

CHAPTER XIV

TRACEABILITY AND HYGIENE PACKAGE

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SUMMARY: 1. The concept of “Traceability”. – 2. Food Traceability under EU Law. – 3. Traceability of food and feed in Regulation No 178/2002. – 4. Traceability in EU sector-specific legislation (signally: bovine meat and GM food and feed). – 5. EU Food Hygiene legislation and the “Hygiene Package”: an overview. – 6. Regulation No 852/2004 on Food Hygiene: scope and extent. – 6.1. Food hygiene requirements for primary production. – 6.2. Food hygiene requirements for (other) Food Business Operators. – 6.3. HACCP. – 7. Regulation No 853/2004 on hygiene of food of animal origin. – 8. Regulation No 854/2004 on official controls on products of animal origin. – 9. Regulation No 1831/2003 on feed hygiene.

1. The concept of “Traceability”

The notion of “*Traceability*” can be traced back to some decades ago. It first originated in different fields related to health, space and arming activities, but it has also extended to industrial sectors, including the food industry sector, in the context of the quality system issues.

The first international definition of traceability was provided in 1987 in ISO 8402 standard (and later assumed in ISO 8402:1994 edition), where it was defined as the ability to retrieve history, use or location of an entity [i.e. an activity, a process, a product, an organization or a person] by means of recorded identifications. Later, the concept of traceability was introduced in ISO 9000 series of standards on quality assurance systems as a key element of any quality management product. Under ISO 9000:2005 (now revised by ISO 9000:2015) ⁽¹⁾ traceability means the

⁽¹⁾ International Organization for Standardization, ISO 9000:2005 and ISO 9000:2015, *Quality Management Systems – Fundamentals and Vocabulary*.

“ability to trace the history, application or location of that which is under consideration”; when a product is concerned, the notion signally refers to *“the origin of materials and parts, the processing history, and the distribution and location”*. Afterwards, ISO 22005:2007 ⁽²⁾ specifically referred this concept to the feed and food chain, and defined it as *“all data and operations able to maintain the desired information about a product and its components during a segment or the whole chain of production and use”*.

Similarly, the Codex Alimentarius Commission defines traceability (or product tracing) as *“the ability to follow the movement route of a food product through specified stage(s) of production, processing and distribution”* ⁽³⁾.

Traceability, as intended within the framework of non-mandatory rules and standards set out by international organisations, allows thereby the tracking of a product (both by competent authorities and by business operators themselves) with a view to follow its path from raw materials until exposure for selling, and to the final consumer (Ene, 2013).

In the EU, the discussion about traceability firstly arose in various sector specific legislations. Only at a later stage traceability reached the status of a general principle of food law and became a landmark of the whole EU food safety framework; the idea is that where a problem or safety concern with a particular food or food ingredient is identified, all affected products should be readily recognized throughout all stages of production, processing and distribution, through the use of identification and record system, as well as thanks to communication between operators.

2. Food Traceability under EU Law

Under EU law, requirements concerning food traceability were initially prescribed during the 80s and 90s for several specific products,

⁽²⁾ International Organization for Standardization, ISO 22005:2007, *Traceability in the feed and food chain – General principles and basic requirements for system design and implementation*.

⁽³⁾ Codex Alimentarius Commission, *Principles for traceability/product tracing as a tool within a food inspection and certification system*, CAC/GL 60-2006. See also Codex Alimentarius Commission (CAC), *Procedural Manual*, Twenty-first Edition, 2013.

such as live bivalve molluscs ⁽⁴⁾, food-producing animals ⁽⁵⁾, organic agricultural products ⁽⁶⁾.

Interest in food traceability has then intensified due to various food scares – namely BSE and dioxine crisis – that severely affected many European countries. The BSE scandal stands as a turning point in this perspective: it represented a serious policy failure for the EU and led to the establishment of a more efficient system for the identification and registration of bovine animals at the production stage as well as a specific EU labelling system in the beef sector (para. 4). The aim was to re-establish market stability and consumer confidence in public authorities, industry and science (Ansell & Vogel 2006; Vos 2000).

