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June 20, 2011 (Monday)   Pre-Congress Seminars

Ministry of Rural Development   **Kossuth Lajos tér 11. Budapest V.**
CONFERENCE ROOM   **Monday 10:00 – 18:00**

1.3. NEW QUALITY AND SAFETY REGULATIONS AND DEVELOPMENTS ON THE AGRIFOOD AREA

Seminar Chair: Zoltán Kálmán, Ministry of Rural Development, Hungary

14.20 Food Safety, Quality, and Legality: Stakeholders with Increasing Impact on Food Producers
Hans Buser, Federation of the Swiss Food Industries, Switzerland

Buser, Hans (Switzerland)

Hans Buser graduated in education, teaching and natural science at the University of Bern, Switzerland. For many years, he has been working as a free-lance auditor and trainer mainly in food companies for ISO 9001, ISO 14001 and ISO 22000. He is involved in the training of quality managers, food law and food safety specialists, food inspectors and third party auditors. In addition, he was author and co-author of publications like "Quality Manual for the Swiss Food Industry", "Digest of Environmental Law for the Swiss Food Industry" and "Guidance on Quality Management for the German Food Industry". From 2000 to 2006 Mr Buser held the position of Secretary General of IQNet – The International Certification Network, including representations in international organisations like IAF (International Accreditation Forum), ISO/CASCO, ISO/TC 176 and 207 and GFSI (Global Food Safety Initiative). In this period he made two presentations at EOQ Annual Conferences: 2004 in Moscow and 2005 in Antalya. Since 2006 Mr Buser is engaged as scientific advisor to the Federation of the Swiss Food Industries continuing his activities as a free-lance auditor and trainer for an international certification body operating mainly in food business.

Foederation der Schweizerischen Nahrungsmittel-Industrien
Fédération des Industries Alimentaires Suisses
Federazione delle Industrie Alimentari Svizzere

EOQ Congress Budapest, June 20 - 23, 2011

Food Safety, Quality, and Legality: Stakeholders with Increasing Impact on Food Producers

Hans Buser, Federation of the Swiss Food Industries, Bern/Switzerland

Summary:

Food producers in Switzerland and worldwide, experience growing pressure from all sorts of stakeholders like clients, authorities, inspection and certification bodies, and consumer organisations.

Food law and food safety, HACCP-systems, traceability, specifications of ingredients and food contact materials, recall procedures, allergen declarations and health claims mix up with new issues like nanotechnology and printing inks. Are the organisations in the food chain prepared to cope with all these traditional as well as future requirements?

Third party certification is still one of the major tools for food producers to demonstrate compliance with food safety, quality, legality, and other requirements like environmental, social, and health protection issues towards clients, customers and authorities.

A recent survey conducted among food producers in Switzerland demonstrates ongoing confidence in third party certification, based on approved standards as well as on new food safety requirements. It will be interesting to see, which of all these standards will be the winners in the near future.

For successful food producers it is important to communicate and cooperate with all stakeholders in the food chain, implementing knowledge-based management systems considering external expertise from clients and suppliers, professional associations, consultants, lawyers, authorities, inspection and certification bodies, and auditors. The only promising way for all organisations in the food chain is the mutual way.

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1. Introduction

On 15 March 1987, ISO (The International Organization for Standardization) issued the first version of the ISO 9000 family for "Quality Management Systems". This standard had an unexpected worldwide impact on most economic areas. It formed the generally approved basis for quality management systems and saved costs through a substantial reduction of suppliers' audits. The precondition was that the organisation could demonstrate to be in conformity with the requirements of this international standard.

This was the birth of the "Quality manual for the Swiss Food Industries", which was presented to the German and Austrian Food producers in Bonn/Germany on 21.03.1990. Finally, this guidance document became a reference for the food industry in the German speaking countries.

