

# Chapter 3

## Origin and nature of food risk

<b>3.1.</b> Origin and nature of biological risks .....	<b>66</b>
<b>3.2.</b> Origin and nature of physical risks .....	<b>83</b>
<b>3.3.</b> Origin and nature of chemical risks .....	<b>87</b>
<b>3.4.</b> Emerging risks .....	<b>109</b>
<b>Appendices</b> .....	<b>114</b>



## 3.1. Origin and nature of biological risks

Biological risks arise from contamination of food by pathogenic organisms (e.g.: worms) or micro-organisms, mainly **viruses, bacteria, fungi**, protozoa, prions,<sup>1</sup> etc. These organisms are often **associated with humans** and **raw products** that enter the food production chain. Several form part of the natural flora of the environment where food is produced and grown.

Examples of biological hazards (Source: FAO training manual, 2010)	
Sporulating bacteria	Viruses
<i>Clostridium botulinum</i> <i>Clostridium perfringens</i> <i>Bacillus cereus</i>	Hepatitis A and E viruses Rotavirus Group of Norwalk viruses
Asporulating bacteria	Protozoa and parasites
<i>Brucella abortis</i> <i>Brucella suis</i> <i>Campylobacter</i> spp. Enteropathogenic <i>Escherichia coli</i> ( <i>E. coli</i> 0157, H7, EHEC, EIEC, ETEC, EPEC) <i>Listeria monocytogenes</i> <i>Salmonella</i> spp. ( <i>S. typhimurium</i> , <i>S. enteridis</i> ) <i>Shigella</i> ( <i>S. dysenteriae</i> ) <i>Staphylococcus aureus</i> <i>Streptococcus pyogenes</i> <i>Vibrio cholerae</i> <i>Vibrio parahaemolyticus</i> <i>Vibrio vulnificus</i> <i>Yersinia enterocolitica</i>	<i>Cryptosporidium parvum</i> <i>Diphyllobotrium latum</i> <i>Entamoeba histolytica</i> <i>Giardia lamblia</i> <i>Ascaris lumbricoides</i> <i>Taenia solium</i> <i>Taenia saginata</i> <i>Trichinella spiralis</i>

Most are **destroyed** or **inactivated by cooking** and their number can be kept at a low level when product handling and storage conditions (hygiene, temperature and duration) are controlled.

Most cases of food poisoning associated with the consumption of fresh fruit or vegetables or those that have undergone initial processing (e.g.: trimming, washing, crown reduction, etc.) are caused by **pathogenic micro-organisms**.

<sup>1</sup> For example, the infectious agent of BSE (bovine spongiform encephalopathy) is responsible for so-called 'mad cow disease'. BSE is a degenerative infection of the central nervous system of cows caused by a molecular infectious agent of a particular type (neither a virus nor a microbe) known as 'prion protein'. Prions are found in mammals (responsible for transmissible spongiform encephalopathies) and in certain fungi such as *Saccharomyces cerevisiae* (baker's yeast). This type of protein infectious agent, however, has to date never been detected in plants.

Micro-organisms, as their name suggests, are microscopic organisms. Some can be seen with the naked eye (mould, for instance) but others only under a microscope. They are found everywhere: in the air (transmission by draughts), in water, in the ground, on materials (work surfaces, packaging, etc.) and on living beings (humans and animals).

For risks of a biological nature, **two important elements** have to be considered:

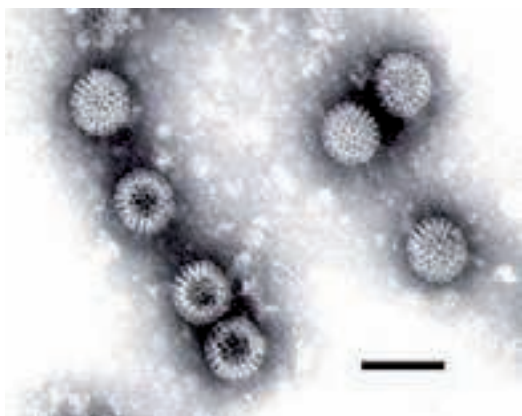
1. Their occurrence on or in food is primarily due to a **lack of hygiene and sanitary conditions**. Depending on the pathological nature of the biological agent, even a minor contamination can result in food poisoning that can have serious effects.
2. **Faecal matter is the main vector** and can contaminate food directly (e.g.: through contact with soiled hands) or indirectly (e.g.: **through the water used**).

**The operator therefore has a large measure of responsibility** in this area: **poor practices** are the source of most contaminations, via the soil, water or the employees' hands!

### 3.1.1. Foodborne viruses

#### □ Origin of foodborne viruses

Viruses can originate in food or in water or be transmitted to food by humans, animals or other contacts. Unlike bacteria, viruses are incapable of reproducing outside a living cell. Consequently, they **cannot multiply in food** but can merely **be carried** by food.

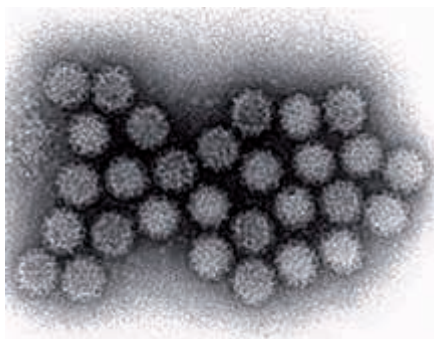


Viruses on leaves or on fruit and vegetables, often identified through symptoms or yield losses, are not dangerous for consumers. On the other hand, some foodborne viruses are pathogenic for man because they can cause serious digestive or liver problems (the **Norwalk virus**, **hepatitis A virus**, **Rotaviruses**, etc.). These viruses are **transported by water**.

*Rotavirus*

The **control of hygiene and of the quality of water** used for irrigation and to wash fruit and vegetables is therefore essential to reduce this type of risk.

#### ❑ The Norwalk virus (norovirus)



The Norwalk virus causes an infection and mainly infects **consumers of raw or undercooked products**, generally following contamination from **faecal matter**. The virus does not multiply in food, so the infections are not related to food storage conditions (e.g.: the cold chain).

Symptoms include vomiting, diarrhoea and cramps that appear suddenly after a day or two. The illness is not serious and usually lasts from one to three days, but it does not confer immunity. Ingestion of a small number of viruses is enough to cause the illness because the infectious dose is very low (a single virus is enough).

The virus is transmitted mainly by affected persons who do not take proper hygiene measures and directly contaminate raw or undercooked food. Ill employees must not be allowed to work and it is also essential to ensure personal hygiene and sanitary conditions in growing areas. The virus resists freezing and disinfectants.

#### ❑ Rotaviruses

Rotavirus infection is the result of **contamination by human faecal matter** and causes gastro-enteritis. Symptoms are generally more serious than in the case of the Norwalk virus. The fever, diarrhoea and vomiting can lead to severe dehydration. These symptoms appear after two to four days and the illness lasts two to ten days. The illness does not confer immunity and can be carried by healthy subjects.

Rotavirus is the **leading cause of severe acute diarrhoea in young children** worldwide. The virus is highly concentrated in human faecal matter and survives for a long time in the environment. A person with diarrhoea caused by a rotavirus excretes a large number of viruses for around ten days.

Infectious doses can be caught quickly from **contaminated hands**, objects, **food** and **water**. Ingestion of a small number of viruses (100 or so viral particles) is enough to cause illness. Personal hygiene (first and foremost) and full cooking of food eliminate most problems.

#### ❑ The hepatitis A virus (hepatovirus)

Hepatitis A (formerly known as infectious hepatitis) is an acute infectious disease of the liver caused by the hepatitis A virus, **generally through orofaecal transmission from contaminated food or water**. The hepatitis A virus primarily affects individuals who eat raw or undercooked products. It is resistant to the cooking of food and survives for long periods in the environment. It also resists freezing and disinfectants and survives for several weeks in water.

Hepatitis A is a two-stage liver infection:

1. around 15 to 45 hours after ingestion, a gastro-enteritis appears and lasts one to three days;
2. the victim is contagious for two to four weeks, during which the virus enters the bloodstream and attacks the liver (hepatitis). The presence of bile is observed in the blood and urine, which become dark (jaundice); in rare cases the disease can degenerate into cirrhosis of the liver and be fatal. Other symptoms are vomiting, anorexia, fever, nausea and fatigue.

Ingestion of a small number of viruses (one to 100) is enough to bring on the disease. Ingestion of products contaminated from polluted water is associated with a high risk of infection. In regions with poor hygiene conditions, the incidence of infection with this virus is close to 100% and the disease is generally contracted in early childhood.

Detection methods are difficult because the virus multiplies slowly and results are often not available until the foods have been consumed.

HAV epidemics still occur because of **poor hand hygiene** among infected persons. Sometimes restaurant employees with symptoms fail to wash their hands after using the toilet. The most serious epidemic of hepatitis A in the USA affected at least 640 people (killing four) in north-eastern Ohio and south-western Pennsylvania at the end of 2003. The epidemic was attributed to **contaminated green onions** in a restaurant in Monaca, Pennsylvania.

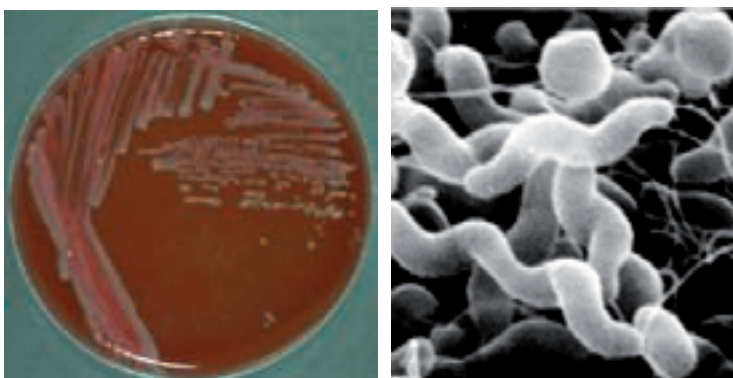
*Prevalence of hepatitis A worldwide:*



**Preventing ill employees from working** and ensuring appropriate personal hygiene and sanitary conditions are the best ways to prevent infections.

### 3.1.2. Bacteria (microbes)

The majority of foodborne infections reported are caused by pathogenic bacteria. Certain raw foods contain such bacteria naturally. Poor handling and storage conditions foster their proliferation in food. If not properly handled and stored, raw food is often a fertile culture medium for the growth of these undesirable germs.



Colony of *Campylobacter jejuni* in a culture medium. On the right: the bacteria.

**Bacteria are therefore the most important biological food risk.** They are at the root of the majority of cases of foodborne illness outbreaks (FBI).

In Europe, the micro-organisms most often mentioned in reports from Member States are, by order of importance: *Salmonella* (e.g.: in 2007, 8,922 persons concerned, 1,773 hospitalisations and 10 deaths), viruses, *Campylobacter*, *E. coli*; *Bacillus*, *Clostridium*, *Staphylococcus* and bacterial toxins (Source: EFSA).

Foodborne bacteria that are pathogenic to man are regularly detected in routine analyses carried out on apparently wholesome products.

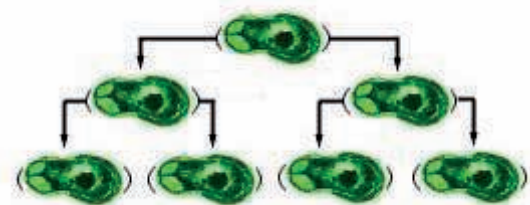
In general, the bacterial flora present in fruit and vegetables can be broken down into **three groups**:

- ▶ **Saprophytic or spoilage flora:** enterobacteria (*Erwinia*, etc.), *Pseudomonas*, *Bacillus* and lactic bacteria. This flora develops to the detriment of the quality of fruit and vegetables.
- ▶ **Phytopathogenic flora** (pectinolytic): certain species of *Erwinia*, *Pseudomonas* and *Clostridium* or other species that cause leaf spot (plant diseases). This flora is responsible for the deterioration or alteration of the taste, appearance, etc. of fruit and vegetables.
- ▶ **Flora of animal origin** (coliform bacteria, enterococci) and land-based origin (earth, water, sewage sludge). **The pathogenic germs responsible for food poisoning, if developed beyond contamination levels, are found in part of this flora.**



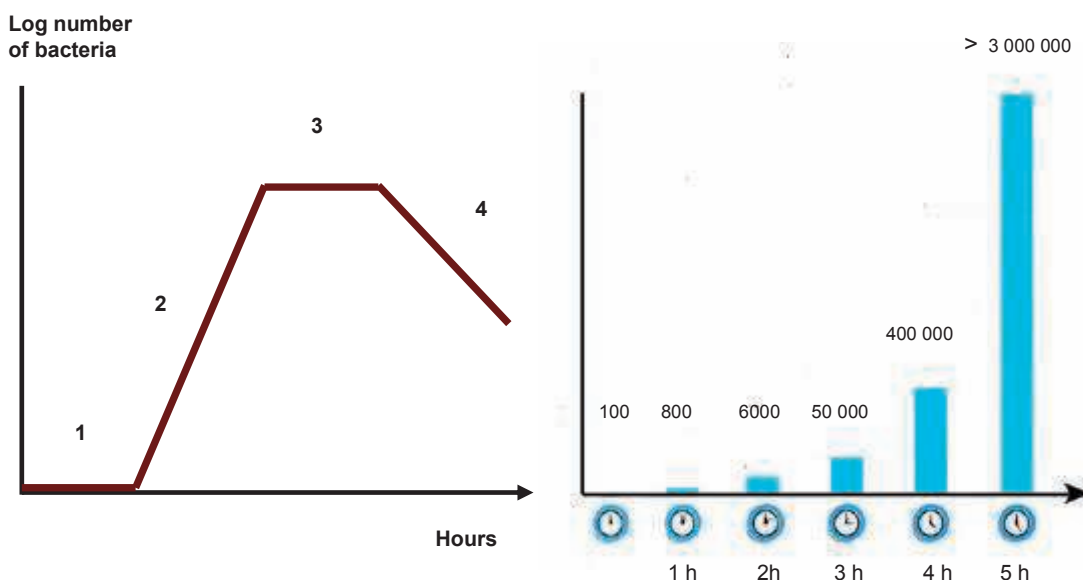
❑ **Bacteria multiplication and the importance of hygiene**

Classic diagram of bacteria multiplication:



**The population doubles with every generation.** When conditions are favourable, the population's development is exponential (it doubles on average of every 20 to 40 minutes *in vitro*, and every 2 to 5 hours *in vivo*).