In the aftermath of the BSE crisis, more generally, the EU decided to carry out an action plan for promoting a comprehensive and integrated approach to the whole food chain (*from farm to fork*). In the *Green Paper on General Food Law Principles* of 1997 ⁽⁷⁾, the European Commission started the discussion on whether further rules on traceability should have been laid down in legally binding instruments, or covered by voluntary instruments. Later, in the *White Paper on Food Safety* of 2000 ⁽⁸⁾, traceability of feed and food has been recognised as a cornerstone of the EU food safety policy. Signally, the Commission advocated the introduction of a general obligation on food and feed businesses to ensure that adequate procedures are in place to withdraw feed and food from the market where a risk to the health of the consumer is at stance.

On this wake, after having been taken into account for years only in the context of sector-based provisions, leaving therefore room for private initiative in several production and distribution chains in the food sector, traceability became mandatory in the EU for all food business operators under Regulation No 178/2002 (*General Food Law*).

⁽⁴⁾ Directive 91/492/EC.

⁽⁵⁾ Directives 90/425/EEC, 91/496/EEC, 92/102/EEC.

⁽⁶⁾ Council Regulation (EEC) No 2092/1991.

⁽⁷⁾ European Commission, *The General Principles of Food Law in the European Union*, COM (97)176 final.

⁽⁸⁾ European Commission, *White Paper on Food Safety*, COM(1999)917 final.

3. Traceability of food and feed in Regulation No 178/2002.

Regulation (EC) No 178/2002 has provided for food and feed business operators, as from 1st January 2005, a new general obligation to ensure that any food and food ingredient, as well as feed, could be traceable along the whole food chain. Traceability stands as a risk management tool aimed at ensuring a high level of food safety, thus representing one of the practical developments of the 'from farm to fork' approach advocated in the White Paper on Food Safety (MacMaoláin, 2015).

The concept of traceability is defined in Article 3(15) of Regulation No 178/2002 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"*.

According to article 18 of Regulation No 178/2002, food and feed business operators must be able to trace any food, feed, food-producing animals and any other substance intended to be, or expected to be, incorporated into a food or feed at all stages of production, processing and distribution. Food businesses must also identify any person or business that has supplied them with any food or ingredient, or to which their products have been supplied. Therefore, they are required to have systems in place which guarantee that this information is made available to the competent authorities on demand ⁽⁹⁾. The way for ensuring traceability is left to the discretion of the businesses concerned. However, one of the best ways of ensuring that a food or feed is traceable is the use of labelling and a system of documentation-information, in accordance with the relevant requirements of more specific provisions ⁽¹⁰⁾.

The primary aim of the mandatory traceability system is therefore to enable the identification of food safety problems at the source, and along the entire food chain, so that affected products can be withdrawn from the market. However, by facilitating products to be identified, traceability also allows the reliability of information supplied to consumers and fair trading amongst operators, playing a role in facilitating attribution of liability to verify labelling claims (Van der Meulen 2014; Alemanno 2007).

⁽⁹⁾ Art. 18(1-4), Reg. 178/2002.

⁽¹⁰⁾ Art. 18(5), Reg. 178/2002.

It should be noted that traceability is conceived as a step-by-step process: information is not required to follow the entire production process and distribution chain through to the market, but it is rather confined to the specific stage of the production concerned. Consequently, mandatory traceability does not necessarily deliver any information to consumers about the products they are buying; it thus differs, in this way, from origin labelling schemes.

A guidance document issued by the Standing Committee on the Food Chain and Animal Health (SCFAH) provides an interpretation of Art. 18, as well as of further pivotal provisions contained in Regulation No 178/2002 ⁽¹¹⁾. The document points out that a traceability regime relies on the "one step back-one step forward" approach: regarded as a supply chain process, traceability can be conducted both forward and backward, establishing respectively a "supplier-product" and a "customer-product" link ⁽¹²⁾. However, EU law does not require food businesses to guarantee an "internal" traceability, establishing a link between incoming and outgoing products within an organization; that is to say that an operator must know where the ingredients came from and where the products went, but not necessarily which ingredients went into which product (Van der Meulen 2014). It is up to food business operators, according to the nature of their activities, to decide whether and how to realize such an internal traceability system.

