The following specific features characterize the application of HACCP in the EEC: a high level of awareness; the introduction of the principles of HACCP into the European food legislation, with particular implications on the official control of the hygiene of foodstuffs and other matters such as the development of guides to good hygienic practice, microbiological criteria for foods or product liability considerations; the linkage of HACCP with the development of quality systems based on EN 29 000 series of standards which constitute a specific environment for the application of HACCP; the need for specific assistance to SMEs to facilitate an industry-wide application of the HACCP concept.

Keywords: HACCP; safety; quality

INTRODUCTION

Since the HACCP concept was first presented in 1971 and, following the publication by ICMSF (1988) of a most comprehensive description of the system and its application, much was written and discussed in Europe about the value and applicability of this system. At present HACCP is implemented in every country, although some differences may exist from sector to sector and from plant to plant.

This paper focuses on some general but specific features about the application of HACCP in the EEC which are: a high level of awareness; the introduction into the European legislation of the principles of HACCP and its multiple implications; the linking of HACCP with quality systems based on EN 29 000 series of standards; the specific need for assistance to small- and medium-sized enterprises (SMEs).

AWARENESS OF HACCP

One feature of the application of HACCP in Europe is, undoubtedly, the high level of awareness of the concept. Numerous papers, conferences and symposia have disseminated the HACCP concepts, principles and logical sequence of activities. Definitions and descriptions are abundant and available in every country. Technical guides aimed at facilitating the practical implementation of the system have been prepared by recognized research associations (e.g. CFDRA, 1992; available in several languages).

Tools for direct 'how-to' assistance exist or are in preparation, ranging from rather sophisticated software (in the UK, Sweden and France) to a very simple guide (ILSI, 1993).

Scientific councils, governments of member states and independent groups of experts have endorsed the philosophy of HACCP and encouraged the use of this highly structured and preventative approach for ensuring a high standard of hygiene. The Richmond Report (1990) stated that 'the adoption of the principles of HACCP at all stages of food production will greatly enhance food safety' and recommended that 'all food processes should be designed on HACCP principles, operated by properly trained staff using validated control programs in premises with appropriate hygienic facilities . . .'.

The concept has been continuously evolving in the food industry, with an unambiguous statement by the Confederation of the Food and Drink Industries of the EEC (CIAA, 1991) that 'food hygiene is a main concern for the community food and drink industries' and that 'the control of procedures to assure safety cannot be concentrated on any particular part of the food chain and appropriate control must be exercised throughout the chain, i.e. from the farm to the plate. The application of HACCP directs such control, by analysing potential hazards and risks concerning production, manufacture, distribution and use of a particular food, identifying where control is best achieved'.
Many Member States have implemented programmes to support or to guide food companies in improving quality and hygiene assurance, together with HACCP-related research programmes, e.g. the Dutch Quality and Hygiene Assurance Plan (van Logtestijn, 1990) and the French Assurance Quality programme (Sequal, 1991). The European Commission itself took initiative by sponsoring a concerted action initiative within the Food Linked Agro-Industrial Research (FLAIR) programme to encourage cooperation between scientists and industrialists so that a more systematic and unified approach to HACCP and multiple preservation systems can be achieved. The specific characteristics of this programme are that, considering quality and safety, all major sectors of food and drink manufacturing, distribution, retailing and catering are included in the studies (systems are applicable to currently marketed and new products with emphasis on those preserved by multiple parameters) and data are suitable for mathematical modelling and inclusion in hazard analysis and risk assessments. There are 40 participants from 13 countries with representation from universities, government and industry research institutes and associations, food manufacturing and catering. The HACCP subgroup has 25 participants from 10 countries (the UK, France, Denmark, Spain, Sweden, Portugal, Belgium, The Netherlands, Ireland and Greece).

There have been several meetings as well as interaction with other international initiatives (viz. FLAIR Flow on the need to publicize the research findings; Codex Alimentarius on issues relating to the implementation of HACCP on Codex guidelines; World Health Organization on HACCP systems for food inspection and on training considerations). Some achievements in connection with IIACCP include: production of a glossary of terms commonly used in HACCP implementation; production of a user’s guide; compilation of a bibliographic database of more than 250 references on HACCP documents; training exchanges involving reciprocal visits between laboratories and institutes in France, Ireland, Spain, Sweden, Denmark, Slovenia, Italy, Germany and Portugal.

