FOOD SAFETY

ISO 22000

From intent to implementation

How close is the intent of ISO 22000:2005 and its implementation by users? An expert who took part in its design and development has reviewed feedback from early users and gives some pointers to tackling the issues they raise.

by **Didier Blanc**

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ISO 22000:2005, *Food safety management systems – Requirements for any organization in the food chain* is the first management system standard on food safety to go beyond the recommendations put forward in 1993 by the Codex Alimentarius Commission. Inevitably, the arrival of this brand new standard with its updated approach is accompanied by issues of interpretation and how to meet its requirements.

ISO 22000 goes beyond the food safety recommendations put forward in 1993 by the Codex Alimentarius Commission

The main interpretation and implementation challenges revolve around requirements that did not appear in the 12 Hazard Analysis and Critical Control Point (HACCP system) application steps described in the Codex Alimentarius, nor in any of the quality or food safety management systems standards used so far by companies in the food chain (e.g. ISO 9001, BRC, IFS, DS 3027 or others). **Table 1** *(overleaf)* lists and interprets the key new elements.

These innovations mainly relate to the interpretation, consistency and thoroughness of the HACCP method of controlling food safety hazards. Indeed, ISO 22000 is the first standard that not only endorses the Codex Alimentarius recommendations, but also attempts to fill the gaps and inconsistencies brought to light by 13 years of accumulated experience with HACCP.

What's new?

Figure 1 illustrates the links between ISO 22000 and the 12 HACCP steps and highlights the stages that have been added (broken outline), or significantly altered and consolidated (yellow background).

These innovations apply as much upstream – the requirement for the selection and implementation of appropriate prerequisite programmes (PRP's)[1], before proceeding to hazard analysis – as to the core of the HACCP system itself: hazard analysis, selection, validation and monitoring of adequate control measures.

A generic requirements-based standard designed for certification purposes cannot provide examples or recommendations, so I will provide some here. In addition, the systems approach of ISO 22000 states requirements in terms of *results* rather than *means*.

Although this approach, successfully applied in ISO 9001 and ISO 14001, has been widely supported by representatives of the food industry, it can prompt questions such as the following:

- What do I have to do?
- What are the baselines?
- Can I have examples?
- How will I validate my choices?
- How can I be sure not to go too far, or not far enough?

Clause in the standard	New element
5.5 *Food safety team leader*	Responsibility and authority for: organizing the team's training and work; ensuring the implementation and updating of the system; reporting to management; communicating.
5.6 *Communication*	External communication relating to food safety hazards throughout the food chain (upstream and downstream); Internal communication to ensure that the HACCP team is informed in real-time of all changes (e.g. raw materials, facilities and installations, recipes, requirements, etc.) likely to affect the system.
6.2 *Human resources*	The requirements of (demonstrated) competence of the HACCP team members and the staff having an impact on food safety.
7.2 *Prerequisite programmes (PRP's)*	The company should itself select and implement appropriate good hygiene practices (instead of merely applying those imposed upon it).
7.4.2 *Hazard identification and determination of acceptable levels*	Taking into account the various stages in the food chain (primary production, processing, distribution) where hazards can occur; Determination of acceptable levels in the finished product.
7.4.4 *Selection and assessment of control measures*	Selection of (combinations of) control measures associated with hazards assessed as requiring control; Assessment of the effectiveness of control measures; Method for assigning these (combinations of) control measures either to the HACCP plan ("conventional" CCP), or to operational PRP's (new concept).
7.5 *Establishing the operational prerequisite programmes (PRP's)*	Establishment of a monitoring system (procedures, responsibilities, corrective actions) for the (combinations of) control measures assigned to the operational PRP's.
8.2 *Validation of control measure combinations*	Prior validation of the effectiveness of the (combinations of) control measures to ensure observance of the predefined acceptable level for the relevant hazard.
8.4.2 *Evaluation of individual verification results*	Systematic review of individual results of the plan and verification (e.g. implementation of operational PRP's and CCP's, compliance with acceptable levels, and analysis of products and services, etc.).
8.4.3 *Analysis of results of verification activities*	Analysis and overall review of the implementation, operation and efficiency of the system and of the trends in terms of hazard control, with management reporting.