The guidance also clarifies that Article 18 covers food business operators at all stages of the food chain, from primary production (food producing animals, harvests), to food/feed processing and distribution. Consequently, transporters and storage operators are also required to comply with traceability obligation, as well as, to some extent, charities, while manufacturers of veterinary medicinal products and of agricultural production inputs (such as seeds) do not undergo such obligation ⁽¹³⁾. Likewise, exporters in trading partner countries are not legally required to fulfil the traceability requirement, since the provisions

⁽¹¹⁾ See Guidance on the Implementation of Articles 11,12, 16, 17, 18, 19 and 20 of Regulation (EC) n. 178/2002 on General Food Law, Conclusions of the Standing Committee on the Food Chain and Animal Health (SCFAH), lastly issued in 2010.

⁽¹²⁾ See SCFAH Guidance document, p. 9.

⁽¹³⁾ See SCFAH Guidance document, pp. 10-11.

of the Regulation do not have an extra-territorial effect outside the EU. Food operators concerned with traceability obligation must keep at least information such as name and address of supplier and customer, identification of products supplied or delivered, date and, where necessary, time of transaction/delivery, and finally volume or quantity.

Although it is widely accepted that traceability can contribute significantly in guaranteeing food safety, it is worth noting that the effective implementation of a traceability regime highly depends on the nature of the activity and on intrinsic features of each kind of product concerned, and consequently on costs entailed for businesses ⁽¹⁴⁾ (Borghini 2003).

4. Traceability in EU sector-specific legislation (signally: bovine meat and GM food and feed)

Under EU law, besides the horizontal provisions on traceability required by Regulation No 178/2002, there are several EU normative acts laying down specific procedures and obligations referred to food products for which traceability is considered of particular importance.

Traceability in the beef sector was firstly imposed by Regulation (EC) No 820/97, which reinforced EC rules on the identification and traceability of bovine animals in the light of BSE epidemic. Afterwards, in order to improve transparency in production and marketing of beef, and thus to maintain and strengthen the confidence of consumers, Regulation No 1760/2000 ⁽¹⁵⁾ established a more comprehensive and efficient system for the compulsory identification and registration system of bovine animals, based on tools such as ear tags, computerised databases, animal passports and individual registers kept on each holding. The Regulation also sets out a specific labelling system of beef and

⁽¹⁴⁾ An analysis about the implementation of traceability requirements and their impact on food and feed business operators has been carried under the so called "Fitness Check" of Reg. 178/2002, in the framework of the Commission REFIT Programme, as part of the EU Better Regulation policy. See, specifically, the following link (last accessed on 10 August 2016) http://ec.europa.eu/food/safety/general_food_law/fitness_check/index_en.htm.

⁽¹⁵⁾ Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000, repealing Council Regulation (EC) No 820/97.

beef products, comprising both compulsory and voluntary measures; detailed rules have then been set out in Commission Regulation No 1825/2000.

Recently, Regulation No 1760/2000 has been amended by Regulation No 653/2014 as regards electronic identification (EID) of bovine animals and labelling of beef ⁽¹⁶⁾. According to the new provisions, operators may replace the conventional identification system (i.e. ear tags) with an EID system based on an electronic identifier (in the form of electronic ear tag, ruminal bolus, or injectable transponder), which must be visible and bear an identification code. As for 18 July 2019, Member States are required to introduce national provisions making the use of an electronic identifier compulsory. Furthermore, identification requirements prescribed for animals that are born in the Union apply also to any live animal imported into the EU market from third countries, except for animals destined directly for a slaughterhouse situated in a Member State.

As regards the compulsory labelling system for beef and beef products, a few more information is required (Member State or third country of birth, all Member States or third countries where fattening or slaughter took place, etc.). For beef imported into the territory of the Union, when not all the above-mentioned information is available, it is sufficient to indicate '*Origin: non-EU*' and '*Slaughtered in (name of the third country)*'. Any information voluntary added to the label, however, must comply with Regulation No 1169/2011 on food information to consumers ⁽¹⁷⁾.