Since then, a wide range of management systems and product related standards have been established for food producers and food products, like BRC, IFS, SQF 2000, Dutch HACCP, DS 3027, ISO 22000, FSSC 22000, Eurep Gap, and ISO 15161. Furthermore, international food producers and catering organizations let their own standards be audited by appointed international third party certification bodies.

The number of accreditation bodies, certifiable standards and certification/registration bodies is still growing, resulting in more than 1'000'000 management system certificates (mainly based on ISO 9001 and ISO 14001). For ISO 22000 "Food safety management systems - Requirements for any organization in the food chain", we currently estimate more than 20'000 certificates worldwide.

The main targets for food producers getting certified are to increase customer satisfaction, credibility, and guarantee safe products, by reducing risks and costs at the same time (less supplier audits, less waste of products, higher efficiency of internal processes, better quality of products and services).

Nevertheless, food safety is an ongoing issue, with increasing legal impacts like dioxins in feed, mineral oil residues in food packaging, or acrylamides in baked products. The fear of such incidents leads to more and more inspections, higher regulatory requirements, and increased company responsibilities.

Therefore, it is not astonishing to hear food producers saying: "Every year, we increase our self-care activities (checks, analyses, inspections, validation, verification and control), but nevertheless we need more and more legal support by specialized consultants or law firms, otherwise we would face a growing amount of problems in many of our markets."

2. fial - Federation of the Swiss Food Industries

The Federation of the Swiss Food Industries (fial) builds the roof for 17 food industry associations, with 200 companies, 250 production sites, and more than 34'000 employees. Total annual revenues are 18.4 billion CHF (approximately 14.5 billion Euro), including 19 % of export sales.

The main target of fial is to safeguard the common economic and relevant political interests of the affiliated associations and their member companies.

Fial acts in areas entrusted by its member associations only. These associations have own responsibilities to treat their industry-specific issues. Fial targets public relation activities and mainly deals with:

- general issues of food legislation and relevant enforcement
- economic and political matters of the manufacturing food industries
- European integration and international trade (WTO, etc.)
- import and export procedures and customs laws; joint research projects
- nutrition and obesity-related topics issues
- vocational education and training in the food industry
- statistical surveys for the affiliated branches

Fial is composed of 17 food industry associations (translation):

- BISCOSUISSE - Swiss Association of the Biscuits and Sugar Confectionery Industries
- CHOCOSUISSE - Association of Swiss Chocolate Manufacturers
- DSM - Federation of Swiss Millers
- DASS - Federation of Swiss Specialty Mills
- IGTG - Interest Group of Tea, Spices and Related Products
- SFF - Swiss Meat Association
- SHV - Swiss Yeast Association
- SCFA - Swiss Convenience Food Association
- SwissOlio - Association of Swiss Manufacturers of Edible Vegetable Oils, Fats and Margarine
- SwissPasta - Association of the Swiss Pasta Industry
- VHK - Association of Manufacturers of Semi-Finished Bakery and Confectionery Products
- SESK - Federation of the Swiss Cheese Spread Industry
- Association of Swiss Ice-Cream Producers
- Association of Swiss Manufacturers of Soups and Sauces
- Association of Swiss Mineral Water Wells and Soft Drink Producers
- VMI - Association of Swiss Milk Industry
- Association of Swiss Manufacturer of Dietary Foods and Foods for Special Nutrition

3. Self control versus external inspection and auditing

3.1 Influence of stakeholders on Swiss food producers

Generally, the food manufacturer is responsible for the food he produces. He must not only fulfil legal requirements, but also work based on HACCP food safety principles (Hazard Analysis and Critical Control Points). In this context, he has to consider a wide range of different perceptions, interests, and views:

- Customer
- Client (shop, manufacturer)
- Supplier (packaging material)
- Quality Manager (producer, client)
- Regulatory Affairs Responsible (producer)
- Public Health Authorities (legal department)
- Inspection Authorities
- Pest Control Company
- External Auditor (Second or Third Party), etc.