Characteristic growth curve for a population of bacteria in a non-renewed medium and consequence of the proliferation phenomenon:



The following **four successive phases** can be observed:

1. Lag phase, the bacteria accumulate nutritive reserves. Acceleration phase, the bacteria reproduce through binary fission.
2. Exponential growth phase.
3. Stationary phase due to lack of nutrients (in a non-renewed medium the bacteria use all nutrients and produce toxic waste, leading to the stationary phase followed by death).
4. Decline phase, exhaustion of nutritive reserves and accumulation of toxic substances.

The generally exponential growth of bacteria in a contaminated product explains the **importance of observing hygiene rules** during food handling and storage.



### The importance of hygiene!

Let's consider a food that will be cooked but in the meantime is left at ambient temperature for four hours before being prepared. For the product to be edible, the number of bacteria at the exact time of consumption must be no greater than 50 germs/100 g (authorised limit).



**Let's compare two situations:** a food that has been produced in keeping with hygiene rules, with a bacteria count at the time cooking starts of 10 germs/100 g (Case no 1), and a food produced without regard to basic hygiene rules, with a bacteria count of 100 germs/100 g (Case no 2). Is this initial contamination difference really important since the food will not be eaten until it has been cooked?

Considering that an initial population doubles every 20 minutes when conditions are right (substratum, temperature and humidity), the development of bacteria in the product can be roughly estimated as follows:

$$N_t \text{ (number of bacteria in the product at time } t) = N_0 \times 2^{(3 \times t)}$$

Where  $N_0$  = initial number of bacteria  
t = time in hours

	$N_t$	$N_t$
If $N_0$ is:	Case no 1 10 (germs/100 g)	Case no 2 100 (germs/100 g)
After 1 h	80	800
After 2 h	640	6.400
After 3 h	5120	51 200
After 4 h	40 960	409 600

*If the product is cooked and the cooking process reduces the bacteria population by 99.9 %, is the food still edible?*

In the first case, the population counted after cooking will be around 41 bacteria/100 g, which ensures **risk-free consumption**. In the second case, in spite of cooking, the final number of germs/100 g exceeds 400, which is still around **10 times above the authorised limit!**

**This example underlines the importance of Good Hygiene Practices to limit initial contamination of products:** even processes that are 99.9% effective are unable to offer the desired safety guarantees. Often the contamination difference between hygienic and non-hygienic productions will be much greater than a factor of 10. Furthermore, the development of bacteria on the product leads to other consequences such as greater product spoilage, the presence of toxins (that remain after cooking) and so on.

□ Origin of pathogenic bacteria and conditions for their development

Origins and growth conditions of a few pathogenic bacteria:

Bacteria responsible	Origin of the bacteria	Foods often contaminated	Growth conditions
<b>Salmonella</b>	Intestines, animal or human stools (ill or healthy carriers) Dirty hands Manure Purification station	Eggs, egg products, meat-based products, poultry, raw milk, prepared meat products Vegetables (especially pre-cut) Fruit juice Seafood Ice cream	Min. T°: 5°C Optimal T°: 37°C Min. A <sub>w</sub> : 0.94 Min. pH: 4  Max. T°: 65°C
<b>Listeria monocytogenes</b>	Work environment Floor, water, intestines, excrements, dust	Prepared dishes, smoked fish (salmon!) Vegetables Raw milk-based dairy products, Prepared meat products	Min. T°: 0°C Optimal T°: 37°C Min. A <sub>w</sub> : 0.89 Min. pH: 4  Max. T°: 70°C
<b>Staphylococcus (Staphylococcus aureus and S. epidermis)</b>	Abscesses Saliva, throat, nose, wounds and infections (animal or man) Dirty hands Animals	Meat products (minced meat), prepared meat products, desserts made from eggs and milk, ice cream, pre-cooked dishes, slow reheating	Min. T°: 6 °C Optimal T°: 37 °C Min. A <sub>w</sub> : 0.90 Min. pH: 4.5  Max. T°: 65 °C (thermal-resistant toxins)
<b>Clostridium perfringens</b> (sulphite-reducing anaerobe)	Intestines, animal or human stools Spores in nature, soil, dust Plant sediments	Vacuum-packed foods, cooking in large quantities, in broth, leftover sauce, foods cooked the day before, dishes cooled too slowly, etc.	Min. T°: 12 °C Optimal T°: 45 °C Min. A <sub>w</sub> : 0.95 Min pH: 5
<b>Clostridium botulinum</b> (sporulating anaerobe, fatal)	Spores in nature (soil, air, water) and intestines of animals Plant sediments	Preserved or semi-preserved food Prepared meat products	Min. T°: 10 °C Optimal T°: 37 °C Min. A <sub>w</sub> : 0.94 Min. pH: 4.6



<b><i>Escherichia coli</i></b>	Human digestive tract, water contaminated by excrements Treatment plant Evisceration Droppings	Fruit, salads and raw vegetables Minced meat Raw milk, dairy products	Min. T°: 10 °C Optimal T°: 37 °C Min. A <sub>w</sub> : 0.95 Min. pH: 4.4  Max. T°: 65°C (thermal-resistant toxins)
<b><i>Bacillus cereus</i> and <i>Bacillus mesentericus</i></b>	Plant seedlings Cereals, rice Cocoa	Bread Crumb (inside) of bread Rice dishes	Min. T°: 10 °C Optimal T°: 37 °C  Max. T°: 65°C

There are other important pathogenic bacteria but they are specifically **associated with animal products** or products of animal origin. For example, the ***Campylobacter*** genus (*C. jejuni* and *C. coli*) includes some of the most frequent and most pathogenic bacteria, which come from the intestines of wild or farmed animals and contaminate chicken, duck and turkey meat, pre-cut poultry, etc.

To develop in food, bacteria need:

- **Water in any form** (liquid, steam, mist, etc.). The availability of water (described as 'water activity', A<sub>w</sub>) is a **critical factor** for bacterial growth.
- An appropriate **temperature** (N.B.: some bacteria can develop in cold storage and refrigerators, despite temperatures below 5 °C.).
- **Nutrients** (sugar, fatty substances, vitamins).
- **A neutral or low-acid pH** (5 to 8).
- **Oxygen** as a rule, but this varies depending on the species, and some bacteria are even anaerobic (e.g.: *Clostridium botulinum*, responsible for botulism, is a strict anaerobic bacterium).



There are risks when preserving food at home, because factory production theoretically provides protection against poisoning by *C. botulinum*.

Infection can be avoided when preparing food if simple hygiene rules are observed. Checking temperature, salt concentration and pH is essential to prevent the formation of *C. botulinum* spores.

*Clostridium botulinum*, **bacteria responsible for botulism**.

### ❑ Microbiological cross-contamination

Microbiological cross-contamination is a **major problem**, especially for certain bacteria like *Listeria monocytogenes*. It can occur through direct contact with **dirty unprocessed products** (e.g.: vegetables pulled from the ground or picked fruit), personnel wearing **dirty clothes, sprays** (e.g.: produced by a pulsed-air hand dryer), **contaminated instruments** (e.g.: using a knife that was used to harvest products), unwashed material, etc. The problem is even more serious when cross-contamination occurs at the end of the process (just before shipping) and for products that will **not be cooked** before being eaten (e.g.: lettuce contaminated by soil).

Cross-contamination can occur at any stage of the process when the product is exposed to the environment, including harvest, transport and processing. **Traffic** flows of employees, raw materials and material must be limited and controlled between product 'reception areas', 'processing areas', 'storage areas' and 'finished product areas' in order to prevent the transfer of pathogens from unprocessed (or raw) products to processed products.<sup>2</sup>

It is therefore important to apply the principle of a **workflow from dirty to clean areas** (the 'processing chain' should be designed on the basis of this principle to **prevent unprocessed and finished products from crossing paths** on entry or exit) and measures to prevent contamination of products that have already been sanitized (e.g.: use different coloured containers/baskets for unprocessed and finished products).

### ❑ What are the acceptable limits?

Regulation (EC) 178/2002 establishes general food safety requirements, in particular that food cannot be placed on the market if it is unsafe. The general aim is to ensure consumer safety: food must not contain micro-organisms or their toxins or metabolites in quantities that would present an unacceptable risk to human health.

Food business operators are obliged to take unsafe food off the market. To contribute to the protection of public health and to **prevent different interpretations**, regulations therefore establish, on the basis of scientific findings, **harmonised safety criteria** for food acceptability, particularly with respect to the presence of certain pathogenic micro-organisms (**Regulation (EC) 2073/2005** on microbiological criteria for foodstuffs<sup>3</sup>).

These '**microbiological criteria**' serve both as **references** for authorities in charge of food controls and as **objectives** for food business operators (e.g.: the HACCP plan can be 'gauged' to these criteria).

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<sup>2</sup> Cross-contamination is also possible via the work surface (e.g.: cutting vegetables on a work surface used to cut up poultry) or even in refrigerators (e.g.: liquid dripping from meat onto vegetables) if germs are transferred from carcasses to cut vegetables. It is therefore recommended to use different work surfaces for meat, fish and vegetables, to perform tasks in a certain order (cutting vegetables first) and to avoid using hard-to-clean wooden chopping boards or instruments.

<sup>3</sup> Regulation (EC) 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. Official Journal of the European Union L 338/1, of 22.12.2005.

The 'microbiological criterion' defines the acceptability of **a food product** (or a food lot) or **a process**, based on the absence or presence or number of micro-organisms, and/or the quantity of their toxins/metabolites per unit of mass, volume, area or lot.

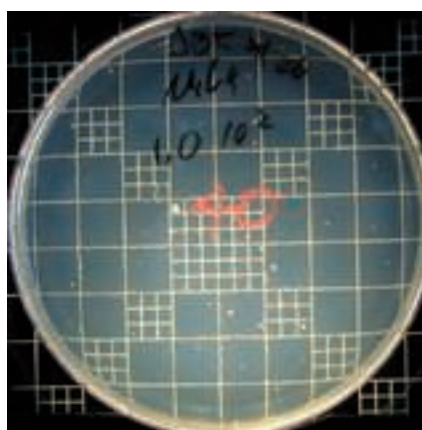
It should nevertheless be kept in mind that **food safety cannot be guaranteed merely by meeting criteria** but that it also requires compliance with 'Good Hygiene Practices' and use of HACCP, where necessary.

There are **two types** of microbiological criteria:

- ▶ **imperative standards (safety criteria)**: these are public health criteria. Failure to observe an imperative standard results in action on the product lot concerned (e.g.: withdrawal, recall, destruction) and in corrective action on production/processing.
- ▶ **other criteria (process criteria)**: these serve to verify good hygiene practices and processes in general. Failure to observe these criteria does not result in specific action on the products concerned but the origin of the weakness must be identified and corrective actions introduced.

A microbiological criterion is composed of the following elements:

- ▶ indication of the micro-organisms and/or their undesirable toxins/metabolites;
- ▶ analytical methods used to detect and/or quantify them;
- ▶ a plan defining the **number of samples to be taken (n)**, as well as the **size** of the analytical unit (25g, 20 g, 10g or 1g). The number and size of analytical units per lot tested should be as stated in the sampling plan and must not be changed.
- ▶ **acceptable limits** for the micro-organisms or toxins considered appropriate for the food, expressed either qualitatively (presence/absence) or quantitatively (e.g.:  $10^4$  cfu/g of product<sup>4</sup>);
- ▶ **the number of analytical units that should conform to these limits.**



The microbiological criterion must also define:

- ▶ the point in the food chain where it applies;
- ▶ the actions to be taken when the criterion is not met.

The values of the '**acceptable microbiological limits**' that will be set should **take into account the risks** associated with the micro-organisms and the conditions under which the food is expected to be handled and consumed.

Microbiological limits should also take account of the likelihood of uneven distribution of micro-organisms in the food, and of the variability inherent to the analytical method. If a

<sup>4</sup> Cfu: *colony-forming unit*. Unit used to count bacteria in microbiological analysis: every live bacterium isolated during sorting of the sample on a medium creates a 'colony' that appears in the Petri dish as a spot. Every spot, or colony, originates from one microbe that has divided. The measure is given in cfu/ml (liquid sample) or cfu/g (solid sample).

criterion requires the absence of a given micro-organism, the size and number of the analytical unit (as well as the number of analytical sample units) should be indicated.

