as to result in meeting acceptable levels of relevant hazards specified as Food Safety Objectives and/or related objectives and criteria, or end product criteria that have been established to express the level of protection for

the specific situation. Guidelines for applying the principles with respect to physical, chemical and microbiological hazards are provided in this section as well. Details given in Annex II provide guidance on the establishment and management of control measures used to achieve safety and suitability during and after processing.

For the effective implementation of the provisions in this Section, milk should be produced in accordance with Section 3 and Annex I of this Code.

5.1 Control of food hazards

The combination of control measures should effectively control the identified hazards in milk and milk products.

The combination of control measures should be designed in a systematic way, and the chosen combination should be adapted to the hygiene status of the milk and raw materials used with consideration given to the relevant microbiological, chemical and physical hazards of concern and to the establishment of Food Safety Objective(s) and/or related objectives and criteria.

Where appropriate control measures and/or control measure combinations are chosen to control hazards that are reasonably likely to occur, the procedures described in sections 5.1.1 to 5.1.3 and corresponding guidelines contained in Annex II should be implemented in order to minimize or prevent the likelihood of a health risk to the consumer.

The following procedures are intended to enhance and supplement those aspects of the HACCP Annex to the *International Recommended Code of Practice – General Principles of Food Hygiene*, which are critical to the successful design of a system of food safety controls.

5.1.1 Hazard identification and evaluation

All potential hazards should be identified.

This should be done before control measures are selected and is the first step in the hazard analysis.

The identification should be based on the initial descriptions developed during preliminary steps and on experience, external information, as well as epidemiological and other historical data that have been associated with the type of food under consideration, the type of raw materials and ingredients used, and that may be introduced during processing and distribution. To insure a comprehensive approach, the various step(s) in the manufacturing process, from material selection through processing and distribution, where a hazard may occur or be introduced should be identified.

Each potential hazard should be evaluated to determine the severity of its adverse health effects and reasonable likelihood of occurrence.

Potential hazards that are determined to have severe adverse health effects and/or are reasonably likely to occur should be subject to control by the system of control measures.

5.1.2 Control measure selection

Following hazard evaluation, control measures and control measure combinations should be selected that will prevent, eliminate, or reduce the hazards to acceptable levels.

The next step in the hazard analysis process is to select control measures that will be effective in controlling those hazards. A number of such control measures are further described in Annex II, Parts A and B.

Guidance on how to provide reference validations of individual control measures or control measure combinations against individual hazards in various media is given in *Guidelines for the Validation of Food Hygiene Control Measures* (CAC/GL 69-2008).

5.1.3 Establishment of process criteria

Process criteria for control measures should be established in order for the process to be applied in a manner that will meet the performance required, i.e., assure the adequate delivery of the control measure.

Process criteria should be established at such intensities that the control measures actually deliver the expected performance, taking into account normal process deviations.

5.2 Key aspects of hygiene control systems

5.2.1 Temperature and time controls

From milk production through to finished products, products should be stored at appropriate temperatures and for appropriate times such that the growth or development of a food safety hazard will be minimized and the product's suitability will not be adversely affected.

Because milk and many milk products have a sufficient moisture content to support the growth of pathogens, temperature and time controls represent key microbiological control measures to control growth throughout the manufacturing process, from the handling of milk to the distribution and storage of perishable milk products (e.g., pasteurized drinking milk, desserts, and soft cheeses, depending on shelf life). For instance, for liquid milk, increased storage temperature will decrease the shelf life.

5.2.1.1 Management of products within the plant

Incoming milk

When arriving at the dairy plant, and provided that further processing does not allow otherwise, the milk should be cooled and maintained at such temperatures as necessary to minimize any increase of the microbial load of the milk.

The principle of "first arrived, first processed" should apply.

Intermediate products

Intermediate products that are stored prior to further processing should, unless further processing does not allow it, be kept under such conditions that limit/prevent microbial growth or be further processed within a short time period.

The ultimate safety and suitability of milk and milk products, as well as the intensity of the control measures that need to be applied during processing, depends not only on the initial microbial load upon receipt at the dairy plant but also on preventing the growth of micro-organisms. Application of proper storage temperatures and management of raw materials is an essential factor in minimizing microbial growth. The ability of a product to meet intended Food Safety Objectives and/or related objectives and criteria is dependent upon the proper application of the control measures, including time and temperature controls.

There should be adequate stock rotation, based on the principle of "first in, first out".

5.2.1.2 Distribution of finished products

It is essential that milk and milk products be kept at an appropriate temperature in order to maintain their safety and suitability from the time it is packaged until it is consumed or prepared for consumption.

While the storage temperature should be sufficient to maintain the product's safety and suitability throughout the intended shelf life, the appropriate storage temperature will vary depending upon whether the product is perishable or non-perishable. For perishable products, the distribution system should be designed to maintain adequate low-temperature storage to ensure both safety and suitability. For non-perishable products designed to be shelf-stable at ambient temperature, extremes of temperature should be avoided, primarily to assure maintaining suitability. Reasonably anticipated temperature abuse should be taken into account in designing the normal patterns of distribution and handling.

5.2.1.3 Establishment of shelf life

It is the responsibility of the manufacturer to determine the shelf life of the product and the conditions for storage.

Limitation of shelf life is a control measure that, in many cases, is decisive for the safety and suitability of the product. The corresponding storage conditions are an integral aspect of product shelf life.

5.2.2 Specific process steps

Annex II, Appendices A and B contain examples of processes used during the manufacture of milk products that can control hazards that are reasonably likely to occur. These processes include both extrinsic and intrinsic factors that influence the growth of micro-organisms.

Extrinsic factors *refer to factors impacting the product from the environment in which the food is placed. Examples include temperature, time, and relative humidity of the air.*

Intrinsic factors *refer to internal factors in the product itself (food matrix), influenced by or as consequence of extrinsic factors, that have an impact on the growth and/or survival of micro-organisms. Examples include water activity, pH, nutrient availability, competition of micro-organisms, and bacteriocins or other growth inhibitors.*

5.2.3 Microbiological and other specifications

Where they are employed, microbiological criteria, including those used to verify the effective application of control measures within the framework of HACCP principles, should be developed in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods*, CAC/GL 21-1997, including the use of a risk assessment approach as specified in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment*, CAC/GL 030-1999.

5.2.3.1 Incoming milk

Manufacturers should establish incoming milk criteria that take into account the end use of the milk and the conditions under which the milk was produced.

Depending upon the end use of the milk, particularly for milk used in the production of raw milk products, certain specific microbiological criteria may be appropriate to verify the microbiological quality of the milk used as raw material.

Corrective action taken for non-compliance with incoming milk criteria should be commensurate with the potential risks presented by the non-compliance.

Incoming milk that is out of compliance with established criteria indicates that the control measure system is not working properly and corrective action should be taken to identify and resolve causative problems.

5.2.3.2 Microbiological criteria

Microbiological criteria may be necessary to be established at different points in the process for carrying out the design of control measure combinations and for the verification that the control system has been implemented correctly.

In some cases, for example where more comprehensive control measures are put into place to ensure the safety and suitability of milk (such as may be the case for raw milk intended to be used in the production of raw milk products), it may be necessary to establish criteria for in-process product, intermediate product or finished product in order to verify that the more comprehensive set of control measures have been properly carried out.

5.2.4 Microbiological cross contamination

The flow of the product and of the ingredients within equipment and through the processing facility should maintain a forward progression from raw material receipt to finished product packaging so as to avoid cross contamination.

The flow of the water, air, effluents, and milk should be carefully evaluated to ensure that the potential for cross-contamination does not occur. Similarly, the flow of personnel should be evaluated to ensure that their actions couldn't contaminate milk.

There should be adequate separation of areas with different levels of contamination risk.

Milk products that have been returned from other locations should be identified, segregated and stored in a clearly designated area.

