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Preface

In order to meet the requirements and to be of help to the business organizations in our country the National Chamber of Skilled Crafts (NCSC), the Regional Craft Chamber - Sofia (RCC) and the Balkan office of SME Support became part of a Consortium whose purpose is to acquaint the organizations representing the business with the 'acquis communautaire' and its implementation in the national economies.

As partners in the Consortium NCSC, RCC-Sofia and the Balkan Bureau are taking part in a project that joins the efforts of experts from Germany, Bulgaria, Romania, Croatia, Turkey, Slovenia, Luxemburg and Denmark.

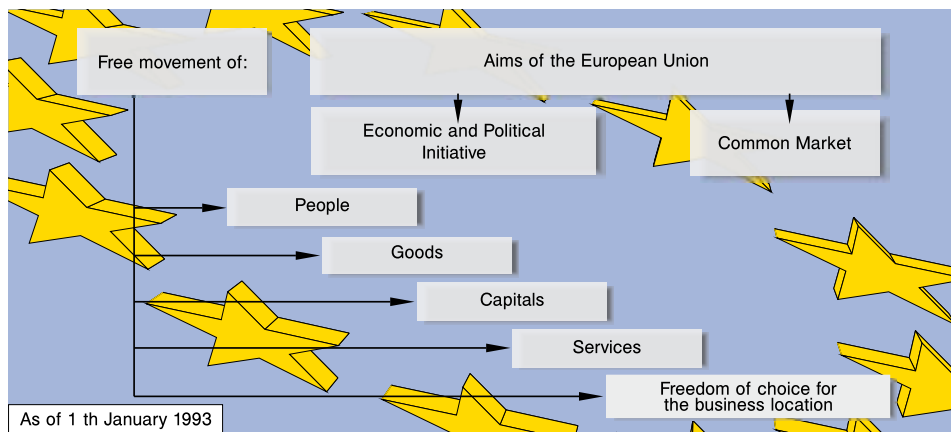
The purpose of the project is to strengthen the capacity of the business representative organizations in Bulgaria, Romania, Croatia and Turkey by deepening their competency in various aspects of the 'acquis communautaire', which will enable them to be as helpful as possible to their members by providing up-to-date information, analysis and consultation in the alignment of their national legislations to the Community legislation.

The project activities include:

- Holding several international and national conferences
- Training of 9 experts from the 4 organizations
- Publishing and distributing of three "Manuals", dedicated to the key issues of the conferences.

The first international conference under the project was held from 21 to 23 April 2008 in Sofia, Bulgaria on "Food and product quality and safety". This manual is dedicated to the same subject and covers reports and presentations of Bulgarian, Romanian, Croatian and Turkish experts from the member countries of the project consortium.

Genko Genkov,
Regional Craft Chamber - Sofia



Partners

1. SEQUA GmbH (affiliated non-profit company of ZDH)
2. Chambre des Metiers du Grand-Duche de Luxembourg / Luxembourg Chamber of Trades
3. Dansk Industri / Confederation of Danish Industries
4. HwK Koblenz / Koblenz Chamber of Skilled Crafts-Mittelstandsburo Balkan
5. Obrtna Zbornica Slovenije / The Chamber of Crafts of Slovenia
6. UCECOM - National Union of Handicraft and Production Co-operatives of Romania
7. National Chamber of Skilled Crafts / Национална занаятчийска камара (НЗК)
8. Hrvatska Obrtnicka Komora / Croatian Chamber of Skilled Crafts
9. Regional CraftChember of Sofia / Регионална занаятчийска камара - София (РЗК)
10. Antalya Esnaf ve Sanatkarlar Odalari Birligi / The Antalya Union of Tradesmen and Craftsmen

New requirements of the EU food legislation

1. The new legislation is introduced with several main regulations of the so called “Hygiene package”

These are:

REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 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.

REGULATION (EC) No 852/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the hygiene of foodstuffs.

REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 laying down specific hygiene rules for food of animal origin.

REGULATION (EC) No 854/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

REGULATION (EC) NO 882/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

2. What does the new approach consist in?

The regulations:

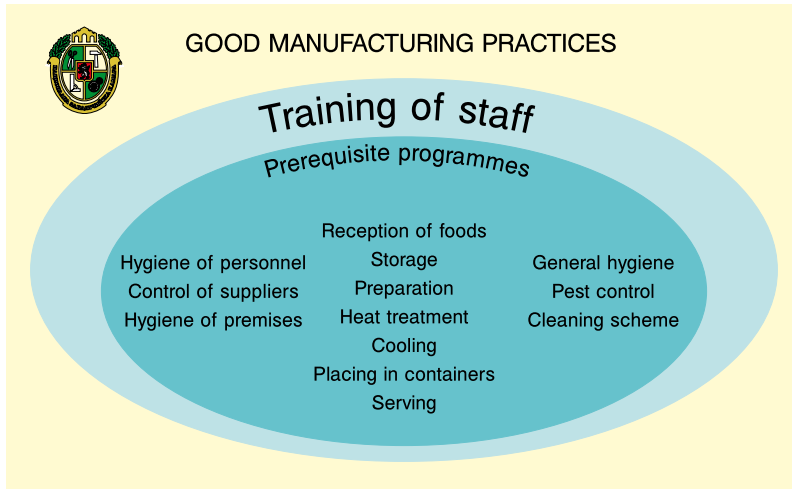
- describe the aims to be achieved by the implementation of the regulations
- it is less instructive
- describe what is to be achieved, not how it is to be achieved
- apply both to small and medium-sized enterprises
- use expressions such as “where necessary, appropriate and adequate”.

3. What is new?

- The chief responsibility for food safety lies with the food business operator.
- “Food business operators shall ensure that all stages of production, processing and distribution of foods under their control satisfy the relevant hygiene requirements”.
- It is necessary to ensure food safety throughout the food chain, starting with primary production.

3.1 Compulsory introduction of good practices

New hygiene requirements are introduced in respects of premises, staff, packaging, storage and transportation of foods. The terms **“where necessary”**, **“where appropriate”**, **“adequate”** and **“sufficient”**- food business operators are given the freedom to decide. Whether the requirement is necessary, appropriate, adequate and sufficient depends on the nature of the food and its intended use.



4. Introduction of HACCP

Food business operators shall put in place, implement and maintain a food safety management system or a system for hazard analysis and critical control points (HACCP), and where overall introduction of the system is inapplicable - procedures based on the HACCP principles.

Such units may include - pavillions, exhibition stalls and transport means for sale of foods, establishments serving mainly beverages (bars, cafes, etc.), small shops for sale of foods (for groceries), transport and storage of pre-packaged foods or non-perishable foods, i.e. establishments not normally carrying out food preparation.

5. Traceability

The purpose of traceability is to prevent foodstuffs and products, which are unfit for human consumption or present a risk to consumer’s health, from being placed on the market.

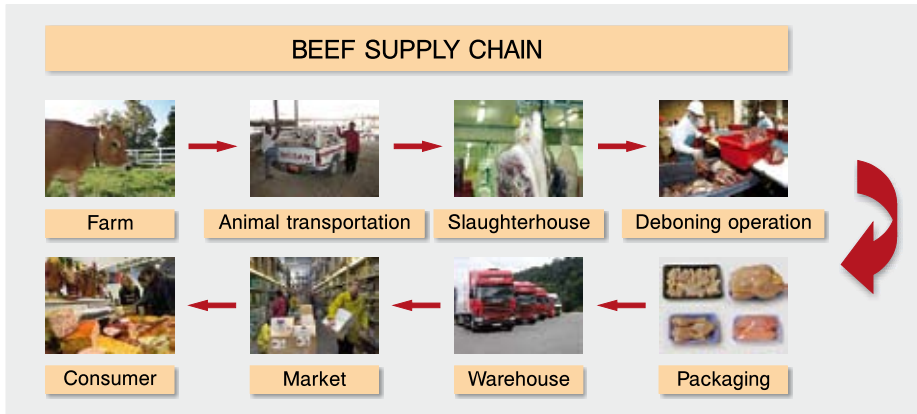
What can be traced?