So a lot of expertise and money has been devoted to the promotion of a HACCP-based preventative approach for better control of food safety. This process is now irreversible, even if some reservations still exist, as is usual when instituting a change in attitude.

**HACCP AND EUROPEAN FOOD LEGISLATION**

The most prominent feature concerning HACCP as applied in the EEC is the way the principles of HACCP have been introduced into the European food legislation, with its implications on official control activities and related matters such as the development of guides to good hygienic practice, standardization, use of microbiological criteria for foods and product liability.

**The facts**

The principles of HACCP are now introduced into the European food legislation, implicitly in the last vertical directives and explicitly in the horizontal food hygiene directive. The vertical directives lay down the hygienic conditions required for the production and the placing on the market of specific food commodities. In the last three directives (DIR 91/493 on fishery products, DIR 92/5 on meat-based products and DIR 92/45 on milk and milk-based products) a general provision is made to require persons responsible for an establishment to 'carry out their own checks based on the following principles:

- identification of critical points in their establishment on the basis of the manufacturing process used;
- establishment and implementation of methods for monitoring and checking such critical points;
- taking samples for analysis in an approved laboratory by the competent authority for the purpose of checking cleaning and disinfection methods and for the purpose of checking compliance with the standards established by (the) Directive;
- keeping a written record of the preceding points with a view to submitting them to the competent authority.'

Such principles with their special reference to identification and monitoring of critical (control) points, verification procedures and record keeping are implicit references to HACCP principles. This, however, needs clarification. To that aim, a draft proposal for a decision of the Commission providing rules for the application of the above-mentioned article of the directives has been prepared, which is essentially an attempt to correlate more closely the terms of the directives to the concepts and principles of HACCP. At the moment this paper is submitted for publication, the draft proposal has only recently been submitted to Member States for official comments.

The horizontal directive on the hygiene of foodstuffs (DIR/93/43/EEC) is a framework directive which lays down the general rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules. Article 3, the key part of this directive, establishes a general requirement for hygiene at all stages of the food chain. To that aim, in addition to complying with general rules listed in the annex to the directive, 'food business operators shall identify any step in their activities which is critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented, maintained and reviewed on the basis of the following principles, used to develop the system of HACCP:

- analysing the potential food hazards in a food business operation;
- identifying the points in those operations where
food hazards may occur;

- deciding which of the points identified are critical to food safety (the critical points);
- identifying and implementing effective control and monitoring procedures at those critical points;
- reviewing the analysis of food hazards, the critical control points and the control and monitoring procedures periodically and wherever the food business operations change.

Reference to the principles of HACCP is explicit, but to the principles only.

The implications

Under these directives, food business operators are required not only to comply with general and specific hygiene rules but also to develop procedures for food hygiene control based on the principles used to develop the HACCP system, with the aim of improving the level of food hygiene and increasing confidence in the standard of hygiene of foodstuffs in free circulation.

The first implication results from the fact that reference is made to HACCP principles only. This means that the HACCP system as such, and as described in full in reference documents such as ICMSF (1988), NACMCF (1992), Codex (1993) etc. is not a formal requirement of the directives. What is enforceable is a systems approach which has to be developed under each food business operator’s responsibility, integrating hazard analysis, risk assessment and other quality assurance techniques, aimed at providing evidence that relevant safety hazards have been properly identified and assessed and that appropriate procedures for safety have been identified, implemented, monitored and reviewed. Different tools can therefore be used to comply with the requirement of the directives, provided they are based on the same principles as HACCP. This is beneficial as it allows for some flexibility, which is necessary to adapt the principles to a particular situation, together with enhanced responsibility for any food business operator when deciding the most effective technique to be used to assure food safety. There is, however, a greater advantage in using HACCP: first, because it is now properly described and the descriptions are easily available; second, because of the general recognition of its effectiveness to cover safety matters (Baird Parker, 1990); and third, because it is becoming, through its introduction into Codex Alimentarius General Principles and Codes of Practice, a rule for international trade.

A second implication refers to the official control of foodstuffs. An important objective of such controls is food hygiene and general rules for their performance have been laid down by DIR/89/397/EEC. Carried out in accordance with this directive, official controls must evolve to take into account the introduction of provisions about the development of the principles of HACCP. Official control shall ensure that, in addition to compliance with general and relevant specific hygiene rules, food business operators have identified, implemented, maintained and reviewed adequate safety procedures (own checks), on the basis of the principles used to develop the system of HACCP.

