

ANNEX 3: THE HAZARD FACTSHEETS – EXAMPLES

Changes highlighted¹ - Last update – July 2016

3.1. LIST OF THE HAZARDS

The different hazards dealt with in this code, which can be controlled by hygiene practice indicators and/or the HACCP study are the following: (non-exhaustive list²)

HAZARD	HAZARDOUSNESS	ORIGIN OF THE HAZARD	MECHANISMS AT THE ORIGIN OF THE HAZARD	METHODS OF PREVENTING THE HAZARD	HACCP STUDY
Allergens	Toxicity	Fa: Raw materials OP: Equipment used Staff	Cross contaminations	Staff awareness raising Maintenance of the equipment	
<i>Bacillus cereus</i>	Toxicity	Fa: Raw materials Soil Env: Dust	Temperature increase – Condensation phenomenon	Ventilation – Cleaning of grains – Cleaning of the site	
Foreign bodies	Hygiene practice indicators	Fa: Raw materials OP: Equipment used Staff	Lack of awareness Maintenance defect	Staff awareness raising Maintenance of the equipment Cleaning of the grain	
Dioxins	Toxicity	Fa: Grain dryer without heat exchanger or using bad quality fuels	Proximity of a polluting site	Risk analysis and Monitoring plan if necessary	
Ergot	Toxicity	Fa: Raw materials supplied contaminated	Presence of sclerotia in the field (soil) + rainy, humid and cool weather	Recommendations of farming methods to farmers, Cleaning of the grain	Yes
Polycyclic Aromatic Hydrocarbons (PAHs)	Toxicity	Fa: Raw materials supplied contaminated	Fuel oil dryer without heat exchanger	Farmer and staff awareness raising	
Insects and dust mites	Alteration of the stored foodstuffs	Fa: Contaminated raw materials OP: Contaminated equipments	Increase in storage temperature Condensation phenomenon	Staff awareness raising Cleanliness of the equipment Cooling ventilation	Yes
Heavy metals	Toxicity	a: Raw materials nv: Atmospheric pollution, Soil pollution	Accumulation Proximity of a polluting site	Monitoring plan Farmer awareness raising	

¹ The clarifications highlighted in yellow in GTP Annex 3 are applicable as from 1st July 2016

² For specific products not indicated in this Annex, operators are advised to consult the relevant guides (http://ec.europa.eu/food/food/index_en.htm) for the specific risk analyses

Moulds including bunt	Alteration of the stored foodstuffs	Fa: Raw materials supplied contaminated OP: Poor storage methods and conditions	Condensation Increase in storage temperature Pre-storage too long	Ventilation – Cleaning of the grains Appropriate pre-storage duration Recommendations of farming methods to farmers	Yes
Mycotoxins	Toxicity	Fa: Raw materials supplied contaminated OP: Poor storage methods and conditions	Increase in storage temperature Condensation phenomenon Pre-storage too long	Ventilation – Cleaning of the grains Temperature monitoring Appropriate pre-storage duration	Yes
Radioactivity	Toxicity	Env: Atmospheric pollution, Soil pollution	Proximity of a polluting site	Risk analysis and Monitoring plan if necessary	
Pesticide residues	Toxicity	OP: Pesticide treatment equipment leak, incorrect settings, unsuitable treatment, overdosage etc.	Maintenance defect Lack of awareness Barn storage awareness	Maintenance of the equipment Staff awareness raising	Yes
Rodents and fowl and/or their macroscopic traces	Hygiene practice indicators	OP: Poor maintenance of premises and their surroundings	No protection of premises or measures to combat the problem	Measures for protecting the premises (nets, doors etc.) and preventive measures	
Salmonellas	Toxicity and hygiene practice indicators	OP: Pests Birds, Rodents, contaminated raw materials and hygienic conditions during processing	Presence of vectors	Staff awareness raising Protection of premises and their surroundings	
Botanical impurities	Hygiene practice indicators	Fa: Raw materials OP: Equipment used	Lack of awareness	Farmer and staff awareness raising Cleaning of the grain	

NB:

- ❖ the word staff is understood to mean the staff of the operator or any other contributor
- ❖ Origin of the hazard: Fa = farmer – OP = Operator – Env. = environment

Each operator must conduct a study of the hazards linked to its outlets and its environment to ensure the food and feed safety of the products sold. Some of the hazards in this list may not be taken into account while others might be added.

With regard to pesticide residues other than storage pesticide residues, heavy metals, foreign bodies, dioxins, pathogenic flora, rodents and fowl, allergens and radioactivity, their relative risk is not specific to a given stage in the process; they are dealt with using general hygiene rules.

3.2. HAZARD FACT SHEETS

These sheets present the different hazards referred to in this code, either because they are pathogenic and/or toxigenic, because they alter the foods stored, or because they are indicators of hygienic practices.

For the purpose of clarity and to provide an overview, each hazard sheet contains the following information: nature, origin, characteristics, development conditions and applicable regulations when they exist.

There are three types of hazard:

Physical hazard

- ❖ Foreign bodies

Chemical hazards

- ❖ Heavy metals
- ❖ Residues from storage pesticides
- ❖ Dioxins & Furans, Dioxins like PCBs, Non-dioxin-like PCB
- ❖ Melamine
- ❖ Nitrites
- ❖ Radionucleides
- ❖ PAHs
- ❖ Storage insecticide residues and specific feed PPP MRLs

Biological hazards

- ❖ Insects and dust mites
- ❖ Rodents and fowl and/or their macroscopic traces
- ❖ Mould
- ❖ Mycotoxins
- ❖ Salmonellas
- ❖ Bacillus cereus
- ❖ Allergens

DISCLAIMER: COCERAL has further detailed the list of hazards together with their maximum limits or levels in order to inform interested parties with respect to the requirements in the EU legislation. The list will be regularly updated in the light of future regulatory developments. However, COCERAL is not liable for any errors or outdated information referred to in this list.

3.3. FOREIGN BODIES

Nature of the hazard

- ❖ Physical hazard

Classification

Level of impurities is one of the qualitative criteria in commercial contracts.

The below types of impurities are distinguished:

- ❖ Broken grains
- ❖ Impurities constituted by the grains
- ❖ Sprouted grains
- ❖ Miscellaneous impurities

The “foreign bodies” category belongs to this final type of impurity.

The main foreign bodies:

- ❖ Glass
- ❖ Plastic
- ❖ Particles of metal
- ❖ Pebbles, stones
- ❖ Plant debris
- ❖ Wood
- ❖ Soil
- ❖ Sand

Origin

- ❖ Raw materials supplied
- ❖ Maintenance of the equipment
- ❖ Loss of objects by staff

Food and feed safety risks

The presence of foreign bodies can cause risks to:

- ❖ The consumer’s safety (cut by glass)
- ❖ Their food and feed safety (transmission of bacteria)

3.4. HEAVY METALS

Nature of the hazard

- ❖ Chemical hazard

Classification

The term “heavy metals” is used in everyday language, but it actually refers to mineral trace elements (MTE). They are normally present in the environment as traces (< 100mg/kg).

MTEs are mainly metallic (although some such as arsenic and selenium are not). The majority is trace elements, that is, in small concentrations they are necessary to sustain life. However, lead and cadmium are not essential to sustaining life. They are toxic metallic contaminants.

Origin

They can be found in the form of trace elements in grains and their by-products following atmospheric pollution (lead) or soil pollution (cadmium).

Food and feed safety risks

Lead (Pb), Cadmium(Cd) and Mercury(Hg) are not essential to sustaining life (animals and vegetal) while Arsenic (As) is non-essential for plants but Essential for Animals. They are toxic metallic contaminants. Pb, Cd and Hg are particularly toxic and “bio-accumulate” in the food and feed chain As (a metalloid), is essential for animals but is quickly toxic at low doses and needs a specific monitoring. For few heavy metals, only some forms are toxic: For Mercury the organic form is more toxic than the inorganic whilst for Arsenic, the inorganic forms are more toxic.