The following values are examples of acceptability levels (acceptable limit value: no sample must exceed this value):

Hepatitis A	Absence
Rotavirus	Absence
Norovirus (Norwalk Like)	Absence
<i>Salmonella</i>	Absence in 25 g or ml
<i>Listeria monocytogenes</i>	Absence in 25 g or ml
<i>E. coli</i> O:157 enterohaemorrhagic	Absence in 25 g or ml
Toxins of <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>Clostridium perfringens</i> , <i>Clostridium botulinum</i>	Absence

Microbiological analyses, wherever possible, must only employ sampling and analytical **methods** whose reliability (accuracy, repeatability, inter and intra-laboratory variations) has been statistically established in the framework of comparative or interlaboratory studies. Preference should also be given to **methods validated for the product concerned**, especially when these are reference methods developed by international organisations. Chapter 3 of Regulation (EC) No 2073/2005 describes rules for sampling and preparation of test samples.

Although methods must offer maximum sensitivity and repeatability for the intended aim, tests conducted in companies often partially sacrifice sensitivity and repeatability to speed and simplicity. They must nevertheless be tested methods, capable of giving a sufficiently reliable estimate of the information required (Hygiene of food, *Codex Alimentarius*, 2009).

### 3.1.3. Mould, yeast and fungi



**Mould** and **yeast** found on fruit and vegetables are primarily spoilage flora.

Certain moulds (e.g.: *Alternaria* spp., *Aspergillus favus*, *Fusarium* spp., etc.) are **toxigenic**, in particular due to the **production of mycotoxins**. They also present a risk for product quality.<sup>5</sup>

**Yeasts** are **normal micro-organisms** on fresh fruit and vegetables. The majority of yeasts present on fruit and vegetables are spoilage micro-organisms. They are not a source of food poisoning.

Grey mould on onion

The following are examples of acceptable limits to be applied to ready-to-eat food placed on the market:

Mould	10 <sup>4</sup> /g
Yeast	10 <sup>4</sup> /g

### 3.1.4. Animal parasites

The specific hosts of parasites are often animals. However, the hosts can also include humans during the parasite life cycle. Parasite infections are usually associated with eating **undercooked meat products** or ready-to-eat food, but **fruit and vegetables can also be carriers** of some of these parasites. Effective freezing can get rid of this type of parasite in food that will be eaten raw, marinated or partially cooked.

#### □ Protozoa

Protozoa are small single-cell organisms less than a millimetre in size, which can form colonies. They live only in water or damp ground. They are known to cause many diseases such as malaria, certain forms of dysentery such as **amoebiasis**, and **toxoplasmosis**.

The pathogen responsible for amoebiasis is a rhizopod, *Entamoeba histolytica*. It is the only amoeba that is really pathogenic to humans. **Contamination by this amoeba is oro-faecal**, i.e. through ingestion of its cysts present in **soiled water or food**.

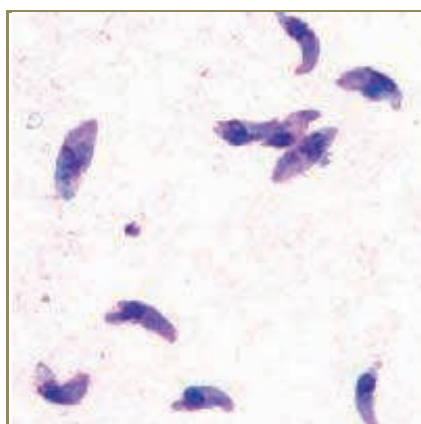
Toxoplasmosis is a parasite infection caused by the protozoan *Toxoplasma gondii*. The parasite usually infects warm-blooded animals, including man, but its definitive host is a felid (including cats). The oocysts are present on **plants or ground soiled by animal**

<sup>5</sup> The health risk associated with the presence of 'mycotoxins' will be developed further in this chapter.

**droppings** (cats in particular). From there, they can contaminate food, hands or drinking water and then be ingested. The presence of cysts in **meat** is frequent: 80 % of adult small ruminants are contaminated, while pork is generally contaminated in less than 40 % of cases. Other animal species can all be contaminated, but the extent is not known. When meat is eaten raw or undercooked, the cysts are not destroyed and develop in the host organism. In the case of an infection during pregnancy the risk is greatest to the foetus and the effects are particularly serious if the infection occurs during the first two months of pregnancy.



Photo of an amoeba



Tachyzoites of Toxoplasma gondii

**Lamblia** is an infection (due to *Giardia intestinalis*, also called *Giardia lamblia*) that often goes unnoticed. However, the parasite that causes it is one of the most frequent in Europe, especially among children. It is a major oro-faecal disease, probably the most widespread intestinal parasitosis in the world. It is a frequent cause of **travellers' diarrhoea**.

#### □ Intestinal worms<sup>6</sup>

Dozens of different types of worms and the other intestinal parasites that infest humans are present in every country in the world. They are more frequent, however, in tropical and sub-tropical regions and are widespread during the rainy season. Parasitic diseases caused by roundworms or nematodes that live in human intestines are called *intestinal helminthiases*.

The eggs of these parasites are introduced into the human system **through food or water** (e.g.: fruit and vegetables soiled by impure water). Food soiled by earth or washed with non-potable water therefore represents a major source of contamination from intestinal worms.

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<sup>6</sup> Other parasites that go through the skin, such as bilharziasis (schistosoma worms) found in stagnant waters in Asia, Africa and South America, or the larvae of ankylostoma, which penetrate the skin, will not be considered here.



The transmission of intestinal worms to man is due to **poor hygiene conditions**:

1. A person infected by the parasite contaminates the environment by **excreting stools** in nature that contain worm eggs. The soiled ground and plants are contaminated by the parasite eggs.
2. Other people become infected by eating food soiled by the excrements or through touching food with soiled hands.
3. In individuals infected by the parasite, the eggs or larvae develop into adult worms that produce large numbers of eggs, which in turn will be excreted.

The most widespread infections of this type in the ACP countries are:

- ▶ ascariasis, caused by roundworm;
- ▶ trichocephalosis, caused by whipworm (*Trichuris* sp.);
- ▶ ankylostomiasis, caused by hookworm.

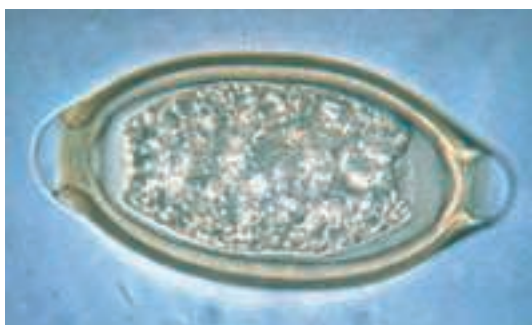
There are many others, however, and we describe below the main characteristics of the parasites encountered most often.



Roundworm (*Ascaris lumbricoides*) is a parasite that causes ascariasis.

**Roundworm** lives in the intestines of humans and animals and can grow to a length of 17 centimetres. It is transmitted through soiled water or **poorly washed fruit and vegetables**.

*Ascaris lumbricoides*



**Trichocephalosis** is a parasite infection caused by the nematode *Trichuris trichiura*. It is more frequent in warm and damp regions, and in areas where **untreated human faecal matter is used as fertiliser**. Contamination is oral, and caused by ingestion of fertile eggs that soil hands or food or pollute drinking water.

*Egg of the Trichuris trichiura nematode*

**Pinworms** are small white worms measuring around one centimetre long and found **in the ground**. Children, who place their hands on the ground and come into contact with the eggs of these parasites, are infested much more often by intestinal worms than adults, because they then touch their mouths and the eggs enter the body. The parasites develop in the intestine and during the night the females migrate to the anus. They lay eggs, which causes the itching typical of this infection. Eggs are also found in underwear, bedding and even on the floor. If the child scratches himself and then touches his mouth,

the contamination continues and the parasites can be transmitted to other family members.

The worms can cause an inflammation of the intestines and lungs, nausea, vomiting, major weight loss and fever. In some cases, the parasites can cause intense itching in the area around the rectum. Most of these parasites are not serious for people in good health, but some can have after-effects, particularly when they develop in the brain or lungs. Among immunodeficient individuals, such as AIDS patients, the parasites can be fatal.

To be complete, we will mention other parasitic worms that can be found in food, but **only in meat**.

*Trichinella spiralis* or **threadworm** is a parasitic worm (nematode) that causes trichinosis in man and in many mammals. The worm can develop in the small intestine and its larvae then migrate to the muscles where they encyst. Humans can be infected by eating the parasite-infested meat of pigs, warthogs or any other mammal.

Fish and meat can also be infected, with **tapeworm** for example. This parasite (Cestode) attaches to the intestines of pigs and cows using its hooks. It is made up of a series of rings that enclose highly resistant eggs that will develop into worms. In cows and pigs, tapeworm can encyst in muscles. Humans can therefore be contaminated by eating **raw or undercooked meat**. Three months later, the first rings are excreted in the stools, a process that can continue for years!

## 3.2. Origin and nature of physical risks

### 3.2.1. Origin and gravity of physical risks

Physical risks, which seem to pose fewer problems than chemical and biological risks, can nonetheless have a serious impact on consumers' health when caused by hard, cutting or sharp objects. They also result every year in a significant number of product withdrawals and recalls.<sup>7</sup> Foreign bodies have also become the leading source of consumer complaints in the agri-food industry.

The origin of physical risks is the **unintentional presence** in a food product of either a foreign body (e.g.: metal fragments in minced meat) or of natural objects (e.g.: fish bones, bits of mussel shells, bone shards in salami, hard bits in packs of potato crisps, etc.) that are dangerous to consumers. A food can be contaminated by such agents at any stage of the production or packaging process.

*Example of a recall notice (translated from the AFSCA (food safety authority) website, Belgium, 2009):*



**Press release**  
**Londerzeel, 17 April 2009**

*La William recalls Américaine Maison sauce 650 ml as a precautionary measure.*

*A shard of glass was discovered in a jar. La William asks its customers to return to the place of purchase any 650 ml jars of Américaine Maison sauce bearing the code 19/02/10 1F4A, 19/02/10 1F4B and 19/02/10 1F4C. La William applies the strictest quality and safety criteria and has decided to recall this product without delay as a precautionary measure.*

*La William asks its customers not to consume this product and to return it to the place of purchase. Returned products will be reimbursed. This recall does not concern any other La William products.*

*La William apologises to its customers for this inconvenience*



<sup>7</sup> Many recalls for products sold in jars result from the presence of shards of glass in the product. Such shards can result when the screw thread is crushed during the process of screwing on the cover (excessive twisting due to poor adjustment of the machinery, poor quality glass or a manufacturing flaw in the jar).

The gravity of the occasional danger depends on the **nature** and origin of the foreign body, but also on the consumer's **age and state of health**.

A child can choke more easily by swallowing objects (this type of accident mainly concerns children aged 1 to 3 years. Any object with a diameter of less than 32 mm can go down the windpipe rather than the oesophagus).<sup>8</sup>



Foreign bodies also pose a risk of choking for the elderly or the ill who have difficulty swallowing.

The intrinsic danger of foreign bodies also comes into play: **glass or metal fragments** are the most dangerous because they can cause:

- ▶ cuts in the mouth or throat;
- ▶ injuries to the intestines;
- ▶ injuries to the teeth or gums.

Synopsis of possible health effects:

Dangers	Harmful effects on health
<b>Glass</b>	Cuts, bleeding – can require surgery to find and remove the object
<b>Wood</b>	Cuts, infection, choking – can require surgery to find and remove the object
<b>Stones</b>	Choking, broken teeth
<b>Metal</b>	Cuts, infection – can require surgery to find and remove the object
<b>Insulating material</b>	Choking – long-term effect for asbestos
<b>Bone</b>	Choking
<b>Plastic</b>	Choking, cuts, infection – can require surgery to find and remove the object
<b>Personal effects</b>	Choking, cuts, broken teeth – can require surgery to find and remove the object

<sup>8</sup> Groundnuts cause 50 % of choking incidents among children. Sometimes it is not until weeks later, when the groundnut or other object caught in the bronchial tubes becomes infected, that the tragedy occurs. The foreign body has to be removed as a matter of urgency, but the child dies in 10 % of cases.

The consequences of ingesting a foreign body range from a broken tooth to intestinal occlusion (e.g.: a Belgian girl had to have surgery in 2010 because of a piece of mussel shell attached to the intestinal wall) or perforation of the stomach, which in the most serious cases can be fatal.

### 3.2.2. Most frequent physical risks

The main sources of physical risks in food are as follows:

- ▶ **glass**: frequent sources in food processing establishments are light bulbs and glass containers (jars, bottles);
- ▶ **metal**: frequent sources of metal are fragments from the equipment used (shards, blades, broken needles, pieces of used utensils, staples, etc.). The intensification and modernisation of agriculture is such that the production of fruit and vegetables is increasingly motorised (tractors, grading equipment, etc.). If technical specifications for use, maintenance, hygiene and sanitary conditions are not sufficiently mastered, **machinery** can be a potential source of direct or indirect contamination from foreign bodies: bits of metal, pieces of blades, etc.;
- ▶ **plastic**: frequent sources of hard or soft plastic are: packaging material, gloves worn by employees, utensils used to clean equipment or tools used to remove products stuck to machinery blades;
- ▶ **stones**: field crops, such as green peas or beans, for example, may contain small stones collected during harvest; stones can also come from the establishment's structures and concrete floors;
- ▶ **wood**: splinters from wooden structures and pallets used for storage and transport of ingredients or products;
- ▶ **natural parts** of foods that are hard, sharp, cutting: shards of bone in meat, fish bones, pieces of pits, etc.