This demonstrates that a growing number of stakeholders have an increasing impact on the business activities of Swiss food producers. The most important stakeholder is the client.

Another important group of stakeholders are the authorities and inspection bodies, creating and enforcing national and international food laws. Food is a highly regulated area, with sometimes diverging and fast changing requirements.

3.2 Basic requirements of Swiss food legislation

Swiss Food Law was born on December 8, 1905 and was put into force on July 1, 1909. The entire Swiss food legislation in these days consisted of 1 law, 11 regulations, in total 180 pages, and 200 g by weight.

Today, Swiss food legislation consists of a growing and constantly changing documentation with thousands of pages of laws, regulations, directives, instructions, guidance documents, leaflets, approvals, permissions, and court decisions. But it becomes a real challenge, when silent or implicit agreements have to be considered, or when "not officially published permissions" suddenly are no longer valid without notice or any transition period.

Basics: Swiss Food Law (SR 817.0)

(Unofficial translation; official versions in German, French and Italian are available on www.admin.ch)

Art. 1 Aim

The aim of this Act is:

a. to protect consumers from foodstuffs and utility articles that may present a risk to their health;

b. to ensure that foodstuffs are handled hygienically;

c. to protect consumers from deception relating to foodstuffs.

Art. 23 Self-supervision

1 Anyone who manufactures, processes, offers, imports or exports foodstuffs, additives or utility articles must ensure in the course of his activities that the goods are in conformity with legal re-quirements. He must analyse them or have them analysed according to "Good Manufacturing Practice".

2 Official inspections do not imply a dispensation from the obligation to carry out self-supervision.

Art. 23a Traceability

1 Foodstuffs, animals intended for food, manufacture and all substances pertaining thereto or which may be expected to be processed into a foodstuff, must be traceable through all stages of manufacturing, processing and distribution.

2 Systems and processes must be put in place so that the authorities can, at their request, be notified of any necessary information.

Example: Verification of legality of "Printing inks" in Switzerland

To review legality of one single letter of packaging ink on the outside of a food packing (which is not even intended to come into direct contact with food), the following legal documents (252 pages) apply as a minimum (EU has no such regulation in place yet):

- Swiss Regulation on Objects and Materials (SR 817.023.21); 98 p.
- Annex 6, list of accepted substances for production of packaging inks, with ap-proximately 6'000 chemical substances (latest version 2011-05-01); 154 p.

3.3 Basics for auditing legal requirements

Food safety audits and inspections verify in most cases what food law already requires.

So, where do we find added value regarding auditing legal requirements through stan-dards like BRC Food 5, IFS Food 5, ISO 22000:2005, or ISO/TS 22002-1:2009?
(Legal requirements = Statutory and regulatory requirements)

Requirements of legality in food safety standards (examples)

BRC Food 5

3.1.1 The policy shall state the company's intention to meet its obligation to produce safe and legal products to the specified quality, and its responsibility to its customers.

3.9.4 Where rework or any reworking operation is performed, traceability shall be maintained. In addition, the company must be able to demonstrate that this does not affect the safety or legal status of the finished product, e.g. ingredient declaration, allergy information or identity preservation.

5.1.5 Procedures shall be in place to confirm that product packaging conforms to relevant food safety legislation and specification and is suitable for its intended use.

IFS Food 5

4.5.1 All packaging shall comply with the current relevant legislation.

4.5.8 The conformity of the product with its labelling shall be reviewed each time before a new label is issued for use. Such review shall take into account the product requirements and particular relevant legislation in the designated countries, where the product is to be marketed.

4.18.3 Finished products containing allergens requiring declaration shall be declared in accordance with current legal requirements. For the adventitious (unintended) presence, the labelling of legally declared allergens and traces shall be based on a hazard analysis.

ISO 22000:2005

Scope: This International Standard specifies requirements to enable an organization, …
b) to demonstrate compliance with applicable statutory and regulatory food safety requirements.