Regulations

Concerning **foodstuffs**, Regulation (EC) No 1831/2003 as amended of 19 December 2006, as amended, sets the following maximum levels expressed in relation to fresh weight:

- ❖ Lead: - 0.20 mg/kg of cereals including buckwheat and legumes and pulses
- 0.10 mg/kg (ppm) in vegetables
- ❖ Cadmium: - 0.10 mg/kg: cereals excluding wheat and rice
- 0.20 mg/kg: wheat grains, rice grains, wheat bran, wheat germ
- 0.20 mg/kg: soybeans (and derived products such as SBM or SBO)
- ❖ Arsenic: 0.1 ppm for vegetables and fats (based on Codex Alimentarius norm)

Concerning **raw materials for animal feed of plant origin**, Council Directive 2002/32/EC, as amended, sets the following maximum levels:

- ❖ Lead (Pb): 10 mg/kg (ppm) for feed materials
- ❖ Cadmium (Cd): 1 mg/kg (ppm) for feed materials of vegetable origin
- ❖ Mercury (Hg): 0.1 mg/kg (ppm) for feed materials of vegetable origin
- ❖ Arsenic (As): 2 ppm in feed materials and 4 ppm in PKE (Palm Kernel Expeller) (but max 2 ppm inorganic arsenic)
- ❖ Fluorine: 150 mg/kg in feed materials of vegetable origin

3.5. STORAGE PESTICIDE RESIDUES

Nature of the hazard

- ❖ Chemical hazard

Classification

A pesticide is any substance used to combat the presence or appearance of insects and mites in stored grains.

Origin

- ❖ Raw materials supplied
- ❖ Pesticide treatment
- ❖ Pesticide treatment equipment
- ❖ Cross contamination with residues of treated previous cargoes or residues of pesticides on walls/floors/handling equipments

Food and feed safety risks

Toxicity above the regulatory concentration threshold.

When products are to be used for **FEED and FOOD**, it is important to:

- First check in the FEED Directive 2002/32/CE “undesirable substances” if the concerned Active substances are listed in the Appendix and if a specific maximum content has been fixed for them.
- If not, then check in the EU pesticide Regulation ((EC) No 396/2005 as amended) database if a specific MRL has been fixed for this simple product or group of products- If not , the default max 0.01ppm* (* = Lower Limit of Analytical Determination) will apply for simple not processed products http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database-redirect/index_en.htm
- Check whether footnote (1) of Annex I to Regulation (EC) No 396/2005 applies. The footnote (1) provides for all the products listed in Annex I that the MRLs therein contained do not apply to products or parts of the product used exclusively as ingredients for animal feed, until separate MRLs will be applicable.
- For processed products, the Regulation (EC) No 396/2005 as amended foresees the possible use of “processing factors” for the evaluation of pesticides residues. Such processing factors could be yet included in Appendix VI of Regulation (EC) No 396/2005 (concentration or dilution factors) and related to the pesticide solubility in fat (F factor) or in water (LogPow or “Octanol/water partition coefficient” which can be found in the ICSCs and also take into account the concentration or dilution factor of the product.

Article 18(3) of Regulation (EC) No 396/2005 as amended allows Member States to authorise the use of product which may contains residues of post-harvest fumigants treatments with a level above the MRLs provided:

- a) That the product is not intended for immediate consumption (this should cover the fact that some cargoes received could have a content of Phosphine above 0.1 ppm, provided that it does not present danger for the workers);
- b) Appropriate controls are in place to ensure that such products cannot be made available to the end user or consumer, if they are supplied directly to the latter, until the residues no longer exceed the maximum levels specified in Annexes II or III of Regulation (EC) No 396/2005 as amended; and
- c) The other Member States and the Commission have been informed of the measures taken.

Article 18(4) of Regulation (EC) No 396/2005 as amended also states that “In exceptional circumstances, and in particular further to the use of plant protection products in accordance with Article 8(4) of Directive 91/414/EEC or pursuant to obligations set out in Directive 2000/29/EC (1), a Member State may authorize the placing on the market and/or the feeding to animals within its territory of treated food or feed not complying with paragraph 1, provided that such food or feed does not constitute an unacceptable risk. Such authorizations shall immediately be notified to the other Member States, the Commission and the Authority, together with an appropriate risk assessment for consideration without undue delay with a view to setting a temporary MRL for a specified period or taking any other necessary measure in relation to such products.”

Datura seeds must be taken into account under the food and feed safety risks because of the tropane alkaloids. Self-checking is also necessary for cereals that are not specifically intended for infants and toddlers.

The list of substances (fumigants) concerned by this Article 18(3) has been published in EU Regulation (EC) No 260/2008 as amended adding an Annex VII to EC Regulation (EC) No 396/2005 as amended, including Hydrogen phosphide, Aluminium phosphide, Magnesium phosphide (the 3 covers as well uses in cereals than in oilseeds and oilfruits) and sulfurlyfluoride (for cereals only).

Regulations and main MRLs

Characteristics of the active materials approved for the treatment of stored cereals.

Only aluminium and magnesium phosphide are approved for pesticide treatment of stored oilseeds.

- Regulation (EC) No 396/2005 as amended
- For verification of EU Pesticides MRL database, consult DG SANTE web database: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database-redirect/index_en.htm
- Sampling methods for official controls of pesticides residues to be done according to EU Directive 2002/63/EC.
- Performance of analytical methods and the interpretation of results to be done according to Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC
- Method validation and Quality control procedures for pesticides residues analysis in Food and Feed based on Document SANCO/10684/2009 396/2005

Any numerical reference to the MRLs should be understood as subject to changes in the Regulation (EC) No 396/2005 as amended. For more information (e.g. residues of pesticides applied during cultivation), please check EU DG SANTE PPP database: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database-redirect/index_en.htm

3.6. DIOXINS & DIOXIN LIKE PCBs & NON-DIOXIN LIKE PCBs

Nature of the hazard

- ❖ Chemical hazard

Classification

Dioxins are Persistent Organic Pollutants (POP) that are found worldwide in any environment (ubiquitous molecules). They are molecules which can only be destroyed at a very high temperature (they are chemically and thermally stable). Moreover, they are very lipophilic (soluble in fats) and not very biodegradable. They therefore accumulate along the food chains (bioaccumulation).

Dioxins belong to a group of 75 polychlorinated dibenzo-p-dioxin (PCDD) congeners and 135 polychlorinated dibenzofuran (PCDF) congeners, of which 17 are of toxicological concern. Polychlorinated biphenyls (PCBs) are a group of 209 different congeners which can be divided into two groups according to their toxicological properties: 12 congeners exhibit toxicological properties similar to dioxins and are therefore often referred to as 'dioxin-like PCBs' (DL-PCB). The other PCBs do not exhibit dioxin-like toxicity but have a different toxicological profile and are referred to as 'non-dioxin-like PCB' (NDL-PCB).

Each congener of dioxins or DL-PCBs exhibits a different level of toxicity. In order to be able to sum up the toxicity of these different congeners, the concept of toxic equivalency factors (TEFs) was introduced to facilitate risk assessment and regulatory control. As a result the analytical results relating to all the individual dioxin and dioxin-like PCB congeners of toxicological concern are expressed in terms of a quantifiable unit, namely the TCDD toxic equivalent (TEQ).

The sum of the six marker or indicator PCBs (PCB 28, 52, 101, 138, 153 and 180) comprises about half of the amount of total NDL-PCB present in feed and food. That sum is considered as an appropriate marker for occurrence and human exposure to NDL-PCB. For maximum limits, directive 2002/32/EEC should be consulted.

Origin

Dioxins are released from industrial atmospheric waste and certain combustion processes. They are found in soils and in water.

PCBs were widely used for many applications, especially as dielectric fluids in transformers, capacitors and coolants. Processing and distribution of PCBs have been prohibited in almost all industrial countries since the late 1980s but they still can be released into the environment from electrical appliances, building paint and sealants and waste sites that contain PCBs.

Food and feed safety risks

The term "dioxins" encompasses 210 congeners. Among them, 17 congeners are toxic, although they do not all possess the same toxicity. To translate this difference, a toxic equivalence factor (I – TEF) has been defined (each toxin is weighted by a factor compared to the factor of 1 allocated to the most toxic dioxin).

The toxicity of a sample is quantified by the quantitative measurement of the 17 toxic congeners to which the toxic equivalence factors are applied. This shows a sample's Toxic Equivalent Level or I – TEQ.