Table 1 – *Key innovations of ISO 22000*

Investing in skills

In a nutshell, while the requirements for means often involve investment in infrastructure, the obligation to achieve results leads rather to investing in manpower, in the skills of the HACCP team and its leader, and in the staff that impact on the control of food product safety.

> ISO 22000 states requirements in terms of ***results*** rather than ***means***

However, corporate culture limitations often arise as soon as the qualification and empowerment of staff are involved, while many companies do not have the resources to employ highly trained HACCP management.

In addition to the financial resources needed to fund a team of competent managers and specialists, it may prove difficult to find appropriate training and recruit experts, and develop the necessary experience and skills on the job. Nevertheless, an organization can find a solution suited to its size and circumstances by measures such as the following:

1) Prerequisite programme (PRP): basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption. (ISO 22000).

- exchanging or sharing HACCP team members, and functions such as internal auditing and data analysis, among several companies;
- integrating supplier or client experts into the team, to bring in hazard control expertise from other levels in the food chain;
- using e-learning when the required vocational training is not available in appropriate timeframes, locations or quality [2].

Some examples

One of the difficulties in complying with the requirements of a standard is to find a starting point on which to build the implementation. Examples can help set the right course and boost confidence in the implementation process. Two such examples are described hereafter.

Selection of control measures

Clause 7.4.3, *Hazard assessment* of ISO 22000 (see **Figure 1**) serves to determine which of the potential hazards identified require specific control measures. To ensure such control, the standard requires the selection of (or combination of) control measures (clause 7.4.4, *Selection and assessment of control measures*).

2) See, for example, the HACCP and ISO 22000 courses on the I-Cube Academia platform developed by Liège University, Belgium, and Lausanne Polytechnic, Switzerland – **www.i3academia.com**

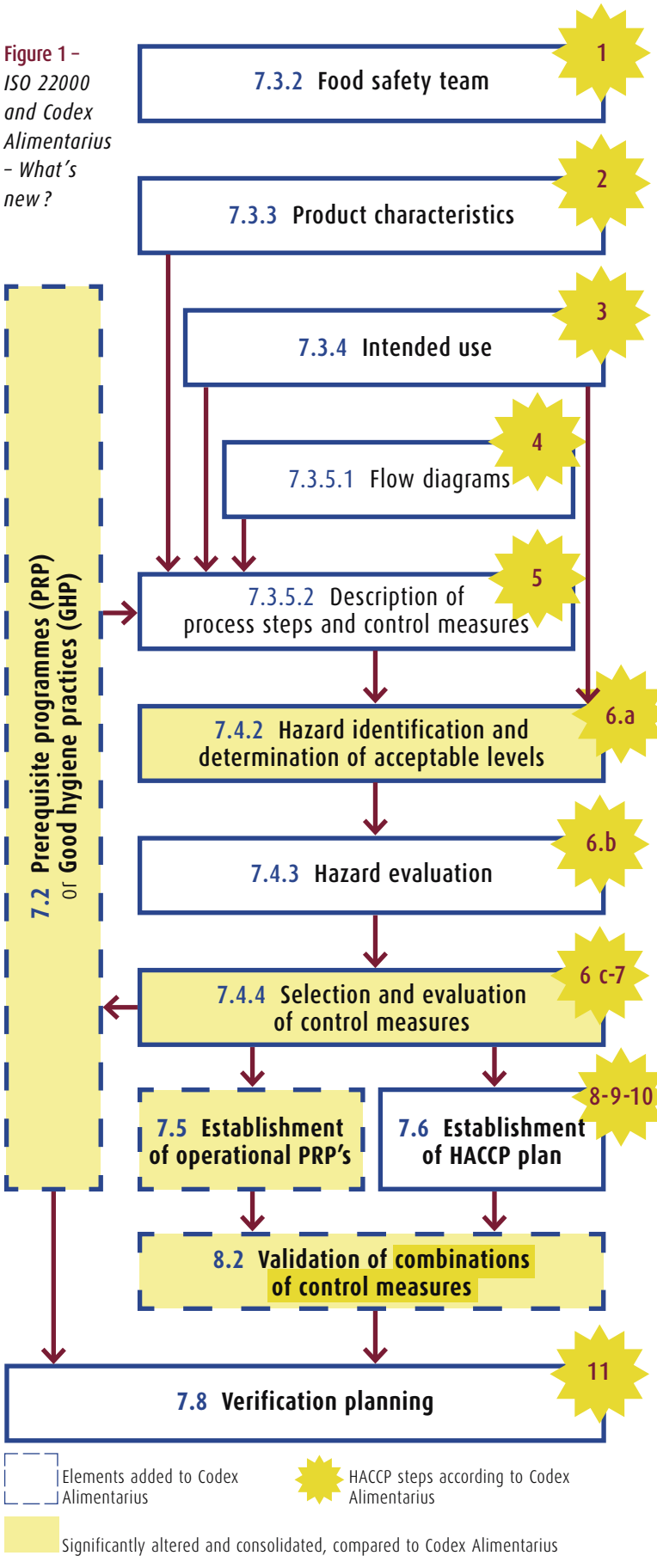
For French speakers...