- Everything, which is recognizable (distinguishable)
- Which has sufficient characteristics to allow everybody to distinguish it from everything else
- Which has places where stickers can be put or identification marks attached.

According to the legislation it is the food industry that bears the main responsibility for the safety of foods intended for human consumption. The consumers’ need for information and public health protection are the key mechanisms of an effective traceability system. The management of

the production process, the protection of the respective product category and the branding are significant issues for any business organization.

The food industry is responsible for the establishment of an effective traceability system. Within the system the industry has to assume the responsibility for the “traceability of suppliers” - of the raw materials and ingredients; “traceability of processing” - in the processing and packaging and “traceability of consumers” - of the final product to the direct consumer.



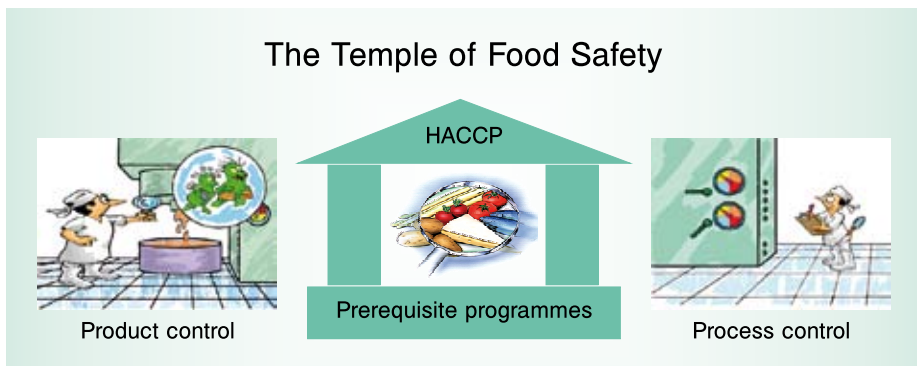
The food traceability model includes:

- What comes in?
- What goes out?
- Maintaining accountability.
- Ensured exchange of information with consumers and the relevant authorities.
- Receiving information from suppliers.

With the introduction of the above rules the Temple of Food Safety is built

The new EU legislaion leads to:

- More responsibility for the producer.
- More indirect intervention on the part of government.
- The companies have to prove that they conduct their business in the right way.



Food safety is a shared responsibility

What exactly do we understand by 'shared responsibility' in the EU context?

- In the first place - this is the transition in food safety management and control - from responsibility for everything to delegated responsibility
- In the second place - transition from the principle of "total control" to the principle of "own control and control over the own control"
- In the third place - traceability along the whole food chain.

There are four groups of partners involved in shared responsibility - food producers, food processors and distributors, control authorities and consumers.

Each food business operator in the food chain has an own vision of how to organize the food safety management but it is the control authorities that are obligated by law to coordinate those systems. Official controls serves to prove the degree of efficiency of the food safety management systems introduced by the individual food business operators and consumers obtain a guarantee that only safe foodstuffs are placed on the market.

When talking about safe food we mean three basic criteria:

- the food is not harmful to human health
- the food has not undergone any alteration or spoilage
- the food has not been counterfeited or manipulated.

How can we manage safety within the food chain?

Food safety is a supranational priority because the following have to be ensured:

- food safety throughout the food chain
- unified control on the food chain.

The introduction of the Community legislation is practically introduction of "THE RULES OF THE GAME" of the Common Market, which are:

- the principle of free movement of goods
- the principle of mutual recognition
- full responsibility of the producer for the safety of the offered foodstuffs.

Since the placing of foods on the Common Market shall not threaten the interests of the consumer in the EU member states it may not be related to risk of lowering the food safety standards.

Basic goals of self-control

TO GUARANTEE THE ORIGIN OF THE FOODS

TO CONFIRM THE CORRESPONDENCE OF FOODS WITH
THE ONES DESCRIBED IN THE TECHNICAL DOCUMENTATION

TO GIVE SAFETY TO THE CONSUMERS

TO ENSURE CONSTANT QUALITY TO THE PRODUCED FOODS

TO ENSURE LOYAL COMPETITION AMONG THE PRODUCERS

Persons, implementing the systems of own control, must:

know the systems in detail and are convinced
in the need to implement them

acquire the necessary knowledge and skills
to ensure the proper functioning of the systems

100% implementation of GMP

assess the hazards in order to be able
to control them at any stage of the food chain

are instructed and acquainted with
the necessary procedures for hazard prevention

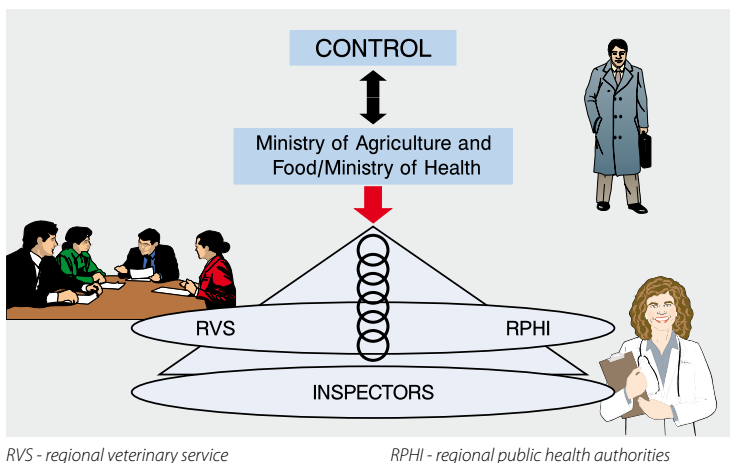
OFFICIAL FOOD SAFETY CONTROLS

The official control authority is entitled to conduct planned or random inspections in case of non-compliances on the part of the producer.

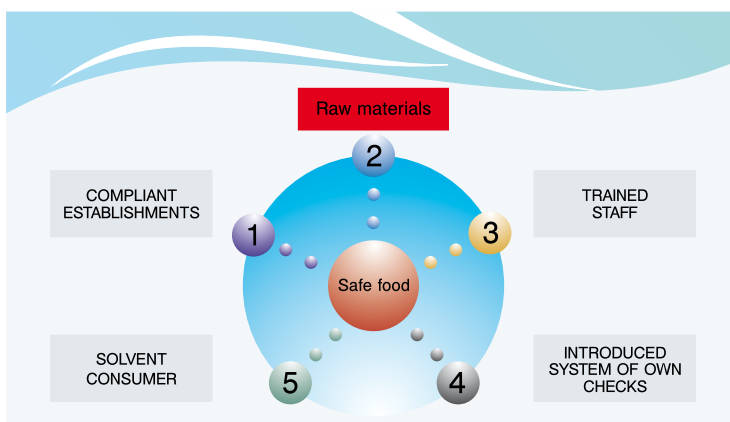
Inspections might be:

- documentary
- visual
- by taking measurements
- by sampling and analyses
- by another method selected by the person performing the inspection.

The control authorities are:



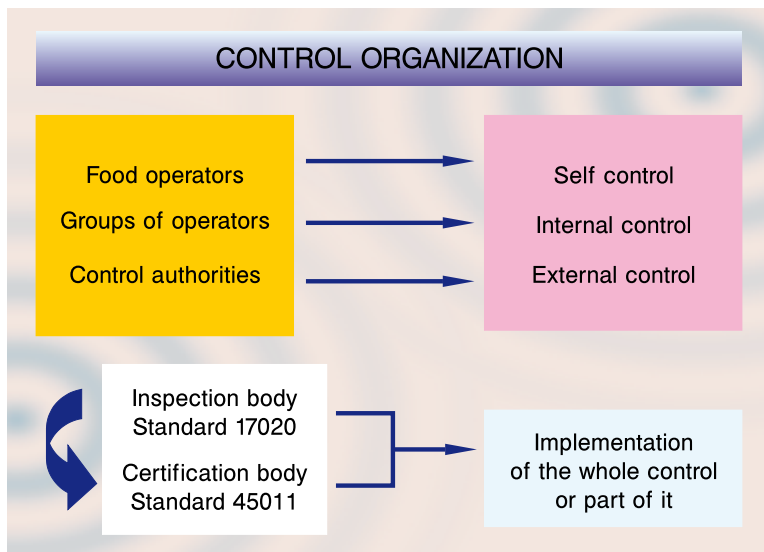
Food safety actually starts at the point when the whole system is established in terms of documentation but the process of shared responsibility starts at the point when all those principles deeply penetrate the company and consumer culture.