Monitoring and controls

When products originate from areas where risks of inadequate management of dryers are known, a regular monitoring of PCBs and dioxin-like PCBs should be implemented as well as those mentioned in Regulation (EU) No 2015/1905 as amended. Depending on levels found (near action limit or near max levels, actions should be taken to:

- ❖ Find source of contamination and correct it, and
- ❖ Eliminates/Recalls/Withdraws products for which levels are above MRLs (with adequate information to authorities and customers)

Regulations and EU Norms

a) For FOOD

For food products, [Regulation \(EC\) No 1881/2006](#) as amended by subsequent legal acts sets the following maximum level relative to a food:

contaminant	FOOD product concerned	EU max limits	basic EC legislation	application date
Sum of Dioxins	5.12.Vegetable Oils and fats	MRL: 0,75 pg/g fat- (Who-PCDD/F-TEQ)	Reg 1881/2006 dd 19Dec2006	01-Jan-12
sum of Dioxins & Dioxin like PCBs	5.12.Vegetable Oils and fats	MRL 1,25 pg/g fat (WHO-PCDD/F-TEQ)	Reg 1881/2006 dd 19Dec2006	in force
Non-dioxin-likePCBs (Sum of PCB 28, PCB52, PCB 101, PCB 138, PCB153 and PCB 180 (ICES – 6)	5.12.Vegetable Oils and fats	MRL : 40 ng/g fat	Reg 1881/2006 dd 19Dec2006	01-Jan-12
contaminant	FOOD product concerned	EU max limits	basic EC legislation	application date
Dioxins + Furans	cereals & Oilseeds	MS control authorities ACTION LEVEL (WHO-TEQ-2005) ⁽¹⁾ 0,50 pg/g wet weight product	Recommendation 2013/711/EU dd 03 Dec 2013 for Food & feed as amended by Recommendation 2014/663/EU dd 11 sept 2014	as from 3 Dec 2013
Dioxin-like PCBs	cereals & Oilseeds	MS control authorities ACTION LEVEL (WHO-TEQ-2005) ⁽¹⁾ 0,35 pg/g wet weight product	Recommendation 2013/711/EU dd 03 Dec 2013 for Food & feed as amended by Recommendation 2014/663/EU dd 11 sept 2014	as from 3 Dec 2013
<p>⁽¹⁾: <i>Upperbound concentrations: Upperbound concentrations are calculated assuming that all the values of the different congeners less than the limit of quantification are equal to the limit of quantification. EU recommendation 2013/711/EU dd 3 Dec 2013 , as amended by Recomm 2014/663/EU dd 11 sept 2014 (replaces Recom 2011/516/EU) requests EU MS to random monitor presence of Dioxins & Furans (sum PCDDs and PDCFS) and , DL PCBs in Food and Feed products by setting some Action Levels. EU Reg No 589/2014 of 2 June 2014 as amended lays down methods of sampling and analysis for the control of levels of dioxins (sum of PCDDs and PCDFS), dioxin-like PCBs and non-DL PCBs in certain foodstuffs and repeals Reg (EU) No 252/2012 as amended "</i></p>				

b) For FEED

For feed products, [Council Directive 2002/32/EC](#) as amended by subsequent legal acts sets the following maximum level relative to a feed with a moisture content of 12%:

contaminant	FEED product concerned	Maximum content or Threshold	Basic Regulation
DIOXINs (sum of PCDD & PCDF)	a) Feed materials of plant origin except veg oils and their by products	Maximum content: 0,75 ng/kg (ppt) Action threshold at 0,5 ng/kg of OMS-PCDD/F-TEQ/kg (ppt) relative to a feed with amoisture content of 12 %	Dir 2002/32/EC as amended by Reg 277/2012- testing base Reg 278/2012 (base 152/2009)
Sum of dioxins and dioxin-like PCBs (sum (PCDDs),PCDFs and (PCBs)	a) Feed materials of plant origin except veg oils and their by products	Maximum content 1,25 ng/kg (ppt) -of OMS-PCDD/F-PCB-TEQ/kg relative to a feed with amoisture content of 12 %	Dir 2002/32/EC as amended by Reg 277/2012- testing base Reg 278/2012 (base 152/2009)
Dioxin-like PCBs	a) Feed materials of plant origin except veg oils and their by products	Action Threshold 0,35 ng/kg (ppt) of OMS-PCDD/F-TEQ/kg relative to a feed with amoisture content of 12 %	Dir 2002/32/EC as amended by Reg 277/2012- testing base Reg 278/2012 (base 152/2009)
Non-dioxin-likePCBs (Sum of PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180 (ICES – 6)	a) Feed materials of plant origin	Maximum content: 10 µg/kg (ppb) relative to a feed with amoisture content of 12 %	Dir 2002/32/EC as amended by Reg 277/2012- testing base Reg 278/2012 (base 152/2009)

contaminant	FEED product concerned	MRIs or Threshold	Basic Regulation
DIOXINs (sum of PCDD & PCDF)	b) vegetable oils and their by products	Maximum content: 0,75 ng/kg Action threshold at 0,5 ng/kg of OMS-PCDD/F-TEQ/kg (ppt) relative to a feed with amoisture content of 12 %	Dir 2002/32/EC as amended by Reg 277/2012- testing base Reg 278/2012 (base 152/2009)
Sum of dioxins and dioxin-like PCBs (sum (PCDDs),PCDFs and (PCBs)	b) vegetable oils and their by products	Maximum content 1,5 ng/kg - of OMS-PCDD/F-PCB-TEQ/kg (ppt) relative to a feed with amoisture content of 12 %	Dir 2002/32/EC as amended by Reg 277/2012- testing base Reg 278/2012 (base 152/2009)
Dioxin-like PCBs	b) vegetable oils and their by products	Action Threshold 0,5 ng/kg - i- (ppt) of OMS-PCDD/F-TEQ/kg (ppt) upperbond concentration relative to a feed with 12% moisture	Dir 2002/32/EC as amended by Reg 277/2012- testing base Reg 278/2012 (base 152/2009)

Determination of the levels of dioxins and PCB in FEED products as per EU Reg 278/2012 dd 28 march 2012 amending Reg 152/2009

EU Reg Nr 709/2014 dd 20 June 2014 amends part B of Annex V of Reg 152/2009 for "methods of Determination of the levels of Dioxins (PCDD/PCDF) and Dioxin-Like PCBs"
EU recommendation 2013/711/EU dd 3 Dec 2013 , as amended by Recomm 2014/663/EU dd 11 sept 2014 (replaces Recom 2011/516/EU) requests EU MS to random monitor presence of Dioxins & Furans (sum PCDDs and PDCFS) and , DL PCBs in Food and Feed products by setting some Action Levels.

Sampling and analysis

For sampling and analysis of these products, please refer to:

- Regulation (EU) No 252/2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs (*repeals* Regulation (EC) No 1883/2006).
- Regulation (EU) No 152/2009 laying down the methods of sampling and analysis for the official control of **FEED** (annex I p. 4 for sampling, annex II p. 9 general provisions on methods of analysis and Annex V (B) p. 97 for determination of dioxins (PCDD/PCDF) and DL PCBs) as amended by Regulation (EU) No 278/2012 as regards the determination of the levels of dioxins and polychlorinated biphenyls.
- Regulation (EC) No 333/2007 as amended recently by Regulation (EC) No 836/2011 lays down methods of sampling & analysis for lead, cadmium, mercury, inorganic tin, 3-MCPD and Benzo(a)pyrene in **FOOD**.

3.7. MELAMINE

Nature of the hazard

Melamine is a substance that can react together with cyanuric acid to produce melamine cyanurate. This is a crystalline complex which is highly insoluble in water and which causes kidney problems which may result in death.

Classification

- ❖ Chemical hazard

Origin

Melamine is produced in high volumes mainly for the synthesis of melamine-formaldehyde resins used in the manufacture of laminates, plastics and coatings, including food contact materials such as kitchenware. In addition, melamine and a number of related compounds are used as flame retardants. The WHO1 (2009) reports the use of melamine containing sanitizing agent, like trichloromelamine and the use of sodium dichloroisocyanurate as disinfection agent of drinking-water. The latter can contain residual cyanuric acid, which can form an insoluble complex with melamine.

Control Measures

Products of Chinese origin need to be particularly monitored as well as those having a high protein content (such as oilseed meals, protein concentrate of SKM).