In **fresh fruit and vegetables**, physical risks are mainly associated with the presence of **foreign bodies** such as:

- ▶ earth or sand;
- ▶ pebbles (gravel);
- ▶ insects or insect debris, or even certain rodents;
- ▶ pieces of wood (e.g.: splinters from boxes);
- ▶ straw, stems or roots of weeds;
- ▶ glass debris or metal fragments (e.g.: staples, nails, jewellery, etc.);
- ▶ pieces of cardboard, paper, cigarette butts, etc.;
- ▶ bits of bandages or 'grafting' (natural or synthetic locks of hair affixed to natural hair);
- ▶ pest excrements (droppings);

In principle, it might seem difficult to ingest accidentally a foreign body like earth, sand, a pebble or glass debris, because as a general rule fruit and vegetables are washed as part of the packaging process and/or before being eaten.

However, precautions are needed to ensure the product's hygienic and marketable quality. The impact of a foreign body can be more or less serious depending on whether the food is eaten by a child or an adult, a person in good health or an ill person, etc.

### 3.2.3. What are the acceptable limits?

The values considered as 'acceptable' for foreign bodies in food vary from one sector to another, one industry to another and one product to another. The following is an example of acceptable levels for physical hazards:

Physical hazards		
Honey	Insoluble matters < 0.1 % Debris < 500 µm Absence of exogenous elements	Legal standards Customer requirements (tender specifications)
Fruit pulp	Absence of metallic and non-metallic foreign bodies with diameter > 1 mm	Internal requirement (private specification)

In the absence of another source, we can refer to the guidelines of the Food and Drug Administration (FDA, USA) for the presence of hard and sharp objects in food. The FDA states, for example, that there is a physical risk to consumers' health for:

- ▶ hard or sharp objects measuring **7 to 25 mm**<sup>9</sup>;
- ▶ natural parts of food that are hard or sharp (such as shells): these represent a physical risk because consumers can be injured if they are not aware of their presence;
- ▶ hard or sharp objects that have been incompletely removed from food (e.g.: pits in pitted cherries, walnut shells, etc.).

These conclusions are based on the practical experience of the FDA Commission which, from 1972 to 1997, ruled on more than 4000 cases of foreign bodies discovered in food (in most cases, glass or metal). The *Keuringsdienst van Waren* (Netherlands) applies the FDA conclusions. The Dutch inspectorate considers the presence of hard or sharp objects measuring 7 mm or more as an unacceptable risk to consumers. For food for small children or other high-risk groups, the inspectorate applies a limit of 2 mm.

<sup>9</sup> Foreign bodies measuring 7 to 25 mm can be a potential danger to the average consumer in ready-to-eat foods or those which, according to package instructions, simply require reheating, since this operation does not eliminate or neutralise foreign bodies before consumption of the food. Foreign bodies larger than 25 mm are visible enough and are therefore noticed by the consumer. Smaller objects (2-6 mm) are only a danger for people who depend on the care and attention of others for their food and drink; this is the case of small children, the ill and the elderly.

### 3.3. Origin and nature of chemical risks

Food production and processing entails a **large number of chemical hazards**. Chemical contaminants can exist **naturally** in food, **be added to it** during processing (technological additives), **migrate from packaging** or even **form** during cooking (e.g.: acrylamide). In high doses, harmful chemicals are associated with acute food poisoning, and in repeated low doses they can be responsible for chronic diseases such as cancer.

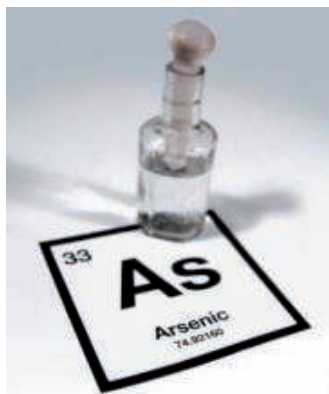
Examples of chemical hazards (Source: FAO Training Manual, 2010)	
<b>Toxic compounds and elements</b>	Lead Zinc Cadmium Mercury Arsenic Cyanide
<b>Natural chemical compounds</b>	Mycotoxins Allergens Scombrottoxins (histamine, in fish) Ciguatoxin Fungal toxins Shellfish toxins
<b>Industrial chemical contaminants</b>	Dioxins and polychlorobiphenyls (PCB) Agriculture products (pesticide residues, fertilisers, antibiotics, growth hormones) Food additives Vitamins and minerals Contaminants (lubricants, cleaning and disinfecting agents, protective agents, coolants, paints, water and boiler treatment agents, rat poison, insecticides)
<b>Contaminants from packaging</b>	Plastic compounds (e.g.: bisphenol A) Banned products: vinyl chloride Label/coding ink Adhesives Lead Tin

European regulations apply to most of these chemical components and limits have been set for amounts that can be contained in food.



### 3.3.1. Risks associated with 'heavy metals'

#### □ Definition and origin of heavy metals



Metals are minerals. The term '**heavy metals**' refers to their **high density** (greater than 5) but this term has no scientific basis or legal application. The main 'heavy metals' are **lead** (Pb), **cadmium** (Cd), **mercury** (Hg) and, to a lesser extent, **chromium** (Cr) and **nickel** (Ni). Following adoption of the *Heidelberg Protocol* (1986), other elements were classified with heavy metals, including arsenic (As, a non-metal), selenium (Sn) and antimony (Sb), or even certain organic compounds that have a significant impact on health. So it is preferable to speak of 'trace elements' or **metallic trace elements (MTE)**.<sup>10</sup>

MTEs found in the environment have basically two origins:

- ▶ **natural origin:** rocks in soil that contain such elements (arsenic, lead, etc.), volcanic eruptions, forest fires and slash-and-burn technique, etc.
- ▶ **human origin:** contamination varies depending on the zone: industrial (or peri-urban), agricultural, urban, or road and motorway zones. The origins of these metals are numerous and varied depending on the elements: air pollution (lead, cadmium, etc.), fertilisers (cadmium, lead, arsenic, etc.), urban sewage sludge (mercury, lead, cadmium, etc.). Lead (Pb) comes from exhaust gases, accumulator batteries (particularly in cars), piping, welded seams, old paints, anti-corrosion paints (red lead) and hunting ammunition. Mercury (Hg) is used for many purposes, including dental amalgams, the extraction of gold and electric batteries. Chromium (Cr) is used as a red pigment and for chromium plating of coins. Zinc (Zn) is used to galvanize steel and in moulded vehicle parts, while nickel (Ni) is used for stainless steel.

Many MTEs are useful in biological processes: iron, for instance, is an essential component of haemoglobin, and zinc and copper are essential trace elements.

#### □ Effects on health

However, their presence in the environment at excessive concentrations poses real problems for public health because they are not degradable and can therefore accumulate in the ground. These heavy metals **can be absorbed by plants or animals** (in drinking water, fodder, etc.) and enter the food chain, producing **chronic or acute effects**:

- ▶ they replace or serve as a substitute for essential minerals;
- ▶ they have an antibiotic effect, which increases bacterial resistance;
- ▶ they produce free radicals and affect our genetic code;
- ▶ they neutralise amino acids used for detoxification;
- ▶ they cause allergies;
- ▶ they damage nerve cells.

<sup>10</sup> In European law, some of these elements are included among 'hazardous substances'.



As a general rule, the unborn, followed by infants and children, are much more sensitive and more exposed to MTEs than adults because they absorb them in much larger quantities.

Saturnism is the name of the condition corresponding to acute or chronic lead poisoning. Absorbing too much lead by eating contaminated products can cause headaches, anaemia, blindness, kidney disease, paralysis and even brain damage. Severe lead poisoning can sometimes be fatal. Young children are most affected by lead because their bodies are small and growing. Lead is absorbed more easily during periods of fast growth.

Cadmium (Cd) is an element that has the property of accumulating in the body and it is toxic to the organism. Chronic ingestion (at small repeated doses over a long time) of cadmium disrupts the functioning of the liver, kidneys and blood pressure and causes pain in the joints.

#### ☐ Accumulation of heavy metals in plants



It has been demonstrated that **plants, both wild and cultivated, are good 'collectors'** of these elements. Certain species have a specific **propensity to accumulate certain elements** present in soil, water or air. Soil pollution clean-up techniques have even been developed on this principle (the MTE is 'trapped' with the aid of specific plants that are then eliminated using controlled processes to clean up contaminated industrial sites, for example).

This property of plants is also used to measure air pollution indirectly through the presence of metallic trace elements.

So it is easy to understand the importance of making sure that toxic elements (such as **lead, mercury and cadmium**), which may be present in soil (industrial use of site) or added to soil (via fertilisers, sewage sludge, settling from the air, fires, etc.), cannot accumulate in cultivated plants. Producers are advised to find out the **history of the cultivated soil**.

**Lead (Pb) and cadmium (Cd)** are two elements that should be **monitored most closely** with regard to **fruit and vegetables** (e.g.: potatoes). These two elements are covered by Regulation (EC) No 1881/2006<sup>11</sup>

The maximum levels for the EU are as follows:

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<sup>11</sup> Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs, OJ L 364 of 20.12.2006. Maximum levels for certain contaminants in foodstuffs such as Pb and Cd.

For lead	Maximum levels (mg/kg fresh weight)
Vegetables (excluding brassica vegetables, leaf vegetables, fresh herbs and fungi. For potatoes the maximum level applies to peeled potatoes).	0.10
Brassica vegetables, leaf vegetables and cultivated fungi	0.30
Fruit (excluding berries and small fruit)	0.10
Berries and small fruit	0.20

For cadmium	Maximum levels (mg/kg fresh weight)
Vegetables and fruit (excluding leaf vegetables, fresh herbs, fungi, stem vegetables, pine nuts, root vegetables and potatoes).	0.050
Leaf vegetables, fresh herbs, cultivated fungi and celeriac	0.20
Stem vegetables, root vegetables and potatoes (excluding celeriac; for potatoes the maximum level applies to peeled potatoes).	0.10



During summer 2006, the European Union's rapid alert system was triggered for unacceptable levels of cadmium in preserved pineapples originating in Kenya. In October, the first lots were taken off the market in Switzerland. Eight samples of preserved pineapples imported from South Africa and sold in Switzerland were contaminated by cadmium. Three boxes from the same lot had cadmium levels of between 0.11 and 0.12 mg/kg, exceeding the limit value of 0.050 mg/kg.

The source of the contamination was probably the **use of a fertiliser** (phosphate) that was overly rich in cadmium. Part of the cadmium, a labile element, migrated from the soil into the fruit.

### 3.3.2. Risks associated with mycotoxins

#### ❑ What is a mycotoxin?

The term mycotoxin comes from the Greek '*mycos*' meaning fungus and from the Latin '*toxicum*' meaning poison. It refers to toxic chemical substances produced by certain moulds that develop on certain foods, in particular on cereals but also on dried fruit and vegetables.

Mycoflora is estimated at between 200 000 and 300 000 species. Moulds (*Fungi imperfecti*) present two aspects (Dupuy, 1994):

- ▶ a **beneficial aspect: the transformation** of food raw material (especially during fermentation), the production of antibiotics, enzymes, condiments, flavouring agents and proteins that can be useful to human health and used widely in the agri-food industry. However, a strain used by the food industry is not necessarily atoxic and can become toxigenic in certain media.
- ▶ a **harmful aspect: the spoilage of food**, since imperfect forms of pathogens cause mycoses, allergies and the production of metabolites (mycotoxins) that are toxic to man and animals. Mycotoxins are **secondary metabolites**, meaning that they are not necessary for the development of the fungus, unlike amino acids, fatty acids, nucleic acids and proteins. Around **360 species** of fungi produce **mycotoxins**: primarily the genera *Aspergillus*, *Fusarium*, *Penicillium*, *Alternaria*, etc. Other genera also include toxigenic species: *Stachybotrys*, *Trichoderma*, *Trichothecium*, *Cladosporium*, *Claviceps*, etc. Around **25 % of foods are contaminated** by mycotoxins, the secondary metabolites of various moulds.

#### ❑ Main mycotoxins<sup>12</sup>

Mycotoxin group	Mycotoxins	Conditions for emergence	Moulds	Substrata
<b>Aflatoxins</b>	Aflatoxins B1, B2, G1 and G2	Tropical and subtropical climates	<i>Aspergillus parasiticus</i> , <i>Aspergillus flavus</i>	Groundnuts Sorghum Spices and condiments Fruit Dried fruit Cereals and cereal products

<sup>12</sup> Mycotoxins are also found in other matrices. For example: Aflatoxins M1 in milk products, mycotoxins in products used in feed, in meat, etc.

<b>Ochratoxins</b>	Ochratoxins A, B, C and D	Damp climates During storage	<i>Aspergillus ochraceus</i>	Maize, rice, cocoa, tea, coffee, spices Flour Dried fruit
<b>Zearalenone</b>	Zearalenone	Ubiquitous moulds	<i>Fusarium</i> sp.	Maize Sorghum Flour Cereals and cereal products Oilseed products
<b>Deoxynivalenol</b>	Vomitoxin (DON) Nivalenol, Fusarenon X (Trichothecene B)	Ubiquitous moulds	<i>Fusarium</i> sp.	Maize Flour Bread and pasta Cereals and cereal products
	T2 toxin, HT2 toxin, Diacetoxyscirpenol (Trichothecene A)			
<b>Fumonisin</b>	Fumonisin	Temperate and warm climates	<i>Fusarium moniliform</i> , <i>Fusarium proliferatum</i> , <i>Fusarium</i> sp.	Maize Flour Cereals and cereal products Bread and pasta

Also worth mentioning are:

- ▶ the mycotoxin that was historically the most widely known in Europe and the world: **rye ergot** *Claviceps purpurea* (rye and other cereals). Thanks to the sorting of seed and the use of fungicides, this cereal disease has almost completely disappeared, although it is still endemic.
- ▶ **patulin**, a mycotoxin that forms during the storage of apples infested by the fungus *Penicillium expansum* and that is consequently found in apple juice.