Where there is the potential for cross-contamination between end products and raw materials or intermediate products, and from contaminated areas such as

construction and rebuilding areas, consideration should be given to a physical separation, such as by the application of barrier hygiene (the application of physical or mechanical barriers to prevent or minimize the transfer of contaminants or potential sources of contaminants) and wet/dry area segregation.

5.2.5 Physical and chemical contamination

Preventive measures should be implemented to minimize risks of contaminating milk and milk products with physical and chemical hazards and foreign substances.
Avoiding physical and chemical contamination of milk and milk products during processing requires the effective control of equipment maintenance, sanitation programmes, personnel, monitoring of ingredients and processing operations.
Preventive measures should include those that will minimize the potential for cross contamination of allergenic components and/or ingredients that may present in other products to a milk product in which these components and/or ingredients are not supposed to be present.

5.3 Incoming material (other than milk) requirements

Ingredients used for the processing of milk products should be purchased according to specifications, and their compliance with these specifications should be verified.
Contaminated ingredients have been known to lead to unsafe/unsuitable milk products, since these ingredients are often added during processing where no further control measures are applied.
Preferably, specifications for raw materials should be established such that their use will result in a safe and suitable product. No raw material should be accepted if it is known to contain chemical, physical or microbiological contaminants that would not be reduced to an acceptable level by normal sorting and/or processing. Raw materials should, where appropriate, be inspected and sorted before processing. Any claims that raw materials meet safety and suitability specifications should be verified periodically.

5.4 Water

Dairy processing establishments should have potable water available, which prior to its first use, should meet the criteria specified by the competent authorities having jurisdiction and should be regularly monitored.

Water recirculated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use.
Proper maintenance of water conditioning systems is critical to avoid the systems becoming sources of contamination. For example, filter systems can become sources of bacteria and their metabolites if bacteria are allowed to grow on the organic materials that have accumulated on the filter.

Appropriate safety and suitability criteria that meet the intended outcomes should be established for any water used in dairy processing.
These criteria depend upon the origin and the intended use of the water. For example, reuse water intended for incorporation into a food product should at least meet the microbiological specifications for potable water.

Reconditioning of water for reuse and use of reclaimed, recirculated and recycled water should be managed in accordance with HACCP principles.
Any reuse of water should be subject to a hazard analysis including assessment of whether it is appropriate for reconditioning. Critical control point(s) should be identified, as appropriate, and critical limit(s) established and monitored to verify compliance.

6. ESTABLISHMENT: MAINTENANCE AND SANITATION

These principles and guidelines are supplemental to those contained in Section 6 of the *General Principles of Food Hygiene* (CAC/RCP 1-1969).

6.1 Maintenance and cleaning

Processing areas should be kept as dry as possible.
Use of dry cleaning methods, and limiting the use of water in processing areas, helps to avoid the spread of contamination by water. Wet cleaning (other than Cleaning-in-Place) has been known to lead to milk product contamination due to the production of aerosols.

All food product contact surfaces in piping and equipment, including areas that are difficult to clean such as by-pass valves, sampling valves, and overflow siphons in fillers should be adequately cleaned.

6.2 Cleaning programmes

A routine programme to verify the adequacy of cleaning should be in place.
All equipment and utensils used in processing should, as necessary, be cleaned and disinfected, rinsed with water which is safe and suitable for its intended purpose (unless the manufacturer's instructions indicate rinsing is not necessary), then drained and air dried where appropriate.

7. ESTABLISHMENT: PERSONAL HYGIENE

No specific requirements beyond those contained in the *General Principles of Food Hygiene* (CAC/RCP 1-1969) are needed.

8. TRANSPORTATION

These principles and guidelines are supplemental to those set forth in Section 8 of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and, as appropriate, those set forth in *Code of Hygienic Practice for the Transport of Foodstuffs in Bulk and Semi-Packed Foodstuffs* (CAC/RCP 47 – 2001).

8.1 Requirements

Products covered under this Code should be transported at time/temperature combinations that will not adversely affect the safety and suitability of the product.

8.2 Use and maintenance

In the case of refrigerated products, the vehicle product compartment should be cooled prior to loading and the product compartment should be kept at an appropriate temperature at all times, including during unloading.

9. PRODUCT INFORMATION AND CONSUMER AWARENESS

These principles and guidelines are supplemental to those contained in Section 9 of the *General Principles of Food Hygiene* (CAC/RCP 1-1969).

9.1 Labelling

Milk products should be labelled in accordance with the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985), the *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999) and the relevant labelling section of Codex commodity standards for individual milk products.
Unless the product is shelf stable at ambient temperatures, a statement regarding the need for refrigeration or freezing should be included on the label of the product.

Additional provision for raw milk products

Raw milk products should be labelled to indicate they are made from raw milk according to national requirements in the country of retail sale.

10. TRAINING

These principles and guidelines are supplemental to those contained in Section 10 of the *General Principles of Food Hygiene* (CAC/RCP 1-1969).

10.1 Training programmes

Milk producers and personnel involved in the collection and transport and retail of milk should be trained as necessary and have appropriate skills in the areas listed below:

- health of animals and use of veterinary drugs;
- manufacturing and use of feeds (more specifically fermented feeds);
- herd management;
- hygienic milking;
- storage, handling, collection and transport of milk (cleaning of storage tanks, temperature requirements, sampling procedures, etc.);
- microbiological, chemical and physical hazards and their control measures.

ANNEX I

GUIDELINES FOR THE PRIMARY PRODUCTION OF MILK

INTRODUCTION AND OBJECTIVES

The detailed information contained in this annex should be implemented in order to reduce the likelihood of milk contamination through inadequate primary production practices. This information will enable the implementation of the principles laid down in Section 3 of the main body of the Code by providing guidelines for their application.

These measures, in combination with microbiological control measures found in Annex II, should be used to effectively control the microbiological hazards in milk products. There is a close relationship between the hygienic conditions found in primary production and the safety and suitability of processed milk products based on the control measures presented in Annex II.

SCOPE

This Annex provides details of the approaches that should be used for the primary production of milk intended for further processing of an unspecified nature. The milk should be subjected to the application of microbiological control measures described in Annex II.

The degree to which on-farm practices control the likelihood of occurrence of food safety hazard in milk will have an impact on the nature of controls needed during the subsequent processing of the milk. Under normal circumstances, milk will be subjected to control measures sufficient to address any hazards that may be present. Where the subsequent processing of milk does not involve the application of control measures necessary to address any hazards that may be present, the focus then becomes preventative in nature in order to reduce the likelihood that such hazards will occur during the primary production phase of the continuum. Likewise, in certain primary production situations, the occurrence of food safety hazards may be less avoidable, which will mandate the application of more stringent control measures during subsequent processing in order to insure the safety and suitability of the finished product.

USE OF ANNEX I

The information in Annex I is organized to correspond with the relevant sections in the main part of the Code and the *General Principles of Food Hygiene* (CAC/RCP 1-1969). Where a particular principle has been identified in the main body of the Code, guidelines for the application of that principle will be located in the corresponding section of this Annex.

ANNEX II

GUIDELINES FOR THE MANAGEMENT OF CONTROL MEASURES DURING AND AFTER PROCESSING

INTRODUCTION AND OBJECTIVES

The detailed information contained in this annex should be implemented in order to prevent, eliminate or reduce hazards associated with incoming materials to acceptable levels and to reduce the likelihood of milk contamination resulting from inadequate control of manufacturing operations. This information will enable the implementation of the principles laid down in Section 5 of the main body of the Code by providing guidelines for their application.

These measures should be used in combination with guidelines on primary production found in Annex I in order to effectively control the microbiological hazards in milk products. There is a close relationship between the control of manufacturing operations and the safety and suitability of processed milk products based on the control measures presented in Annex II.

SCOPE

The provisions in this Annex reinforce and supplement the principles and guidelines specified in Section 5 of the Code (Control of Operation), in particular Section 5.1, and should apply to the manufacture of any milk product. The principles in Section 5, Control of Operation, as well as the hazard identification provisions of this annex apply not only to the control of microbial hazards but also to the control of chemical and physical hazards.