The following products trigger a higher risk to contain hazardous levels or exceeding maximum limits of melamine:

- ❖ Of vegetal origin, where during cultivation, cyromazine containing pesticides are / were used or where during cultivation melamine containing fertilizers are / were used
- ❖ Where during sanitizing, products got into contact with melamine or melamine analogues containing sanitizing agents (e.g. trichloromelamine);
- ❖ Where during processing, water is used which is disinfected with sodium dichloroisocyanurate (being degraded to, amongst others, melamine);
- ❖ Products susceptible / of risk for adulteration by adding of melamine, are high protein products, like wheat gluten, rice protein, soy bean products, dairy products, fish meal, high protein concentrates.

Food and feed safety risks

Illegal adulteration of food and feed with melamine has resulted in illness and deaths of human infants and pet animals (cats and dogs), primarily as a result of kidney damage caused by crystals or stones in the urinary tract. The pets were given feed adulterated with crude ("scrap") melamine also containing its analogues, and the crystals consisted of complexes of melamine with cyanuric acid. In the human infants, who were given infant formula adulterated with a relatively pure preparation of melamine, the crystals consisted of complexes of melamine with uric acid which occurs naturally in urine. Crystals have also been reported in livestock given feed contaminated with melamine and in experimental animals dosed with melamine either alone or together with cyanuric acid (EFSA3, 2010). The adulteration occurs, because commonly used methods for protein analysis cannot distinguish between nitrogen from protein sources and nitrogen from non-protein sources. It results in incorrectly high protein measurements for products containing non-protein nitrogen sources like melamine and provides an economic incentive for their (illegal) addition (WHO1, 2009).

Up to mid-2010 still batches of melamine contaminated milk products were found in China, originating from the incident in 2008. These batches should have been destroyed, but were not offered for destruction and again illegally mixed into food products

A specific risk in humans is the lack of uric acid oxidase (WHO1, 2009). Co-precipitation of melamine with uric acid is likely to occur in humans because they excrete more uric acid in the urine than most mammals due to a lack of the enzyme urate oxidase.

Regulations and norms

Melamine content in **FEED** is EU Regulated by Directive 2002/32/CE as amended by EU Regulation 574/2011, with following MRLs:

- ❖ Max 2.5 ppm (mg/kg) for all feed materials with 12% moisture for feed materials (except GAA guanidine acetic acid, urea and biuret)

Melamine content in **FOOD** is EU Regulated by Regulation (EC) No 1881/2006 as amended by Regulation (EU) No 594/2012, with the following MRLs:

- ❖ Max 2.5 ppm (mg/kg) for food, with the exception of infant formulae and follow-on formula³

³ The maximum level does not apply to food for which it can be proven that the level of melamine higher than 2,5 mg/kg is the consequence of authorized use of cyromazine as insecticide. The melamine level shall not exceed the level of cyromazine.

3.8. INSECTS AND DUST MITES

Nature of the hazard

- ❖ Biological hazard

Classification

Insects and mites belong to the branch of arthropods which are characterized by the presence of quite a rigid cuticle covering the body. Insects bring about an alteration in grains and other processed products derived thereof and are sources of soiling and contamination. Mites mainly feed on grain debris or mould (secondary pests). It is not always possible to detect a batch contaminated by insects. Certain insects such as weevils develop inside the grains.

The main insects and mites found in stored grains:

- ❖ Insects: Grain weevil, rice weevil, tribolium castaneum, tribolium confusum, oryzaephilus surinamensis, cryptolestes, lesser grain borer, khapra beetle, wheat beetle, dried fruit moth, angoumois grain moth.
- ❖ Mites: Flour mite, rapeseed mite, hairy mite, Cheylet.

Origin

- ❖ Equipment (storage and handling facility)
- ❖ Raw materials supplied

Development factors in stored cereals

- ❖ Temperature
- ❖ The grains' water level

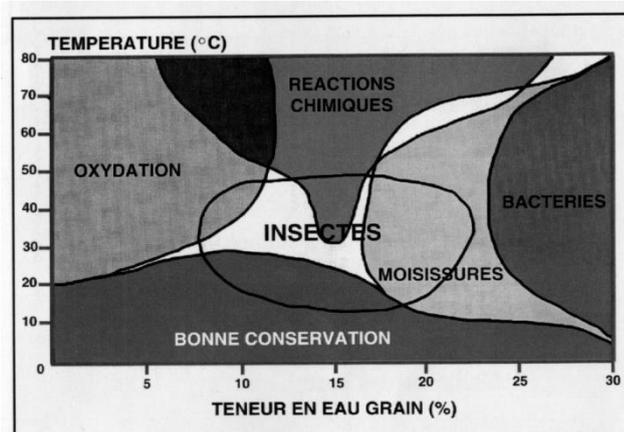
Survival of insects

- ❖ At a threshold of less than 12°C, the insects cease to develop
- ❖ Subjected to a temperature lower than 5°C for several weeks, the insects die
- ❖ Exposed to a temperature of 60°C for 3 minutes, the insects are destroyed.

Survival of mites

- ❖ For low temperatures, there are very large sensitivity differences between the various mite species
- ❖ For high temperatures, exposure to a temperature of 45°C for 5 hours kills all species.

The graph below shows the risks a mass of cereals is subject to according to its temperature and water level:



FRENCH	ENGLISH
REACTIONS CHIMIQUES	CHEMICAL REACTIONS
OXYDATION	OXIDATION
INSECTES	INSECTS
BACTERIES	BACTERIA
MOISSISURES	MOULDS
BONNE CONSERVATION	GOOD STORAGE
TENEUR EN EAU GRAIN (%)	GRAIN WATER LEVEL (%)

Francis Fleurat-Lessard and Bernard Cahagnier INRA – Villenave d'Ornon and Nantes

Food and feed safety risks

Germ carriers

3.9. RODENTS, FOWL AND/OR THEIR MACROSCOPIC TRACES

Nature of the hazard

- ❖ Biological hazard

Classification

By consuming grains, rodents and fowl cause damage, soiling, contamination and alteration of the grains.

- ❖ The rodents likely to attack stored grains are rats, mice and field mice
- ❖ As regards fowl, it mainly concerns pigeons, sparrows or seagulls in port areas.

Origin

Poor maintenance or protection of:

- ❖ Premises
- ❖ External surroundings.

Food and feed safety risks

Germ carriers

Birds carry more than 60 diseases, including histoplasmosis which is an acute respiratory disease, as well as ectoparasites and salmonellas.

Dropping from birds are corrosive and can damage building roofs, walls and any outdoor machinery. Nest debris can also congest drains and gutters.

Technical interventions

The three common interventions techniques against birds are:

- Repellents: to help male socializing or breeding birds feel uncomfortable.
- Exclusion: helps preventing birds from breeding and keep them away. Doors should be kept closed when not in uses and all openings in exterior walls should be sealed with nets or other materials.
- Relocation: to remove birds and nest.

3.10. MOULDS

Nature of the hazard

- ❖ Biological hazard

Classification

Moulds represent a group very heterogeneous of about 11 000 species of which almost 100 are able, potentially, to produce mycotoxins. These toxicological species can be grouped in the classes of Deuteromycota and Ascomycota. Moulds are also well known allergens. Moulds growth may indicate the likely development of mycotoxins. Some moulds are also allergenic to animals or humans.

- Moulds grow a number of spores (dissemination mechanisms) which have a high longevity. These spores are disseminated by air or water and colonize new substrata.
- When the mould's growth is sufficiently advanced, it forms a mycelium (generic term used to refer to all of the filaments forming the vegetative part of fungi) that is visible to the naked eye.
- Non-photosynthetic, mould can only grow on organic media, causing damage, changing their appearance or causing organoleptic alterations.
- Types forming field fungi, the most common types are *Alternaria*, *Fusarium*, *Helminthosporium*, *Epicoccum*, *Septoria* and *Verticillium*; this flora which requires humidity to develop normally regresses in stored grains.
- Types forming intermediate fungi
Mucorales like *Rhizopus*, *Absidia* and *Mucor* and certain yeasts: these types largely predominate in specific conditions and mainly in grains that are not dry enough.
- Types forming storage fungi, mainly *Aspergillus* and *Penicillium*.