Traceability rules are laid down also for GMOs and GM food and feed ⁽¹⁸⁾. Regulation No 1830/2003 ⁽¹⁹⁾ established an harmonized framework for the traceability of products (food or feed) which consist of or contain GMOs, with the aim of facilitating labelling, monitoring the effects on the environment and on health, as well as the implementation of the appropriate risk management measures, including, if necessary,

⁽¹⁶⁾ Regulation (EU) No 653/2014 of the European Parliament and of the Council of 15 May 2014.

⁽¹⁷⁾ See Chapter XIX.

⁽¹⁸⁾ See Chapter XXII.

⁽¹⁹⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council.

withdrawal of products ⁽²⁰⁾. Regulation No 1830/2003 imposes that full information on the presence of a GMO in a food or feed is transmitted from an operator to the others receiving raw materials or products from him, included the unique identifier code assigned to that GMO ⁽²¹⁾. At every subsequent stage, the same information must be passed on for each ingredient or additive that it concerns. In so doing, the regime set out for GMOs would ensure “internal” traceability (Van der Meulen 2014). Member States must ensure compliance through controls according to the technical guidelines established by the Commission ⁽²²⁾.

Regulation 1830/2003 set out also labelling requirements for products consisting of, or containing, GMOs. However, products that contain “adventitious or technically unavoidable” traces of authorized GMOs must not be labelled, and some traceability requirements do not apply. Namely, “traces of GMOs in products” do not trigger traceability and labelling requirements if they do not exceed the threshold set in Directive 2001/18 and Regulation No 1829/2003 (i.e. 0,9%), provided that these traces are adventitious or technically unavoidable (Rosso Grossman 2005).

Specific traceability requirements also apply to ovine and caprine animals (Reg. 21/2004), eggs (Reg. 2295/2003), fish and aquaculture products (Reg. 2065/2001 and Dir. 2006/88), food of animal origin (Reg. 931/2011), sprouts and seeds intended for the production of sprouts (Reg. 208/2013).

5. EU Food Hygiene legislation and the “Hygiene Package”: an overview

EU legislation on the hygienic production and marketing of food is contained in three main Regulations, No 852/2004, No 853/2004, No 854/2004 ⁽²³⁾. These acts, together with Regulation No 882/2004 on

⁽²⁰⁾ The introduction of traceability requirements for GMOs was firstly envisaged in a Working document of the Commission Services on Traceability and labelling of GMOs and products derived from GMOs (ENV/620/2000).

⁽²¹⁾ See Commission Regulation (EC) No 65/2004 of 14 January 2004.

⁽²²⁾ Cf. Commission Recommendation of 4 October 2004.

⁽²³⁾ Regulation (EC) No 852/2004 on the hygiene of foodstuffs; Regulation (EC) No 853/2004, laying down specific hygiene rules for food of animal origin; Regulation

official controls ⁽²⁴⁾, form the so called "*Hygiene Package*", a body of EU law addressed not only to food operators, but also to EU bodies (signally, the Commission and the Standing Committee on the Food Chain and Animal Health) and Member States, as well as consumer organisations and further authorities at the national level.

Provisions on food hygiene had been introduced in the European context since '60s through several vertical directives concerning food hygiene and health conditions for the production and placing on the EC market of certain products of animal origin (fresh meat and fresh poultry meat products, milk, fishery products, eggs, etc.).

After several years, Directive 93/43/EC provided the general rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules. The idea was that food business operators should individuate any critical step in their activities to ensure food safety by identifying, implementing, maintaining and reviewing safety procedures on the ground of a permanent hazard analysis and critical point system (para. 6.3).

Against this fragmented backdrop the Commission advocated a coordinated and holistic approach towards hygiene, with the aim to introduce consistency and clarity throughout the food production chain ⁽²⁵⁾. In 2004 the EU therefore adopted a new comprehensive legislation on food hygiene.