Moreover, inspections by competent authorities shall include a general assessment of the potential food safety hazards associated with the business (DIR 93/43, article 8); controls shall be carried out at a frequency which has regard to the risk associated with the premises; during their visits, inspectors shall pay particular attention to critical control points, as identified by the food business, to assess whether the necessary monitoring and verification controls are being operated.

The assessment of potential food safety hazards and the assessment of critical control points and controls as established by food companies are a new and important supplement to traditional official control techniques which concentrated mainly on inspection, sampling and analysing. This means that public officers have to be specifically trained in such assessment procedures (preferably in joint sessions with personnel from industry for the sake of a uniform comprehension of the HACCP principles and their application). This also means that food authorities should provide inspectors with codes of practice for inspection and maintain a documented management system to ensure consistency of interpretation and approach and that inspections are carried out to a uniform standard. The general features of such codes and systems have to be coordinated at a European level.

The adaptation of regulations and controls to new hazards and risks, the implementation of controls according to common rules such as control at source, and the development of coordinated programmes for controls including training of inspectors are some of the objectives of the Commission proposal for a strategic programme to enhance the effectiveness of the single market (EC Commission, 1993). The application of HACCP principles to the official control of foodstuffs will greatly contribute towards meeting these objectives.

The third implication is the recommended development of complementary documents of voluntary application such as guides to good hygienic practice. Such guides are basically aimed at providing information and guidance to aid food business operators in complying with the essential requirements and, more particularly, with the requirement to operate appropriate safety procedures and controls (own checks) based on the principles of HACCP. To effectively meet this goal, such guides should preferably be developed by using an approach based on the principles of hazard analysis, risk assessment and quality assurance techniques, i.e. the HACCP approach; they should provide guidance to identifying critical control points and appropriate control, monitoring and verification procedures, while taking into account the general and specific rules of hygiene identified in general or specific regulations.

However, and this is of paramount importance in the
application of HACCP principles as it results from the European regulatory approach, such guides (a) should not be considered as a substitute to the development, by each food business operator and under its own responsibility, of an individual process to identify critical steps in its particular activities and to operate a specific system for safety control based on HACCP principles and (b) should be used on a voluntary basis, which means that observance of such guides is not imposed by any legal force. According to this logic, guides to hygienic practice may include some sort of 'HACCP models' but these models should not be considered as 'regulatory'.

Such guides should be developed by food business sectors and representatives of other interested parties, in consultation with interests substantially affected. Competent authorities play a specific role in regard to these guides – they should encourage their development; assist food business sectors and other representatives in their preparation; provide for assessment of the guides with a view to determining the extent to which they comply with the essential requirements about hygiene and safety and forward them to the Commission. In addition, such competent authorities should give due consideration to guides to good hygienic practice, where they exist, when carrying out official controls, but are not in a position to enforce them, the food business operator being primarily responsible for the hygiene conditions in his food business.

A specific consideration about guides to good hygienic practice refers to their standardization. As indicated in the directive on food hygiene, such guides may be developed under the aegis of a standard institute (national or European). There is a strong belief among such standardization bodies that the development of codes of practice belongs to their area of activity, but standardization of such guides is still a matter of discussion among industry and other parties involved. In the same way, standardization of HACCP with a possible 'certification' of HACCP systems has been advocated. At present, such a proposition is far from gaining general acceptance but it should still be very carefully considered, preferably on an international basis.

Two additional, indirect, implications refer to the adoption of microbiological criteria for foods and to product liability and due diligence. Microbiological criteria for foods may be adopted for the implementation of both vertical and horizontal directives (some exist already, e.g. milk and milk-based products). The introduction of the requirement to operate preventative control systems based on the HACCP principles will make it necessary to reconsider the use of such criteria.

Traditionally, microbiological criteria for foods were used as reference values to decide on the acceptability or non-acceptability of batches of end products, on the basis of a systematic analysis (traditional quality control procedures). One of the basic characteristics of HACCP is that, when such a system has been properly conceived, implemented, monitored, verified and reviewed, it provides a better assurance of the microbiological status of the products than when relying on end product testing. Clearly, systematic end product testing is not necessary in such a case, with the exception of products of unknown origin or when specially designed for specific groups of consumers. End product testing is nevertheless necessary on a periodic basis for validation or verification purpose.