Shared responsibility means a new challenge to food business operators and control authorities. It gives all of us as consumers the necessary assurance in the safety of offered foodstuffs.

What are the main objectives of control?

- To ensure that the product originates from a certain territory
- To verify the compliance of the product characteristics with those listed in the technological documentation
- To give assurance to the consumer
- To strengthen the product reputation
- To ensure loyal competition among the producers.



CONFERENCE REPORTS

EXPERIENCES ABOUT IMPLEMENTATION OF THE FOOD LAW WITH HACCP SYSTEMS

Stefan Tannenberg

IHK (Chamber of commerce and industry) Koblenz

*Officially authorised and sworn expert for production hygiene and product hygiene in the food sector,
Lead Auditor for IFS and 9001:2000 Auditor*

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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. This Regulation shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.

Article 2 Definitions

“Food” (or “foodstuff”) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

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

“risk analysis” means a process consisting of three interconnected components: risk assessment, risk management and risk communication.

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

Article 8 Protection of consumers’ interests

1. Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of:

- fraudulent or deceptive practices
- the adulteration of food
- any other practices which may mislead the consumer.

Article 10 Public information

Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health.

Article 11 Food and feed imported into the Community

Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.

Article 14 Food safety requirements

1. Food shall not be placed on the market if it is unsafe.
2. Food shall be deemed to be unsafe if it is considered to be:
 - Injurious to health
 - unfit for human consumption.
3. In determining whether any food is unsafe, regard shall be held:
 - to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution
 - to the information provided to the consumer, including information on the label.
4. In determining whether any food is injurious to health, regard shall be held:
 - not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations
 - to the probable cumulative toxic effects
 - to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

Article 18 Traceability

“Traceability” means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.
2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

Article 19 Responsibilities for food: food business operators

If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof.

The principal objective of the new general and specific hygiene rules is to ensure a high level of consumer protection with regard to food safety.

It is necessary to ensure food safety throughout the food chain, starting with primary production.

It is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain.

Article 5 Hazard analysis and critical control points (HACCP)

1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.
2. The HACCP principles referred to in paragraph 1 consist of the following:
 - a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels
 - b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels
 - c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards
 - d) establishing and implementing effective monitoring procedures at critical control points
 - e) establishing corrective actions when monitoring indicates that a critical control point is not under control
 - f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively
 - g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

Food business operators shall:

- provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business
- ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times
- retain any other documents and records for an appropriate period.

Article 6 Official controls, registration and approval

1. Food business operators shall cooperate with the competent authorities in accordance with other applicable Community legislation or, if it does not exist, with national law.
2. In particular, every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.

Food business operators shall also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.

3. However, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required:
- under the national law of the Member State in which the establishment is located
 - under Regulation (EC) No 853/2004.

Article 7

Member States shall encourage the development of national guides to good practice for hygiene and for the application of HACCP principles in accordance with Art. 8.

Article 9

When Community guides are prepared, the Commission shall ensure that they are developed and disseminated:

- by or in consultation with appropriate representatives of European food business sectors, including SMEs, and other interested parties, such as consumer groups.

Primary production and associated operations

Applies to primary production and the following associated operations:

- the transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature
- the transport of live animals, where this is necessary to achieve the objectives of this Regulation
- in the case of products of plant origin, fishery products and wild game, transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment.

As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary products will subsequently undergo. Measures to control contamination arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and the storage, handling and disposal of waste.

Measures relating to animal health and welfare and plant health that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents. Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records on:

- the nature and origin of feed fed to the animals
- veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods
- the occurrence of diseases that may affect the safety of products of animal origin
- the results of any analyses carried out on samples taken from animals or other samples taken for

- diagnostic purposes, that have importance for human health
- any relevant reports on checks carried out on animals or products of animal origin.

General requirements for food premises

Food premises are to be kept clean and maintained in good repair and condition.

The layout, design, construction, siting and size of food premises are to permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations.

To be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces; To permit good food hygiene practices, including protection against contamination and, in particular, pest control.

An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled.

An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food are to be separate from the hand-washing facility.

There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.

Food premises are to have adequate natural and/or artificial lighting.

Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area.

Cleaning agents and disinfectants are not to be stored in areas where food is handled.

Highlights of Dr. Wolfgang Lutz' presentation

Dr. Wolfgang Lutz

Deutscher Fleischer-Verband, Frankfurt

Topics

- 1. Market & Trends for Meat and Milk**
- 2. European Regulations for Food Quality**
- 3. Guidelines for Good Hygiene Practice (GHP)**

Meat sector in Germany (2007)

1. Slaughterhouses and cutting plants (industry: ca. 500)
2. Processing plants (industry: ca. 700)
3. Supermarkets (service ca. 40.000, selfservice ca. 20.000)
4. Craft butchers

16 761	businesses
over 10 733	affiliates
= 17.2 Mrd. €	gross turnover
= 155 000	employees

Trends in Germany (meat and milk)

1. High quality (sensoric) & good price
2. Convenience: "ready-to-heat", "ready-to-eat"
3. Pre-packed (self-service)
4. Also: traditional production, "hand-made", over the counter sale
5. Poultry (fresh meat + products)
6. Wellness: less fat, less calories, less salt
7. Organic
8. "Cross-over-products": meat/milk + fruits/vegetables, meat + cheese, new spices

How to feel the trends?

- Visit food-related trade-fairs: Anuga, Intermeat, IFFA, IBA, Grüne Woche
- Visit quality-competitions: DLG = Deutsche Landwirtschafts-Gesellschaft; International: DFV on IFFA in Frankfurt
- Look at European supermarkets + butcher shops / bakeries
- Contact people
- Read food-magazines and newspapers

Requirements for business success

- Company: good organisation/management, technology, finance resources
- Staff: excellent know how, experience, skilled and trained employees
- Product: perfect consumer perception (right time, right place)
- Nice price
- Good image of product and company

- Good public relations and advertisement
- Distribution: right partners, good service

European Food Law

Food Regulations

- Regulation (EC) 178/2002 laying down general principles and requirements
- Regulation (EC) 2074/2005 about microbiological criteria
- Regulations about food additives
- Regulations about residuals and contaminants

Hygiene Regulations

- Regulation (EC) 852/2004 on the hygiene of food stuffs
- Regulation (EC) 853/2004 laying down specific rules for food of animal origin
- Regulation (EC) Nr. 854/2004 laying down specific rules of the organisation of official controls
- Regulations about transitional measures
- Guidance Documents

Labelling

- Directive 2000/13/EC about labeling, presentation and advertisement

others

- Animal Welfare, Animal disease
- Animal by-products
- Market regulations

Hygiene obligations for meat and milk

all

- 852 = general hygiene rules
- HACCP
- Training
- Microbiological analysis

+

Approved establishments

- 832: specific hygiene rules
- Inspection and approval procedure

+

Registered establishments - national law

Hygiene Regulation (EC) 853/2004

Essentials for meat / milk

1. General: Approval of establishments
2. Exemption: "retail" (registration only) - production and handling at the point of sale at the final consumer
3. Flexible requirements, based on risk analysis
4. Deadline: end of 2009

Important requirements for slaughter houses

- General hygiene requirements
- Adequate lairage facilities & waiting pens: watering/feeding, if necessary
- Adequate rooms, construction and equipment
- Separation of clean and unclean operations (in space or time)
- Separate room for emptying and cleaning of stomachs and intestines (exceptions!)
- Facilities for disinfecting: 82 °C or alternative system
- Ante- and post-mortem inspection
- Good slaughter hygiene
- Flexibility, depending on risk

Important requirements for cutting plants

- General hygiene requirements
- Separate cutting room (no cutting in slaughter house!)
- Ambient temperature: 12°C or alternative system
- Meat temperature: 7°C (offals: 3°C)
- Facilities for disinfecting: 82°C or alternative system
- Flexibility, depending on risk

IMPLEMENTATION OF THE FOOD SAFETY REQUIREMENTS IN BULGARIA

Dr. Svetla Chamova

Executive Director of the Association of Meat Processors in Bulgaria

Nowadays food safety is a key issue not only in Europe but throughout the world because food is a global industry. Every person in the world is a client of the global food industry. In developed countries, consumers are constantly raising their expectations with regard to food safety. Consumers expect from producers to ensure food safety without overlooking quality and price issues. Safer food has many benefits: less human suffering from food borne diseases, lower cost of public health, fewer barriers to world trade, lower loss of labour productivity and better overall food security. Food safety could indeed be considered one of the most important concerns of our time. The threat to public health from food-borne diseases occurs in both developed and developing countries, with the greatest impact on children, pregnant women, the poor and the elderly.