Regulation No 852/2004 establishes general baseline hygiene requirements that are applicable to all food business operators. In addition, Regulation No 853/2004 lays down more detailed rules governing food business operators dealing with foods of animal origin, while Regulation No 854/2004 adds specific food inspection rules for such operators. Regulation No 882/2004, on its part, sets out controls in order to prevent, eliminate or handle risks to humans and animals and guarantee fair practices in feed and food trade to protect consumers.

Simultaneously, Directive 2004/41/EC was enacted in order to repeal most of the old product specific hygiene Directives, which have been replaced by the Hygiene Package as for 1 January 2006.

(EC) No 854/2004, laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

⁽²⁴⁾ See Chapter XVII.

⁽²⁵⁾ See White Paper on Food Safety, p. 25.

Over the years, some implementing regulations have been enacted by the Commission with the aim to provide more detailed provisions and further specifications of hygiene rules ⁽²⁶⁾, as well as several guidance documents. The European Commission is assisted by the Standing Committee on the Food Chain and Animal Health and is obliged to consult the European Food Safety Authority on any matter falling within the scope of Regulations No 852, 853 and 854/2004 that could have a significant impact on public health and, in particular, before proposing or amending criteria, requirements, targets or rules of technical nature set out in the three hygiene regulations.

6. Regulation No 852/2004 on Food Hygiene: scope and extent

Under the terms of Regulation No 852/2004 (Food Hygiene Regulation), 'food hygiene' means "*the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a food-stuff taking into account its intended use*" ⁽²⁷⁾. The Regulation applies to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirement relating to food hygiene ⁽²⁸⁾. This responds to the integrated approach to food safety, which is aimed to cover the whole food chain, from the primary production up to and including placing on the market and export ⁽²⁹⁾.

⁽²⁶⁾ Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs; Commission Regulation (EC) No 2074/2005 laying down implementing measures for certain products under Regulation No 853/2004; Commission Regulation (EC) No 2075/2005 laying down specific rules on official controls for *Trichinella* in meat; Commission Regulation (EC) No 2076/2005 laying down transitional arrangements for the implementation of Regulations No 853/2004, No 854/2004 and No 882/2004. For an overview on EU guidance documents, see: http://ec.europa.eu/food/safety/biosafety/food_hygiene/guidance/index_en.htm (last accessed on 10 August 2016). It should be mentioned, recently, the Commission Notice of 30 July 2016 on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles (2016/C 278/01), whose aim is to provide a practical guidance in order to facilitate and harmonise the implementation of the EU requirements on hygiene and HACCP-based procedures.

⁽²⁷⁾ Art. 2(1)(a), Reg. 852/2004.

⁽²⁸⁾ Art. 1(1), Reg. 852/2004.

⁽²⁹⁾ Recital 8, Reg. 852/2004.

Regulation No 852/2004 provides that food business operators must comply with the provisions laid down in Annex I (primary production) and Annex II (other operators), which contain the substantive technical hygiene rules. Besides, food business operators should adopt further specific hygiene measures and procedures, with a view to ensure compliance with microbiological criteria and with temperature control requirements for foodstuffs, as well as the maintenance of the cold chain and the performance of sampling and analysis.

Among food business operators' obligations provided for by Regulation No 852/2004, those related to the establishment and implementation of HACCP-based procedures, and those concerning official controls, registration and approval are also specified ⁽³⁰⁾. With regard to the latter, the Regulation requires every food business operator to apply for registration of each establishment under its control that carries out any of the stages of production, processing and distribution of food.

Food business operators, specifically, must ensure that the competent authority always has up-to-date information on establishments, by notifying any significant change in activities and any closure of an existing establishment; they are also required to ensure that establishments are approved by the competent authority, following at least one on-site visit, when this is prescribed under the national law of the Member State in which the establishment is located, or under Regulation (EC) No 853/2004 (para. 7).