The most common microbiological control measures are addressed in further detail in Part A (microbiostatic control measures) and Part B (microbiocidal control measures), respectively. However, this does not preclude in any way the use of additional and/or alternative microbiological control measures, provided that the general guidance provided in this Annex is followed.

USE OF ANNEX II

The information in Annex II is organized to correspond with the relevant sections in the main part of the Code and the *General Principles of Food Hygiene* (CAC/RCP 1-1969). Where a particular principle has been identified in the main body of the Code, guidelines for the application of that principle will be located in the corresponding section of this part of the Annex.

These guidelines are supplemental to those contained in Section 5 of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) (including the Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application Annex) and to the overarching principles presented in Section 2.3 of the base document.

The guidelines presented in this annex are intended to enhance and supplement those aspects of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) HACCP Annex which are critical to the successful design of a system of food safety controls. The users of this document are encouraged to implement the guidelines contained in the HACCP Annex when designing a HACCP system and to refer to those Annex II guidelines for further details on the hazard analysis, control measure selection and critical limit determination.

DEFINITIONS

The definitions below apply for the purpose of this Annex, and in addition to those definitions contained in Section 2.5 of the main body of this Code.

Microbiocidal treatments are control measures that substantially reduce or practically eliminate the number of micro-organism present in a food.

Microbiostatic treatments are control measures that minimize or prevent the growth of micro-organisms present in a food.

Pasteurization is a microbiocidal heat treatment aimed at reducing the number of any pathogenic micro-organisms in milk and liquid milk products, if present, to a level at which they do not constitute a significant health hazard. Pasteurization conditions are designed to effectively destroy the organisms *Mycobacterium tuberculosis* and *Coxiella burnettii*.

UHT (ultra-high temperature) ***treatment*** of milk and liquid milk products is the application of heat to a continuously flowing product using such high temperatures for such time that renders the product commercially sterile at the time of processing. When the UHT treatment is combined with aseptic packaging, it results in a commercially sterile product.[7]

5. CONTROL OF OPERATIONS

5.1 Control of food hazards

It is important that control measures are applied during both primary production and processing to minimize or prevent the microbiological, chemical or physical contamination of milk. In addition, special attention should be given during the processing of different milk products so that inadvertent cross-contamination does not occur, including with respect to ingredients that may contain allergenic substances. *Note: A distinction can be drawn between the types of control measures used for microbiological hazards and those used for chemical and physical hazards.*

[7] The concepts of aseptic packaging and commercially sterile can be found in the Codex documents on Low Acid and Acidified Canned Foods (CAC/RCP 23-1979) and Aseptic Processing (CAC/RCP 40-1993).

The control measures used for chemical and physical hazards in food are generally preventive in nature, i.e., they focus on avoiding the contamination of food with chemical or physical hazards in the first place rather than on reducing or eliminating such hazards once they have been introduced into the product. It should be noted however that there are some exceptions to this type of distinction, e.g., the use of filters, screens and metal detectors to remove certain physical hazards.

Microbiological food hazards are controlled by appropriate selection of control measures applied during primary production in combination with control measures applied during and after processing. The result of applying any microbiocidal control measure depends significantly on the microbial load (including the concentration of microbiological hazards) in the material subjected to it. It is therefore important that preventive measures are applied in primary production to reduce the initial load of pathogenic micro-organisms as well as during processing to avoid contamination within the processing environment. The initial microbial load significantly impacts the performance needed for the microbiological control measures applied during and after processing as well as the performance required for suitability. The safety and suitability of the end product depends not only on the initial microbiological load and the efficiency of the process, but also on any post-process growth of surviving organisms and post-process contamination.

Individual control measures should be selected and applied in such combination as to achieve a sufficient performance as to result in end products with acceptable levels of hazards.

Acceptable levels of contaminants in the end product should be identified and be based upon:

- Food safety objectives, end product criteria and similar regulatory requirements, as applicable;
- Acceptable levels derived from the purchaser constituting the subsequent link of the food chain; and/or
- The maximum levels found acceptable by the manufacturer, taking into account acceptable levels agreed with the customer and/or regulatory measures established by public health authorities.

The guidelines contained in sections 5.1.1 to 5.1.3 are intended to be supplemental to the *General Principles of Food Hygiene* (CAC/RCP 1-1969) HACCP Annex.

5.1.1 Hazard identification and evaluation

Hazard identification can be separated into two distinctly different parts, the identification of all potential hazards and the evaluation of the identified potential hazards to determine which are considered to have severe adverse health effects and/or are reasonably likely to occur and therefore need to be controlled through the implementation of effective control measures.

The hazard identification should be based on the initial descriptions developed during preliminary steps contained in the *General Principles of Food Hygiene* (CAC/RCP 1-1969), HACCP Annex and on experience, external information, as well as epidemiological and other historical data that have been associated with the type of food under consideration, the type of raw materials and ingredients used, and that may be introduced during the processing distribution. To insure a comprehensive approach, the various step(s) in the manufacturing process, from material selection through processing and distribution, where a hazard may occur or be introduced should be identified.

The potential hazards for such consideration should be listed in relation to the identified acceptable levels, including established FSO(s), where available.

For microbiological hazards, the likelihood of occurrence will depend on the actual prevalence in the milk and raw materials used. Factors influencing the prevalence are climatic conditions, animal species, prevalence of animal disease (sub-clinically or clinically) caused by the organism, prevalence of mastitis including the relative distribution of causing organisms, the adequacy of primary production practices including the potential of environmental contamination (feeding practices, water quality, milking hygiene level), and the potential for human contamination. Consultation of the competent authorities having jurisdiction in relation to the herds is appropriate.

When evaluating potential microbiological hazards, consideration should be given to which of the organisms are likely to be present in the milk. For instance, microbiological hazards that are not relevant in the geographical area of concern (e.g. because the prevalence is insignificant or zero) can be ruled out at an early stage. Also, where it can be verified that specific sanitary measures are successfully applied during primary production to prevent or significantly reduce introduction of a pathogen into the herd, including efficient eradication programmes, the pathogen in question may be ruled out. The manufacturer or other appropriate party is responsible for documenting the conditions that support such a determination. This can be accomplished by documenting the OIE status (e.g. disease-free area), the effectiveness of national programmes, the effectiveness of individual producer screening programmes, on the basis of documented historical evidence, and through the development of epidemiological evidence.

Regular analysis of the milk (including but not restricted to microbiological analyses) received at the manufacturing establishment producing milk products can be used to verify the implementation of control measures affecting the likelihood of occurrence of a hazard, depending upon the technology used and the kind of milk product being made.

Hazard identification should take into consideration the allergenic nature of some foods. Milk products may contain ingredients such as nuts, eggs and cereal grains that are known to be allergens.

Further, any additional hazards that can be introduced into the milk product during and after processing (e.g. environmental contamination, human contamination) should also be considered. During such considerations, the effectiveness of preventive measures taking place in the manufacturing environment (e.g., environmental and equipment sanitation programmes, employee practices, pest control programmes, etc.) should be evaluated to determine the likelihood of occurrence of potential hazards.

5.1.2 Control measure selection

Note: While the following guidelines are focused on the control of microbiological hazards, the concepts presented herein can be applied as well to the control of chemical and physical hazards.

The next step in the hazard analysis process is to select control measures that will be effective in controlling those hazards. A number of such control measures are further described in Appendices A and B of Annex II.

Selection of individual control measures

Individual microbiological control measures can be grouped according to primary function as follows:

- *Microbiocidal control measures* that reduce the microbial load, for instance by killing, inactivation or removal. These may be applied during processing as processing steps (e.g. microfiltration, thermization, pasteurization) or after the processing as intrinsic factors (e.g. ageing).
- *Microbiostatic control measures* that prevent, limit or retard the growth of micro-organisms by chemical or physical means. These are used to stabilize the product against activity of pathogens and spoilage organisms and may apply after milk production, during processing (e.g. in between processing steps) and after processing. Microbiostatic control measures still imply some probability of growth. Microbiostatic control measures that are efficient after processing may be applied towards the product (e.g. temperature/time control) as extrinsic factors or be built into the product as intrinsic factors (e.g. preservatives, pH).
- *Microbiostatic control measures that prevent direct contamination* of product, for instance by closed circuits or by appropriate packaging to protect the product. These are used to physically prevent contamination, in particular, during packaging and/or after processing.

