Food safety in the dairy chain

I. Hygiene at the core of our business

The dairy sector has a long tradition of guaranteeing and improving the quality of its products, including from a food hygiene perspective. With regards to wishes for more transparency and information, and to allow a better understanding of the tremendous work and effort behind the scenes for the high level of food safety achieved in the EU today, we are happy to present herewith the food safety approach of the dairy sector - how farmers and operators in the dairy chain work to ensure that every dairy product meets the highest standards of quality and safety. The main purpose of this fact sheet is to do so by providing an overview of the food safety system in the European Union with a focus on dairy, starting with good agricultural and manufacturing practices to proceed with a summary of the relevant EU legislative framework, control activities, risk management procedures, and conclude with shortly presenting the European Rapid Alert System for Food and Feed (RASFF).

Definition of ‘food hygiene’ in the EU

Food hygiene, hereinafter called ‘hygiene’, means the measures and conditions necessary to control hazards and ensure fitness for human consumption of a foodstuff considering its intended use (Reg. 852/2004).

CODEX Alimentarius definitions

- **Food hygiene**: all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain
- **Food safety**: assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use
- **Food suitability**: assurance that food is acceptable for human consumption according to its intended use

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II. Why the system functions well

Food safety is the result of the compliance with legal requirements in terms of food and feed hygiene and of industry’s own checks. In the dairy sector, all these requirements and principles have been in application for decades and are updated on a regularly basis.

The key attention with regards to food safety is based on the idea that during the process of the production (from raw material till end product) every food business operator takes care of their part of the chain, to confirm a safe product ‘from grass to glass’ (this stepwise approach is the base of traceability, see page 13).

What is a risk-based food safety management?

Food business operators (FBOs) must guarantee the safety and quality of their products with a transparent, scientific and documented approach: a risk-based food safety management allows all aspects of a food safety system, from farm-to fork (raw material, food processing, consumer behaviour...), to be taken into account, ensuring that the combined efforts of all FBOs along the food chain provide safe and suitable dairy products rather than separating responsibility for any particular component of the chain [1].

For this food safety management, the dairy industry has in place high quality infrastructure, e.g. internal laboratories for regular tests and specially trained staff.

An important element of such infrastructure is the traceability of raw materials and products across the entire chain, which allows to tackle problems quickly and effectively as soon as they arise. To this end, the contacts along the chain are in close cooperation since many years.
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Good agricultural and manufacturing practices (GAPs and GMPs)

Both on farm and manufacturing sites, there is a maximum effort to protect the product safety and quality and hence the reputation of the dairy sector as such. This translates into huge efforts at the raw milk production and manufacturing sites, e.g. cool chain for products requiring chilled storage.

It is not only the final product safety that is guaranteed, but legislation demands certain standards at agricultural and manufacturing sites. These GAPs and GMPs go much further than many rules in other parts of the world.

Appropriate feed is the starting point in the dairy chain, and a very important one, as it contributes to good milk production and overall quality by preventing contamination of the milk. In addition, strict quality requirements apply to all water sources. At farm level, milk producers also pay special attention to hygiene on milk production holdings, animal health, prudent use of medication such as antibiotics, milk equipment, milk production and storage. Then, raw milk must be safely transported from the farm to the dairy factory. There, it is usually heat treated, such as pasteurised or sterilised, and processed into a range of healthy and sustainable consumer products as well as into ingredients that are used by food, feed, pharmaceutical and other companies, still abiding by the highest quality and safety standards. Moreover, special standards exist both at dairy producer level and manufacturing level.

European Food Safety Principles

- Producers are responsible for the safety and quality of their products.
- Producers must take all necessary measures to guarantee that their product is sound and safe and respect the legal requirements at all stages of production.
- Producers comply with basic common hygiene requirements, possibly further specified for certain categories of food. [2]
III. Relevant legislative framework

Standards for milk and dairy products production are very high across the whole dairy chain. They are based on the European Regulation No. 178/2002 known as the General Food Law (GFL), including:

- **Hygiene rules for production of feed**
- **Hygiene rules for production of food**
- **Specific rules for production of food from animal origin**
- **Regulation No. 2017/625 on Official Controls**
- **Regulation No. 2019/627**
- **Regulation No. 183/2005**
- **Regulation No. 852/2004**
- **Regulation No. 853/2004**

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Overview of European General Food Law

Over the years, the EU has developed a food policy approach and set food safety standards at a very high level of public and animal health protection. This led to the establishment of a general food law setting essential food safety principles. The dairy chain works according to regulations set by the European Union, based on the General Food Law.