Anyway, some food business operations fall outside the scope of the Food Hygiene Regulation, according to a certain "flexibility" which deeply characterized the whole Hygiene package ⁽³¹⁾ (Lawless 2012). One of the commercial operation excluded from the scope of Regulation No 852/2004 is the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer. It is on Member States to establish, under national law, rules governing this activity ⁽³²⁾. The provisions of Regulation No 852/2004 do not apply also as regards "primary production for private domestic use", "domestic preparation, handling or storage of

⁽³⁰⁾ Art. 5 and Art. 6, Reg. 852/2004.

⁽³¹⁾ See also Commission Staff Working Document on the *Understanding of certain provisions on Flexibility provided in the Hygiene Package: Guidelines for the competent authorities*, SEC(2010) 986 final.

⁽³²⁾ Art. 1(2)(c) and (3) Reg. 852/2004.

food for private domestic consumption, collection centres” and to “tanneries which fall within the definition of food business only because they handle raw material for the production of gelatin or collagen” ⁽³³⁾.

6.1 *Food hygiene requirements for primary production*

Regulation No 852/2004 clearly states that it is necessary to ensure food safety throughout the food chain, starting with primary production ⁽³⁴⁾.

To this aim, food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in part A of Annex I, as well as with any specific requirements provided for in Regulation No 853/2004 ⁽³⁵⁾. According to Part A of Annex I to Regulation No 852/2004, primary production provisions also apply to all transportation, including that of live animals, as well as storage and handling of primary products, provided this does not substantially alter their nature.

Food business operators must ensure, as far as possible, that their products are protected from contamination, including those arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and the storage. They must also adopt measures concerning handling and disposal of waste, animal health and welfare and plant health that have implications for human health, (e.g. programmes for the monitoring and control of zoonoses and zoonotic agents). Further requirements apply to business operators rearing, harvesting or hunting animals or producing primary products of animal origin, and to those producing or harvesting plant products. Furthermore, food operators are under the strict obligation to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business.

Ultimately, it should be noted that primary products, under the terms of Regulation No 852/2004, include (only) fresh fruit and vegetables, as

⁽³³⁾ Article 1(2)(a)(b)(d), Reg. 852/2004.

⁽³⁴⁾ Article 1(1)(b), Reg. 852/2004.

⁽³⁵⁾ Article 4(1), Reg. 852/2004.

well as products of stock farming, of hunting or fishing ⁽³⁶⁾; as a consequence, further agricultural products listed in Annex I to the Treaty (e.g. wine, sugar, wheat) do not undergo the hygiene rules provided for by the Regulation (Costato et al. 2015).

6.2 *Food hygiene requirements for (other) Food Business Operators*

Annex II lists the main requirements which food business operators other than those engaged in primary production must apply at any stage of production, processing and distribution of food. Annex II is composed by 12 chapters.

Chapter I sets out general requirements for food premises, which are to be kept clean and maintained in good repair and condition. The layout, design, construction, siting and size of food premises must permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, provide adequate working space for the hygienic performance of all operations; food premises should also be protected from accumulation of dirt, formation of condensation or mould, as well as contamination. Requirements are imposed also as regards flush lavatories and washbasins, as well as ventilation, lighting, drainage facilities, cleaning agents and disinfectants.

Chapter II concerns the requirements for rooms used for the preparation, treatment and processing of food, except for dining areas, and provides that their design and layout must be allow good food hygiene practices, including protection against contamination between and during operations.

Specific requirements on premises movable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles), or premises primarily used as a private residence but regularly used for commercial food preparation are laid down in Chapter III.

Chapter IV deals with the transportation of food. Specifically, conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in condition to protect foodstuffs from contamination.

⁽³⁶⁾ Article 2(1)(b), Reg. 852/2004

Chapter V sets requirements for fittings and equipments, which must be effectively cleaned and, where necessary, disinfected; they should also be constructed with materials, be kept in such good order, repair and condition as to minimise any risk of contamination and be installed in a way to allow adequate cleaning of the equipment and the surrounding area.

Chapter VI deals with separation and disposal of food waste, providing that all food waste, non-edible by-products and other refuse are to be deposited in closable containers which must have an appropriate construction and must be kept in sound condition, be easy to clean and, where necessary, to disinfect.

Chapters VII and VIII concern respectively water supply and personal hygiene of workers in a food-handling area.