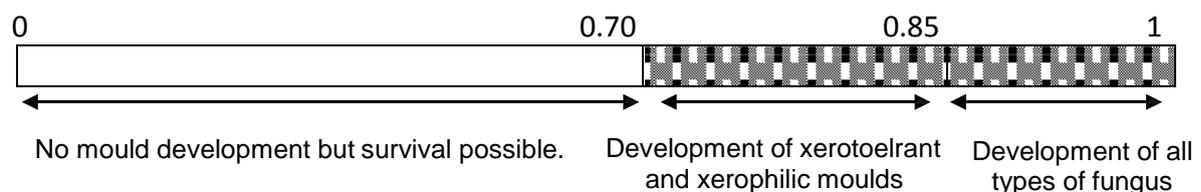
Origin

- Raw materials supplied
- Storage methods and conditions
- Equipment (storage and handling facility)

Development factors

Physical conditions influencing the growth of mould in stored cereals:

- The relative humidity which can be compared to the grain's humidity. An increase in the grains' water level activates the growth of mould.
- The activity of water (A_w) which is equal to the relative humidity divided by 100.



➤ Temperature

The majority of moulds have growth optimums between 25 and 35°C and react to a rise in temperature by accelerating their growth.

➤ pH

Mould grows between pH 2 and pH 11.

Chemical conditions influencing the growth of mould in stored cereals:

➤ The composition of the atmosphere

The lower the oxygen composition of the atmosphere, the lower the growth rate of moulds, which are aerobic organisms. However, the oxygen level is unlikely to fall low enough to slow down the growth of mould.

Attention should be paid also on Ergot sclerotium.

Food and feed safety risks

Moulds present no direct food and feed safety risk but are good indicators of potential other hazards.

Regulations

No specific regulations.

3.11. MYCOTOXINS

Nature of the hazard

- ❖ Biological hazard

Classification

Mycotoxins are “secondary metabolites” produced by certain moulds. They are molecules which have a very low molecular weight; they are not proteinic and do not therefore cause immunological reactions.

They are natural contaminants in foods and animal feed. They resist all treatments, sterilization, oxidation, acidity and alkalinity and have a lifespan in the contaminated product that is a great deal longer than that of the mould which synthesized them. However, not all moulds produce toxins and not all strains of the species that are able to, do so systematically, even if all of the conditions optimal to toxin production are combined.

Field mycotoxins

Mycotoxins	Moulds	Main media
Trichothecenes	<i>Fusarium</i>	Maize, barley, wheat, oats
Zearalenone	<i>Fusarium graminearum</i>	Maize, wheat, sorghum
Fumonisin	<i>Fusarium moniliforme</i>	Maize
Aflatoxins*	<i>Aspergillus flavus</i> and <i>Aspergillus parasiticus</i>	Maize
Ergot alkaloids	<i>Claviceps purpurea</i>	Rye and wheat

* Aflatoxins are mainly storage mycotoxins but under extreme climatic conditions and pest attacks they may be produced during cultivation.

Ergot : In October 2015, the EU published a [Commission Regulation 2015/1940](#) of 28 October 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of ergot sclerotia in certain unprocessed cereals and the provisions on monitoring and reporting. The 1940/2015 Regulation sets a maximum level of ergot sclerotia of 0.5 g / kg of cereals except maize and rice. The maximum level applies to unprocessed cereals placed on the market for first-stage processing. Cleaning, sorting and drying procedures are not considered "primary." The Member States and professional organizations are recommended to monitor the presence of ergot alkaloids in cereals and cereal products intended for human consumption or intended for animal feeding, in pasture/forage grasses for animal feeding and in compound feed and food. The objective is to set maximum levels of ergot alkaloids⁴ in cereals (excluding maize and rice) by 1st July 2017.

T2-HT2: On March 27th 2013, the EU published a Commission Recommendation 2013/165/EU on the presence of T-2 and HT-2 toxin in cereals and cereals products) asking Member States to perform with the active involvement of the feed and food business operators monitoring on the presence of T-2 and HT-2 toxin in cereals and cereals products intended for human consumption or intended for animal feeding (rice and rice products are not included. The purpose is to encourage that samples are simultaneously analysed for the presence of T2 & HT-2 and other fusarium-toxins such as DON, ZEA and FUMOMO B1+B2 and to allow the extent of co-occurrence to be assessed. For the sampling and testing of FOOD products, operators should use Regulation (EC) No 401/2006 (annex I part B and Annex II point 4.3.1(g) and for FEED products, the Regulation (EC) No 152/2009 as amended should be used. The sampling

⁴ The term ergot alkaloids represent the sum of 12 following ergot alkaloids: ergocristine / ergocristinine; ergotamine / ergotaminine; ergocryptine / ergocryptinine; ergometrine / ergométrinine; ergosine / ergosinine; ergocornine / ergocorninine.

Regulation (EU) No 844/2011 introduces specific pre-export certification rules on OTA controls by CANADA of exports of Wheat and wheat flour to the EU

- **Deoxynivalenol (also called vomitoxin):**
 - ❖ 1250 µg/kg for unprocessed cereals other than durum wheat, oats and maize,
 - ❖ 1750 µg/kg for durum wheat, oats and maize (with the exception of unprocessed maize intended to be processed by wet milling).
- **Zearalenone:**
 - ❖ 100 µg/kg for unprocessed cereals other than maize,
 - ❖ 350 µg/kg for maize (with the exception of unprocessed maize intended to be processed by wet milling).
- **Fumonisin:**
 - ❖ 4000 µg/kg for unprocessed maize (with the exception of unprocessed maize intended to be processed by wet milling)
 - ❖ 1000 µg/kg for maize intended for direct human consumption

➤ **T2 and HT2:**

EU Recommendation 2013/165/EU sets indicative levels for the sum of T-2 and HT-2 (µg/kg – ppb) in cereals and cereals products (rice excluded) from which onwards/above which investigations should be performed, certainly in case of repetitive findings (indicative levels are NOT feed and food safety levels!):

- ❖ For unprocessed cereals: 200 ppb for barley (incl. Malting Barley) and maize, 1000 ppb for oats (with husks) and 100 ppb for wheat, rye and other cereals
- ❖ For cereals grains for direct human consumption (i.e. which have undergone drying, cleaning, de-husking and sorting processes and on which no further cleaning and sorting processes will be performed before their further processing in the food chain): 200 ppb for oats, 100 ppb for maize and 50 ppb for other cereals

• Maximum mycotoxin levels for products intended for feed (basic text: Directive 2002/32 as amended)

- **Aflatoxin B1:**
 - ❖ 0.02 mg/kg for all raw materials

• Recommended maximum mycotoxin levels for cereals intended for animal feed (Commission Recommendation 2006/576/CE):

- **Deoxynivalenol:**
 - ❖ 8 mg/kg for all cereals and max 12 ppm for maize by products (DDGS/CGF)
- **Zearalenone:**
 - ❖ 2 mg/kg for all cereals and max 3 ppm for maize by products (DDGS/CGF)
- **Ochratoxin A:**
 - ❖ 0.25 mg/kg for all cereals
- **Fumonisin B1 + B2:**
 - ❖ 60 mg/kg for all cereals (affects mainly maize and maize BP)

➤ **T2 and HT2:**

EU Recommendation 2013/165/EU sets indicative levels for the sum of T-2 and HT-2 ($\mu\text{g}/\text{kg}$ – ppb) in cereals and cereals products (rice excluded) from which onwards/above which investigations should be performed, certainly in case of repetitive findings (indicative levels are NOT feed and food safety levels!):

- ❖ For unprocessed cereals : 200 ppb for barley (incl. Malting Barley) and maize, 1000 ppb for oats (with husks) and 100 ppb for wheat, rye and other cereals
- ❖ For cereals products for feed and compound feed (base 12% moisture): 2000 ppb for oats milling products (husks), 500 ppb for other cereals products and 250 ppb for compound feed

Sampling and testing

- For FOOD, Regulation (EC) No 401/2006 as amended lays down the methods of sampling and analysis for official controls of the levels of mycotoxins in FOOD.
- For contractual large lot sampling it is recommended to use the norm AFNOR NF XP V03-777 or the ISO CEN 24333 standard (for grains). Operators, can also use, for internal or contractual monitoring some sampling Rules such as GAFTA 124 (for grains and products thereof and oilseeds meals) or FOSFA methods (for oilseeds and vegetable oils.).
- Regulation (EC) No 882/2004 as amended on official controls also applies.
- An EU guidance document for the sampling of cereals for mycotoxins has also been published by the EU Commission.
- In Nov 2010, the EU Commission also released a Guidance Document for competent authorities for the control of compliance with EU legislation on aflatoxins.
- For FEED, Commission Regulation (EC) No 152/2009 as amended laying down the methods of sampling and analysis for the official control of feed.
- Commission decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results.