The use of a single processing step may have subsequent microbiological effects (e.g. reduction of pH, water content), while other microbiological control measures only reduce the number of micro-organisms at the point in the manufacturing process, where it is applied.

Combination of microbiological control measures

More than one microbiological control measure is usually needed to control microbial content, to retard or prevent spoilage and to help prevent food borne diseases. Suitable combinations can be devised in order that specific organisms of concern can be reduced in number and/or no longer grow/survive in the product.

Such suitable combinations are sometimes referred to by the dairy industry as "hurdle technology".

The combination of control measures has two main objectives:

- During processing: Providing assurance that the levels of the pathogens (and/or spoilage organisms) of concern, where present, are kept at or reduced to acceptable levels.
- After processing (packaging, distribution and storage): Providing assurance that the acceptable levels of the pathogens (and/or spoilage organisms) of concern that have been achieved during processing are kept under control throughout shelf life.

It may be necessary to ensure that growth of micro-organisms is kept to a minimum prior to processing, in between different processing steps, and after processing. The microbiostatic control measures used should be adapted to the need of the particular product in the particular situation. The resulting outcome in terms of the safety and suitability of the end product does not depend only on the initial microbial load and the effectiveness of the process, but also on any post-process growth of surviving organisms and post-process contamination. Therefore, all microbiological control measure combinations should be supported by appropriate preventive measures prior to and after the process, as deemed necessary.

Depending on the source and possible routes of contamination, the hazard(s) may be kept under control by preventive measures implemented at primary production level and/or in processing environments. When evaluating microbiological preventive measures, it is particularly important to know which of the hazards are affected by the preventive measure and to what extent the measure reduces the probability of the hazard contaminating the milk product during milking, processing and/or distribution. Those microbiological hazards that are not managed adequately by preventive and microbiostatic control measures need to be managed and controlled by adequate microbiocidal control measures with sufficient combined performance.

Microbiological control measures having effect only at the point of application must be applied in appropriate combinations with other microbiological control measures.

The combination of microbiological control measures is most efficient when it is *multi-targeted*, that is, when various individual measures are selected so that different factors effecting microbial survival are targeted, e.g., pH, A_w, availability of nutrients, etc. In many cases, a multi-targeted combination using microbiological control measures with low intensity may be more effective than one single measure with high intensity. The presence of a number of microbiological control measures inhibiting or reducing the number of micro-organisms may be *synergistic*, that is that interaction occurs between two or more measures so that their combined effect is greater than the sum of their individual effects. Therefore, the utilization of synergistic effects can allow for combining microbiological control measures of less intensity than would be otherwise expected from each measure individually.

Where flexibility from provisions in Annex I is granted for small holder dairy farms, particular attention should be paid to the nature of the granted deviations and their potential consequences in terms of hazard levels in the milk.

Attention should be paid to the application of microbiocidal control measures with such performance that they effectively eliminate any risks associated with the transfer of additional zoonotic hazards to the milk. Similarly, where certain animal diseases are present in herds producing the milk, particular attention should be drawn to the recommendations in the OIE *Terrestrial Animal Health Code*, as specific microbiocidal control measures or performances thereof may be necessary to eliminate the animal health risks associated with these diseases.

5.1.3 Establishment of process criteria

From the performance required, the corresponding process criterion or criteria (as appropriate to the nature of the microbiological control measure) should be established. They are intended for the appropriate implementation (set-up) of a processing step and for application in practical process control (e.g. filter size, pH, concentration of preservative, time/temperature combinations). In the context of HACCP, process criteria may or may not constitute critical limits.

The performance of control measures and control measure combinations selected should be validated using procedures outlined in the *Guidelines for the Validation of Food Hygiene Control Measures* (in preparation). The validation of control measures or control measure combinations is especially important when establishing the effectiveness of new or developing technologies. validation may not be necessary in situations where well established control measures or technologies are considered to be acceptable.

If the performance required cannot be achieved by the control measure(s) or if it is estimated and/or monitoring shows that the hazards are not under sufficient control by the selected combination of microbiological control measures, modification of the control system design is necessary.

Examples of some of the modifications that can be made until the hazard of concern is considered under control include:

- Increase of the intensities of the microbiological control measure(s) applied.
- Identification of additional microbiological control measure(s) that target the hazard of concern.
- Implementation of more stringent on-farm control measures.
- Introduction of specifically targeted measures at farm level that reduce the prevalence of the hazard of concern in the milk used.
- Reduction of the intended shelf life and/or amendments of the intended storage conditions.

Additional provisions for the manufacture of raw milk products

It is critical for a dairy farm, when producing milk intended for the manufacturing of raw milk product, to comply with the provisions (including the identified additional provisions) detailed in Annex I and in section 5.2.3.1 of this Annex,

and these activities should be frequently monitored and evaluated for their effective implementation. This evaluation may lead to the identification of needed improvements at the primary production level (practices, equipment, environment, etc.) or in the classification of dairy farms according to their ability to provide milk for the processing of raw milk products.

Any non-compliance detected either at the farm level or at the milk reception of a manufacturing plant should result in immediate action that may affect the farm, the manufacturing establishment or both. For this reason, there should be clear communication between the manufacturer and the farm and, if necessary, technical assistance should be provided to the primary producer by the manufacturer.

5.2 Key aspects of hygiene control systems

5.2.1 Time and temperature control

5.2.1.2 Distribution of finished products

Perishable products

- The storage temperature should be sufficient to maintain product safety and suitability throughout the intended shelf life. If the temperature of the product is the principal means of preservation, it is essential that the product be maintained at the appropriate temperature. Validation of the selected temperature should be carried out except in situations where well established storage temperatures are considered acceptable.
- Regular and effective monitoring of temperatures of storage areas, transport vehicles and store display cases should be carried out where:
  - the product is stored, and
  - the product is being transported, within the product load, which could be done by using temperature indicating and recording systems;
  - the product is being presented for retail sale.
- Particular attention should be paid throughout storage and distribution to:
  - periods of defrosting of refrigeration units;
  - temperature abuse; and
  - overloading the cold storage facility.

Products stable at ambient temperatures

Products that can be stored at ambient temperatures, should be protected against external agents and contamination, e.g., direct sun radiation, excessive heating, moisture, external contaminants, etc. from rapid temperature changes which could adversely affect the integrity of the product container or the safety and suitability of the product.

5.2.1.3 Establishment of shelf life

- Product shelf life is influenced by a number of factors, such as:
  - applied microbiological control measures, including storage temperatures;
  - cooling methods applied to product;

- type of packaging (e.g., hermetically sealed or not, modified atmosphere packaging);
- likelihood of post-process contamination and type of potential contamination.

– The shelf life of milk products may be limited by microbial changes (e.g., deterioration and growth of pathogenic and spoilage micro-organisms to unacceptable levels).
– When establishing product shelf life, it is the responsibility of the manufacturer to assure and, as necessary, to demonstrate, that the safety and suitability of the milk product can be retained throughout the maximum period specified, taking into consideration the potential for reasonably anticipated temperature abuse during manufacture, storage, distribution, sale and handling by the consumer.
– These temperature abuses may allow the growth of pathogenic micro-organisms, if present, unless appropriate intrinsic factors are applied to prevent such growth. **Explanatory note:** Reasonably anticipated temperature abuse takes into account the normal period of transporting of purchased products to appropriate consumer storage facilities and normal patterns of handling during consumption, for instance, the number and length of periods in which the product is removed from the refrigerator and subjected to ambient temperatures until the whole package has been consumed.
– The possible reactivation of pathogens with time should be taken into account when determining the shelf life.
– Shelf life determination can be carried out at the plant level by testing products subjected to the storage conditions specified or by predicting microbial growth in the product under the specified storage conditions. Reasonable anticipated temperature abuse can be integrated into the study or be taken into account by applying an appropriate safety factor (e.g., by shortening the maximum durability specified in the labelling or by requiring lower storage temperatures).