Chemical hazards are another significant source of food-borne diseases. Public concern has been heightened by episodes of microbiological and chemical contamination of foodstuffs. Threats such as salmonella, mycotoxins, BSE, dioxin and residues from antibiotics affect more than one country and in some cases more than one continent.

As stated in the White Paper on Food Safety a series of crises concerning human food and animal feed (BSE, dioxin, etc.) has exposed weaknesses in the design and application of food legislation within the EU. This has led the Commission to include the promotion of a high level of food safety among its policy priorities with particular focus on improving quality standards and reinforcing systems of checks throughout the food chain, from farm to table.

In this context it is not surprising that **food safety is a key issue for eu accession** as well. The EU message in terms of food safety is clear: The challenge is to bring standards in the Candidate Countries up to current EU standards as the EU would not tolerate any weakening of food safety levels within the enlarged internal market.

The EU position in this respect is clear:

Enlargement cannot threaten the interests of consumers in the current and future EU member-states - it does not impose any risk of lowering food safety standards on the Common market.

The position of the accession countries is also clear:

EU membership = immediate access to the Common market = increased responsibilities - responsibility not only towards your country but also towards member-state consumers

At the 9th East-West Agricultural Forum Green Week in Berlin on 10-12 January 2002 European Commissioner for Health and Consumer Protection David BYRNE spoke of the new challenges to ensure food safety in the scope of enlargement:

"The real work is for the candidate countries", he said, "for it is they who must not only adopt the Community's acquis, but must implement it."

The Preparation for EU Accession is practically the preparation of the business for EU common market integration while the EU acquis in fact lays down “the rules of the game” for the Common market, in particular:

- the principle of free movement of goods
- the principle of mutual recognition
- the principle that the full responsibility for ensuring the safety of food on the Common market rests with the food business.

The latter involves:

- Introduction of GMP in establishments
- Introduction of HACCP in establishments
- Traceability of food products and plan for dangerous product recalls and notification of competent authorities

How did Bulgaria manage to cope with this ‘real work’ - the adoption and implementation of food safety legislation?

What happened in Bulgaria in the years of transition from planned to market economy? In the first years of transition in both milk and meat sectors there was a clear tendency towards dramatic increase of the number of establishments. Unfortunately the majority of them were far from being compliant with the EU food safety requirement. Particular efforts were needed in relation to the adoption, implementation and enforcement of veterinary and phytosanitary requirements and upgrading of establishments to meet EC standards, particularly with regard to the inspection and control arrangements for protecting the EU external borders. In the framework of the upgrading of agri-good establishments in Bulgaria, launched by the national competent authorities, the number was significantly reduced based on compliance.

What were the companies supposed to do?

- To plan - no matter how impossible this might seem
- To find the necessary resources rapidly
- To empower their staff and to communicate the message for commitment all along the company's hierarchy
- To be convinced in the need to continue with the implementation of the self-control programs

A major obligation of the regulatory agencies was to provide the necessary conditions for the industry to fulfil its obligations in ensuring food safety.

The official food safety control in Bulgaria is split between the Ministry of Agriculture and the Ministry of Health. The first, through its specialised bodies, is in charge of products of animal origin and the second - for products of non-animal origin. The veterinary public health authorities, which are the specialized control body of the Ministry of Agriculture, are in charge of the control of the whole chain of animal product manufacturing - from the animal to the consumer - in particular they are responsible for the control of slaughterhouses, cutting plants and meat processing establishments, animal welfare, laboratory control and ecological requirements.

The enforcement of legislation has remained solely in the hands of producers. It is the obligation of the industry to control the process in order to ensure production of safe, full value and wholesome products in compliance with the legislation. The industry is responsible for the enforcement of all requirements applicable to the whole food chain – from the stable to the table, including: animal nutrition, animal welfare, animal health, veterinary public health, environmental requirements, phytosanitary requirements, pharmaceutical and biological products, feeding and watering, wastes.

To ensure the safety of the food they produce food operators must have:

- a compliant establishment;
- safe raw materials,
- trained staff
- a system of own checks in place
- solvent consumers to make the above affordable.

The process of upgrading of agri-food establishments, and in particular of meat establishments, in Bulgaria was hard and painful.

What do we actually understand by shared responsibility in the EU context? From one side, this is the transition in terms of food safety management and control – from responsibility for everything to delegated responsibility. The second important point is the transition from the principle of “total control” to the principle of “self-control and control over the self-control”. In third place is the principle of traceability of food. If in a food chain there is even one unit that does not ensure the traceability of the production and the clarity of the origin of a given raw material or product, ultimately there is no way to guarantee that the product is safe. If a single supplier fails to provide the necessary guarantees for their products that would be enough to cause even the best defined food safety management system, introduced via the relevant documentation, to fail.

According to the theory of food quality and safety management there are three groups of partners having relation to the shared responsibility. On the one hand, there are those producing and distributing food. On the other - there are the food control authorities. These official competent authorities represent a main partner, when speaking of shared responsibility. And as the third, of course, come the consumers, who play a very active role, when they come to realize their place in the food chain.

FOOD QUALITY AND SAFETY - PRESENT SITUATION IN ROMANIA

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The European business environment owes its high level of competitiveness to constant concern for consumers' protection. This preoccupation is concretized into the EU principles regarding consumers' protection, stipulated in a series of directives about products' safety and consumers' rights. These principles describe the minimum protection level that each EU Member State has to assure for the consumers. The specific details existent at national level, regarding precise rights and how they could apply, depend mostly on the way that each country has implemented the EU directives into national legislation. Generally, the national legislation offers a higher protection degree than the EU legislation.

Food products are much more important for the consumers than other kinds of products. Besides the fact that they assure the daily nourishment needs, if they are spoiled or contaminated, they affect directly the consumers' health and can even endanger their life.

The most important risks on health, associated with aliments are:

- **food's microbiological contamination**
- **chemical contamination with pesticides, heavy metals or other toxic substances**
- **use of banned food additives or accepted additives in larger quantities than allowed**
- **the presence of antibiotics in food composition.**

Also, at EU level there are regulations regarding pork, beef, sheep and goat meat etc. In the years before the Romanian accession there has been a continuous change of national regulations regarding the food domain, having the purpose to assimilate the communitarian acquis in quality policy domain. The standardization, control and quality assurance for food are only few of national empowered bodies priorities, aiming for a better position of local food products on the internal and external markets.

Since the accession, the EU legislation was transposed into national legislation, an important chapter being consumers' protection, including significant aspects about food quality.

In Romania there are regulations that refer to food quality control, consumers' protection, official food control, food hygiene, food labelling (especially for meat and milk products), contaminants, ionizing radiations, food additives, flavours, materials that come in contact with food, extraction solvents.

Other present regulations that have an influence on food quality domain: G.O. no. 21/1992 regarding consumers' protection (states the major consumers' rights in Romania), Law no. 148/2000 regarding publicity, **Law no. 296/2004 regarding the Consumption Code**, G.O. no. 99/2000 regarding the selling of products and services on the market, G.D. no.106/2002 regarding food labelling, G.D. no. 947/2000 regarding the way to indicate the prices for the consumption products etc.

Also, the EU ascension imposed numerous requirements on companies with activities in the food sector. Thus, they are obliged, according to the national legislation that transposed the 93/94/CEE Directive regarding food hygiene and 178/2002 EU Regulation, to implement a food safety management system according to the HACCP (Hazard Analysis Critical Control Point) principles. The HACCP system represents a method for hygienic-sanitary food protection, internationally recognized, that proves that the risks related to food products safety are identified, evaluated and managed.