3.12. SALMONELLAS

Each operator is advised to follow EU and current national requirements. It is recognised that the requirements regarding Salmonella vary by Member State within the EU.

Nature of the hazard

- ❖ Biological hazard

Classification

Salmonellas are bacteria that belong to the family of Enterobacteria, which are pathogenic for humans and animals.

Salmonellas have characteristics which explain their very widespread distribution:

- ❖ They are carried by a large range of hosts (humans, mammals, birds, reptiles, insects etc.).
- ❖ They have a very high survivability in the environment.

From an epidemiological point of view salmonellas can be classed into three main groups:

- ❖ Strains that only infect humans and are responsible for typhoid fever with septicaemic dissemination, which are not pathogenic for other animal species.
- ❖ Strains specifically adapted to particular species of vertebrates (poultry, sheep etc.), some of which are pathogenic for humans.
- ❖ Strains that do not have a specific preferred host and infect both humans and animals. This is the reservoir in which the main agents of the salmonellas currently encountered are found.

Salmonellas can be dangerous for humans or animals.

Origin

The principal habitat of Salmonella is the intestinal tract of humans and animals. Salmonella is disseminated in the natural environment through human or animal excretion. It should be described as follows: "Fecal contamination by pests (mainly birds and rodents) but also contaminated dust or remains of previously transported/handled or stored materials."

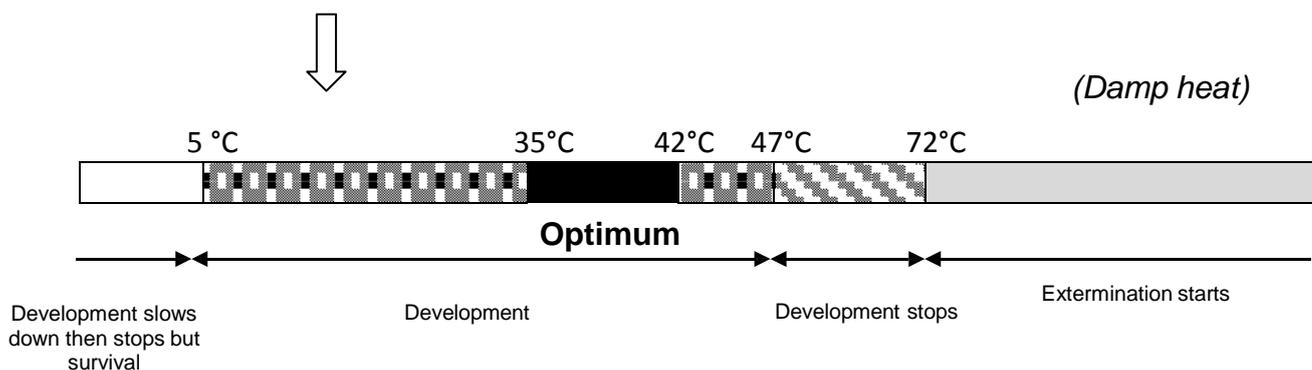
- ❖ Pests (mainly birds and rodents) but also contaminated dust or remains of previously transported/handled or stored materials
- ❖ For meals, unhygienic conditions during processing in the oil mills
- ❖ Staff hygiene

Development factors

- ❖ Temperature

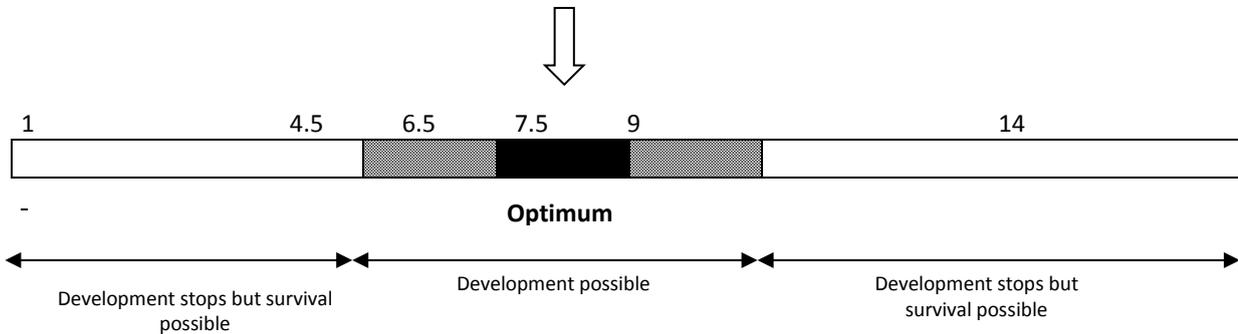
In case a heat treatment is necessary, the operator is advised to work according to the EU, local and national legislations or according to a recognised methodology.

Salmonella is sensitive to heat.



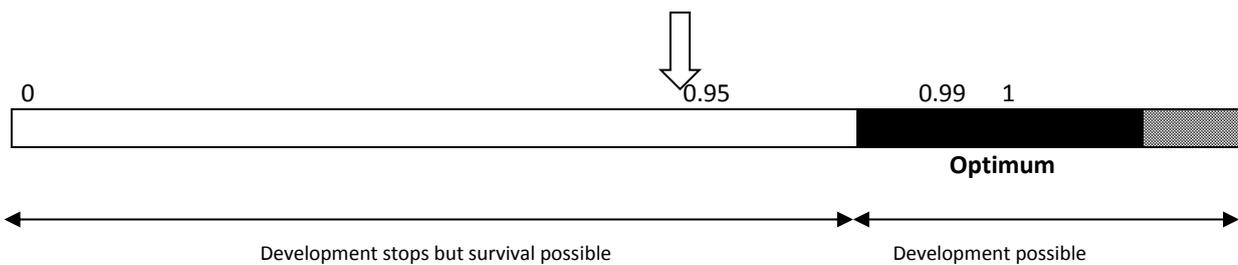
❖ pH

Acid treatment should be done according to the applicable current EU and national legislation. When such a methodology is used, appropriate labelling and information should be provided to the customers.



❖ Activity of water

Special attention should be taken in assuring that products are in an adequate low moisture level and that condensation is avoided as much as possible.



Control and Monitoring

With reference to products at risk such as oilseeds meals, and depending on the origin and the reported alerts, a regular monitoring and testing of products must be done while using adequate sampling and testing procedure (see & 3.1 and 3.2 of chapter 1 of this Guide). In case of a positive testing, procedures of serotyping, communications to customers & authorities, information on preventive treatments (chemical and/or by heat), disinfection of equipments and stores and labelling should be implemented, depending on the local national applicable rules or regulations. Research of the origin/source of contamination should be undergone in order to reduce/eliminate the contamination. An experienced person should pay attention in order to prevent condensation via proper ventilation system. The storekeeper should check on regular basis that storage and handling facilities are maintained as to prevent the occurrence of salmonella. This should be done applying appropriate sampling and testing methods and procedures. Contaminated products can be treated using a thermic treatment (with adequate duration and temperature level above 72°C) in approved facilities, if required at national level. Other treatments such as approved organic acids can help in preventing salmonella's development.

Food and feed safety risks

Mainly intestinal disorders.

Regulations and norms

There is no EU harmonised legislation for salmonella in feed materials. Each Member State has its own legislation and rules fixing the occurrence status and the actions to be taken in case of detection (who should be informed, which treatment, etc).

For more information, please refer to Article 15 (2) of Regulation (EC) No 178/2002 as amended. Please refer also to EFSA 2008 Scientific opinion regarding further information about Salmonella.

Regulation (EC) No 2160/2003 targets mainly 5 dangerous serotypes (strains) although attention should also be paid to other serotypes: S. Enteritidis – S. Typhimurium –S. Infantis – S. Hadar – and S.Virchow and any other serovar regulated at national Member state level. Presence of any of those serovars must usually be notified at animal production levels (primary and breeding). This Regulation applies to feed.

3.13. BACILLUS CEREUS

Nature of the hazard

- ❖ Biological hazard

Classification

- ❖ *Bacillus cereus* belongs to the family of Bacillaceae, formed of bacilli which produce heat resistant spores. It is pathogenic for humans and animals. This micro-organism is frequently found in products rich in starch (rice, cereals etc.).
- ❖ *Bacillus cereus* is capable of producing two types of toxins one of which is heat stable. It is responsible for food poisoning due either to ingestion of the preformed toxin in the food, or ingestion of the bacterium.
- ❖ *Bacillus cereus* produces spores which give it a high survivability (form of heat, pressure and low Aw etc. resistance).