The same toxin can be produced by different species of fungi but not necessarily by all strains belonging to the same species. Similarly, in some cases, a single species of fungus can produce several mycotoxins.

Ongoing research shows that many other toxins, produced mainly by the genera *Penicillium* and *Aspergillus*, may also come into consideration. The list of mycotoxins continues to grow, but data are usually lacking for serious exposure studies.

#### ❑ Special case of *Alternaria* mycotoxins

*Alternaria alternata* and *A. radicina* are two moulds that can develop on cereals, sunflower seeds, pepper, sesame, olives, different fruits, tomatoes, carrots and celery. These moulds produce various secondary metabolites (alternariol, alternariol methyl ether, altertoxin, radicin, etc.). These metabolites in food can be dangerous to humans. Some have demonstrated embryotoxic and teratogenic effects in mice and hamsters and cytotoxic effects for bacteria and mammal cells. Certain extracts of *A. alternata* are mutagenic for different microorganisms and mammalian cells.



Mould spores. Tomato and pepper infected with *Alternaria alternata*.

For the moment, there are no limits or guide values for *Alternaria* mycotoxins because human exposure through food is limited. Attention should nonetheless be drawn to specific groups of products such as vegetable juices and baby food (made from carrots or apples). Action may be taken in the future if further information suggests a need.

#### ❑ Factors promoting the appearance of mycotoxins

Mycotoxins can appear in different circumstances, for example during **fermentation, processing, refining, removal from storage** of foods, etc. In fact, mould spores often contaminate food that has not been sterilised or pasteurised because one of the common characteristics of fungal species found in foods that are not highly hydrated is sporulation or rapid dispersal.

The development of mycotoxins is closely linked to **conditions in their environment**. The many factors that influence their dissemination can be grouped into two categories:

1. **Biological factors:** the dissemination of mycotoxigenic fungi depends on their infectious potential: some have high sporulation intensity and very long-lived spores that are disseminated faster and more easily than others, through the air (*Aspergillus*, *Penicillium*, etc.) or water. **Mites** or **insects** help disseminate them and alter the natural defences of substrata through the lesions they cause. The local spread of

mould depends on **speed of growth**, which varies considerably from one species to the next. Growth is generally around a few millimetres per day. In terms of nutrition during the growth phase, a mould can encounter competitive fungal micro-organisms such as *Trichoderma viride*, an exclusive species because it does not tolerate the presence of other species,<sup>13</sup> or bacteria, which multiply much more quickly than moulds when they have optimal physico-chemical conditions, especially water activity (Aw).

2. **Physico-chemical factors:** moulds and toxins develop in certain specific conditions of humidity, temperature and gas levels. Each strain has specific conditions that promote its development. **Humidity** contributes to the development of mould on a given substratum. Spores can germinate from a certain degree of **relative humidity of the ambient air**. To survive and continue to grow, however, the mycelium must find **'available water'**<sup>14</sup>. Mould can develop at the usual food storage temperatures (between 0 and 35°C). They need oxygen to develop since they are **aerobic organisms**. Some can nevertheless more or less tolerate partial pressure of low oxygen, high concentrations of carbonic gas, or a combination of the two (a relatively frequent situation in food preservation).

There are also concerns that **organically farmed products** may be more susceptible to contamination by mycotoxins because of the **absence of fungicide protection** (or insecticide for stored cereals). A number of research projects have explored this issue. The findings show that situations and results vary in terms of the type of mycotoxin and the foodstuff. In Belgium, studies have been carried out on levels of **ochratoxin A** (OTA): fairly high levels have been detected in organic products (e.g.: in cereals used to make beer). The same observation has been made for **patulin** in apple juice, suggesting that higher levels can occur in organic products (but only if the apples are stored before being juiced).

**For fruit and vegetables**, there is a **host specificity** for parasite species: *Penicillium expansum* on apples and other pome fruit trees, *Penicillium digitatum* on lemons, *Phytophthora infestans* on potatoes, *Trachysphaera fructigena* on bananas, etc.



Mould due to  
*Penicillium expansum* on apple



*Trachysphaera fructigena* on banana

<sup>13</sup> It is therefore easy to understand why the use of certain fungicides (strobilurins group) that destroy antagonistic flora on cereals during the period close to ear emergence increases the level of mycotoxins on grains.

<sup>14</sup> There is a relationship between water activity (Aw) and the product's water content. Available water is measured by establishing a sorption curve for the substratum concerned. This point will be covered in chapter 4 on preservation of products.

#### ❑ What damage is caused and what are the health risks?

Mould and mycotoxins pose economic problems for grain merchants (poor quality grain, low yield for cereal production), poultry and livestock producers (poor animal performance and diminished reproduction, losses due to disease) and industries that produce feed and food.

Indirect economic drawbacks are the production of unmarketable substances (due to the food's change of appearance, alteration of organoleptic or chemical characteristics), a higher net price for detoxification (protection through fungicides) or destruction when substances are too contaminated. For stock farmers, this implies a higher price for non-contaminated feed or costs to decontaminate feed or treat affected animals. At a global level, this leads to losses estimated at 5 to 10 %.

Mycotoxins only represent a potential risk to human and animal health if absorbed in large quantities. The food safety problem therefore only arises in case of massive infection of cereals, generally due to **poor cultivation and storage conditions**.

#### ❑ Acceptable limits

Since the discovery of aflatoxins in the 1960s, many countries have adopted regulations to protect consumers from the harmful effects of mycotoxins that can contaminate food and also to ensure fair food trade practices. Regulations are based mainly on known toxic effects for the mycotoxins currently considered as the **most significant** (e.g.: aflatoxins, ochratoxin A, patulin, etc.). The European Union set **maximum levels** for mycotoxins in food with Regulation (EC) No 1881/2006,<sup>15</sup> adopted in 2006. Acceptable levels vary depending on the mycotoxin, the mycotoxin group (sum) and the food.

### 3.3.3. Risks associated with residues of plant protection products

#### ❑ Plant protection products and Good Practices<sup>16</sup>



Plant protection products (commonly known as 'pesticides') are used to combat crop enemies and protect harvests.

The products used most often are fungicides, herbicides and insecticides applied by **spraying on the plants** during their growth, or sometimes even after harvest (e.g.: to prevent fruit rot or infection of grain during storage).

<sup>15</sup> Annex (section 2) of Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs, OJ L 364 of 20.12.2006. The annex lists maximum levels for aflatoxins (B1, sum of B1, B2, G1 + G2 and M1), ochratoxin A, patulin, deoxynivalenol, zearalenon, fumonisins and toxins T2 and HT2.

<sup>16</sup> For more information, see PIP Manuals Nos 4 (Toxicity) and 7 (Crop Protection).

Plant protection products used by farmers are available in different 'commercial forms' (referred to as **formulations**: solid – powders, pellets – or liquid – emulsifiable concentrates, aqueous solutions, aqueous emulsions, concentrated suspensions in water or oil). These commercial products contain one or more **active substances** responsible for the product's biological activity and have their own properties.

Before being placed on the market, each commercial product undergoes an **evaluation of its effectiveness and risks**, particularly for the operator, consumers and the environment. The criteria laid down in regulations vary somewhat depending on geographical areas, but the principles and even the evaluation methods are relatively comparable and increasingly convergent.

After evaluation, each product is authorised by law:

- ▶ for a **given use** (crop to which it can be applied, with possible use restrictions or specific application arrangements<sup>17</sup>);
- ▶ at an established **maximum dose** (usually expressed as g or ml/ha);<sup>18</sup>
- ▶ for a **maximum number of applications** to the same crop during the season;
- ▶ for an application in accordance with **given arrangements** (volume/ha, stage, etc.);
- ▶ and with **an interval to be observed between final application and harvest** (PHI: pre-harvest interval, in days).

All these elements, which must be detailed on the product label, make up what is known as GAP or '**Good Agricultural Practices**' (within the regulatory meaning).

The producer's **compliance with GAP** offers a **guarantee** of the treatment's **effectiveness** and the **conformity** of the harvest with established residue standards (MRL – maximum residue limits, in mg/kg food).

In Europe, Regulation (EC) 1107/2009<sup>19</sup> lays down rules for **applications for authorisation to place on the market** plant protection products used in agriculture. **Only products containing one or more active substances shown in an 'approved list' (Regulation EU 540/2011) can be used in Europe and a maximum residue level is set for each active substance for a given crop** (different from the limit of determination).

Authorisation criteria for biocides (products used in the area of hygiene) are detailed in Directive 98/8/EC.<sup>20</sup>

<sup>17</sup> For example, the prohibition on applying the product during the flowering period or after a given stage of crop development, or restrictions on seed treatment, etc.

<sup>18</sup> The dose can be reduced or split up (while respecting the PHI), if authorised by law.

<sup>19</sup> Regulation (EC) 1107/2009 of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309/1 of 24.11.2009.

<sup>20</sup> Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market, OJ L 123/1 of 24.04.1998.



Unlike other chemical compounds resulting from involuntary or accidental contamination (e.g.: dioxins, Bisphenol A, mycotoxins, etc.), residues of plant protection products result from **voluntary introduction of these compounds into the food chain**.

Producers who use chemical products are therefore **particularly responsible for the risks** they can cause to consumers by using an **unauthorised substance** or by **failing to observe the conditions of use** for these products (GAP) laid down by regulations!

#### □ Origin and definition of residues of plant protection products

After application, the amount of the plant protection product that remains on the plant **tends to diminish over time** under the combined effects of the environment and the characteristics of the plant.

This process entails two **phenomena**:

- ▶ **physical dilution** (through plant growth) and **transport** (leaching, volatilisation);
- ▶ **biological and/or physico-chemical transformation**. In the first case, this results from metabolism by the plant itself or of micro-organisms (metabolisation); in the second, photolysis and/or hydrolysis alter the molecule (degradation).

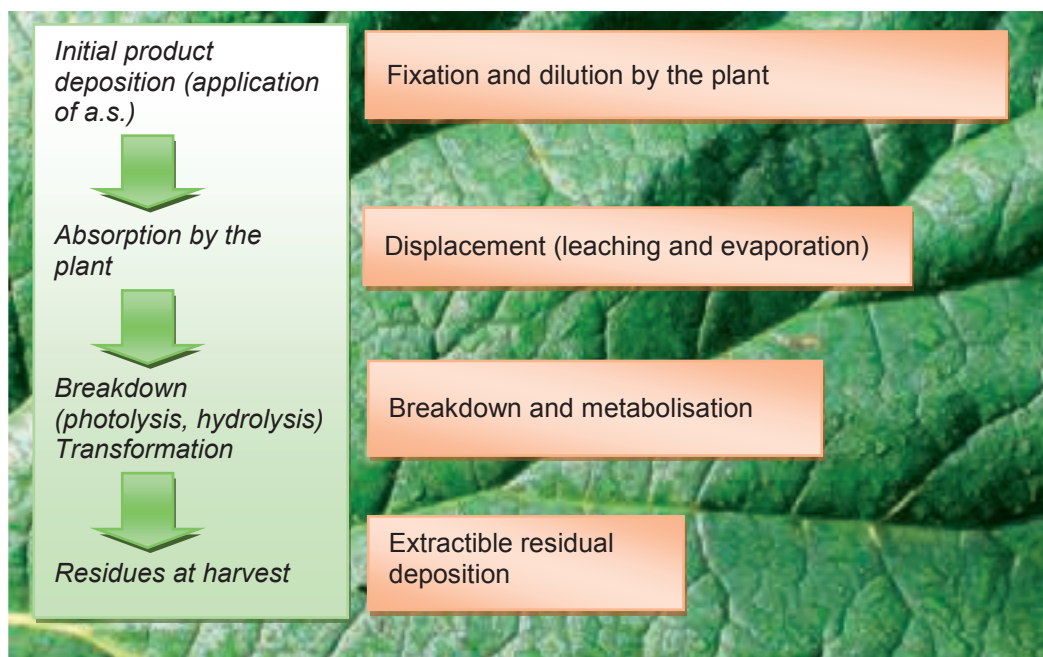


Every active substance, depending on its properties (polarity, solubility, affinity for fats), reacts in its own way with the plant surface. Some of the substance can become affixed to the surface of the leaves upon contact with the cuticular wax, some can penetrate the superficial layers of the cuticle and some can penetrate more deeply, reaching the parenchyma (the internal tissue of leaves) or even spreading throughout the rest of the plant (the 'systemic' nature of the active substance).