5.2 Top management shall ensure that the food safety policy…
b) conforms with both statutory and regulatory requirements and with mutually agreed food safety requirements of customers.

5.6.1 Food safety requirements from statutory and regulatory authorities and customers shall be available.

7.2.2 / 7.3.3.1 / 7.3.3.2 The organization shall identify statutory and regulatory requirements related to: PRPs, raw materials, ingredients, product-contact materials, and end products.

ISO/TS 22002-1:2009

10.3. Allergens present in the product, either by design or by potential manufacturing cross-contact, shall be declared. The declaration shall be on the label for consumer products, and on the label or the accompanying documentation for products intended for further processing.

14.1 Rework shall be stored, handled and used in such a way that product safety, quality, traceability and regulatory compliance are maintained.

3.4 Legality-based non-conformities in food-safety audits

Auditing means sampling, which makes it difficult in many cases for detailed and evidence based decisions.

What is the expected action, when auditors detect a failure to achieve legal or statutory requirements?

In many cases, "A failure to achieve legal or statutory requirements" will lead to a major nonconformity.

But what, if
- Law is right, but nobody knows it?
- Law is right, but nobody cares about it?
- Law is wrong, but nobody knows it?
- Law is wrong, but nobody cares about it?

Faults in Swiss Food Law are often based on inadequate translations. In Switzerland, all laws and regulations must be published in German, French and Italian. Each version is considered as equal and correct. But this target is not at all easy to be achieved.

Such translation or denomination problems are also found in Food Safety Standards:
- use of "risk" instead of "hazard" (= danger)
- use of "control" (= manage) instead of test, inspect, analyze.

EU Regulation 178/2002 defines:

hazard' *means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect.*

'**risk**' *means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.*

3.5 Food safety auditors: Knowledge of food law

Food safety auditors must know the basics in food law. They do not need to know the relevant food laws and regulations by heart, since these requirements are constantly changing. But they must be able to interpret the various requirements in a correct way. Auditors should also know, where law is correct, and where not.

Managers of Swiss Food Inspection Authorities pass an extended food safety management training as part of their "Master of Advanced Studies".

They are trained in Swiss and in European Food Law, among others. The training part for European Food Law starts with the following general remarks:

1. It is not important to know all legal requirements; it is important to know how and where to look, and to know the right people to ask.
2. If you want to know and fully understand EU food law, you will stop doing anything else.
3. It is fundamental to be able to use internet in an efficient way.

Benefits of external audits for the food producers

The term "audit" is standardised and well defined. According to ISO 9000:2005 and ISO 19011:2002, the audit is a "systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled."

Auditors must be **competent** for the function they perform. Among the audit objectives, the auditor should be able to qualify the organisation regarding the "compliance of the audited company with legal and other requirements".

Auditor's competence requests that the auditor knows the sector specific terminology, processes and practices. In addition, the auditors should know the characteristics of the processes, products and services in the companies they audit. This again asks for adequate experience, knowledge and training in food technology and food law.

Reasons for successful food safety audits:

- Four eyes see more than two
- Auditors look into the company from outside
- Food safety auditors are specialists, also in food law
- External opinions can support internal processes
- Detect deviations
- Requests for corrective and preventive actions
- Recommendations for improvement
- Customer recognition through certificates

Audit requirements are not always clearly specified

Food safety auditors work based on requirements defined in standards. But, as the following example on "Storage of packaging material" in BRC Food Standard 5 demonstrates, already the different language of a standard can set different requirements.

Therefore, auditors should know, where the audited standards are correct, and where not. Auditors should be able to interpret the various requirements of the standards in a correct way whenever needed. Example:

Storage of packaging material (BRC Food Version 5, clause 5.4.2)

German
Verpackungen sind nicht in der Nähe von Rohstoffen oder Endprodukten zu lagern. (*Packaging shall not be stored near raw materials or finished products*).