The General Food Law (GFL) (Regulation (EC) 178/2002) is the cornerstone of the EU regulatory framework since it covers the entire agri-food sector, i.e. ‘from farm to fork’, and all stages of production, processing and distribution of food and feed. [3]

Precautionary principle:
in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures may be adopted, pending further scientific information for a more comprehensive risk assessment. [4]

This European General Food Law establishes:

- Common definitions (e.g. definition of ‘food’ and ‘food/feed business operator’), objectives, and general principles to underpin national and EU food law
- General requirements mainly addressed to food and feed business operators relating to own controls to check compliance with EU and national food law, food and feed safety, traceability and withdrawals/recalls of unsafe food and feed
- The European Food Safety Authority (EFSA) as an independent body entrusted with EU risk assessment
- The main tools and procedures for the prevention and management of food crises, such as the Rapid Alert System for Food and Feed (RASFF)

Responsibilities in the General Food Law

Operators
- Ensuring that all stages for which they are responsible are carried out hygienically
- Traceability
- Withdrawal of non-compliant food + info consumer
- Information to competent authorities + collaboration

Members States
- Enforcement of food law and Official controls
- Public communication on food safety and risk
Legal requirements for dairy products at farm level

General rules for food production (Reg. 852/2004)

Regulation 852/2004 [5] applies to all stages of production, processing and distribution of food, and to exports. It lays down general rules for food business operators on the hygiene of foodstuffs, considering the following principles:

- Primary responsibility for food safety of the food business operator
- Food safety throughout the food chain
- Maintenance of the cold chain
- Application of good hygiene practice + General implementation of procedures based on the Hazard Analysis and Critical Control Point (HACCP) principles (see page 12)
- Guides to good practice aiding food business operators with compliance with food hygiene rules and with the application of the HACCP principles
- Microbiological criteria and temperature control requirements based on a scientific risk assessment
- Imported foods of at least the same or equivalent hygiene standard as food produced in the EU

Specific rules for production of food from animal origin (Reg. 853/2004)

Focus on Animal Health, on farm hygiene and criteria for raw milk

For the dairy sector, an important area of attention is the safety, quality and composition of the base element of most dairy products: raw milk.

First, safe raw milk of high quality comes from healthy cows, making animal health a top priority. Regulation 853/2004 [6] regulates some animal diseases (brucellosis, tuberculosis) [7] and drug use on the farm, and housing for the dairy herd. Adequate hygiene at milk production holdings is also crucial for safe milk. To prevent milk to be contaminated with dirt or microbes:

...the cow must be kept in good hygienic conditions,

...the dairy farm premises and equipment must be well maintained and sanitised (i.e. milking machine, milking parlour and milking robot),

...and there are also procedures for the disposal of manure, trash and dangerous substances to abide by.

Raw milk is the milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40 °C or undergone any treatment that has an equivalent effect.
In addition, the quality of milk is maintained to the highest standards through proper refrigeration and cooling during storage and transport. Namely, immediately after milking, milk must be cooled immediately to not more than 8°C in the case of daily collection, or not more than 6°C if collection is not daily. During transport, the cold chain must be maintained and, on arrival at the establishment of destination, the temperature of the milk must not be more than 10°C. [7]

With regards to transport, Regulation 853/2004 also sets hygienic procedures for the transport – in specially designed tankers – of raw milk from the dairy farm to the processing plant. In practice, that will encompass pickup and delivery, design, construction, installation and maintenance of milk tankers, cleaning and disinfection, and overall documentation.

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Somatic cells and plates are two types of cells naturally present in any milk, but that multiply heavily in case of illness. The current European legislation requires a maximum of 400,000 somatic cells per ml and a maximum of 100,000 plates for raw cow’s milk with the idea of supporting animal health and welfare via Good Agricultural and Good Manufacturing Practice (GAP and GMP, see page 3) and uses the somatic cell count (SCC) as indicator for that.

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**Chapter I. Raw milk primary production**

**Health requirements for raw milk production**

**The animal:**
- Good general state of health
- No symptoms of infectious diseases communicable to humans through milk
- No udder wound likely to affect the milk
- No use of unauthorised substances or products
- Substances administered: observation of withdrawal periods
- A herd free of brucellosis and tuberculosis

**Hygiene on milk production holdings**

- Requirements for premises and equipment
- Hygiene during milking, collection and transport
- Staff and plant hygiene

**Criteria for raw milk**

- Plate count, somatic cell count and antibiotic residues
Legal requirements for dairy products at processors level

Just like for raw milk production, its processing is also regulated by EU law – namely the General Food Law, the hygiene package and other EU regulations covering a broad range of issues including microbiological criteria and contamination of food, pesticides and veterinary medicines’ residues.