Introduction of principles of HACCP into food legislation will undoubtedly affect the rules for using microbiological criteria. Proposals have been made by ICMSF for an adjustment of Codex Alimentarius General Principles for the Establishment of Microbiological Criteria for Foods (Alinorm 81/13). Such a proposal and its related Codex decision have to be taken into account when adopting microbiological criteria in Europe with regard to the development of the principles of HACCP.

Another point is that the principles of HACCP refer to the establishment of critical limits for monitoring operations. Special consideration has to be given to the fact that such critical limits refer to process control and have to be unambiguously distinguished from microbiological criteria as they apply to end products.

The legal status of product liability and due diligence is governed in the EEC by DIR85/374/EEC. Some delays still exist for the transcription of this directive into the legal system of Member States as it often calls for complex adjustments. It establishes that anyone who sells a product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability. This means that any manufacturer (or seller) is responsible for the well-being of the people who consume its products. That responsibility is commensurate with the manufacturer's ability to predict and avoid harmful consequence in a reasonable manner; he is required to do what he reasonably can to prevent injury from occurring. This basic rule for product liability no longer includes the technical defence and proof requirements that previously protected manufacturers; HACCP, with its hazard analysis, risk assessment, control and assurance procedures, provides an appropriate answer to this demanding standard and a good support to a due diligence defence (Van Schothorst and Jongeneel, 1992).

HACCP AND QUALITY SYSTEMS)

Apart from statutory regulations for foodstuffs and their implications, the extensive development in the food sector of quality management systems based on the EN 29000 series of standards provides a specific environment for the application of HACCP in Europe. The development of such quality management and quality assurance systems resulted from the rapid development and spread in Europe of the concepts of quality. EN 29000 standards have been popular since this development began, mainly because of the facility
to document and implement a quality assurance system to these standards which can be certificated by a third party (itself operating according to the appropriate standards of the EN 45 000 series).

By far the most popular choice for certification is EN 29 002 (Quality Systems – Specification for Production and Installation) which contains 18 of the 20 paragraphs found in EN 29 001 (Quality Systems – Specification for Design/Development, Production, Installation and Servicing) and differs only in that it lacks the paragraphs relating to design and servicing. EN 29 003, which refers only to specification for final inspection and test, is generally thought inappropriate for certification in the food sector.

EN 29 000 standards define a quality framework within which a certified company operates as a minimum; under such a framework, quality assurance techniques are introduced at each stage of the life-cycle of the product and at each step of the manufacturing process; the company which has a documented and certified quality system is better organized to meet the customer’s explicit and implicit needs (definition of quality according to ISO 8402 standard) than one which has not.

An acceleration of that movement also resulted from the general approach of the European Commission to quality problems. Under such an approach, and as expressed in 1985 in the White Paper on the completion of the internal market, the legislative activities of the Commission will be restricted to essential requirements (protection of the public health and safety matters in particular) whereas business operators are referred to documents of voluntary application (appropriate standards where they exist, and to EN 29 000 standards for quality systems, much favoured by the Commission) to provide evidence of compliance with such essential requirements (as well as with other specified or implicit customer’s needs).

Such an approach is well implemented in the sector of industrial and non-edible products, where it has been completed by a modular approach for conformity assessment (Council Decision 90/663/EEC) integrating quality assurance systems based on EN 29 000 and certification as a means of demonstrating compliance with essential requirements.

In the food sector, this approach has not received, at present, any further regulatory application than the general economy of the horizontal directive on food hygiene (essential requirements to carry out operations in a hygienic way at all stages of the food chain and to ensure adequate safety procedures on the basis of the principles of HACCP; reference to documents of voluntary application such as guides to good hygienic practice to have these essential requirements implemented).

However, in the food sector, the general movement toward quality has meant that food business operators are much more aware of the benefits of developing quality assurance systems and quality assurance techniques with regard to EN 29 000 standards and are actually implementing such systems and techniques, or intend to do so, often prior to introducing or using HACCP or its principles.