5.2.2 Microbiological and other specifications

5.2.2.1 Milk

– The milk used for the manufacture of products covered by this Code should be evaluated based on sampling of milk from individual farms or milk collection centres.
– Upon receiving, the milk should be subject to olfactory and visual inspection. Other criteria (e.g., temperature, titratable acidity, microbiological and chemical criteria) should be used to detect unacceptable conditions.
– Any-non-compliance with the above mentioned criteria, and in particular with regards to pathogens, should result in immediate corrective actions at the farm level and in the manufacturing establishment, for example: rejection of the milk for the processing of raw milk products; corrective actions on the milking procedure (cleaning and sanitation procedures of the milking equipment, cleaning or sanitation procedures of the udder, etc.,); quality of feed; the hygienic quality of the water supply; practices in animal holding areas; individual check of animals to find the animal(s) that may be the carrier; isolation of that animal from the herd as necessary. Corrective actions should be identified and implemented, and specific assistance to the dairy farm may need to be provided.

– In some cases, where more comprehensive control measures are put into place to ensure the safety and suitability of milk, as may be the case for raw milk intended to be used in the production of raw milk products, it may be necessary to classify farms into two categories: those acceptable for use in raw milk products and those that are not.

Additional provisions for milk used in the manufacture of raw milk products

– Depending on the hazard analysis performed by the manufacturer and the combination of microbiological control measures applied during and after processing of milk products, specific microbiological criteria regarding pathogens (for example: *Salmonella* spp., *Listeria monocytogenes*) may need to be established.

APPENDIX A
MICROBIOSTATIC CONTROL MEASURES

Note: The control measures described in this appendix are presented as descriptive examples only and require validation prior to use with respect to their effectiveness and safe use.

Microbial growth is dependent upon many conditions in the organism's environment such as: ingredients, nutrients, water activity, pH, presence of preservatives, competitive micro-organisms, gas atmosphere, redox-potential, storage temperature and time. Control of these conditions can therefore be used to limit, retard, or prevent microbial growth.

Such microbiological control measures as well as microbiological control measures protecting the product against direct microbial contamination from the surroundings have microbiostatic functions.

Many microbiostatic control measures act by interfering with the homeostasis[a] mechanisms that micro-organisms have evolved in order to survive environmental stresses.

Maintaining a constant internal environment requires significant energy and material resources of the micro-organism, and when a microbiological control measure disturbs the homeostasis there will be less energy left for the micro-organism to multiply. Consequently, the organisms will remain in the lag phase and some may even die out before the homeostasis is re-established.

[a] Homeostasis is the constant tendency of microorganisms to keep their internal environment stable and balanced. For instance, microorganisms spend considerable efforts keeping their internal pH and osmotic-pressure within narrow limits.

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Nederlandse Voedsel- en Warenautoriteit
Ministerie van Economische Zaken

INFORMATIE BLAD 85 / juli 2016

Interpretatiedocument NVWA m.b.t. Verordening (EG) nr. 2073/2005 inzake microbiologische criteria voor levensmiddelen

1 INLEIDING

Sinds 1 januari 2006 is Verordening (EG) nr. 2073/2005 inzake microbiologische criteria voor levensmiddelen (afgekort: VMC) van kracht. Deze Verordening richt zich met name op de verplichtingen voor exploitanten van levensmiddelenbedrijven in alle stadia van de productie, verwerking en distributie van levensmiddelen, inclusief de detailhandel, met betrekking tot de beheersing van de microbiologische veiligheid van levensmiddelen (artikel 3, eerste lid).

In de VMC worden een viertal hoofdzaken verplicht gesteld voor het bedrijfsleven. Exploitanten van levensmiddelenbedrijven dienen minimaal:

1. Hun op HACCP-beginselen gebaseerde procedures en goede hygiënepraktijken te valideren of te verifiëren en op basis van een risicobeoordeling een eigen microbiologisch controleprogramma op te zetten voor de in deze Verordening genoemde microbiologische criteria. In het geval van karkassen, gehakt vlees, vleesbereidingen, separatorvlees en vers pluimveevlees, dienen bedrijven zich te houden aan de in de Verordening voorgeschreven minimale bemonsteringsfrequenties (artikel 4, eerste en tweede lid).
2. Specifieke studies met betrekking tot de uitgroei van pathogene micro-organismen en in het bijzonder *Listeria monocytogenes* uit te voeren (artikel 3, tweede lid en artikel 5, tweede lid).
3. Zich te houden aan microbiologische voedselveiligheidscriteria met betrekking tot de aanwezigheid (een bepaalde hoeveelheid) van pathogene micro-organismen. Indien deze criteria overschreden worden, zijn de producten te beschouwen als schadelijk voor de volksgezondheid en moeten deze uit de handel genomen worden dan wel een nadere behandeling ondergaan, waardoor het desbetreffende gevaar wordt weggenomen (artikel 7, tweede lid).
4. Zich te houden aan microbiologische proceshygiënecriteria, welke dienen om te controleren of het productieproces beheerst wordt. Bij overschrijding van deze criteria dient het productieproces aantoonbaar gecontroleerd te worden en dient adequate actie ondernomen te worden (artikel 7, vierde lid).

Tevens wordt in artikel 1 van deze Verordening geregeld dat de bevoegde autoriteit moet verifiëren of levensmiddelenbedrijven zich aan de voorschriften houden en heeft ze het recht zelf monstername en onderzoek uit te voeren en op basis daarvan gepaste maatregelen te nemen.
Daarnaast toetst de NVWA de correcte implementatie van de VMC door andere toezichthouders (COKZ/CPE) middels het beoordelen van de jaarplannen.

In dit document wordt de interpretatie van de Nederlandse Voedsel en Warenautoriteit (NVWA) beschreven met betrekking tot de verplichtingen van exploitanten van levensmiddelen in het kader van de VMC:

- Beoordeling van de bemonsteringsprogramma's inclusief bemonsteringsfrequenties, eisen aan laboratoria en gebruikte analysemethoden.
- Studies met betrekking tot *Listeria monocytogenes*.
- Werkwijze van de NVWA met betrekking tot de handhaving op de VMC (Interventiebeleid NVWA).

2 IMPLEMENTATIE IN NEDERLANDSE WETGEVING

VWS wetgeving[1]
Artikel 2, derde lid en artikel 10a van het Warenwetbesluit hygiëne van levensmiddelen (WHL), artikel 4 van het Warenwetbesluit Bereiding en behandeling van levensmiddelen (WBBL; voedselveiligheidscriteria).

EZ wetgeving[2]
Artikel 6.2, eerste lid van de Wet dieren, gelet op artikel 2.4, eerste lid van de Regeling dierlijke producten.

Import
Op Nederlands grondgebied geldt de wetgeving zoals hierboven omschreven. Voor te importeren producten is artikel 10 van Verordening (EG) nr. 852/2004 van toepassing:
De voor de hygiëne van ingevoerde levensmiddelen toepasselijke voorschriften van de levensmiddelenwetgeving, bedoeld in artikel 11 van Verordening (EG) nr. 178/2002, omvatten ook de in de artikelen 3 tot en met 6 van deze Verordening vastgestelde voorschriften.
Hierbij dient te worden opgemerkt dat de VMC is vastgesteld op basis van artikel 4, vierde lid van Verordening (EG) nr. 852/2004.