The proof of implementation of this system at company level is the HACCP certification. There are a series of standards that are used to obtain the certification.

In Romania, the companies have the possibility of HACCP certification following:

- **Codex Alimentarius** (comprises general and specific rules regarding good hygienic and production practices for the companies that process, transport, store or sell food products)
- **DS 3027E:2002** (document that introduces all the rules for the Codex Alimentarius into a system that can evaluate it's performances)
- **ISO 22000:2005** Food safety management systems. Requirements for the companies in the food sector (the first international certification standard for the HACCP system) - very important because of the risks that could appear in this sector, in any stage of food processing. Thus, a proper control action is essential during the entire food production process. As a result of an international agreement, this standard transposes the requirements regarding a food chain management system and offers a common solution for good practices at global level.

Among the HACCP certification advantages we can remind:

- identification and better control of food security related risks
- prevention of possible disease contamination from animal to human
- client assurance regarding the safety of the products, that are processed using a system that doesn't endanger their life or health
- continuous improvement of good practices regarding food safety
- meeting the present market requirements regarding the production of ecological products
- gaining access on new markets
- meeting possible auction criteria
- reduction of energy, water consumption etc.
- lowering the incidents that may implicate the company juridically
- improving the working conditions.

All companies that are part of the food production chain must respect the good practices of production, storage, transport, distribution, processing and consumption.

The food chain is comprised of 4 links:

- raw materials producers (agricultural producers)
- producers of end products (producers, processors)
- distributors (merchants)
- consumers.

Few rules that need to be respected by the producers and the distributors:

- to verify the health of their animals
- not to give for consumption animal products from animals that have just been under antibiotics treatment
- not to use pesticides in larger quantities than the ones specified by the law, to respect the hygiene rules, not to use food additives that are not allowed or in quantities that are not permitted.

Another important aspect for obtaining a proper food quality is represented by standards. The UN and the International Standardization Organization (ISO) created the international standards that are intended to assure food quality and security. This insures a “template” for certain segments of the technological process, assuring products that are in accordance to a well defined pattern and safe for the consumers.

For example, the ISO 9001 standards assure the quality of the resulting products. The products of the companies that have an ISO 9001 certification are considered to be obtained in safe and controlled conditions. The ISO 9001 standards don't apply only to the food products.

In Romania, until now, all international standards (management, quality, work security and health, food safety and the integrated one) were transposed.

Regarding food domain, the national legislation contains a series of regulations, general (for all kind of food products) and specific for certain products (products with special nourishment purposes, ecological products, biotechnological new aliments etc.).

Also, a special attention was given to adopting the communitarian acquis regulations regarding commercial policies in the agricultural-alimentary domain. Alimentary policies refer to a series of objectives regarding the food market and competitory policy, food security and quality assurance (starting from the plants' health control and sanitary-veterinarian controls).

The legal framework in food safety domain was continuously improved in the last years, but the necessary infrastructure for implementation is not yet consolidated enough to solve in a concrete manner the food producers' and food quality control units/laboratories problems.

The most important institution involved in the consumers' protection (that includes food quality and safety domain) is The National Consumers' Protection Authority (ANPC), specialized body of public central administration, under the Romanian Government's coordination.

ANPC coordinates and elaborates strategies and Government's policy in consumers' protection domain, preventing and fighting against practices that endanger the producers' health, security and economic interests and evaluating the effects of the products and services surveillance systems on the market.

The main ANPC attributions are:

- elaborate and implement the national strategy
- proposes to the Government regulation projects in this domain, in accordance with the EU legislation
- participates to the realization of internal and international programs in this field
- makes analyses and verifications in the certified or own laboratories
- informs, councils and educates the consumers, including through specialized publications
- supports the consumers associations to promote the consumers' interests, to inform and educate them
- controls if the consumers' protection regulations are followed and periodically informs the Government and other central public administration bodies
- determines the contraventions and is able to take penalty actions, proposes the suspension or withdrawal of license or authorization, informs the necessary authorities
- receives and solves consumers' and associations' complaints regarding the breaking of consumers' rights
- trains specialists and offers specialised consultancy to companies
- controls if the advertising actions (for products and services destined for consumption) are legal; urmareste legalitatea publicitatii pentru produsele si serviciile destinate consumatorilor
- establishes and approves the brands used by producers, importers and merchants; stabileste si aproba marcile utilizate de producatori, importatori si comercianti
- authorises activities with precious metals, their alloys, precious stones and undertakes control actions imposed by the law
- elaborates specific control procedures for different product and service groups
- identifies, within the RAPEX system, the products that may be dangerous for the life, health and safety of the consumers.

Over 100 private consumers' protection associations (in all 42 Romanian districts) have developed with the direct support of ANPC and external financing.

In 2004 The National Sanitary-Veterinarian and Food Security Agency (ANSV) was created, as a national body, which included in one structure all the previous organisms that had responsibilities

in food quality and safety. To assure a high level of consumers' protection, this body is very active in different fields, the elaboration of the Guide for Food Safety being one of the actions carried on. The Strategy for agriculture, food industry and silviculture development aims (among others) for the stable development of the agricultural-alimentary sector.

In the last years, in Romania there have been implemented a number of programs (PHARE, ISPA, SAPARD) with financial and logistical international or European support, that refer mainly to the agricultural sector and have as main objectives:

- the acceleration of the EU standards to national standards transposing process for the food and sanitary-veterinarian sector
- the development of the necessary infrastructure for implementation (at national level) of the legislation
- the strengthening of the entire Romanian agricultural-alimentary system
- the stable development of agriculture and agricultural-alimentary systems.

More and more importance is given to research in the food sector, the main criteria being food quality and safety. Through existent capabilities, the scientific activities are encouraged (in the research and development units), aiming to develop the technological transfer in the industrial field. Thus, through international, European and national programs, important funds were allocated to research in food and nutrition domains.

More and more companies opted for quality products in the last years. Nevertheless the number of producers that implemented the quality management system (according to ISO 9000) is still small. The introduction of all EU regulations, leads, naturally, to increased production costs, but at the same time, to a constant high level of quality (thus assuring and guaranteeing the food's safety); in this way the increase of expenditure is refunded.

To draw a conclusion, if we talk about quality of food as just goods or if we talk about quality in the whole food sector (starting from raw material and process to company level) we can outline a perspective that presents favourable conditions for better quality of aliments. Nevertheless we have to mention that this evolution will be dependent to the existence of a quality culture that will have to be present at company and consumers' level and that will promote at all levels the concept of quality.

FOOD SAFETY AND QUALITY - COMMUNITY LAW AND NATIONAL LEGISLATION IN TURKEY

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As it is known very well, there was a convention on HACCP in Vancouver in 1994, which was attended by experts from FAO. This convention aimed to eradicate different applications by various countries in order to prevent problems in international food trade.

As the result of the convention, it was decided that the governments (or member states) would apply the HACCP standards in their domestic laws regarding food control and they would need to implement food quality and health criteria in line with the principles of SPS agreement. The governments shall prepare food quality criteria which are suitable to food control systems related to HACCP in terms of scientific, technical and regulatory dimensions in accordance with SPS agreement codes to augment the weaknesses in the food quality systems in the existing codes of law".

Turkey was a signatory to the agreement and accepting to adapt its legislation to the relevant European Union Law. In order to carry out its responsibilities within this framework, Turkey has issued a decree, number 560, in 25 June 1995, which regulates 'Production, Consumption and Supervision of Food Products'.

As the necessity and result of this decree in 16 November 1997 the regulation on "Turkish Food Codex" was issued and on 9 June 1998 the "Regulation on Food Production, Consumption and Inspection" was issued and entered into force. With these regulations, Turkey has introduced the required framework of "Workplace Responsibilities" by HACCP.

The rules and regulations on bakery products, dairy products and meat products.

The Requirements and the rules of Bread, confectionary and pastry cooks; meat and meat products; milk and milk products were changed in accordance with the European Union.

Law in 5 June 2004 and eventually the policy document on 'Production, Consumption and Inspection of Food Products' was published and became law.