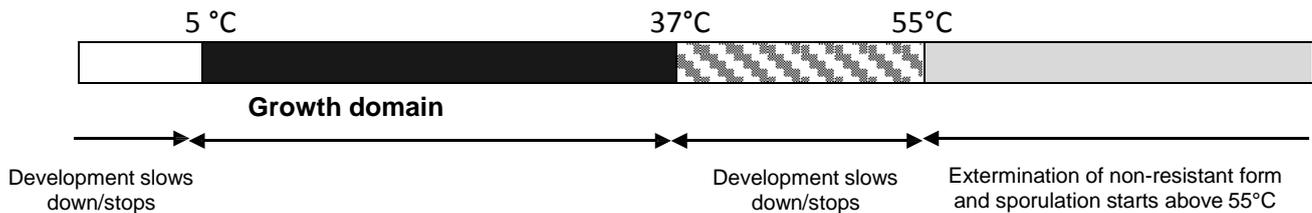
Origin

- ❖ Dust
- ❖ Soil
- ❖ Raw materials supplied

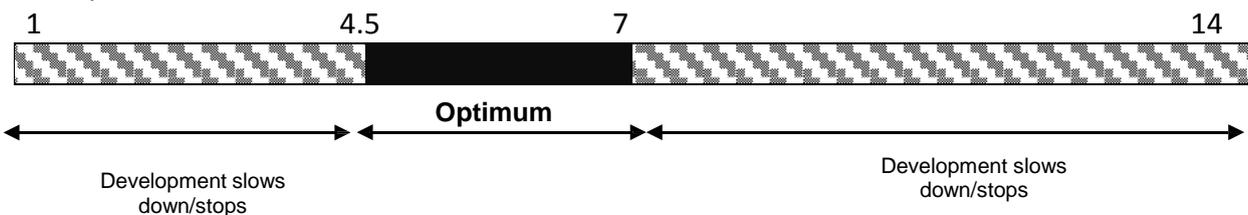
Factors in the development of *Bacillus cereus* and toxin production

- ❖ Temperature

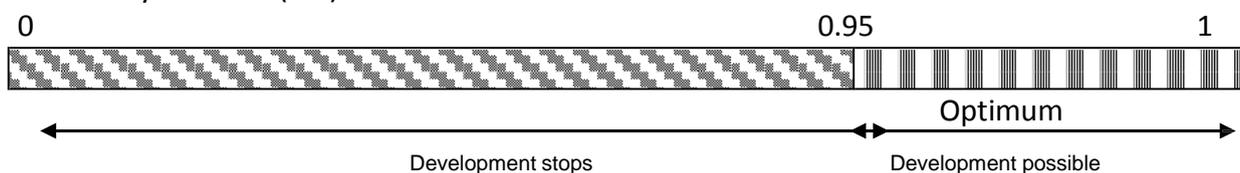
Certain strains are capable of multiplying in the cold.



- ❖ pH



- ❖ Activity of water (Aw)



Food and feed safety risks

Gastrointestinal disorders.

3.14. AMBROSIA

Various botanical impurities can be found in food and feed materials as a consequence of not being fully removed during harvesting or because of cross contamination during handling and storage or transport operations. Some of these seeds do present some risks when consumed by humans or by animals.

Nature of the hazard

- ❖ Allergen hazard

Classification AMBROSIA

The genus *Ambrosia* (Asteraceae family) is distributed worldwide. *Ambrosia artemisiifolia* (common ragweed) has heavily colonised several areas of South-East Europe. *Ambrosia* spp., both in their native range and in invaded areas, are of public health concern due to the allergenic properties of their pollen.

A. artemisiifolia is a weed of waste ground and agricultural land that flourishes wherever soil is newly disturbed. Dispersion of *Ambrosia* occurs naturally through seed drop, movement by animals and surface water, and often follows human activities entering the different regions by transport with agricultural machines and excavated material.

Inhalation of the plant pollen causes rhino-conjunctivitis and asthma, with skin allergies and food allergy playing minor roles. *Ambrosia* may cross-sensitize patients to other allergens, including food allergens. There is some evidence for allergenicity of *Ambrosia* pollen in animals. However, there are some indications that *A. artemisiifolia* could become highly invasive in certain environmentally-valuable habitats and might be linked to an impoverishment of species richness; therefore further ecological studies are needed. The EFSA CONTAM Panel focused on the relative importance of animal feed, bird feed in particular, on the dispersion of *Ambrosia*. *Ambrosia* seeds may contaminate feed.

Animal feeds, including maize, wheat, sunflowers, millet, peanuts, soybean, peas and beans may contain seeds of *Ambrosia*. Commercial feed for livestock is processed prior to use and the procedures of grinding, pelleting and/or heating almost completely destroy the *Ambrosia* seeds. In contrast, bird feed used for the feeding of wild and ornamental birds, which is often contaminated with seeds of *A. artemisiifolia*, is generally not processed and hence may contribute to the dissemination of viable ragweed seeds. Therefore, bird feed seems to play an important role in introducing *Ambrosia* to new, previously not infested areas.

Origin of hazard

- ❖ Botanic impurities not fully removed during harvesting or during cleaning at reception silos
- ❖ Cross contamination during handling and storage or transport operations

Regulations and EU norms

a) For FEED

Section VI of EU Directive 2002/32/EC on undesirable substances in FEED sets the following limits AMBROSIA in Feed materials

Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
6. Seeds from Ambrosia spp.	Feed materials (⁵), with the exception of:	50
	— Millet (grains of Panicum miliaceum L.) and sorghum (grains of Sorghum bicolor (L) Moench s.l.) not directly fed to animals (³)	200
	Compound feed containing unground grains and seeds	50

⁵ "In case unequivocal evidence is provided that the grains and seeds are intended for milling or crushing, there is no need to perform a cleaning of the grains and seeds containing non-compliant levels of seeds of Ambrosia spp. before milling or crushing on the condition that

- the consignment is transported as a whole to the milling or crushing plant, and
- the milling or crushing plant is informed in advance of the presence of high level of Ambrosia spp. seeds in order take additional prevention measures to avoid dissemination into the environment, and
- solid evidence is provided that prevention measures are taken to avoid dissemination of Ambrosia spp. seeds into the environment during transport to the crushing or milling plant, and
- the competent authority agrees to the transport, after having ensured that the abovementioned conditions are fulfilled.

In case these conditions are not fulfilled, the consignment must be cleaned before any transport into the EU and the screenings must be appropriately destroyed."

3.15. NITRITE

Nature of the hazard

Nitrate (formula NO_3) and nitrite (formula NO_2) are nitrogen compounds which are part of the nitrogen cycle. Through human activity (especially excess use of fertiliser) large amounts of extra nitrogen are added to certain phases of the natural nitrogen cycle. This leads to leaching and acidification. Nitrite is the conversion product of nitrate.

Nitrite is formed naturally by the nitrogen cycle during the process of nitrogen fixation and it is subsequently converted to nitrate, a major nutrient assimilated by plants. Two main nitrite salt forms occur, namely sodium and potassium nitrite.

Classification

- ❖ Chemical

Origin

- ❖ Excess uses of nitrates/nitrogen fertilisers. Nitrite in drinking water is regulated in Europe, with a maximum level of 0.5 mg/L. Nitrate levels in forages are naturally high and the inter-conversion of nitrate to nitrite is the largest contributor to nitrite exposure in food-producing animals.

Control measures:

- ❖ Establish purchasing requirements
- ❖ Expert use of fertilisers
- ❖ Monitor cultivation area (certified)
- ❖ Plot history
- ❖ Prevent overdosing of nitrate
- ❖ Received product analysis
- ❖ Soil history
- ❖ Water management

The control measures specified in this fact sheet are all control measures which can be used depending on the product and/or process step.

Food and feed safety risks

It may act as a carcinogen for chronic exposure. Acutely, nitrite is approximately ten-fold more toxic than nitrate and three main toxicological endpoints have been identified: methaemoglobin formation (in a wide range of species including man), hypertrophy of the adrenal zona glomerulosa (rats), and equivocal evidence for carcinogenesis (female mice). In monogastric animals, most nitrite is formed and absorbed in the upper digestive tract. In contrast in ruminants, nitrite and nitrate is metabolised by the rumen flora. Reports of adverse effects after excessive nitrite exposure in livestock exist, and pigs and ruminants, as major food producing animals, are particularly susceptible: this is because of relatively low nitrite reductase activity and high levels of rumen conversion of exogenous nitrate to nitrite, respectively.