Chapter IX sets out specific provisions on the hygienic preparation, packaging and treatment of foods. Business operators must not accept raw materials or ingredients, other than live animals, or any other material used in processing products, which is or is expected to be contaminated to the extent that the final product would be unfit for human consumption. Similarly, at all stages of production, processing and distribution, food must be protected against any contamination likely to render the food unfit for human consumption.

According to Chapter X, equally, material used for wrapping and packaging should not be a source of contamination for food.

Lastly, Chapters XI and XII set out requirements as regards heat treatment and training for staff.

It is worth noting that Member States may adopt national measures adapting the requirements laid down in Annex II, such as measures aimed at enabling the continued use of "traditional methods", at any of the stages of production, processing or distribution of food. In such cases, Member States must notify the Commission and other Member States, providing them with a detailed description of the requirements to be adapted and the nature of the adaptation sought, a brief description of the foodstuffs and establishments concerned, an explanation of the reasons for the adaptation, as well as any other relevant information ⁽³⁷⁾.

Similarly, in accordance with Regulation No 2074/2005, it is provided that Member States may grant establishments manufacturing

⁽³⁷⁾ Art. 13 (3)(4)(5), Reg. 852/2004.

"*foods with traditional characteristics*" individual or general derogations from the requirements set out in Annex II to the Hygiene Regulation. Foods with traditional characteristics, under the terms of Regulation No 2074/2005, are foods with traditional features that in the Member State in which they are traditionally manufactured are historically recognised as traditional products, manufactured according to codified or registered technical references to the traditional process, or according to traditional production methods, or protected as traditional food products by a Community, national, regional or local law ⁽³⁸⁾. This category is therefore deemed to include also – but not exclusively – foods produced through "traditional methods".

6.3 HACCP

The so-called HACCP system (*Hazard analysis and critical control points*) represents one of the most important instruments set out by Regulation No 852/2004.

The HACCP-based approach was originally developed by the Space Agency NASA as a method of food production aimed at eliminating all possible hazards from the production process. It was then recommended at the international level as a means to enhance food safety throughout the food chain ⁽³⁹⁾. Afterwards, it has been implemented also in EU legislation, initially through Directive 93/43 and then by means of Regulation No 852/2004.

According to Regulation No 852/2004, all food business operators, at any stage of production, processing and distribution of food after primary production, must establish and constantly maintain a system aimed at identifying hazards that must be prevented or reduced, signally by detecting the critical points at which action must be taken to minimize such hazard, establishing and implementing effective monitoring

⁽³⁸⁾ Art. 7, Reg. 2074/2005.

⁽³⁹⁾ See CAC/RCP 1-1969, General Principles on Food Hygiene, last reviewed in 2003. This text, as well as further standards related to food hygiene in the food chain have been published in Codex Alimentarius, *Basic texts on Food Hygiene*, 4rd edition, FAO, Rome, Italy, 2009.

procedures at such critical control point and, in case, establishing corrective actions, setting up procedures to verify that the system is *working*. *Lastly, they have to establish documents and records in order to demonstrate the effective application of the measures mentioned above, ensuring that any documents is updated at all times and providing the competent authority with them, when is required* ⁽⁴⁰⁾.

Since it is a responsibility of food operators to apply such procedures, HACCP is often referred to as an “imposed self-regulation”; as a matter of facts, while the legislator expressly leaves to food business operators the task to establish procedures for ensuring food hygiene, in practice, the latter have no discretion in that regard, since they are obliged to do so (Van der Meulen 2014).

As provided for in Regulation No 852/2004, National and EU guides to good practice should be developed to assist food operators in the uniform application of HACCP procedures, as well as for hygiene principles and practices; anyway, food business operators may use these guides on a voluntary basis ⁽⁴¹⁾.

Finally, it should be noted that the HACCP mandatory system codified in EU law is usually integrated by private standards, which food business may decide to apply also with the aim to enhance their own commercial visibility. In this perspective, it comes with no surprise that HACCP private schemes are elaborated also by food operators of the primary sector, although they are exempted from Regulation No 852/2004.