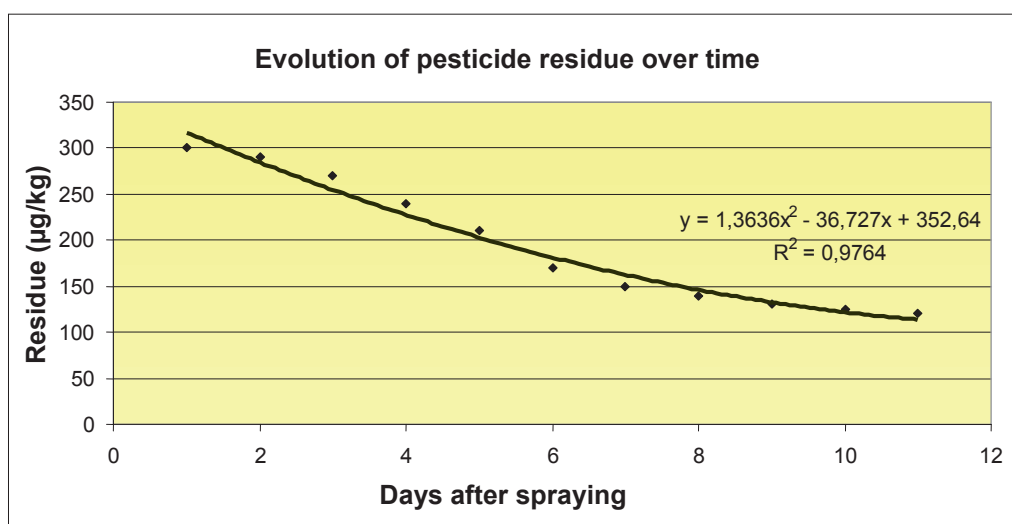
'Residues' from an application **can therefore be either superficial or found on and in the leaves, stems, fruit and even the roots or tubers** of treated plants, even if they are not directly exposed. Residues represent the part of the active substance that can be extracted and measured.

Since the cuticle of every plant has different properties that can vary depending on the stage of vegetation or in terms of the upper or lower leaf surface (the latter contains openings called 'stomata'), it is easy to understand the **complexity of the phenomena involved** and the impossibility of foreseeing the evolution of the active substance (a.s.) that settles on a crop without carrying out tests in different environmental conditions (temperature, rainfall, light, relative humidity, etc.) and growing conditions (density of vegetation, varieties grown, use of fertiliser, irrigation, etc.).

Diagram of the evolution of a plant protection product applied to a crop:



By conducting field trials and **sampling and analysing** the residual deposits at regular intervals, the quantitative evolution can be monitored and the **decay curve** of the residues over time can be determined.



- **Photolysis** and **hydrolysis** are the two main physico-chemical processes responsible for the breakdown of residues (the compounds obtained by these processes are referred to as 'breakdown products' ).

- ▶ **Metabolisation**, the transformation of the active substance through the plant's metabolism action, concerns **penetrating and systemic** substances. By altering the structure of the initial molecules, breakdown and/or metabolic processes contribute to the decay of the initial deposition and can generate new substances with different properties (the compounds resulting from this process are known as '*metabolites*').

The use of active substances can result in the presence of '**residues**' in **treated products**, in **animals feeding on these products** and in **honey** produced by bees exposed to these substances. Regulation (EC) No 396/2005<sup>21</sup> defines 'pesticide residues' as '*residues, including active substances, metabolites and/or breakdown or reaction products of active substances currently or formerly used in plant production products*'.

#### □ What is the definition of 'residue'?

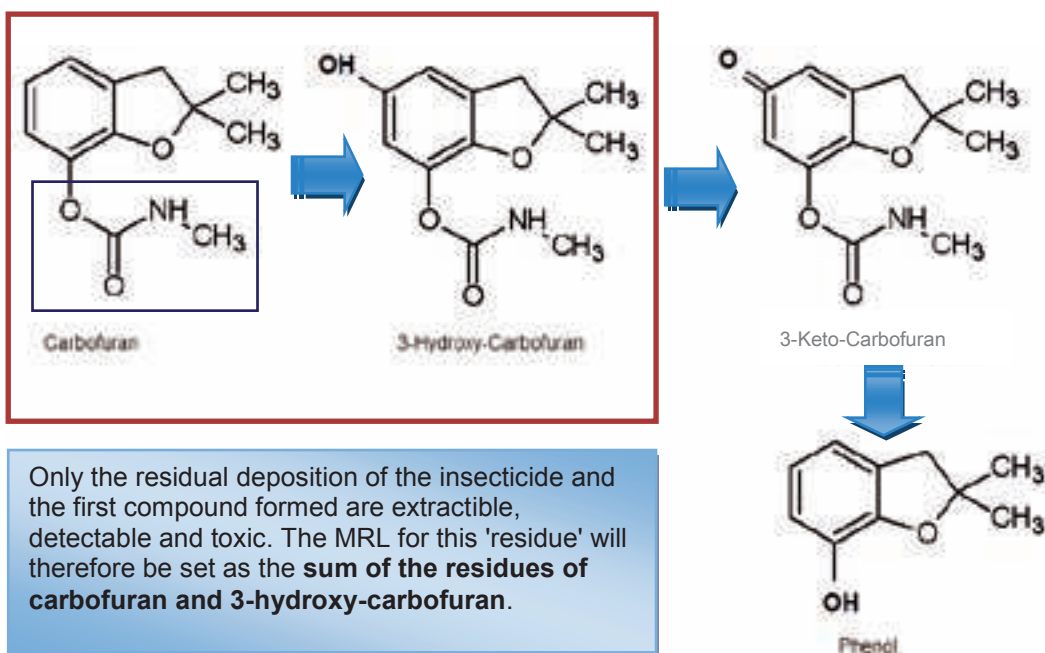
The **definition of 'residue'** in the *Codex Alimentarius* (FAO/WHO) or in European regulations is **limited to the initial molecule and specific derivatives**, such as breakdown products and metabolites **that present a fair degree of toxicological importance**. It does not correspond to the chemical definition, which refers to all breakdown products of the initial molecule or metabolites that form, but that do not have recognised toxicity.

Every active substance has **specific properties**: toxicity, solubility, persistence of action, environmental persistence, photosensitivity, volatility, adsorption capacity, effects on fauna and flora, etc. The same can be said for breakdown products and metabolites that form upon contact with plant substrata. Some of these compounds conserve the chemical groups responsible for the biocide effect (e.g.: the N-methyl-carbamate group, which can interact in the nervous system with acetylcholinesterase), but others do not (e.g.: phenol).

An example is the evolution of a systemic insecticide of the carbamate family: carbofuran (also called 'furan'). Its toxicity (for insects but also for man) is associated with the presence of the N-methyl-carbamate group (outlined in blue in the diagram below) in the molecule. After penetrating the leaf, the molecule is transformed into *3-hydroxy-carbofuran*, then into *3-ceto-carbofuran*. The latter compound is not stable and evolves very quickly to generate a *phenol derivative*.

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<sup>21</sup> Regulation (EC) 396/2005 of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, OJ L 70/1 of 16.03.2005.



□ **What are the risks to consumers' health?**

The risk associated with residues depends on the following **three parameters**:

1. the **toxicity of the residue**: acute and chronic toxicity, severity of the active substance's effects on the organism and possibly of certain of its metabolites or breakdown products;
2. **contamination**: concentration of residues found in food, including drinking water!
3. **exposure**: which depends on consumption (quantity ingested and frequency of the residue in the diet).

Therefore, the **risk of exposure = contamination x consumption.**

The value obtained (estimate) can be compared to a reference toxicological value (scientifically established data).

To estimate the consumer's risk of exposure, two values must be known: the concentration of residues detected in the food (e.g.: results of a laboratory analysis) and the amount of food consumed. For contamination, the average value of the observed result (average residue) can be used, but it would not be accurate to use average consumption to calculate exposure, because some people can consume considerably larger quantities of a food than the average for the population, referred to as large portions (LP).

To cover the risk of exposure for all consumers, it is therefore preferable to use the value corresponding to the 97.5th percentile (P97.5) of the consumption curve.<sup>22</sup>

*Examples for consumption (in g) of a few plant products (Source: Public Health Institute, consumer survey conducted in Belgium in 2004):*

Food	Average	P25	P50	P75	P97.5
Beans	83.4	57	77	103	175
Tomatoes	110.3	88	108	129	178
Bananas	143.9	118	134	160	267
Grapes	144.1	94	129	175	337

As this table shows, some people eat two to three times the average quantities ingested by the population.

There are different types of risks for consumers who ingest the residues of plant protection products used by producers:

- ▶ at **high concentrations**, a risk of acute poisoning exists;
- ▶ at **weak concentrations**, the risk is 'chronic' in nature (repeated exposure to traces of the product).



When the result of an analysis **exceeds the MRL**, a risk assessment must be conducted to check whether the food represents a risk to consumers' health.<sup>23</sup>

**Failure to conform to the MRL does not systematically result in a risk to consumers' health!**

Toxicological risk for consumers (adults and children) must be evaluated through a **calculation** that provides an estimate of the quantity of pesticide residues present in a food that can be ingested by a consumer **in a meal/day**: this is the **PSTI** or *predicted short-term intake*.

Calculation of the PSTI, which is fairly complex, is **detailed in an annex to this chapter**, and an example is given to show that, for the same residue value > MRL, the risk can be different for adults and children.

<sup>22</sup> Unfortunately, there is no reliable consumption survey for the ACP States, which represents an obstacle to a serious estimate of risk for local populations. In the absence of data, we refer to the values of the *GEMS/FOOD Regional Diets*, WHO 2003. This document gives values, for example, for all of Africa, Europe, Latin America and so on.

<sup>23</sup> The analytical uncertainty of the residue value observed should be taken into account to avoid systematically conducting consumer risk assessments for every case of MRL non-conformity. For a result 50 % above the MRL, the only action to be taken should be notification to inform the producer and to request appropriate measures to improve production practices.

The PSTI calculated is compared to available toxicological reference data: acute reference dose (ARfD) or acceptable daily intake (ADI).

### **Reference values for risk of acute poisoning**

**Acute poisoning** from the presence in food of a plant protection product residue is fairly exceptional since in principle residues are residual traces following a treatment applied several days prior to harvest. It cannot be ruled out, however:

- ▶ in the case of plant protection products that present a significant risk of acute toxicity (products with a low LD<sub>50</sub> dose,<sup>24</sup> which act on the nervous system and are persistent). These are usually insecticides, acaricides, nematocides, rodenticides, etc. Most products with a high acute toxicity due to their mode of action have nevertheless been taken off the market gradually and replaced by less toxic products.
- ▶ in the case of short-cycle crops (e.g.: lettuce, leaf vegetables) for which harvested products are eaten fresh (e.g.: if the ARD and/or recommended dose are not respected);
- ▶ for certain groups of particularly vulnerable consumers (e.g.: infants, children – whose body weight is lower than that of adults, making them more sensitive – and consumers of very large portions).

In this case, the **toxicological reference value is the ARfD (acute reference dose)**, expressed as mg of a.s./kg bw/day). ARfD is defined as the estimate of the amount of substances in food (expressed in body-weight) that can be ingested over a short period of time, usually in one day, without appreciable risk to the consumer on the basis of the data produced by appropriate studies and taking into account sensitive groups within the population (children and the unborn).

### **Reference values for risk of chronic poisoning**

**Chronic poisoning** occurs after **prolonged exposure to low and repeated doses**. Certain harmful effects can take weeks or years to be diagnosed and can sometimes prove to be irreversible (e.g.: cancer). The signs of chronic poisoning appear because the poison accumulates in the organism or because the effects caused by repeated exposure accumulate.

For chronic risks, the **reference toxicological value is ADI (acceptable daily intake)**, expressed as mg of a.s./kg bw/day). ADI is defined as the estimate of the amount of substances in food, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable risk to the consumer on the basis of all known facts at the time of the evaluation, taking into account sensitive groups within the population (children and the unborn).

The toxicological reference values ARfD and ADI are set by international bodies: FAO/WHO committees or the European Food Safety Authority (EFSA) for the European Union.<sup>25</sup>

<sup>24</sup> Lethal dose 50. LD50 is frequently used to express acute toxicity. The higher this indicator, the lower the product's toxicity. See PIP Handbook No 4.

<sup>25</sup> These values, and MRLs, are available in the European Commission database (*EU Pesticides Database*, DG SANCO) at the following address: [http://ec.europa.eu/sanco\\_pesticides/public/index.cfm](http://ec.europa.eu/sanco_pesticides/public/index.cfm).

A toxicological risk to the consumer is considered to exist:

- ▶ if the PSTI calculated > ARfD (case where an ARfD value has been set for an active substance);
- ▶ if the PSTI calculated > ADI and if the risk is confirmed after consultation with a toxicologist in case where an ARfD has not been set for an active substance).

#### ☐ Acceptable limits

To ensure that residues of plant protection products do not present unacceptable risks to human beings and, where appropriate, to animals, **acceptable limits** for these residues or **MRLs have been set by regulations** for each pesticide and each foodstuff.

They have been set **at the lowest reasonably achievable level compatible with 'Good Agricultural Practice'**, in order to protect vulnerable groups of consumers such as children and the unborn.

MRLs are standards that have the **dual aim** of:

- ▶ protecting consumers' health;
- ▶ monitoring compliance with recommended Good Agricultural Practice (use of correct dose, respect for ARfD, etc.). Non-conformity with these practices can lead to illegal residue levels that make the product non-compliant.

It is **prohibited to place on the market** foodstuffs containing: residues of unauthorised plant protection products (no MRL) or residues at levels above established MRLs.



*MRL values applicable to plant protection products<sup>26</sup> exist for unprocessed and processed food (e.g.: juices, jams, oils, etc.), for straw, fodder and animal feed, and for meat (animals that feed on plants), honey, milk fat, eggs, etc. They take into account the **transfer of residues from plants to animals**.*

For processed food for which no MRL exists, the level of pesticide residues may not exceed the MRL set for the unprocessed basic food, taking concentration or dilution into account. For mixed foods, the residue level may not exceed the maximum level authorised for the individual unprocessed foods contained in the mixture, taking account of their proportion in the mixture.

