

# Implementation of ISO 9001:2000 in the food and drink industry

On 15 November 2001, ISO published a new standard, ISO 15161, *Guidelines on the application of ISO 9001:2000 for the food and drink industry*, which was overwhelmingly approved by the organization's national member institutes. This article looks at the background to the development of the guidelines and what they offer users in the sector.

Demand for the development of sector-specific guidance for the application of the ISO 9000 series in the food and drink industry first arose in 1994 after a regional seminar in South America where the main problems of the food industry were discussed. The necessity for such guidance was clearly shown by the fact that the use of the ISO 9000 series in the food and drink sector worldwide was somewhat limited.

Some countries, for example the United Kingdom, France and Italy, were of the opinion that industry-specific guidance written in the language of the food and drink sector could assist the latter in understanding the requirements of the ISO 9000 series and, therefore, they developed such national guidance separately. Following the South American conference, a proposal was made for ISO



technical committee ISO/TC 34, *Agricultural food products*, as it was then known, to combine and harmonize the national guidelines at the international level. (In 2000, the title of ISO/TC 34 was changed to *Food products* with the aim of extending its scope to include foods other than of agricultural origin.)

## ISO 9000 and HACCP

The requirement to produce safe food products is of paramount importance in this industrial sector. The Codex Alimentarius Commission of the United Nations provides governments, industry and consumers alike with an international code of practice related to the general principles of food hygiene. This follows the food chain from primary production through to final consumption, highlighting the key hygiene controls at each stage.



It recommends an approach to enhancing food safety wherever possible through a system based on Hazard Analysis and Critical Control Points (HACCP). Based on these recommendations, food safety requirements are detailed in many items of the national legislation of countries. The application of the HACCP system has been generally accepted as the way of ensuring the safety of food production. Therefore, an increasing number of countries have made HACCP, or part of it, obligatory.

This fact resulted in some uncertainty with respect to the implementation of ISO 9000 quality systems in



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the food industry. Some companies thought they did not need ISO 9000 standards as the Codex recommendations and the HACCP system should, at least theoretically, guarantee the quality of their products. However, they were missing the point that *food quality* includes much more than *food safety*.

Of course, without food safety, which is a basic requirement, we cannot speak about food quality, but there are many aspects (nutritional, biological and hedonic value, the stability of the given quality, etc.) which are also very important. For example, an absolutely safe food cannot be sold if its appearance and/or taste and/or odour do not meet the expectations of customers.

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Reconciliation of the obligatory HACCP system with the voluntary ISO 9000 standards also caused problems for some food-producing companies.

The above factors all contributed to the limited implementation of ISO 9000 series in the food industry.

Since the Codex document was under development at the time when the idea for ISO to develop guidance arose, it was clear that for us to produce an acceptable document, the differences and the similarities between the ISO 9000 standards and HACCP systems should be explained. It should also be emphasized that the two systems cannot substitute for

each other, but are, in fact, complementary and their combined application should result in a highly effective quality system.



### The first draft

The development of guidelines for the application of the ISO 9000 series in the food and drink industry was registered in the work programme of ISO/TC 34 in October 1995 with the United Kingdom undertaking the project leadership.

The first Draft International Standard ISO/DIS 15161 was published on 9 July 1998. It included an annex dealing with the possible interaction of ISO 9001 with the most widely used food safety system, HACCP. The purpose of this was to help those who already applied HACCP and wanted also to establish an ISO 9000 quality management system, or those who wished to implement both systems in parallel.

In the event, 31,03 % of the total number of votes cast was negative and so, according to ISO rules which require 75 % of votes cast to be positive, the draft was not approved.

Most of the ISO members who voted against the document did not dispute the importance and the need for such guidance, but due to the then upcoming revision of the ISO 9000 series (published in December 2000), they considered that ISO 15161 would be out-of-date shortly after its publication.

In addition, some members thought that the document laid too much stress on the HACCP concept – which is only one among several other existing possibilities for ensuring food safety – while others found



that the annex on HACCP and ISO 9001 was the most valuable part of the document!

### The second DIS

ISO/TC 34 set to work to develop a new draft which would answer the various objections. With this aim, the United Kingdom Project Leader, with the help of a British Standards Institution expert who was familiar with the draft ISO 9001:2000, made sure that the second DIS was harmonized with the revised quality management standard. In addition, two Codex experts participated in the review of ISO/DIS 15161.

The most important modifications carried out to the document were the following:

- it was completed with an introduction explaining that the application of this standard alongside other common systems in use in food and drink industry may assist an organization better to address customer satisfaction and organizational effectiveness;
- to emphasize the importance of food safety, the annex (except for a figure) which dealt with the possible interaction of ISO 9001 and the HACCP systems was integrated into the main part of the standard;
- to provide users with a more manageable document and avoid them having to buy two standards, the relevant clauses and subclauses of ISO/DIS 9001:2000 were included in boxes in ISO/DIS 15161.2.

The reception of the second DIS was better than that of the first one, 86,36 % of ISO members which had participated in the development approving the new document which, after resolution of the comments accompanying the votes, went out for ballot as a Final Draft International Standard.

### Food quality management

With publication of the guidelines, food producers who want to build up a food quality management system according to ISO 9001:2000 need only buy ISO 15161 as it includes all the clauses and subclauses of ISO 9001:2000 in the same order. They are placed in boxes to distinguish them clearly from the added explanations which assist in interpretation of that section for the food and drink industry, and which draw attention to where national food legislation and the HACCP principles need to be considered.

Finally, it should be mentioned that with the publication of ISO 15161, we do not consider the work finished. During the next few years, we will gather experience related to its application so that at the time of the first revision of the standard, we will be able to enhance its content and make it more specific to the food and drink industry. ■