Regulations

Nitrites content in FEED is EU Regulated by Directive 2002/32/EC as amended, with the following MRLs:

- ❖ 15 ppm (mg/kg) (expressed in sodium nitrite) for feed with 12% moisture for feed materials (except fishmeal, silage and complete feedingstuffs)

3.16. RADIONUCLEIDS

Nature of the hazard

Radioactivity is the special characteristic of a chemical substance that emits radiation. We call that a radioactive substance. This may be a gas, vapor, liquid or solid substance. Known radioactive substances are: Cobalt, Caesium, Iodine, Radium, Uranium and Plutonium. It is necessary to make a distinction between radioactive contamination and Irradiation. Radioactive contamination occurs when radioactive materials deposits on products or animals or is eaten/breathed by an animal, while Irradiation occurs when a living animal/human or an object is submitted to a ionising emission. Contamination is legally defined by an undesirable presence, at a significant level, of radioactive substances in or on a specific mean. In case of irradiation, the objet or animal/human needs just to be put at a greater distance from the emitting source for the irradiation to stop while in case of contamination, especially in case of ingestion of radioactive substance, the internal irradiation is much more difficult to eliminate. In worst case, if the amount of ingested radioactive substance is high, the human or animal or vegetal can become himself a source of irradiation. Radioactive contamination can propagate in the food and feed chain, and a living being becomes contaminated after having eaten a contaminated plant or animal.

Classification

❖ Chemical

Origin

Spillage or explosion of a plant using nuclear fuels or use of plants grown on land having been contaminated by nuclear residues (wastes or atmospheric deposits).

Measuring radioactivity

Ionizing radiation is ubiquitous in the environment, and also comes from radioactive materials, X-ray tubes, and particle accelerators. It is invisible and not directly detectable by human senses, so instruments such as Geiger counters are usually required to detect its presence. There are four different but interrelated units for measuring radioactivity, exposure, absorbed dose, and dose equivalent. These can be remembered by the mnemonic R-E-A-D, as follows, with both common (British, e.g., Ci) and international (metric, e.g., Bq) units in use:

- Radioactivity refers to the amount of ionizing radiation released by a material. Whether it emits alpha or beta particles, gamma rays, x-rays, or neutrons, a quantity of radioactive material is expressed in terms of its radioactivity (or simply its activity), which represents how many atoms in the material decay in a given time period. The units of measure for radioactivity are the curie (Ci) and becquerel (Bq).
- Exposure describes the amount of radiation traveling through the air. Many radiation monitors measure exposure. The units for exposure are the roentgen (R) and coulomb/kilogram (C/kg).
- Absorbed dose describes the amount of radiation absorbed by an object or person (that is, the amount of energy that radioactive sources deposit in materials through which they pass). The units for absorbed dose are the radiation absorbed dose (rad) and gray (Gy).
- Dose equivalent (or effective dose) combines the amount of radiation absorbed and the medical effects of that type of radiation. For beta and gamma radiation, the dose equivalent is the same as the absorbed dose. By contrast, the dose equivalent is larger than the absorbed dose for alpha and neutron radiation, because these types of radiation are more damaging to the human body. Units for dose equivalent are the roentgen equivalent man (rem) and sievert (Sv), and biological dose equivalents are commonly measured in 1/1000th of a rem (known as a millirem or mrem).

For practical purposes, 1 R (exposure) = 1 rad (absorbed dose) = 1 rem or 1000 mrem (dose equivalent). Note that a measure given in Ci tells the radioactivity of a substance, while a

measure in rem (or mrem) tells the amount of energy that a radioactive source deposits in living tissue. For example, a person would receive a dose equivalent of 1 mrem from any one of the following activities:

The becquerel (symbol Bq) is the SI-derived unit of radioactivity. One Bq is defined as the activity of a quantity of radioactive material in which one nucleus decays per second. The Bq unit is therefore equivalent to s^{-1}

In a fixed mass of radioactive material, the number of becquerels changes with time.

Therefore, a sample radioactive decay rate is always stated with a timestamp for short-lived isotopes, sometimes after adjustment to some specific date of interest (in the past or in the future).

Food and feed safety risks

Radiations, depending on their strength, have clear genetic effects, including the effect on cancer risk.

Ionizing (or ionising) radiation is radiation with sufficient energy to remove an electron from an atom or molecule. This ionization produces free radicals, atoms or molecules containing unpaired electrons, which tend to be especially chemically reactive.

The degree and nature of such ionization depends on the energy of the individual particles (including photons), not on their number (intensity). Exposure to radiation causes damage to living tissue, and can result in mutation, radiation sickness, cancer, and death. If the dose is sufficient, the effect may be seen almost immediately, in the form of radiation poisoning.

Regulations

For FEED products:

- [The Annex III of Regulation No 52/2016](#) Euratom fixes an MRL for Sum of Cs-134 and Cs-137:

ANNEX III

MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION OF FEED

The maximum permitted levels for the sum of caesium-134 and caesium-137 shall not exceed the following:

Feed for	Bq/kg ⁽¹⁾ ⁽²⁾
Pigs	1 250
Poultry, lambs, calves	2 500
Other	5 000

(1) These levels are intended to contribute to the observance of the maximum permitted levels for food; they do not alone guarantee such observance in all circumstances and do not lessen the requirement for monitoring contamination levels in animal products destined for human consumption.

(2) These levels apply to feed as ready for consumption.

For FOOD products:

- [The annex I of Regulation No 52/2016](#) fixes MRLs for Sum of Cs-134 and Cs-137.

3.17. POLYCYCLIC AROMATIC HYDROCARBONS AND BENZO(A)PYRENE (PAH & BAP)

Nature of the hazard

- ❖ Chemical hazard

Classification

Benzo(a)pyrene belongs to the group of polycyclic aromatic hydrocarbons (PAH) and is used as a marker for the occurrence and effect of carcinogenic PAH in food including also benz(a)anthracene, benzo(b)fluoranthene, benzo(j)fluoranthene, benzo(k)fluoranthene, benzo(g,h,i)perylene, chrysene, cyclopenta(c,d)pyrene, dibenz(a,h)anthracene, dibenz(a,e)pyrene, dibenzo(a,h)pyrene, dibenzo(a,i)pyrene, dibenz(a,l)pyrene, indeno(1,2,3-cd)pyrene and 5-methylchrysene. C₂₀H₁₂, is a five-ring polycyclic aromatic hydrocarbon whose metabolites are mutagenic and highly carcinogenic. Benzo[a]pyrene is listed as a Group 1 carcinogen by the IARC. A certain number of polycyclic aromatic hydrocarbons (PAH) are genotoxic carcinogens. PAH can contaminate foods during smoking processes and heating and drying processes that allow combustion products to come into direct contact with food. In addition, environmental pollution may cause contamination with PAH, High levels of PAH were found in dried fruits, olive pomace oil, smoked fish, grape seed oil, smoked meat products, fresh molluscs, spices/sauces and condiments.

Origin

Benzo[a]pyrene is a product of incomplete combustion at temperatures between 300 and 600 °C. Benzo[a]pyrene is found in coal tar, in automobile exhaust fumes (especially from diesel engines), in all smoke resulting from the combustion of organic material (including cigarette smoke), and in charbroiled food.

Regulations and EU norms

a) For FOOD

Regulation (EU) No 835/2011 of 19 August 2011 amends Regulation (EC) No 1881/2006 as amended as regards maximum levels for polycyclic aromatic hydrocarbons in foodstuffs.

I	Foodstuffs	Maximum levels (yg/kg)	
		Benzo(a)pyrene	Sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene ⁽⁴⁵⁾
6.1	Benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene		
6.1.1	Oils and fats (excluding cocoa butter and coconut oil) intended for direct human consumption or use as an ingredient in food	2.0	10.0
6.1.8	Processed cereal-based foods and baby foods for infants and young children ⁽³⁾ ⁽²⁹⁾	1.0	1.0
⁽⁴⁵⁾ Lower bound concentrations are calculated on the assumption that all the values of the four substances below the limit of quantification are zero.			