Verder is artikel 11 van Verordening (EG) nr. 178/2002 van toepassing:
Levensmiddelen en diervoeders die in de Gemeenschap worden ingevoerd om er in de handel te worden gebracht, dienen te voldoen aan de toepasselijke voorschriften die door de Gemeenschap als ten minste gelijkwaardig daaraan zijn aangemerkt, of, ingeval er een specifieke overeenkomst tussen de Gemeenschap en het land van uitvoer bestaat, aan de voorschriften daarvan.

De wettelijke grondslag van het verbod van invoer van producten van dierlijke oorsprong is artikel 17, tweede lid, van Richtlijn 97/98/EG tot vaststelling van procedures voor de veterinaire controles in de grensinspectieposten van de Gemeenschap bij het binnenbrengen van producten uit derde landen. Voor producten die onder de Warenwet vallen is door middel van de Warenwetregeling Veterinaire controles (derde landen) deze Richtlijn in Nederland van toepassing. Volgens artikel 4 van deze Regeling is de NVWA de bevoegde autoriteit van deze Richtlijn. Voor producten die onder de wetgeving van het ministerie EZ vallen is deze Richtlijn door middel van de Regeling veterinairrechtelijke voorschriften handel dierlijke producten in Nederland van toepassing. Krachtens deze Regeling en artikel 6 van het Mandaatbesluit LNV Voedsel en Waren Autoriteit zijn bepaalde functionarissen van de NVWA bevoegd om besluiten met betrekking tot deze Richtlijn te nemen. De wettelijke grondslag van het verbod van invoer van producten van niet-dierlijke oorsprong is artikel 19 van Verordening (EG) nr. 882/2004. Voor deze Verordening is in artikel 3 van het Warenwetbesluit hygiëne van levensmiddelen vastgelegd dat de NVWA de bevoegde autoriteit is.

[1] Sanctiemogelijkheden: bestuurlijke boetes dan wel strafrechtelijke afhandeling (voor strafrechtelijke afhandeling is inzet Buitengewoon opsporingsambtenaar (BOA) noodzakelijk).
[2] Sanctiemogelijkheden: vooralsnog strafrechterlijk, hiervoor is inzet BOA noodzakelijk. Binnenkort ook middels bestuurlijke boetes.

3 INTERVENTIEBELEID

Het interventiebeleid van de NVWA met betrekking tot de VMC bestaat uit twee onderdelen:
- Het interventiebeleid met betrekking tot inspectiebevindingen en de acties van exploitanten van levensmiddelenbedrijven, vastgelegd in het document 'IB01-SPEC19 Gemeenschappelijk interventiebeleid voedsel-, voedselveiligheid Dier en Industrie'.
- Het interventiebeleid met betrekking tot afwijkende analyseresultaten van monsters welke door de NVWA bij levensmiddelenbedrijven zijn genomen, vastgelegd in het document 'IB01-SPEC07 levensmiddelen microbiologie'[3].

Bij constatering van afwijkingen zal de NVWA handhavend optreden conform artikel 54 van Verordening (EG) nr. 882/2004. In het interventiebeleid staat geconcretiseerd welke acties bij afwijkingen minimaal verwacht mogen worden.

Volgens de VMC moeten levensmiddelenbedrijven de in hoofdstuk 1 van dit infoblad genoemde verplichtingen integreren in hun HACCP-plan (inclusief uitvoering daarvan). Handhaving richt zich op de volgende punten:

1. Hebben bedrijven een controleprogramma op basis van risicoanalyse in hun HACCP-plan verwerkt (voor voedselveiligheid- en proceshygiënecriteria; artikel 1).

2. Wordt het HACCP-plan correct uitgevoerd met inbegrip van de specifieke voorschriften voor bemonstering zoals vastgesteld in de VMC dan wel goedgekeurde alternatieven, en zijn de microbiologische analysemethoden die het bedrijf gebruikt conform de in de VMC genoemde ISO-methoden dan wel goedgekeurde alternatieven. Deze alternatieven moeten zijn gevalideerd volgens EN/ISO-norm 16140 conform artikel 5, vijfde lid van de VMC. In bijlage 3 van dit infoblad is de procedure beschreven voor bedrijven voor het verkrijgen van toestemming voor het gebruik van alternatieve analysemethoden. In bijlage 4 is de procedure opgenomen voor het verkrijgen van toestemming voor het gebruik van alternatieve bemonsteringsprocedures.

3. Onderneemt het bedrijf passende maatregelen bij overschrijdingen (artikel 7) of bij constatering van een trend richting ontoereikende resultaten (artikel 9). Het analyseren van trends in analyseresultaten is beschreven in bijlage 5.

4. Interventie door de NVWA bij overschrijdingen naar aanleiding van bemonsteringen door eigen inspecteurs. Naast het opleggen van een eventuele sanctie zal
   In het geval van voedselveiligheidscriteria:
   i. De NVWA erop toezien dat de desbetreffende partij uit de handel wordt gehaald of niet in de handel wordt gebracht tenzij het risico voor volks-/diergezondheid wordt geëlimineerd conform artikel 7, tweede lid.
   ii. De NVWA evalueren of het bedrijf nog voldoet aan de eisen zoals hierboven genoemd in de punten 1 t/m 3.

   In het geval van procescriteria:

[3] Het specifiek NVWA interventiebeleid is te vinden op www.nvwa.nl

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Gevaarlijke stoffenOvereenkomst (tripartite)

Voordat een stof c.q. product mag worden vervoerd, moet eerst een overeenkomst worden gesloten tussen het verschepende land, de vlaggenstaat van het schip (schepen) en het (de) ontvangende land(en). Omdat er tenminste drie partijen zijn, wordt een dergelijke overeenkomst een tripartite overeenkomst genoemd.

Afgesloten tripartites worden opgenomen in een jaarlijks in december door de IMO gepubliceerde circulaire (MEPC.2/circ.) en worden van kracht op 1 januari van het volgende jaar. De tripartites die gedurende het lopende jaar worden afgesloten worden gepubliceerd in een lijst op de website van de IMO.

De producent of vervoerder moet een verzoek voor een tripartite indienen bij de overheid van het verschepende land. De contactgegevens worden vermeld in de circulaire MEPC.2/circ.

Voor Nederland kan het verzoek voor een tripartite per email gestuurd worden naar: MARPOL.tripartite@ilent.nl

Het verzoek moet de volgende informatie bevatten:

- naam van de contactpersoon
- naam van de producent
- naam van de stof c.q. product
- namen van de componenten
- plaats van de productie of verscheping

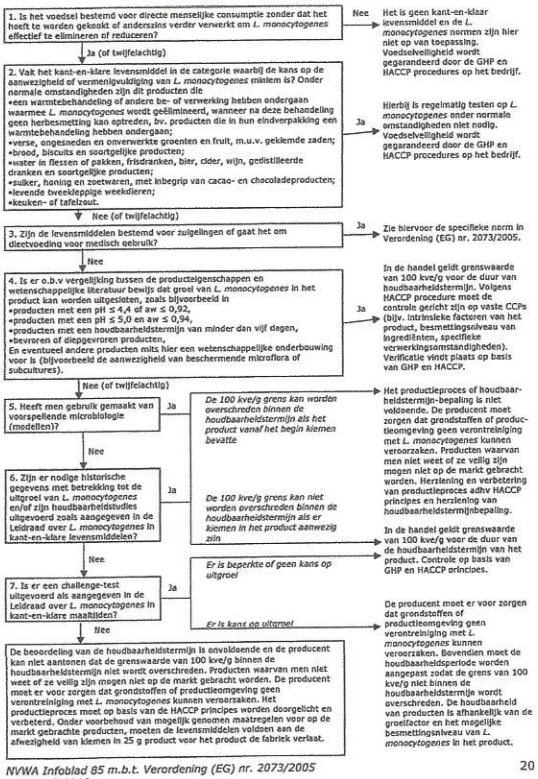
Over het vervolg van de procedure wordt dan contact opgenomen met de verzoeker.

Meer informatie

- Assessment of Bulk Liquid Chemicals

10.