French speakers can find further help on ISO 22000 interpretation and implementation in Didier Blanc's book *ISO 22000, HACCP et sécurité des aliments – Recommandations, outils, FAQ et retours de terrain* (ISO 22000, HACCP and food safety – recommendations, tools, FAQ's and user feedback), on which this article is based.

His book illustrates the principles of the new International Standard with practical examples, and is based on answers to the most frequently asked questions (FAQ's) on food safety management systems, and on the management tools he developed in over 20 years' food safety experience.

ISO 22000, HACCP et sécurité des aliments – Recommandations, outils, FAQ et retours de terrain (ISBN 2-12-445311-4) is published in French by Association française de normalisation (AFNOR), 350 pp, price 42.65 euros, available from **www.boutique.afnor.fr**

Figure 1 – *ISO 22000 and Codex Alimentarius – What's new?*



This is likely to prompt questions such as:

- Where do these control measures come from?
- How do they differ from PRP's?
- Should they be selected from the PRP's – in which case I doubt the value of this additional requirement since the HACCP measure is already in place – or elsewhere?

An organization can find a solution **suited to its size and circumstances**

The required control measures can be selected either:

– from an organization's PRP's (e.g. the slicing sequence of a cross-contamination hazard between cooked meat preparation and air-dried meat products, or a refrigeration chain in the case of fresh products);

– beyond the PRP's, by introducing additional, more advanced technology (e.g. laminar flux, air processing, x-ray detection);

– outside the PRP's relating to that specific business sector, using measures which belong to another level in the food chain (e.g. good agricultural or animal health practices, integrated farming, or EurepGAP certification required by the food industry of its suppliers).

Validation of control measures

Clause 8.2, *Validation of control measure combinations*, basically a new requirement introduced by ISO 22000 that relates to the control measures addressing hazards having been assessed as needing control, control measures that must then be validated before being implemented. This might prompt prospective users to declare, "But I have neither the human nor financial resources to perform scientific validations! Isn't the standard designed mainly for large and wealthy companies alone, and not for the small players?"

ISO/TS 22004, *Food safety management systems – Guidance on the application of ISO 22000:2005* can help allay such fears by providing a list of possible approaches. These are presented in **Table 2** in the form of a systems approach to implementation based on existing validations within a small company in a specific business sector.

Where to start?

Once one is convinced that ISO 22000 is the best approach to controlling impacts on the safety of food products, the inevitable question arises, "Just where do I start?"

Much will depend on the company's certification status in terms of ISO 9001, BRC, IFS, etc. Indeed, certain principles common to all management system standards will have already been assimilated – e.g. control of documents and

Product		
Hazard to be controlled		
Control measure(s)		
Validation methods	**Applicable** yes/no	**Comments**
Third-party scientific validation		
Historical knowledge		
Simulation of production conditions		
Collection of data in normal production		
Admissible in industrial practices		
Statistical programmes		
Mathematical modelling		
Conclusion: internal validation needed? If so, following which method?		