With the acceptance of the law dated 5 Jun 2004, official gazette num.25483 which was changing the decree about "The Production, Consumption and Supervision of the Foods" and with the regulation issued on 9 Dec 2007, "Regulation of the Safety, Quality Control and Supervising the Foods", Turkish Food Legislation was adopted to Community Law. In this way, the businesses making the production, processing and distribution of the foods, the whole process of food and the instruments to touch in food, had been obligated to rule the hygienic process as before and also obligated to rule the application and sustaining of the seven principles of HACCP stated in the regulation.

And also for the procedures of the meat and meat products with milk and milk products which having a different process of production from bread, confectionary and pastry cooks, had been improved with the laws about "veterinary and plant quality".

As a relevant area to the food industry, necessary laws passed on "animal health and surveillance" in January 2004, which forbids certain medication to be used in animal farming and also regulates the inspection, performance and process of veterinary services. And also Investigation Performance of Veterinary Services and Process of Observation the Residue have been improved.

Turkey has a considerable effort on animal health and it has introduced a number of programmes and laws to eradicate BSE, Scrapie, foot and mouth disease, glanders, rabies, pestis in goats and sheep etc. A law on "Compulsory Reporting of Animal Diseases" was passed in April 2004. Turkey has developed a system for registering the movements of cattle and as a result in European Union 9.5 billion cattle have been eared and restricted. Also 1.5 billion fattening business have been registered.

A great progress has been achieved in zootechnology. The law on the Protection of the Animals was published and issued Official Gazette on 1 July 2004.

Similarly, In June 2003, the convey about to "forbid and obligate the rules of the application the hormones and the medicals suchlike hormones on getting the animals growing for food " was accepted and in July 2003, public health is protected by forbidding the materials, harmful for human health with the convey about the forbidden the usage the somatotropin hormones on cattle.

In our country, with the before mentioned current laws and regulations, ensuring food quality has become a legal obligation for all business which produce food or sell for consumption. According to the relevant laws every business that is producing food for mass consumption would have to employ managers who are educated at degree level on food safety.

For providing the food quality producing in the firms, before of else named pre-requested standards of HACCP and also they should apply the minimum standards of GMP (Good Manufacturing Practices) and GHP (Good Hygiene Practices) for all business working on food. "Good Application Guides or Instruction Manuals" are most important resources to provide the food quality and helping the food sector.

Good Application Guides or Instruction Manuals are prepared to submit to food business by the related ministry or governmental department headed by a ministry, producers' organizations, federations and confederations.

On this context, "The guide for Good Hygiene Applications for Businesses Selling Meat and Meat Products" and "The Guide for Good Hygiene Applications for Producing Pastry Cooks and Bread" are prepared by Ministry of Agriculture and Rural Affairs, The Confederation of Tradesmen and Craftsmen, The Federation of Meatsdishes-Pasrty Cooks and Bread Producers, etc. and sent to Ministry of Agriculture and Rural Affairs for approval.

These guides will be published and delivered by TESK to all related federations, unions and chambers. After than, training programmes for all responsible person and masters of bakers, confidentaries, pastry cooks, and all meat or meat products who produce or sell such as butcher or markets , restaurants will be handled.

Today in our country, there are more than 50.000 small or medium businesses producing food and among these businesses a great number of them are producing bread and bakery products serving to large number of people. Therefore the food safety should be most important in this sector, as bakery products are a big part of our daily consumption habits.

Similarly meat and milk products are in high risk groups so that this sector is requires the application of safety management system in food. It is important that all the workers in this sector are trained intensively on food safety.

Because of this need either Ministry of Agricultural and Rural Affairs or the business officials would prepare the training programmes for workers on this sector and inspect the sector strictly to ensure the implementation of the rules.

Turkey receives big numbers of international tourist every year and also as a big country it has a big food industry. Therefore the obligations imposed by the HACCP system is a main duty in order to provide safe food for all those either live in Turkey or visiting as tourist.

THE SITUATION IN CROATIA - NATIONAL LEGISLATION AND EU EQUARAIMENTS

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	EU	Croatia National legislation relevant for the food safety - Official journal
1. GENERAL FOOD LAW	<p>Regulation (EC) No 178/2002</p> <p>Hygiene package - Regulations</p> <p>852/2004 on food hygiene</p> <p>853/2004 on food of animal origin</p> <p>854/2004 rules for official controls on products of animal origin 183/2005 on feed hygiene</p> <p>882/2004 on official controls - feed and food law</p> <p>2073/2005 Microbiological criteria for foodstuffs</p> <p>Directive 2000/13-Food labelling</p> <p>1829/2003 and 1830/2003 - GMO</p> <p>Regulation 1935/2004</p> <p>Directives 89/107, 94/35- Packaging and food contact materials 94/36 EEC and 95/2/EEC Food additives, colours and sweeteners</p> <p>1881/2006 Maximum levels for certain contaminants in foodstuffs.</p>	<p>Food law (46/2007 May 2007)</p> <p>The Food Act is a basic law on food safety in Croatia, which is in accordance with EU Regulation 178/2002. It gives a general overview and requirements on food and feed safety, duties of persons dealing with food, prescribes a system of official control, requirements for laboratories, obligation for food producers to implement HACCP. The Food Act has been adopted and the implementation period for all provisions of the Act is 3 years. Enforcement of laws and regulations is done on a central and local level.</p> <p>The Ordinance on the General Labelling or Marking of Foodstuffs No 114/04</p> <p>The Ordinance on the conditions to be fulfilled by a laboratory for testing, control and monitoring of GMO's and products containing GMO's No 98/04</p> <p>The Nature Protection Act No 162/03</p> <p>The Medicinal Products and Medical Devices Act No 121/03</p> <p>The Food Act No 117/03</p> <p>The Plant Protection Act No 117/03</p> <p>No 10/94</p> <p>The Wine Act No 96/03</p> <p>The Consumer Protection Act No 96/03</p> <p>The Veterinary Act No 105/01</p> <p>No 70/97</p> <p>The Ecological Production of Agricultural Products and Foodstuff Act No 12/01</p> <p>The Regulation on the Quality of Fresh Milk No 102/00</p> <p>The Animal Welfare Act No 19/99</p> <p>The Act on Sanitary Inspection No 27/99</p> <p>The Act on Protection from Radioactive Sources No 27/99</p> <p>The Act on Poisons No 27/99</p>

		<p>The Regulation on Animal Feed Quality No 26/98</p> <p>The Regulation on the Quality of Feed No 26/98</p> <p>The Livestock Production Act No 36/98</p> <p>No 70/97</p> <p>The Veterinary Drugs and Veterinary Medical Products Act No 79/98</p> <p>The Act on Food Safety and Food Safety Surveillance No 1/97</p> <p>The Regulation on the Safety of Food Supplements No 46/94</p> <p>The Act on Transportation of Dangerous Goods No 97/93</p> <p>The Infections Diseases protection Act No 60/92</p>
2. IMPLEMENTATION OF HACCP SYSTEM		<p>Since May 2007 all participants in Republic of Croatia dealing with the food have an obligation to introduce Hazard Analysis of Critical Control Point (HACCP) system The end date (full implementation) is January 1, 2009.</p> <p>For this reason, Croatian food legislative are related very closeed to HACCP.</p> <p>Furthermore, appliance of HACCP in to SME through system's documentation is very important.</p> <p>With implementation of the HACCP system general hygiene was improved as well as hygiene of equipment and personnel. Risk of product contamination is reduced to a minimum level. With effective management of control measures and records, quality of produced will be achieved.</p>
3. IMPLEMENTATION RASAF SYSTEM	<p>RASAFF</p> <p>The legal basis of the system is Regulation (EC) No 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 (O.J. No L 31 of 1 February 2002).</p> <p>The purpose of the rapid alert system for food and feed (RASFF) is to provide the control authorities with an effective tool for exchange of information on measures taken to ensure food safety.</p>	<p>HR RASAFF</p> <p>The Food Act gives also a general establishment of the Croatian Food Agency.</p> <p>In the field of informing about the risk, Agency: provides information about risks and giving professional and scientific information to the Ministry of Agriculture, Forestry and Water Management, Ministry of Health and Social Welfare, subjects in working with food and food for animals, consumers and other legal bodies concerning hazards and food safety and animal food safety.</p> <p>Establishes Rapid Alert System (RASFF), and in that order accepting and proceeding all the information concerning risks in food. Also, establishes Central Information System for exchanging data.</p>

GENERAL SAFETY OF PRODUCTS

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I. European community - countries and enlargement

In accordance with Article 14 of the EC Treaty, the internal market is an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured. This is further strengthened by a series of complementary policies (anti-cartel enforcement, merger control, controls on state aids, public procurement).