BIJLAGE 1: Beslisboom: schematisch overzicht om het risico op uitgroei van aanwezige *L. monocytogenes* tot boven de norm in te schatten, en hoe dit risico te beheersen. (bron: SANCO/1628/2008 ver. 9.3)



Toelichting bij de vragen uit de beslisboom uitgroei *Listeria monocytogenes*

Vraag 1:
De eerste vraag waarop een exploitant van een levensmiddelenbedrijf antwoord dient te geven is of er bewijs is dat het product voor consumptie wordt gekookt of zodanig wordt verwerkt dat *L. monocytogenes* wordt geëlimineerd of tot een aanvaardbaar niveau wordt gereduceerd. In dit geval bestaat er voor het levensmiddel geen specifieke norm, omdat het niet als kant-en-klare etenswaar wordt beschouwd. De voedselveiligheid moet worden gegarandeerd door de GHP en HACCP procedures op het bedrijf, zoals door de controle op de microbiologische status van de grondstoffen, om een beginbesmetting op productieniveau zo laag mogelijk te houden, alsook door controle van het productieproces, enz.
Onder kant-en-klare levensmiddelen worden levensmiddelen verstaan die geen verhitting of andere bewerking hoeven ondergaan om relevante micro-organismen te elimineren of tot een aanvaardbaar niveau terug te brengen of om het product geschikt te maken voor consumptie. Levensmiddelen die alleen hoeven te worden opgewarmd (kant-en-klare pizza, bitterballen, frikandellen) omdat ze in principe klaar zijn voor consumptie, behoren dus tot de categorie kant-en-klare etenswaar.

Vraag 2:
De tweede vraag die levensmiddelenbedrijven moeten beantwoorden, is of het bewezen is dat de aanwezigheid van *L. monocytogenes* in het product onwaarschijnlijk is of vermenigvuldiging ervan beperkt. Onder normale omstandigheden, en volgens voetnoot 4 van Bijlage I van de VMC, vallen de volgende kant-en-klare levensmiddelen in deze groep:
- Producten die een warmtebehandeling of andere be- of verwerking hebben ondergaan waarmee *L. monocytogenes* wordt geëlimineerd, en herbesmetting niet langer mogelijk is (bv. producten die in hun eindverpakking een warmtebehandeling hebben ondergaan).
- Verse, ongesneden en onverwerkte groenten en fruit, met uitzondering van gekiemde zaden.
- Brood, biscuits en soortgelijke producten.
- Water in flessen of pakken, frisdranken, bier, cider, wijn, gedistilleerde dranken en soortgelijke producten.
- Suiker, honing en zoetwaren, met inbegrip van cacao- en chocoladeproducten, levende tweekleppige weekdieren.
- Keuken- en tafelzout.

Deze producten hoeven onder normale omstandigheden niet op aanwezigheid van *L. monocytogenes* te worden gecontroleerd. De voedselveiligheid wordt beheerd door het monitoren van het productieproces op CCP's (bijvoorbeeld de warmtebehandeling). Met het controleren op de aanwezigheid van *L. monocytogenes* aan het eind van de houdbaarheidstermijn kan de doelmatigheid van GHP en het HACCP-programma worden aangetoond.

Vraag 3:
Voor het produceren of verwerken van zuigelingenvoeding of voeding voor medisch gebruik, geldt een speciale norm voor *L. monocytogenes* (afwezig in 25 g, n=10, c=0).

Vraag 4:
Als het levensmiddelenbedrijf wetenschappelijk kan aantonen dat *L. monocytogenes* zich niet vermeerdert in het product, geldt een grens van 100 kve/g voor producten die in de handel zijn gebracht.
Volgens voetnoot 8 van Bijlage I van de VMC kunnen de volgende producten in deze groep vallen:
- Producten met een pH ≤ 4,4 of $a_w \leq 0{,}92$.
- Producten met een pH ≤ 5,0 en $a_w \leq 0{,}94$.
- Producten met een houdbaarheidsdatum van minder dan vijf dagen.

- Bevroren of diepgevroren producten.
- Andere producten mits hier een wetenschappelijke onderbouwing voor is.

Ook de producten uit voetnoot 4 van de Verordening worden niet in staat geacht de vermeerdering van *L. monocytogenes* te ondersteunen (zie vraag 2). In deze groep kunnen andere productcategorieën worden opgenomen, afhankelijk van wetenschappelijk bewijs.
Beheersing van *L. monocytogenes* is gericht op het voorkómen van contaminatie, eventuele afdoding en de productkarakteristieken die de uitgroei belemmeren. De voedselveiligheid wordt volgens de HACCP-procedure bewaakt door het monitoren van vaste CCPs (zoals a_w en pH waarde, verhittingsstap). Controle op de verontreiniging van grondstoffen en ingrediënten en GHP (kruisbesmetting etc.) moet ervoor zorgen dat de grenswaarde van 100 kve/g gedurende de houdbaarheidsperiode gegarandeerd is.

Vragen 5 en 6:
Als op grond van wetenschappelijk bewijs de kans op vermenigvuldiging van *L. monocytogenes* in het product niet kan worden uitgesloten of het product valt niet onder voetnoot 4 of 8 van de Verordening, dan moet het bedrijf onderzoeken of het product gedurende de hele houdbaarheidstermijn voldoet aan de eisen. Dit kan op basis van voorspellingsmodellen (vraag 5), historische gegevens en houdbaarheidstesten (vraag 6).
Aan de hand van houdbaarheidstesten, die met name van toepassing zijn op frequent besmette producten met een prevalentie van meer dan 10%, wordt de groei van *L. monocytogenes* in natuurlijk besmette producten geëvalueerd. Om een uitspraak te kunnen doen, aan de hand van houdbaarheidstesten, of het product gedurende de houdbaarheidstermijn al dan niet voldoet aan de norm, dient het bedrijf ten minste 100 positieve resultaten te evalueren.

Als deze testen zijn uitgevoerd zoals in het Technical Guidance document (Leidraad) wordt beschreven, met in achtneming van het temperatuur- en tijdprofiel zoals weergegeven in Tabel 1 van dit infoblad, en/of als voldoende informatie (bijv. historische data) er op wijst dat het product de grens van 100 kve/g gedurende de houdbaarheidstermijn niet overschrijdt, dan kan het bedrijf aantonen dat het aan de norm voldoet. De voedselveiligheid wordt gegarandeerd door de GHP en HACCP-procedures op het bedrijf waaronder ook de controle op de microbiologische status van de grondstoffen en ingrediënten valt. Met het controleren op de aanwezigheid van *L. monocytogenes* aan het eind van de houdbaarheidstermijn kan de doelmatigheid van het GHP- en HACCP-programma worden aangetoond.

Als iets er op wijst dat de grens van 100 kve/g gedurende de houdbaarheidstermijn waarschijnlijk wordt overschreden kan het bedrijf niet aantonen dat het aan de regels voldoet. Of de houdbaarheidstermijn moet worden herzien en/óf het productieproces moet volgens HACCP-principes worden herzien en verbeterd. Hiertoe behoort o.a. de controle op de microbiologische kwaliteit van de grondstoffen en ingrediënten, het reduceren van de uitgroei mogelijkheden van *L. monocytogenes,* het aanpassen van de intrinsieke factoren van het eindproduct, aanvullende warmtebehandeling etc.

Vraag 7:
Als er onvoldoende informatie voorhanden is om vraag 5 en 6 te beantwoorden, wordt pas gevraagd of men een challenge test heeft uitgevoerd. Als er volgens de aanwijzingen in de Leidraad en dit infoblad een challenge test is uitgevoerd en de kans op vermeerdering van *L. monocytogenes* gedurende de houdbaarheidstermijn niet waarschijnlijk is, kan de grenswaarde van 100 kve/g voor het product worden aangehouden. De voedselveiligheid wordt gegarandeerd door de GHP en HACCP-procedures op het bedrijf. Met het controleren op de aanwezigheid van *L. monocytogenes* aan het eind van de houdbaarheidstermijn kan de doelmatigheid van de controle op de CCPs worden aangetoond.