Table 2 – *Need for and methods of, validating control measures according to ISO/TS 22004*

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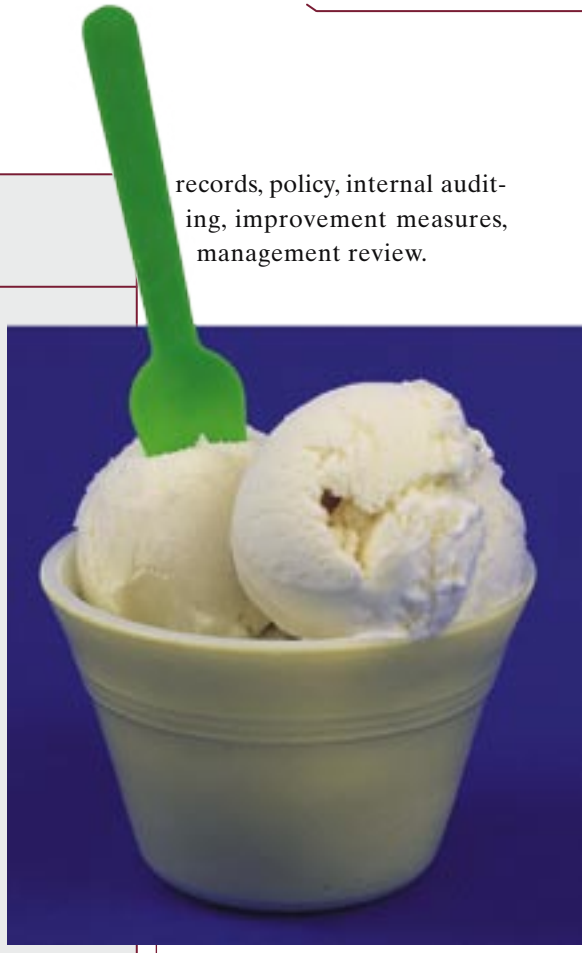

records, policy, internal auditing, improvement measures, management review.

Sources of help

In addition to the official guidance provided by ISO in ISO/TS 22004, examples of food safety management-related frequently asked questions (FAQ's) are available on the author's ProCert Web site – **www.procert.ch** – which also welcomes new questions in English, French and German. A sample question and answer follows.

Question

I see no difference between PRP (or GMF/GHP's) and control measures. For me, PRP's are measures to control existing hazards, otherwise they have no purpose. Moreover, control measures associated with hazards will always be selected from among the PRP's.

Recommendations of ISO/TS 22004:

ISO/TS 22004 provides the following clarifications in this respect:

ISO 22000 reorganizes the traditional concept of dividing control measures into two groups [prerequisites and measures applied at critical control points (CCP's)] in a logical order for the development, implementation and control of the food safety management system. Control measures are grouped into three groups, as follows:

- *prerequisite programmes (PRP's) that manage the basic conditions and activities; the PRP's are not selected for the purpose of controlling specific identified hazards but for the purpose of maintaining a hygienic production, processing and/or handling environment (see 7.2 of ISO 22000:2005);*
- *operational prerequisite programmes (operational PRP's) that manage those control measures that the hazard analysis identifies as necessary to control identified hazards to acceptable levels, and which are not otherwise managed by the HACCP plan;*
- *a HACCP plan to manage those control measures that the hazard analysis identifies as necessary to control identified hazards to acceptable levels, and which are applied at critical control points (CCP's).*

Answer

In view of the clarifications provided by ISO/TS 22004, the answer seems to be twofold:

1) Yes, strictly speaking PRP's are control measures, even though in practice it is recommended not to designate them as such in order to avoid confusion.
2) No, PRP's are not selected to control hazards identified through hazard analysis – this will require specific control measures assigned to operational PRP's or to the HACCP plan – but to create a suitable hygienic environment that is able to keep to a minimum the likelihood of contamination.

For further guidance, the author recommends establishing contact with an expert in another company, or a consultant or auditor, and visiting Internet forums, specialized clubs and FAQ's.

The key is to correctly manage HACCP procedures in conjunction with the additional requirements of ISO 22000 which, while introducing consistency, nonetheless require some effort to assimilate.

Early feedback indicates that one should start by investing in the HACCP skills revisited by ISO 22000

Early feedback on the use of the standard indicates that one should start by investing in the HACCP skills revisited by ISO 22000 in order to reap the full benefits of the new standard. Once these skills are in place and operational, the rest should follow as a matter of course. •