Specific rules for production of food from animal origin (Reg. 853/2004)
Focus on storage temperature, heat treatment, criteria for raw milk, traceability

Chapter 2. Requirements concerning dairy products

Temperature requirements

► Milk quickly cooled to no more than 6°C and kept at that temperature until processed
► Higher temperature allowed under specific conditions (right after milking or for technological reasons concerning certain dairy products)

Requirements for heat treatment

► Compliance with the requirements of Reg. 852/2004 on Hygiene of foodstuffs, HACCP Principles and official controls regulation
► Specific temperatures requirements for pasteurisation and UHT treatment or equivalent combination of time-temperature conditions

Criteria for raw cow’s milk

► Plate count

Inside each dairy company the legislation is translated into specific HACCP plans (see page 12) considering the specificity of each product and production line. If the delay between receiving the (raw) milk and the necessary tests defined in the HACCP-based procedures is exceeded, food business operators manufacturing dairy products must initiate procedures to ensure that, immediately before processing, raw cow’s milk used to prepare dairy products has a plate count at 30°C of less than 300,000 per ml, and processed cow’s milk used to prepare dairy products has a plate count at 30°C of less than 100,000 per ml.
Commission Regulation 2073/2005 [8] on microbiological criteria for foodstuffs lays down:

- Food safety criteria for relevant foodborne bacteria, their toxins and metabolites
- Certain process hygiene criteria

Other hygiene standards like contaminants, pesticides, veterinary drugs...:

- Council Regulation 315/93 [9] laying down Community procedures for contaminants in food
- Regulation 396/2005 [10] on maximum residue levels of pesticides in or on food and feed of plant and animal origin
- Regulation (EU) 2017/625 [12] on official controls
IV. Quality checks for food safety

The first quality check on the milk (antibiotic residues, milk’s smell, colour and temperature) is carried out already at pickup from the dairy farm by specially trained milk tanker drivers. Raw milk is tested for antibiotic residues before processing and will not be processed if the levels exceed the legal restrictions.

The quality checks at the farm and during transport are followed by tests on milk samples collected from milk tankers that are performed by specialised laboratories, looking at contents of milk fat, milk protein and other milk components, cell count, bacterial count, contamination levels, antibiotics, and other parameters, along with in-depth and frequent controls at the manufacturing plant, all under the responsibility of dairy companies.
The EU General Food Law states the primary legal responsibility of the food and feed business operators for ensuring food safety at all stages of production, processing and distribution within the businesses under their control. Simultaneously, Member States are responsible for enforcing EU food law, and monitoring and verifying that food and feed business operators fulfil the relevant requirements. For this purpose, Members States maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution.

EU official control rules are recognised worldwide as an example of best practice. They create a uniform and harmonised framework across Member States, and provides the Commission with audit and control powers in the EU countries and third countries, and with the power to take action at EU level. Controls are performed on the basis of risk for health, and check for chemical and veterinary residues, bacterial/viral contamination, overall hygiene, labelling, proper refrigeration, animal and plant health requirements, animal welfare, and fraud.


Specific rules for official controls on products of animal origin like dairy products, are added step by step as implementing acts, including in Reg. 2019/627 [15], as well as in Reg. 2019/625 [16] with regards to the requirements for the entry into the EU of certain animals and goods.

**Sectors covered by the Regulation N° 2017/625 on Official Controls:**
V. Management of risks by the dairy industry

According to the General Food Law, any food business operator is responsible for the safety of the food imported, produced, processed, or placed on the market. The food operator must control the implementation of the sanitary plan and must be able to prove the good application. By using appropriate records systems, tracing back all incoming materials is ensured. For that purpose, a HACCP system (implying well determined procedures) has been introduced (Reg. 852/2004), or at least the principles thereof depending on certain conditions. Some flexibilities are indeed being foreseen: in certain cases, minimal hygiene requirements should be sufficient to ensure that potential hazards linked to the concerned activity are correctly managed. In such situation, having recourse to guides of good manufacturing practices and applying HACCP principles is recommended.
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Hygiene Guidance developed at national or European level