7. Regulation No 853/2004 on the hygiene of products of animal origin

Regulation No 853/2004 sets out specific hygiene rules for foods produced from animals. This regulation is designed to supplement Regulation No 852/2004, as expressly stated therein, in so far as it specifies the hygiene obligations that must be fulfilled by food business operators that

⁽⁴⁰⁾ Art. 5(1)(2)(4), Reg. 852/2004. See also DG Sanco, *Guidance Document Implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses* the hygiene of food-stuffs, Brussels, 16 November 2005.

⁽⁴¹⁾ Articles 7, 8, 9, Reg. 852/2004.

deal with unprocessed and processed products of animal origin, such as eggs, dairy, meat and fish, but also foods such as honey and those foods products containing blood.

The provisions laid down in Regulation No 853/2004 do not apply to a series of activities or persons: primary production for private use, domestic preparation, handling or storage of food for private domestic consumption, the direct supply by the producer of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer, and equally the direct supply of meat from poultry and lagomorphs slaughtered on the farm or the supply of small quantities of wild game or wild game meat directly to the final consumer. The rules of Regulation No 853/2004 likewise do not apply to retail and to mixed products (i.e. food containing both products of plant origin and processed products of animal origin). It is on Member States to establish rules governing the above mentioned activities and persons ⁽⁴²⁾.

According to the regulation, food business operators handling food of animal origin are allowed to place their products in the EU market only if the latter have been prepared and handled exclusively in establishments which have been registered and approved in accordance with requirements of Regulation No 852/2004, those of Annexes II and III of this Regulation and other relevant requirements of food law ⁽⁴³⁾. Specifically, establishments handling those products of animal origin for which Annex III to Regulation No 853/2004 lays down specific requirements shall not operate unless the competent authority has approved them according to Regulation No 854/2004 (para. 8) ⁽⁴⁴⁾.

Among the specific obligations put on food operators under Regulation No 853/2004 it should be mentioned the identification marking for products of animal origin, which must have been manufactured in accordance with the Regulation and in a registered and approved establishment. The mark is applied according to Regulation No 852/2004 or, where possible, in accordance with Annex II, Section I, of Regulation No 853/2004 ⁽⁴⁵⁾.

⁽⁴²⁾ Art. 1, Reg. 853/2004.

⁽⁴³⁾ Art. 4(1), Reg. 853/2004.

⁽⁴⁴⁾ Art. 4(2)(3), Reg. 853/2004.

⁽⁴⁵⁾ Art. 5, Reg. 853/2004.

Annex II also requires food businesses who run slaughterhouses to comply with the HACCP provisions of the Regulation No 852/2004; they also have to request, receive, check and act upon food chain information in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouse. Annex III, furthermore, sets out more specific requirements as regards several kind of products, such as meat of domestic ungulates, meat from poultry and lagomorphes, wild meat game, etc.

8. Regulation No 854/2004 on official controls on products of animal origin

The organisation of official controls on products of animal origin intended for human consumption is dealt with in Regulation No 854/2004. This regulation is connected with the other two hygiene regulations, in so far as it establishes the way through which Member States should apply the requirements set out therein.

Regulation No 854/2004 sets out the EU approval system for establishments which place products of animal origin on the market. Signally, the competent authority makes an on-site visit to assess the establishment, and in case it meets all of the requirements provided for by Regulations No 852/2004 and 853/2004, it assigns to each approved establishment an approval number to which codes may be added to indicate the types of products of animal origin manufactured. This applies also in case of a conditional approval, which is released when the infrastructure and equipment requirements are ensured at a first stage, and later, during a second on-site visit, the establishment demonstrates to meet also the other requirements set out by the relevant provisions ⁽⁴⁶⁾.

Official controls are carried out by the competent national authorities in conformity with the procedures drawn up by Member States according to Regulation No 882/2004. Member States, at a preliminary stage, should ascertain that food business operators offer all assistance needed to ensure that official controls carried out by the competent

⁽⁴⁶⁾ Art. 3, Reg. 854/2004.