French
Quand c'est nécessaire, les emballages doivent être stockés séparément des matières premières et des produits finis. (*If requested, packaging shall be stored separate from raw materials and finished products*).

English
Where appropriate, packaging shall be stored away from raw materials and finished product.

What means "**where appropriate**"? BRC gives 2 different definitions:

1. BRC Food Standard Version 5 (January 2008)

"Where appropriate": The company will risk assess the actual requirement of the Standard and where applicable put in place systems, processes, procedures or equipment to meet the requirement. The company shall be mindful of legal requirements, best practice standards, good manufacturing practice and industry guidance, and any other information relating to the manufacture of safe and legal product.

2. BRC Food Standard Version 5 - Interpretation Guideline (December 2008)

"Appropriate" is defined as suitable for a particular condition or occasion, and requirements shall be met where it is considered an industry requirement or is justified to do so. This contains a level of judgement. It is designed to provide a degree of flexibility to ensure the operation of policies or procedures that are right for the organization.

4. Swiss Food Industry - Quo vadis certification?

In 2010, a representative number of small, medium and large food producers partici-pated in a survey conducted by fial headquarters in order to detect <u>trends</u> in certification activities.

The following 9 standards were selected:

Not GFSI approved	GFSI approved
ISO 9001	BRC Food
ISO 14001	IFS Food
ISO 22000	FSSC 22000
	Synergy 22000
	SQF 2000
	Dutch HACCP

<u>Questions in the survey</u>

- Which of these certificates did you have in 2007?
- Which of these certificates do you have today (2010)?
- Which of these certificates do you intend to have in 2013?

<u>Results of the survey (extract)</u>

- SQF 2000 and Dutch HACCP: not used in Switzerland
- No certification: 7 % of food producers, but systems in place
- Number of certificates per company: 1 - 5 (peak at 2)
- 9001: ongoing leadership, with stability on a high level
- ISO 14001: growth expected
- BRC and IFS: decrease expected
- ISO 22000, increase expected
- FSSC 22000 and Synergy 22000: increase expected.

<u>Links and abbreviations</u>

- www.iso.org - ISO (International Organization for Standardization)
- www.iaf.nu - IAF (International Accreditation Forum)
- www.mygfsi.com - GFSI (Global Food Safety Initiative)
- www.theconsumergoodsforum.com - The Consumer Goods Forum; former CIES
- www.ciaa.be - CIAA (Confederation of the Food and Drink Industries of the EU)
- www.brc.org.uk - BRC (British Retail Consortium)
- www.ifs-online.eu - IFS (International Featured Standards)
- www.fssc22000.com - FSSC 22000 (Food Safety System Certification 22000)
- www.synergy-gss.com - Synergy (Synergy Global Standardisation Services SA)

5. Conclusion

Food Producers experience an increasing impact from stakeholders on food safety, quality, and legality. As a consequence, a growing number of different standards and specifications are applied worldwide to demonstrate food safety and food consciousness.

Proliferation of food safety standards is a costly burden for the Food Industry. Therefore, the main target of many interested organisations remains unchanged: "One standard, one audit, one certificate".

GFSI white paper of March 2011 states: "Accredited third party certification is today the best available means of ensuring the supply of safe food to the consumer in our globally sourced food system."

A survey conducted among Swiss producers in 2010 demonstrates their will to profit also in future from external auditing and certification activities. New GFSI approved standards like FSSC 22000 show a high acceptance in the Swiss Food Industry. It is therefore a need that these standards and relevant accredited certificates will be globally accepted by wholesalers.

Flexibility of certification and accreditation bodies is requested in order to allocate a sufficient number of competent food safety auditors to fulfil the auditing needs of food industry. Auditor competence is important and requests ability to apply knowledge, skills and experience.

Hans Buser, fial, 2011-04-26