On 1 May 2004 the biggest round of enlargement to date took place. With the accession of 10 new Member States - Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia - the total number of Member States rose from 15 to 25. The accession of Bulgaria and Romania on 1 January 2007 brought this number to 27.

With a population of 457 million, the European Union is the largest internal market in the world today.

II. Internal market - free movement of goods

With the accession of Bulgaria and Romania on 1 January 2007 the EU grew to include 27 Member States. But the enlargement process is continuing:

- accession negotiations with Turkey and Croatia began on 3 October 2005
- the former Yugoslav Republic of Macedonia has been an official candidate country since the meeting of the European Council of 15/16 December 2005. A starting date for negotiations has not yet been agreed
- the remaining countries of the Western Balkans (Albania, Bosnia and Herzegovina, Montenegro, Serbia including Kosovo) are potential candidate countries.

Free movement of goods means that goods must be able to circulate freely throughout the EU internal market. In practice, this movement can be facilitated in two ways: the EU countries can adopt common rules, which is known as harmonisation, or they can follow the principle of mutual recognition where common rules are not in place.

In order to make it easier for goods to move freely, EU countries have adopted common rules - harmonisation at EU level - in many cases in order to protect lives, people's health and the environment. Ahead of the completion of the internal market in 1993, work to achieve harmonisation was stepped up and a new harmonisation method was introduced (the New Approach).

This New Approach means that the Community can only establish concise, basic safety requirements in directives, after which the technical details are worked out by the European Committee for Standardisation. As a result, standardisation has become very important for the functioning internal market.

GENERAL SAFETY OF PRODUCTS

1. Community law

Directive 2001/95/EC on general product safety as of 3 Dec 2001 - GPSD

In order to ensure a high level of consumer protection, the European Community must contribute to protecting the health and safety of consumers. Horizontal Community legislation introducing general product safety requirements contributes to that aim.

It is established at Community level a general safety requirement for any product placed on the market, or otherwise supplied or made available to consumers, intended for consumers, or likely to be used by consumers under reasonably foreseeable conditions even if not intended for them. In all these cases the products under consideration can pose risks for the health and safety of consumers which must be prevented.

The Directive imposes a general safety requirement on any product put on the market for consumers or likely to be used by them, including all products that provide a service and excluding second-hand products that have antique value or that need to be repaired.

A safe product is one which poses no threat or only a reduced threat in accordance with the nature of its use and which is acceptable in view of maintaining a high level of protection for the health and safety of persons:

- taking into account all the relevant aspects, in particular the categories of consumers which can be particularly vulnerable to the risks posed by the products under consideration, in particular children and the elderly
- the safety of a product will be assessed having regard to a number of matters and, in particular:
 - the product's characteristics
 - packaging
 - instructions for assembly and maintenance, use and disposal
 - the effect on other products with which it might be used
 - labelling and other information provided for the consumer
 - the categories of consumers at risk when using the product, particularly children and the elderly.

2. Manufacturer and distributor obligations

Within the limits of their respective activities, producers shall provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks.

The presence of warnings does not exempt any person from compliance with the other requirements laid down in this Directive.

Within the limits of their respective activities, producers shall adopt measures commensurate with the characteristics of the products which they supply, enabling them to:

- be informed of risks which these products might pose

- choose to take appropriate action including, if necessary to avoid these risks, withdrawal from the market, adequately and effectively warning consumers or recall from consumers
- distributor shall participate in monitoring the safety of products placed on the market, especially by passing on information on product risks, keeping and providing the documentation necessary for tracing the origin of products and cooperating in the action taken by producers and competent authorities to avoid the risks.

Examples:

- Giving an indication, by means of the product or its packaging, of the identity and details of the producer and the product reference or, where applicable, the batch of products to which it belongs
- In all cases where appropriate, the carrying out of sample testing of marketed products, investigating and, if necessary, keeping a register of complaints and keeping distributors informed of such monitoring.

Within the limits of their respective activities they shall take measures enabling them to cooperate efficiently.

- Where producers and distributors know or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement, they shall immediately inform the competent authorities of the Member States thereof under specific conditions, giving details, in particular, of action taken to prevent risk to the consumer
- Producers and distributors shall, within the limits of their respective activities, cooperate with the competent authorities, at the request of the latter, on action taken to avoid the risks posed by products which they supply or have supplied. The procedures for such cooperation, including procedures for dialogue with the producers and distributors concerned on issues related to product safety, shall be established by the competent authorities
- The manufacturers must put on the market products which comply with the general safety requirement
- They must provide consumers with the necessary information in order to assess a product's inherent threat, particularly when this is not directly obvious, and take the necessary measures to avoid such threats:
 - e.g. withdraw products from the market
 - inform consumers
 - recall products which have already been supplied to consumers, etc.

“Producer” in relation to a particular product means:

If the manufacturer is established in the Community:

- any person who presents himself as the manufacturer by putting his name or trademark on the product (the brand owner);
- any person who repairs or reconditions the product; or
- other professionals in the supply chain if their activities may affect the safety properties of a product after it has been supplied to them.

If the manufacturer is not established in the Community, the producer will be:

- either the manufacturer's representative in the Community
- the importer of the product into the Community (where there is no Community representative).

A producer is not necessarily just the person who manufactures something. It includes any professional in the supply chain whose activities affect the safety of the product. For example a person who reconditions, works, re-works or customises a product will place a different product on the market to that which he started out with and hence be responsible under the Regulations in so far as his activities may have affected the safety properties of the product. The corollary of this is that to the extent that this person's activities did not affect the safety properties of the product, the original producer will continue to be responsible for its safety.

"Distributor", in contrast, is any professional in the supply chain whose activities do not affect the safety of a product. This can include wholesalers, retailers (shops), agents and auctioneers. However, auctioneers are neither producers nor distributors for the purposes of the Regulations when they are merely acting under instructions to conduct the sale (i.e. controlling the bidding and knocking down to the highest bidder) of an item for the owner, and it is the owner who is the seller. But, an auctioneer who had purchased the contents of a house on a clearance basis would be a distributor and subject to the Regulations when he subsequently auctioned the contents.

- A person who makes a product available for the use of a consumer in the course of delivering a service will for the most part also be considered a distributor.
- However, if the product carries the service supplier's own brand, or if he has in any way altered the characteristic of the product so as to affect its safety properties, he will be considered to be a producer.

3. Application sort of products

The conformity assessment and general safety requirement are different for different groups of products: household product; furniture, playground equipment; childuse and care equipment; toys; clothing, textiles; footwear; cosmetics and personal care products; cleaning products, detergents ...

Use of standards

The conformity of a product to the general safety requirement shall be assessed by taking into account the following elements in particular, where they exist:

- where neither a specific Regulation nor national safety law applies, safety will be assessed taking each of the following into account in turn:
 - voluntary European standards (i.e. SR EN, BDS EN, HRN EN, TS EN)
 - community technical specifications (TS)
 - national standards (which are not versions of European standards)
 - industry codes of good practice
 - state of the art and technology, and the safety which consumers may reasonable expect
 - summary list of titles and references of harmonised standards related to general product safety
 - published in OJ C 171 of 2006-07-22.

The information contained in the summary list is a compilation of the references of standards which have been published in the Official Journal of the European Union.

National standardization bodies for:

- Romania <http://www.asro.ro>
- Bulgaria <http://www.bds-bg.org/>
- Croatia <http://www.hzn.hr>
- Turkey <http://www.tse.org.tr/>

3.1 Products and safety & quality requirements: furniture

Harmonised standards: EN 1129-1:1995; Furniture - Foldaway beds - Safety requirements and testing- Part 1: Safety requirements; EN 1129-2:1995; Furniture - Foldaway beds - Safety requirements and testing- Part 2: Test methods; EN 1130-1:1996; Furniture - Cribs and cradles for domestic use - Part 1: Safety requirements; EN 1130-2:1996; Furniture - Cribs and cradles for domestic use - Part 2: Test methods.

