

# PRESENTATION OF THE NEW EUROPEAN DIRECTIVE CONCERNING HYGIENE

*Summary of the talk by Mrs VION (DGAL) at CECALAIT's AGM 2006*

The food "hygiene package" corresponds to many European regulations, based on the food law (regulation (EC) n° 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). Following the publication of this regulation, many specific texts, addressed to professionals and control services, have been published. Indeed, the regulations (EC) n° 852/2004 on the hygiene of foodstuffs and (EC) n° 853/2004 concerning specific hygiene rules for food of animal origin, constituting a regulatory basis, apply to professionals. To complete these documents, other texts such as the regulations (EC) n° 2073/2005, (EC) n° 2074/2005, (EC) n° 2075/2005 and (EC) n° 2076/2005 have come into effect. This regulatory modification also implied the set up of new national arrangements, and repercussions on the different sectors, in particular for the raw milk – dairy products sector.

## THE BASIC DOCUMENTS

### - Regulation (EC) n° 852/2004

This text applies to all stages of the food chain, including primary production (except for private domestic use) and its related activities (transport, storage, handling...).

This regulation establishes, for food business operators, general rules in matters of food hygiene, such as:

- the declaration of all the establishments and agreements,
- the primary responsibility of the food business operators in matters of food safety,
- the respect of the guidelines on good hygiene practices (maintenance of the cold chain...),
- the procedures based on the principles of HACCP,
- the guidelines on good hygiene practices and application of the HACCP,
- the training of staff.

### - Regulation (EC) n° 853/2004

This text, which applies to foodstuffs of animal origin, completes the regulation (EC) n° 852/2004 using specific requirements. It does not apply to:

- food containing both products of plant origin and processed products of animal origin,
- small quantities of primary products,
- for private domestic consumption,
- local retail establishments (however, a Member State may adopt national measures to apply this requirement).

The annex of this text establishes the definitions, the requirements concerning many products of animal origin (identification marking, procedures based on the HACCP principles; information concerning the food chain) and the specific conditions of each type

of establishment (section IX: raw milk and dairy products).

## COMPLEMENTARY TEXTS

To complete both these regulations, new texts have come into effect. Thus, the regulation (EC) n° 2073/2005 concerning the microbiological criteria for foodstuffs became operative on 1<sup>st</sup> January 2006. This text establishes:

- Food safety criteria defining the acceptability of a product or a batch of products. These criteria are applicable to products on the market. When testing of these criteria provides unsatisfactory results, the product or batch of foodstuffs is withdrawn or recalled.
- Process hygiene criteria defining the acceptability of the processes. These criteria are applicable mainly at the end of the manufacturing process. When testing of these criteria provides unsatisfactory results, the food business operators must take corrective measures.
- Rules for sampling.

Other regulations, such as (EC) n° 2074/2005 concerning implementation of measures for certain products, (EC) n° 2075/2005 concerning specific rules on official controls for Trichinella, and (EC) n° 2076/2005 concerning transitional arrangements (of which one of them concerns the verification of the maximum plate count for raw cows' milk), have also come into force. The measures established in the regulation (EC) n° 2074/2005 derogate from regulation (EC) n° 852/2004 for foodstuffs with traditional characteristics (a ministerial decree and a note to the European Commission are in the process of being written, in order to define the conditions of attribution of the derogations for the use of locals or traditional materials in the context of manufacturing of traditional products).

## THE NECESSITY OF NATIONAL ARRANGEMENTS

The regulations mentioned above are a statutory base, which can be completed by texts from national regulations, if the community regulations give permission or foresee them.

### - National regulation

It was necessary to establish national arrangements in several cases:

- for the areas for which the regulations do not apply,
- when national arrangements are explicitly foreseen by the regulation (traditional method, geographic constraint, national rules until publication of community rules),
- when the regulation is silent (precisions may be absolutely necessary).

Thus, the national regulation will be simplified, compatible with the community regulation, and the redundant or contrary arrangements to the European regulation will be repealed.

The above texts are applicable to all foodstuffs, implying evolutions in the different sectors.

## IMPACTS ON THE RAW MILK – DAIRY PRODUCTS SECTOR

This sector is subject to the regulations mentioned above, particularly the regulation (EC) n° 853/2004. Indeed, many definitions are recovered or specified in annex I of this text. Therefore, the definition of "raw milk" stays the same, whereas other definitions such as "milk production holding" or "dairy products" are specified.

Chapter I of annex III section IX (raw milk and dairy products) specifies arrangements for raw milk-primary production. It specifies:

- health requirements for raw milk production (with regard to brucellosis and tuberculosis),
- hygiene on milk production holdings (premises and equipment, hygiene rules during milking, collection and transport, and staff hygiene rules),
- criteria for raw milk:
  - milk quality: these criteria apply to milk from all species. The criteria concerning micro-organisms and somatic cell contents are the same as the criteria mentioned in the regulation (EC) n°

92/46, but the *Staphylococcus* criterion has disappeared.

- the checking of these criteria may be carried out by the food business operator producing the milk, the food business operator collecting or processing the milk, a group of food business operators, or in the context of a national or regional control scheme.

Chapter II establishes requirements concerning dairy products. It specifies:

- temperature requirements: milk must be quickly cooled and stored at 6°C, except if its processing begins immediately after milking, or within four hours of delivery, or if a competent authority authorises a higher temperature for technological reasons concerning the manufacture of certain dairy products,
- requirements for heat treatment: the requirements described in this part are very general but precisions are described in the regulation (EC) n° 2074/2005 (definition of pasteurisation and heat treatment),
- criteria for raw cows' milk before processing: the micro-organisms content must be < 300000 / ml if dairy products are prepared using raw cows' milk, and < 100000 / ml if using processed cows' milk (see transitional arrangements in the regulation (EC) n° 2076/2005),
- rules for conditioning, packaging, labelling (mention of "raw milk" or "made with raw milk") and identification marking.

To complete this text, the regulation (EC) n° 2073/2005 presents the food safety and process hygiene criteria for milk and dairy products (see tables in "La Lettre de CECALAIT" n° 56, 1<sup>st</sup> quarter 2006). The exceeding of indicator process criteria induces the setting up of controls concerning safety criteria. It is notably the case for the detection of staphylococcal enterotoxins in dairy products, of *Salmonella* spp. and *Enterobacter sakazakii* in dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age.

The enumeration of *Enterobacteriaceae*, *Escherichia coli* and coagulase positive staphylococci have now been introduced in the process hygiene criteria.

You will find the complete texts mentioned in this article on the website <http://eur-lex.europa.eu/en/index.htm>