A number of countries (USA, Russia) and international organisations have set MRL values in line with these principles. The most important for ACP trade are the values set in the *Codex Alimentarius*<sup>27</sup> and the European Union's values.

<sup>26</sup> Values also exist for residues of medicinal products in food of animal origin. They are set in Regulation (EC) 2377/90.

<sup>27</sup> Available on [http://www.codexalimentarius.net/mrls/pestdes/jsp/pest\\_q-e.jsp](http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp).

The MRL value to be taken into consideration is always the value **applied on the market of destination!**

At European level, **MRL values are harmonised** for the 27 Member States under **Regulation (EC) 396/2005**. In the interest of free movement of goods, equal terms of competition between EU Member States, and to ensure a high level of consumer protection, it was essential for MRLs to be established at EU level while taking account of best available agricultural practices.

### 3.3.4. Risks associated with other chemical contaminants

Apart from residues of plant protection products, **many other chemical products** can contaminate food. Some (such as dioxins, PCBs, polycyclic aromatic hydrocarbons or PAH) come from **air pollution**. They are either natural in origin (e.g.: forest fires, volcanic ash) or result from human activity.

Many other contaminants come from cultivation operations, the use of mechanical equipment, materials used for product transport and packaging, etc. These include: fertilisers, antibiotics and growth hormones (in meat and fish), traces of **lubricants**, residues of **cleaning agents** and **residues of biocides** used to disinfect premises and work surfaces, pest control agents (fungicides, rat poison, insecticides), residues of coolants, paints, water and boiler treatment agents, products migrating from packaging, ink, etc.

Maximum acceptable levels for certain contaminants are laid down in Regulation (EC) No 1881/2006. These include (inorganic) tin in canned foods, 3-monochloropropane-1,2-diol (3-MCPD, a product that occurs during fermentation), dioxins, PCBs, and polycyclic aromatic hydrocarbons.

Considering the huge variety of chemical agents and the complexity of conceivable contamination pathways, operators must conduct a **precise evaluation of chemical risks** on their farm, considering their production processes, machinery used, technical agents used, etc., to determine the possible origin and probability of contamination, and to take appropriate action as needed to reduce or prevent such risks.

The following are a **few examples** of some of the most frequently observed chemical contaminants and their source of contamination:



- Fruit and vegetables can be exposed to **contamination from hydrocarbons**, lubricants and different types of oil from the machinery used for cultivation and sorting operations. **Proper maintenance of engines, apparatus and conveying equipment**, together with an appropriate choice of lubricants and oils, make it relatively easy to prevent contamination of fruit and vegetables from hydrocarbons or oils.



- Fruit and vegetables can contain excessive concentrations of **nitrates** (excessive use of nitrate fertilisers or organic fertilisers). Carefully planned management of fertilisers (for example, fractioning of applications) and organic soil conditioners is needed to avoid the presence of residual concentrations of these products or of their by-products in harvests. Maximum levels of nitrates in certain foods (e.g.: spinach, lettuce) are also set in Regulation (EC) 1881/2006.

- Biocides used to combat pests (insects, rodents) must be authorised for this use (**avoid products intended for agricultural use**). They must never be allowed to come into direct contact with food products. Insecticide treatments must therefore be applied when the packhouse is empty. Bait used to trap rodents must be placed in **closed containers** placed on the ground to avoid all contact.



- **Packaging materials**, such as **ink** used to print information (e.g.: best-by date, lot number), can contaminate the product by 'migrating' (passage of the substance or a fraction of the substance or of a material into the product by permeation through the packaging material). For example, 4-methylbenzophenone from printed cardboard packaging migrated into muesli containing chocolate chips. This substance is a photo-initiator used in UV inks and coatings for package printing. The components of the ink can migrate in various ways through the packaging in the absence of an effective barrier, such as aluminium. In this incident, the 4-methylbenzophenone migrated into the muesli through the external cardboard packaging and plastic packaging (Urgent opinion of the AFSCA, 2009). The nature of the packaging materials that come into contact with food is therefore strictly regulated on the basis of a risk assessment.<sup>28</sup>

<sup>28</sup> Regulation (EC) 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338/4 of 13.11.2004.

- **Cleaning agents** (soaps, detergents) used in a packing station must be **carefully selected**. They leave an invisible 'film' on surfaces that can come into contact with products during sorting and packing. They must be stored in separate premises at the packaging station. Cleaning operations must precede and/or follow sorting and packing operations.



### 3.3.5. Risks from allergens

Most individuals eat a wide variety of foods without running the slightest risk. For a small percentage (around 2 %) of the population, however, specific foods or ingredients can cause secondary reactions ranging from a slight redness to a severe allergic response.

An allergen is a substance that **triggers an allergy**, a set of reactions by the organism's immune system on contact, ingestion or even inhalation in the case of a food allergen. The allergen provokes a chain reaction in the immune system that results in the release of antibodies. These antibodies in turn lead to the release of other molecules, such as histamines, which cause a range of symptoms, from a runny nose to coughing, sneezing or itching. In its most serious form, the allergen triggers an extreme reaction (anaphylactic shock, Quincke's oedema) which leads to respiratory insufficiency and death. An individual suffering from a recognised food allergy must **avoid consuming foods** containing the substance that can cause more or less serious disorders. The list of the main allergens (recognised by law) can be found in the annex to this chapter.

Given the frequency of food allergies and their consequences on health, public authorities have adopted consumer information measures. **Labelling is mandatory** for any product containing allergens and the labels must indicate the presence of any allergens (even if only traces are contained). The ingredient must be shown on the label in the list of ingredients with a clear reference to the name of the allergen. For example, if the recipe for a food product contains **soy lecithin** as an emulsifier, this must be mentioned as such in the list of ingredients: 'emulsifier: soy lecithin', and not as 'emulsifier: lecithin' or 'emulsifier: E322'. **This emulsifier can also be added to waxes used on fruit (apples, citrus fruit, etc.)** to disperse them in water. Another example is wine bearing the statement: 'contains sulphites (sulphite concentration > 10 mg/litre).

Labelling rules only concern ingredients **added intentionally by the manufacturer** to the product recipe. The adventitious presence of major allergens (involuntary contamination from contact with other products on the production chain or during storage or transport) is not impossible. The agri-food industry must therefore **evaluate the risks of cross-contamination** and make every effort to reduce them. Labelling of the type 'may contain traces of ...', or 'may contain ...' are a last resort in cases where it is not possible to control the risk of adventitious contamination.



In the sector of fresh (unprocessed) fruit and vegetables the risk of allergen-related poisoning is low, apart from celery (*Apium graveolens* L.) and celery-based products for which there is a proven risk of allergy. Caution is still needed when producing and marketing **novel foods** (fruit or vegetables not widely consumed, new varieties), since some groups of consumers can show unexpected sensitivity to such products.

### 3.3.6. Risks from processing additives and flavourings

To be complete, we will briefly describe the risks stemming from certain processing additives and flavourings. Although use of such compounds (anti-bacterial substances, preservatives, flavourings) is still limited in the fruit and vegetable sector today, their use is on the rise due to **rapidly changing types of presentation and packaging** of plant products (more sophisticated, raw and ready-prepared fruit and vegetable products).



#### ❑ Food additives and processing aids

Food additives and processing aids are substances **added intentionally** to food at the manufacturing, processing, preparation, treatment, packaging, transport or storage stage to meet certain technical functions, for example, to colour, sweeten, improve the appearance of or preserve the product.

Food additives are defined in Regulation (EC) No 1333/2008<sup>29</sup> as '*substances that are not normally consumed as food itself but are added to food intentionally for a technological purpose such as the preservation of food*'. Substances not consumed as food but used intentionally in the processing of foods, which only remain as residues in the final food and do not have a technological effect in the final product, are processing aids.

**Food colourings, preservatives, emulsifiers**, thickeners, stabilisers, gelling agents, flavour enhancers and sweeteners are food additives.

The following are examples:

- ▶ antioxidants and preservatives: sodium, potassium and calcium benzoates, benzoic acid and other benzoates. Products used to prevent the oxidation of oils and fats

<sup>29</sup> Regulation (EC) No 1333/2008 of 16 December 2008 on food additives OJ L 354/16 of 31.12.2008.

used in pastries, broths, dried fruit, etc. Nitrites and sodium nitrate used mainly to preserve processed meats (all prepared meat products) and in certain cheeses. Sulphites (sulphur dioxide, sodium disulphite, potassium disulphite, sulphur dioxide) found in wine, lychee pulp, cider, beer, molasses, frozen fruit juice, etc.

- ▶ artificial sweeteners: acesulfame K (acesulfame potassium), aspartame, etc.;
- ▶ taste modifiers (monosodium glutamate, used to enhance the taste of Chinese dishes);
- ▶ colouring agents: amaranth, erythrosine, cochineal A, tartrazine, chrysoins S, etc.
- ▶ emulsifiers (e.g.: lecithins, fatty acids, morpholine,<sup>30</sup> etc.) **used to disperse waxes in water** and to facilitate the processing of fruit, etc.

Certain additives are **hazardous to health** (in certain conditions benzoate can produce benzene, allergic reactions, hyperactivity in children, endocrine disruption, anaemia or cancer) or **can be transformed in the organism** (e.g.: **nitrates** are transformed into nitrites, which form nitrosamines, carcinogenic compounds). They are consequently strictly regulated (prohibition or maximum authorised concentrations). Food additives are only authorised if:

- ▶ there is a technological need for their use;
- ▶ their use does not mislead consumers;
- ▶ they do not pose a safety concern to consumers' health.

The use of food additives must always be shown on the food package label by category (antioxidant, preservative, colouring agent, etc.) with their name or 'E number'. Labelling requirements for additives in food and additives sold as such to food producers and consumers are laid down in EU legislation (Directive 2000/13/EC, Regulation (EC) No 50/2000 (Food Labelling) and Directive 89/107/EEC).

## □ Flavourings

**Flavourings** are substances used to impart taste and/or odour to foods. European legislation defines different types of flavourings, such as natural, nature-identical and artificial flavouring substances, flavouring preparations extracted from vegetable or animal materials, process flavourings that enhance taste after heating and smoke flavourings.

Regulation (EC) 1334/2008<sup>31</sup> contains the definition of flavourings, and sets out general rules for their use, labelling requirements and maximum levels for substances that raise concerns for human health. The latter substances occur naturally in the flavouring source materials (herbs, for example) and are therefore also present in the flavouring preparations. It is prohibited to add these substances as such to food. The word 'flavouring' must be shown in the list of ingredients on the packaging of foods containing flavourings.

<sup>30</sup> Morpholine is added to certain waxes used to coat apples. It is usually added to the wax in the form of morpholine oleate. This substance dissolves and spreads the wax, making it possible to apply the coating in liquid form (water-based). When the wax is dried with hot air, the morpholine residues evaporate and only traces remain. Its use is authorised in South Africa, the USA and Canada, but not in the EU.

<sup>31</sup> Regulation (EC) 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) 1601/91, Regulations (EC) 2232/96 and (EC) 110/2008 and Directive 2000/13/EC, OJ L 354/16 of 31.12.2008.

## 3.4. Emerging risks

### 3.4.1. Definition of the concept of emerging risk

According to the definition proposed by the EFSA (2006), '*an emerging risk is a problem that may pose a risk to the food chain in the future*'.

Emerging health risks are related to:

- 1) significant exposure to a **hazard not recognised** previously as relevant in the context of food chain safety;
- 2) **higher exposure to a known hazard** (referred to as a re-emerging risk);
- 3) **increased sensitivity** of the population to a known hazard.

In Europe, the EFSA is obliged by Article 34(1) of Regulation (EC) No 178/2002<sup>32</sup> to establish monitoring procedures to systematically search for, collect, collate and analyse information and data with a view to the identification of emerging food risks.

Emerging risks projects have been organised<sup>33</sup> and **international networks of experts** and information systems have been set up on this topic.<sup>34</sup> The European Commission's RASFF – Rapid Alert System for Food and Feed – celebrated its 30<sup>th</sup> anniversary in 2009. Its annual report and the nature of the alert messages issued each year give an overview of the emergence of new forms of risks.



#### Significant exposure to a hazard not recognised previously

- ▶ Progress of science and knowledge:
  - Acrylamide (which forms in fried potatoes and in biscuits during cooking).

<sup>32</sup> Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L31/1, 1.2.2002.

<sup>33</sup> EMRISK is an EFSA project to develop an emerging risk identification system (ERIS) providing tools for the detection of emerging risks. The project involves assessors from many European countries.

<sup>34</sup> To mention a few: OIE -World Animal Health Information System international, WHO/GOARN - Global Outbreak Alert and Response Network, GPHIN - Global Public Health Intelligence Network, IFSS (Food Surveillance System), USDA/APHIS -Center for Emerging Issues, EPA/ORD Research on environmental futures including emerging pollutants (USA), INFOSAN (WHO, International Food Safety Authorities Network), and of course the European Commission's RASFF - Rapid Alert System for Food and Feed .