Als volgens de Leidraad de challenge test uitwijst dat de kans bestaat dat *L. monocytogenes* zich vermeerdert, moet het bedrijf de houdbaarheidstermijn aanpassen

om gedurende de gehele houdbaarheidstermijn aan de grenswaarde van 100 kve/g te kunnen voldoen. Met het controleren op de aanwezigheid van *L. monocytogenes* aan het eind van de houdbaarheidstermijn, conform het criterium, kan de doelmatigheid van de controle op de CCPs worden aangetoond.
Anderzijds kan er voor gekozen worden het productieproces te herzien en verbeteren, zoals hierboven is beschreven.

Als er geen informatie is over het levensmiddel of over de kans op vermeerdering van *L. monocytogenes* in het betreffende levensmiddel, kan het bedrijf niet garanderen dat het aan de normen voldoet dus ook niet dat het voedsel veilig is. Aangezien het in de handel brengen van onveilige producten niet is toegestaan, zal in dergelijke gevallen het productieproces alsook de eisen voor de grondstoffen, ingrediënten etc. aan de hand van HACCP-principes moet worden doorgelicht en indien nodig moeten worden verbeterd. Het levensmiddel moet voldoen aan de afwezigheid van kiemen in 25 g (n=5, c=0) voordat het levensmiddel de directe controle van de exploitant van het levensmiddelenbedrijf die het geproduceerd heeft, heeft verlaten. Met andere woorden: van **elke partij** die wordt geproduceerd zal voor dat het de fabriek verlaat moeten worden bepaald of zij vrij is van *L. monocytogenes* (n=5, c=0). Immers er is geen informatie voorhanden (bijvoorbeeld middels studies) waaruit blijkt dat het levensmiddel gedurende de hele houdbaarheidstermijn voldoet aan de norm < 100 kve/g.

Aandachtspunten
- Als uit studies en/of challenge testen en/of andere (product)informatie blijkt dat geen groei mogelijk is, is aanwezigheid van *L. monocytogenes* in het product na het verlaten van de fabriek tot einde THT wettelijk geen probleem mits aan de eis van <100 kve/g wordt voldaan.
- Het is praktisch onmogelijk om absolute afwezigheid van *L. monocytogenes* te garanderen in producten waarin *L. monocytogenes* kan groeien en/of waar herbesmetting mogelijk is. Echter, er moet alles aan worden gedaan om te voorkomen dat de norm van 100 kve/g wordt overschreden.
- Volgens de VMC moeten producten die (mogelijk) voedingsbodem zijn voor *L. monocytogenes* vrij zijn van *L. monocytogenes* vóórdat de producten de directe controle van de producent verlaten. Hierbij geldt afwezigheid in 25 g (n=5, c=0) voor elke geproduceerde partij en tevens geldt nog steeds dat moet worden voldaan aan de eis van <100 kve/g gedurende de houdbaarheidstermijn. Nota bene, deze eisen gelden ook voor producten waarvoor geen verdere informatie beschikbaar is over uitgroeimogelijkheden van *L. monocytogenes*.
  Echter, als de producent heeft aangetoond, tot tevredenheid van de bevoegde autoriteit, dat het aantal *L. monocytogenes* gedurende de houdbaarheidstermijn onder de 100 kve/g zal blijven, mogen er intermediaire grenswaarden worden vastgesteld die zo laag moeten zijn dat de grenswaarde van 100 kve/g gedurende de houdbaarheidstermijn niet wordt overschreden.
  Voorbeeld: als kan worden aangetoond dat tijdens de houdbaarheidstermijn een toename van maximaal 1 log kve/g mogelijk is, vormt een incidentele contaminatie van <10 kve/g geen probleem.

(1)

Home About How we work

How we work

Most of EFSA's work is undertaken in response to requests for scientific advice from the European Commission, the European Parliament and EU Member States.

We also carry out scientific work on our own initiative, in particular to examine emerging issues and new hazards and to update our assessment methods and approaches. This is known as "self-tasking".

- EFSA organises its work programme – annual and multi-annual – according to priorities agreed with the European Commission and other partners, taking into account available resources.
- We consult closely to ensure that our programme complements those of our partners – particularly **national authorities and food safety agencies** in EU Member States – and to avoid overlap and duplication of work and effort.
- EFSA's scientific advice is mostly provided by its Scientific Panels and Scientific Committee, members of which are appointed through an open selection procedure.
- EFSA staff may also produce scientific outputs on behalf of the agency, such as peer reviews of the assessment of active substances in pesticides, or responses to urgent requests for advice. EFSA staff also monitor and analyse information and data on biological hazards, chemical contaminants, food consumption and emerging risks.

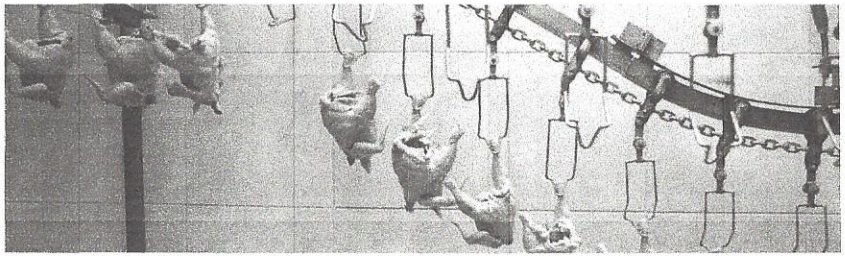
EFSA adheres to a number of principles and practices aimed at ensuring the excellence of our work. These include:

- A commitment to openness and transparency in all our work.

- The development of a comprehensive body of good risk assessment practices to guide our Scientific Committee and Panel experts.
- A quality assurance system that continually monitors and strengthens the quality of EFSA's scientific work. This includes self-review and customer feedback systems which ensure that scientific processes are developed consistently and continuously improved across EFSA's Panels and by staff.
- Reviews and inspections carried out by an internal auditor reporting to the EFSA's Management Board's Audit Committee, which advises senior management on possible improvements to work practices.
- External evaluation: EFSA's Founding Regulation obliges the Authority to commission independent external evaluations of its work and working practices. Based on these evaluations, the Management Board makes recommendations on EFSA's future management plans and strategies.

In addition the Authority is legally bound by European Union legislation on issues such as public access to documents.

12.



Hygiënecode voor transport, opslag en distributie van levensmiddelen

Hygiënecode voor transport, opslag en distributie van levensmiddelen

De nieuwe HACCP Code voor transport, opslag en distributie is sinds 1 januari 2008 van kracht. Deze Code is voor alle bedrijven die met levensmiddelen werken en te maken hebben met vervoer en opslag.

KUNNEN WIJ U HELPEN?

Sven Arnoldus
Ledenadviseur

GERELATEERDE LINKS

(13)

13.1

UNITED NATIONS
ECONOMIC COMMISSION FOR EUROPE

Transport of perishable foodstuffs (ATP)

Objectives-key provisions-benefits

Christopher Smith
UNECE Transport Division

9 September 2014

UNITED NATIONS
ECONOMIC COMMISSION FOR EUROPE

ATP

The Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for such Carriage, adopted in 1970

Preamble: objectives

improve conditions of preservation of quality of perishable foodstuffs during carriage, particularly in international trade and promote the expansion of trade in perishable foodstuffs.

Unwritten objectives: Protecting food safety and preventing threats to human health from unsafe food.

ATP Contracting Parties

ATP 48 Contracting Parties.

Albania, Andorra, Austria, Azerbaijan, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Ireland, Italy, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Luxembourg, Moldova, Monaco, Montenegro, Morocco, Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, Serbia, Slovakia, Slovenia, Spain, Sweden, Tajikistan, The former Yugoslav Republic of Macedonia, Tunisia, Turkey, Ukraine, United Kingdom, United States of America, Uzbekistan.

Most recent Turkey.

Outside UNECE region, Morocco and Tunisia

ATP Contracting Parties