Our EDA-Eucolait guide on ‘Cheese as raw material’ and ASSIFONTE guide on ‘Hygienic practice for processed cheese manufacturing’ were adopted in February 2018 and published in all official languages of the Union on the EU Commission website. This shows the effort of the dairy industry to establish high standards and transparency. The guidance for ‘Cheese as raw material’ has been developed to guide companies in making decisions in line with hygiene regulations. The collection, handling and preparation of cheese as raw material for other products shall therefore be in full compliance with the general regulatory framework of food and feed safety. The fact that no raw material is lost in the process also contributes to sustainability. In various EU member states, national guides on HACCP and good hygienic practices (GHPs) have been developed and are followed by the dairy sector. Most of these can also be found on the EU Commission website.

The 7 HACCP principles:

**Identify:**
- Hazards
- Critical Control Points (CCPs)

**Establish:**
- Critical limits
- Monitoring procedures
- Corrective actions
- Verification procedures
- Documentation and records

Traceability procedure

Food traceability is an essential element when ensuring food safety. Regulation 178/2002 defines ‘traceability’ as “the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution”, and contains rules to ensure the traceability of food and food ingredients. Dairy establishments should also ensure that all their products placed on the market bear an identification mark (Reg. 853/2004, Annex II, Section I). Via the traceability systems and procedures in place, dairies can identify in ‘real time’ production lots and batches in terms of input and in terms of destination and make this information available to the competent authorities on demand.

Identification marks mentioning the Member State and establishment of the last processing step

Recall and withdrawal procedure

As provided for in Reg. 178/2002, the dairy industry – whenever there is a suspicion that the food safety requirements have not been met – will withdraw the affected product from the market as a precautionary measure, and immediately inform the competent authorities. Where the product may have already reached the consumer, the dairy operator will effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them. It can happen that a dairy plant itself discovers a possible issue during manufacturing, or that the request of recall/withdrawal comes from the national authorities’ control bodies. In this case, traceability (see above) is the key element allowing this action.
VI. European Rapid Alert System for Food and Feed (RASFF)

The European Rapid Alert System (RASFF) is a network for the swift exchange of information relating to food and feed risks, EU-wide or national emergency measures, as well as the establishment of a comprehensive plan for crisis management. [3] It is an inter-Member States tool to alert other national authorities about possible non-compliant food or feed, which can have very diverse reasons. The first RASFF scheme was established back in 1979 to allow to share information on detected food safety issues efficiently between the 28 EU Member States, the EU Commission and the food safety authorities of Norway, Liechtenstein, Iceland and Switzerland.

It assures a 24/7 service to ensure urgent notifications are sent, received and responded to collectively and efficiently. The authorities of affected countries have the responsibility to take the necessary emergency measures, including giving direct information to the public, withdrawing products from the market, and making controls on the ground. [17]

Within the milk and dairy processing industry we deal with a very nutritious and natural, but perishable, ‘raw material’: milk. This increases the number of critical control points within the process – and frequently RASFF notifications are issued by information provided to competent authorities by food operators themselves. Still an alert does not mean that a threat is real; alerts can and should be done in case of suspicion, and often can be closed quite quickly. Food safety issues have become increasingly rare.

While there is no direct link between food safety and food fraud, it may happen that a food safety issue reported through RASFF is the result of fraud. The difference for fraud is the intentional breach of food law to cause harm and/or achieve economic gain. [18]
VII. Conclusion

As highlighted all along this fact sheet, the dairy sector is successfully providing the consumer with products among the safest and highest quality on the market. All actors in the dairy chain contribute to this achievement with their daily work and stay firmly committed to keep doing so in the future by continuing to implement this strong sectorial approach to food safety. The overall concept of ‘Food safety culture’ is in place all along the dairy sector. Such approach – a combination of strict compliance to EU hygiene legislation and often special standards specific to our sector – entails good cooperation across the dairy chain, focus on research and innovation, additional survey and monitoring programs, and ability to address new challenges.

In the EU, consumers can drink and eat delicious and healthy dairy products with confidence knowing that the food safety system in place in the dairy chain is structured to tackle efficiently all risks that might occur in an early stage at every step of the chain, from raw milk production at the farm, collection and transport, until milk processing at the factory. Good dairy agricultural and manufacturing practices complement the EU legislative framework in ensuring that all stages are carried out hygienically, supplemented by control activities by both the dairy food business operators and the competent authorities of each Member State, jointly with an effective communication flow on food safety and risk (from dairy companies and Member States to consumers, and among several Member States’ competent authorities).
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