- Benzene (which forms in soft drinks).
  - T2 and HT2 toxins in food and feed.
  - Migration of packaging residues (plastic monomers).
- ▶ New production methods:
- Use of benzoate, which can generate benzene, as a preservative in soft drinks.
  - Microbial decontamination of plant products using chlorine derivatives (hypochlorite).
  - Irradiation of packaging materials by gamma rays.
  - Behaviour of packaging materials in microwave ovens.
- ▶ Entry into the food chain of industrial chemical products and other substances:
- Perfluorinated substances (PFOS, PFOA).
  - Polybrominated compounds (PBDE).
  - Organotin compounds.
  - Phthalates (from plastic).
- ❑ **New or higher exposure to a known hazard**
- ▶ New exposure to a prohibited compound due to:
- Fraudulent use (azoic colouring matters in chili powder, nitrofurans and malachite green in aquaculture products, melanin in pet food or milk powder contamination of milk in China).
  - Accidental contamination of products (by pesticides, fertilisers).
  - Environmental contamination (presence of DDT detected in eggs from free-range hens, malachite green in fish, traces of aldrin (insecticide) in farmed salmon, etc.).
- ▶ Higher exposure to a known hazard due to:
- Change in dietary habits (toxins and contaminants in food supplements, preparations made from plants and spices, etc.).
  - Change in the level of contaminants in specific foods (aflatoxin in Hungarian peppers and Italian maize (polenta), etc.).
- ▶ Unexpected exposure to a known danger due to:
- Contamination during the production process (dioxin in gelatine and fats due to HCl and dioxin contamination of feed through contamination of clays, etc.).
  - Cross-contamination (allergens in specific foods, veterinary medicines in feed, etc.).
  - Environmental contamination (heavy metals and dioxins in food due to industrial activity; PCBs, dioxin and other environmental contaminants in eggs, fish, etc.).
- ▶ Increased sensitivity of the population to a known hazard
- Allergy to celery, lactose intolerance, etc.

In fruit and vegetable production, **emerging chemical risks (pesticides, biocides or mycotoxins not yet regulated)** need to be considered.

In some cases, these are **re-emerging chemical risks**. Problems are seen as re-emerging when the toxin is already known but poses new problems as a result of its detection in new matrices, changes in cultivation practices, climate change, the development of international trade, etc.

Kleter *et al.* (2006) also mention **pesticides of natural origin**, which can include plant extracts of microbiological origin (e.g.: viruses, bacteria, antagonistic fungi), as a standard case of 'emerging chemical risk' (ECR).

### 3.4.2. Classification of Emerging Chemical Risks (ECR)

Emerging Chemical Risks can be categorized as follows, for clearer understanding:

- ▶ Means of entry into the food chain:
  - Natural toxins (plants, fungi, marine, bacterial, etc.).
  - Pesticides, medicines, unauthorised colouring agents and additives.
  - Environmental contaminants (heavy metals, dioxins, PCB, brominated and perfluorinated compounds).
  - Contaminants associated with processing, food preparation, packaging (acrylamide, furans, benzene, semicarbazide, etc.).
  
- ▶ Toxicological mode of action:
  - Carcinogens and genotoxic substances (aflatoxins, polycyclic aromatic hydrocarbons, azoic colours, furans, alkyloxy-benzoate compounds, etc.).
  - Endocrine disrupters (medicines with hormonal effects, certain pesticides and environmental contaminants (dioxins), plant micro-constituents (polyphenols), etc.).
  - Allergens.
  - Other (nephrotoxic and hepatotoxic substances, immunosuppressants, etc.).
  
- ▶ Type of risk:
  - Acute risk: plant toxins, phycotoxins, allergens (e.g.: marine algae in oysters)
  - Chronic risk: endocrine disrupters, carcinogenic products, bio-accumulating products, etc.
  
- ▶ Type of factors that can influence the appearance of ECRs:
  - Agri-industrial factors:**
    - Changes in processes involved in agricultural production and food processing and preparation. For example:
      - Variety selection (enrichment in potentially toxic substances (e.g.: solanine); problem of GMOs banned in Europe, soy's anti-nutritional factors).
      - Soil amendment and fertilisation (sewage sludge, cadmium in phosphate fertilisers, etc.).
      - Protection of crops and preserved foods (change in the nature of pesticide residues, botanical impurities, mycotoxins).

- Intensification of aquaculture (risks of accumulation of persistent pollutants, residues of medicinal products, toxins, etc.).
- Intensification of fruit cultivation and horticulture in developing countries (e.g.: intensive use of pesticides for export).
- Non-containment of production branches (GMO, organic) and problem of undesirable residues (e.g.: banned GMOs in food and feed; contamination of organic production by residues of synthetic pesticides; contamination of medicinal plants by toxic wild plants).
- Economic constraints (economic pressure) and risks of more intense use of illegal products (pesticides, antibiotics in eggs imported from India, prohibited colouring agents).
- Use of inferior quality processing aids (contaminated clays, mineral acids, etc.).
- New contaminants produced during a change of process (drying, heating, frying, autoclaving, etc.) and contact materials (packaging, cling films, ink (ITX), glue, etc.);<sup>35</sup>
- Low-sugar and low-salt products (e.g.: risk of spread of mould in light products).
- New waste streams from the agri-food industry and secondary substitution products (e.g.: rapeseed cake, corn gluten feed resulting from the production of bioethanol or biodiesel).

#### **Societal factors:**

- Travel and the craze for exotic and natural products (food supplements made from exotic plants, spices, medicinal plants, consumption of products that are less well known from the toxicological standpoint, such as herbal teas, essential oils, salads made up of different kinds of flowers, etc.).
- Transcontinental trade (e.g.: greater import of seed contaminated by new microorganisms that produce mycotoxins).
- Consumers' limited perception of real risks (preference for 'natural' foods and medicines without considering possible toxicity and contaminants; preference for food supplements to make up for poor dietary habits with a risk of overdose for certain constituents, vegetarianism, etc.).
- Preference for prepared foods (ready-to-eat) with greater risk of problems during processing (cross-contamination, use of inappropriate or secondary ingredients, contamination by products in contact, etc.).

#### **Geo-climatic factors:**

- Introduction of new fungal species as a result of climate change and **greater risk of production of exotic mycotoxins** (e.g.: aflatoxin in Hungarian paprika and Italian maize; OTA (ochratoxin A) in cocoa).
- Increase in periods favourable to the development of cryptogamic fungi (heat and humidity) and increase in contamination of cereal production by mycotoxins (including aflatoxins).
- Introduction of new species of cultivated or wild plants due to climate change, with the risk of new cryptogamic agents (production of mycotoxins) and botanical impurities.

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<sup>35</sup> Use of products categorised as non-food-grade chemicals.



The experts and professionals who analyse risks in a given sector (and who sometimes participate in drawing up a 'Sector Self-evaluation Guide') must take into account the possibility that **processes and practices** will evolve, creating new risks or heightening risks previously considered to be minor.

It is therefore **important to organise monitoring** that is both **regulatory** (because acceptable levels can change) and **scientific** (publication of scientific opinions, studies on the product, project reports, etc.).

## Appendices

### A.1. Calculating PSTI (Predicted Short Term Intake)

According to DG SANCO 3346 & PSD (Pesticide Safety Directorate), the general formula is as follows:

$$\text{PSTI} = \frac{((U \cdot \text{OR} \cdot v) + (\text{LP} - U) \cdot \text{OR}) \cdot p}{\text{bw}}$$

where

- U*: unit (unit weight of the food) in kg  
*OR*: Observed Residue, result of the analysis (in mg/kg)  
*v*: variability factor = 1, 5 or 7 (depending on the weight of *U*)  
*p*: processing factor, generally = 1, for lack of data  
*bw*: body weight of the group considered (adult: 76 kg – child: 14.5 kg)  
*LP*: large portion consumption data for the food in question over a one-day period (97.5<sup>th</sup> percentile) expressed in kg. If no data are available, British consumption data (PSD) or GEMS/FOOD 2003 data can be taken into account.

Value of U	Examples	Formula to be used depending on sampling conditions
U < 0.025 kg	Cereals, strawberries Peppers, cherries	$\text{PSTI} = \frac{\text{LP} \cdot \text{OR} \cdot p}{\text{bw}}$
U > 0.025 kg & U < LP	Apples, oranges Mangoes Tomatoes	$\text{PSTI} = \frac{(U \cdot \text{OR} \cdot v) + (\text{LP} - U) \cdot \text{OR} \cdot p}{\text{bw}}$
U > 0.025 kg & U > LP	Watermelons Pineapples Melons	$\text{PSTI} = \frac{\text{LP} \cdot \text{OR} \cdot v \cdot p}{\text{bw}}$

#### Comments:

The samples analysed are composite samples. A variation can nevertheless exist in the level of residues among single units of the composite sample. This variability of the residues among single units of the food is taken into account by means of a variability factor that reflects the residue level in the single unit compared with the residue level in the composite sample. This factor depends on the food and its unit weight:

- ▶ food with high unit weight (>250 g): v = 5
- ▶ food with medium unit weight (between 25 g and 250 g): v = 7
- ▶ food with low unit weight (≤ 25 g): v = 1

**Processing factors  $p$**  are sometimes set for certain operations (washing, peeling, cooking, etc.). This factor is applied case by case in terms of the pesticide and the matrix and its processing (food eaten raw or cooked, peeled or not, etc.). The default figure is 1, but this factor can be higher or lower than this value (e.g.: for dried fruit or tomato paste, the value of  $p > 1$ ).

**The following example illustrates how the PSTI is calculated and its usefulness.**



In November 2007, the following notice was published further to the results of an analysis carried out in an accredited monitoring laboratory:

*NOTICE (published on the AFSCA (food safety authority) site, Belgium).  
Recall of tomatoes produced by Haesen. 20/11/2007.*

*As a precautionary measure, the tomato producer Rudy Haesen, based in Rummen, asks consumers not to use the following product: 612 kg of tomatoes packaged in bulk in 102 cases weighing 6 kg each, bearing the lot number (producer number) 10398 and registration number 34.884.*

*This lot of tomatoes was placed on the market during the period from 05/11/2007 to 12/11/2007 inclusive. The retailers concerned have been informed and asked to display this notice prominently in their sales area. A laboratory analysis revealed that this product contains an excessive level of residues of ethephon, a product that fosters ripening. Consumption of these tomatoes is not recommended.*

The risk analysis gives the following results:

- The tomatoes contain an average concentration of 3.5 mg/kg. The use of ethephon on tomatoes is authorised and the MRL is 1 mg/kg. The producer failed to follow the PHI, which explains the non-conformity with the MRL.
- The EFSA has set an ARfD value for ethephon at 0.05 mg/kg bw/day.
- The average weight of a tomato is 85 g. The 97.5th percentile consumption is 283 g. The processing factor is 1 because the food may be eaten as such.

Does this residue present a risk for adult consumers?

The PSTI can be calculated as follows (for adults):

$$PSTI = \frac{(0,085 * 3,5 * 7) + (0,2830 - 0,085) * 3,5 * 1}{76} = 0.0365 \text{ mg/kg bw/day}$$

The PSTI calculated therefore represents 73 % of the ARfD.

**Conclusion:** there is no risk for adult consumers. However, for a young child with a body mass of 14.6 kg, the PSTI represents 380 % of the ARfD! So there is a real risk for the group of young children.

## A.2. List of allergens and allergenic substances

The list of allergens is revised periodically in terms of scientific assessments. The list includes the following (source: DGCCRF, Directorate-General for Competition, Consumption and Fraud Repression, France - 2010):

- ▶ Cereals containing gluten (wheat, rye, barley, oats, spelt, kamut and their hybrid strains) and cereals-based products, apart from:
  - glucose syrups produced from wheat, including dextrose;
  - maltodextrine produced from wheat;
  - glucose syrups produced from barley;
  - cereals used to produce distillate or ethyl alcohol of agricultural origin for spirits and other alcoholic beverages.
- ▶ Crustaceans and crustacean-based products.
- ▶ Eggs and egg-based products.
- ▶ Fish and fish-based products, except for fish gelatine used as a base for preparations of vitamins, and carotenoids or isinglass used as a clarifying agent in beer and wine.
- ▶ Groundnuts and groundnut-based products.
- ▶ Soy and soy-based products, except for:
  - fully refined soy oil and fat;
  - natural mixed tocopherols;
  - phytosterols and phytosterol ester derived from soy vegetable oils;
  - phytostanol ester produced from sterols derived from soy vegetable oils.
- ▶ Milk and milk products (including lactose), except for:
  - whey used to produce distillate or ethyl alcohol of agricultural origin for spirits and other alcoholic beverages;
  - lactitol.
- ▶ Nuts (almonds, hazelnuts, walnuts, cashews, pecans, macadamia nuts, Brazil nuts, Queensland nuts, pistachios and products made from these nuts), except for nuts used to produce distillate or ethyl alcohol of agricultural origin for spirits and other alcoholic beverages.
- ▶ Celery and celery-based products.
- ▶ Mustard and mustard-based products.
- ▶ Sesame seeds and sesame seed-based products.
- ▶ Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/l (expressed as SO<sub>2</sub>).
- ▶ Lupin and lupin-based products.
- ▶ Molluscs and mollusc-based products.

Certain ingredients and substances have been given a temporary exemption pending the results of scientific assessments. The allergenicity of the following nine substances and ingredients has been confirmed:

- ▶ lysozyme (produced from eggs) used in wine;
- ▶ albumin (produced from eggs) used as a clarifying agent in wine and cider;
- ▶ fish gelatine used as a flavour carrier;
- ▶ milk-based products used as clarifying agents in wine and beer;
- ▶ essential oil of celery leaves and seeds;
- ▶ celery seed oleoresin;

- ▶ mustard essential oil;
- ▶ mustard seed essential oil;
- ▶ mustard seed oleoresin.

These nine substances must therefore be mentioned on food labels.