In such a context, two situations are possible. The first situation is when implementing the general rules of hygiene, guides to good hygienic practices and a HACCP-based approach; the association or subsequent development of a quality system based on the EN 29 000 standard is a recognized and an efficient way of organizing the company to develop an environment favourable to a permanent improvement of control of hygiene and safety of food. This led the Commission to invite Member States to recommend food business operators to apply the European Standards of the EN 29 000 series in order to have the general rules of hygiene implemented (DIR 93/43, article 6). The second situation is when a formal quality system exists; the system must integrate the principles of HACCP to the development of safety procedures, this being now a legal requirement.

In both cases, HACCP or its principles provide the perfect vehicle to prepare, implement, verify and review a ‘safety assurance plan’ (Jouve, 1993), delineating all the resources, responsibilities and sequence of activities relevant to a given product safety. Such a safety assurance plan specifically applies to a product/process line; for a given product, it specifically addresses the activities applicable to any identified hazard, including assessment, prevention, monitoring and verification of the effectiveness of control. It helps to focus on key elements and becomes a normal part of any food business operating process, to provide evidence that process and product will be as safe as possible, given the best information and technology available.

A safety assurance plan based on the principles of HACCP falls naturally into EN 29 000. The safety assurance plan is also limited to those activities applicable to the given product safety hazards control and does not extend to other sections or activities of the business; it can be used on request (contractual or regulatory situation) to provide evidence of compliance with specific requirements related to safety. Such an association of HACCP principles and of quality systems based on EN 29 000 standards is a specific feature of the application of HACCP in the FFC. There is now increasing recognition that quality systems designed around EN 29 000, where procedures for safety are set by using HACCP principles and techniques, are the most reliable of all systems.

A specific implication of this attitude refers to quality systems certification. By analogy with the legislation, HACCP should not be a formal requirement for certification against EN 29 001 or EN 29 002 standards. However procedures and controls having incidence to safety must be established according to the principles used to develop the HACCP system. Moreover, such principles shall also apply for the establishment of preventative measures, when such measures will be introduced as a formal requirement of these standards.
as suggested in their present revision process.

Quality assurance plans, and therefore safety assurance plans, are not at present a formal requirement of EN 29 000 standards. However, when established according to HACCP principles and techniques they can much facilitate certification, demonstration of compliance to essential requirements for hygiene, and increased confidence in the supplier's ability to manufacture products that meet consumer's safety expectations.

ASSISTANCE TO SMEs

The principles of HACCP are applicable to all sectors of the food and drink industry. However, whereas large, technically sophisticated companies have no difficulties in accomplishing the many tasks necessary for their application, SMEs may face some difficulties which have to be appropriately overcome. In many Member States, SMEs represent the majority of food businesses and quantitatively play a prominent part in the food supply. In such a context, if only technically sophisticated companies within a given segment of the food industry apply HACCP principles, the value of the process for an EEC-wide improvement of food safety is lost.

The main problems SMEs face in applying HACCP relate to their smaller financial resources (potential cost of the implementation of the system relative to the company's turnover; insufficient purchasing power to exert sufficient influence on their suppliers or retailers to move to HACCP systems); insufficient technical resources (lack of appropriate technical and scientific data; lack of skilled specialist resources, e.g. technologists, microbiologists, food chemists to contribute to the HACCP study); lack of time of available personnel (concentration of functions; difficult to put aside the time required).

The following should be emphasized:

- There is a need for government and industry to work in collaboration to provide any sector of the food industry with appropriate epidemiological and scientific data to aid in identifying hazards, in conducting risk evaluation and in improving HACCP plans.
- There is a need to prepare appropriate information and training materials – this includes not only materials for training in practical applications of HACCP principles and principal activities (specific guides to good hygiene practice and/or HACCP models partly fulfil that objective; materials for on-the-spot actions are still needed) but also specific materials for information to SME managers.
- There is a need for an appropriate mobilization of all segments of the industry through various industry trade associations.
- There should also be efforts towards the adaptation of SMEs to the development of quality systems and certification, as mentioned in the Commission proposal for a strategic programme on the internal market (COM (93) 256 final).

CONCLUSION

The development of a systematic preventative approach to assuring food safety is well advanced in Europe, in particular, with the introduction of HACCP into the European food legislation. This approach is in the short term becoming the rule for control of operations, not only through regulatory applications but also within the framework of the development of quality systems based on the EN 29 000 series of standards, which have gained a large acceptance among food companies. Specific assistance to SMEs, developed within strategic Community programmes, will facilitate an industry-wide application leading to greater consumer protection.

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