Mostly there is no other specific regulation, except standards for other quality characteristics: dimensions, tolerances, mechanical safety requirements, surface resistance to cold liquids, to wet and dry heat, strength and durability, EN 942:2002 - Timber in joinery - General classification of timber quality; EN 518:1996 - Structural timber - Grading - Requirements for visual strength grading standards; EN 14128:2004 - Durability of wood and wood-based products - Performance criteria for curative wood preservatives as determined by biological tests; EN 335-1:1995 - Durability of wood and wood-based products - Definition of hazard classes of biological attack - Part 1: General and SIST EN 335-2:1995 - Durability of wood and wood-based products - Definition of hazard classes of biological attack - Part 2: Application to solid wood.

Ecological wood surface coatings:



3.2 Products and safety & quality requirements: childcare

Harmonised standards: EN 1400-1:2002; Child use and care articles - Soothers for babies and young children - Part 1: General safety requirements and product information; EN 1400-2:2002; Child use and care articles - Soothers for babies and young children - Part 2: Mechanical requirements and tests; EN 1400-3:2002; Child use and care articles - Soothers for babies and young children - Part 3: Chemical requirements and tests ; EN 1466:2004; Child care articles - Carry cots and stands - Safety requirements and test methods; EN 13209 -1:2004; Child use and care articles - Baby carriers - Safety requirements and test methods - Part 1: Framed back carriers; EN 14344:2004; Child use and care articles - Child seats for cycles - Safety requirements and test methods.

3.3 Products and safety & Quality requirements: toys

Toys Directive (88/378/EEC) of 3rd May 1988

Scope of application

The Directive applies to toys, defined as “any product or material designed or clearly intended for use in play by children of less than 14 years of age”. It foresees 21 exceptions for goods not designed for children (for example, detailed scale models for adult collectors) or goods that present a particular risk not covered by the directive (for example, sports equipment).

Mandatory essential requirements

The Directive lays down the safety criteria or “essential requirements” which toys must meet during manufacture and before being placed on the market. The safety criteria cover general risks (protection against health hazards or physical injury) and particular risks (physical and mechanical, flammability, chemical properties, electrical properties, hygiene, radioactivity).

The degree of risk has to take into account the ability of the user (children). If appropriate, the toy must contain a labelling that specifies a minimum age.

All toys marketed in the EU must be provided with an EC conformity marking which:

- symbolises the conformity of the toy with the provisions of the relevant directives
- consists of a unique seal or design, namely the EC seal
- is affixed by the manufacturer or his authorised representative established in the Community.



Age warning

3.4 Products and safety & quality requirements: textile

Directive 96/74/EC (Official Journal L 032, 03/02/1997 p. 0038 - 0055) on textile names requires the labelling of the fibre composition of textile products. It stipulates for checks on whether the composition of textile products is in conformity with the information supplied.

All products containing at least 80% by weight of textile fibres, including raw, semi-worked, worked, semi-manufactured, semi-made, made-up products are covered in the Directive. The labelling indicating the fibre composition is mandatory in all stages of the industrial processing and commercial distribution of a product.

3.5 Products and safety & quality requirements: textile - eco label

Implementing a Quality Control System is an essential part of maintaining an eco-label. The aim of this is to prove to the certifying institute that all products manufactured have the same properties as any test sample sent to the institute. It is important that the institute can carry out tests to check this at any time. The Quality Control System is usually presented in the form of a “Quality Assurance Manual”, produced and maintained by the Quality Manager. This Manual should contain information on:

- dyes and pigments in use along with their C.I. number
- chemicals in use
- material Safety Data Sheet (MSDS) for all items
- processing sequence used and process control check points
- quality parameters of final product
- test methods for each of the items
- frequency at which each test needs to be conducted
- eco-Label requirements
- mode of verification, in case of correction, if any
- conducting a Chemical Audit.

This step will identify all chemicals used in the process that are banned by the selected ecolabelling organisation. A detailed survey of the chemicals used in each production stage must be carried out, to identify all chemicals used in the production of the fabric, from the processing of the raw fibres through the manufacturing process to the production of the finished article.

These can then be compared with the list of banned substances provided by the eco-labelling institute to identify which ones need to be replaced and wherever possible, material safety data sheets (MSDS) for each chemical should be obtained from the supplier.

3.6 Eco-labelling and certificate

An eco-label provides brief information on environment related product qualities. It enables consumers to identify those products that are environmentally safe; that have been manufactured using eco-friendly materials and do not contain chemicals that are harmful to the user. Since “eco-friendliness” is an additional product quality, it can be used for marketing and advertising purposes

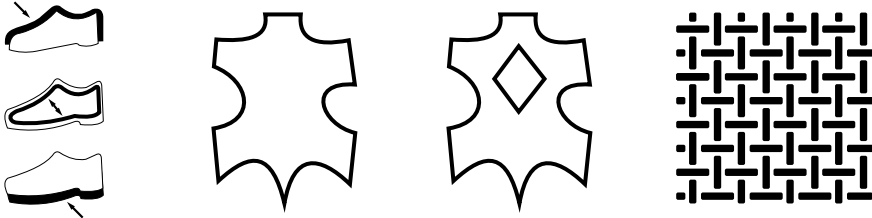


3.7 Products and safety & quality requirements: footwear

Directive 94/11/EC of the European Parliament and of the Council of 23 March 1994 relating to labelling of the materials used in the main components of footwear for sale to the consumer apply to the labelling of the materials used in the main components of footwear for sale to the consumer. The following shall be excluded from the Directive: second-hand, worn footwear; protective footwear covered by Directive 89/686/EEC; footwear covered by Directive 76/769/EEC and toy footwear. The labelling shall convey information relating to the three parts of the footwear - the upper, the lining and sock and the outer sole.

The labelling shall provide information on the material, determined in accordance with Annex I, which constitutes at least 80% of the surface area of the upper, and the lining and sock, of the footwear, and at least 80% of the volume of the outer sole. If no one material accounts for at least 80%, information should be given on the two main materials used in the composition of the footwear.

The labelling must be visible, securely attached and accessible and the dimensions of the pictograms must be sufficiently large to make it easy to understand the information contained therein.



3.8 Products and safety & quality requirements - cosmetics

Official testing of cosmetic products

List of 450 forbidden chemicals and dyes to use for cosmetics
(radioactive, causing cancer, mutagen ...)

Testing on animals not allowed

LABELLING

4. GPSD directive level of risk

If specific Community legislation sets out safety requirements covering only certain risks or categories of risks - determined by the provisions of the specific legislation, while the general safety requirement of this Directive should apply to the other risks.

In order to facilitate the effective and consistent application of GPSD, it is important to establish European voluntary standards covering certain products and risks in such a way that a product which conforms to a national standard transposing a European standard is to be presumed to be in compliance with the safety requirements.

A product shall be presumed safe when it conforms to voluntary national standards transposing European standards, the references of which have been published by the Commission in the Official Journal of the EC. The Member States shall publish the references of such implemented national standards.

If a standard does not ensure compliance with the general safety requirement, the Commission shall withdraw reference to the standard from publication in whole or in part.

Estimate the level of risk, depending on the severity and the probability for injury to a person using or otherwise coming to the contact with product.

Determine the acceptable level of risk, depending on factors such as the type of the user and, for normal adults, whether the product has adequate warnings and guards and whether the hazard is sufficiently obvious:

- marking the products, their packaging or other materials supplied with the product (e.g. instruction booklets)
- with the name and address of the producer (name and postcode is acceptable)
- product reference, and batch number where appropriate, so that they can be identified
- sample testing of products on the market
- investigating complaints relating to safety, and keeping a register of such complaints
- informing distributors of the monitoring work and the results.

More complex and higher risk products may involve a higher level of vigilance and attention from the producer involving an ongoing sampling programme.

5. Safety notice

A producer has a primary duty to place on the market only safe products but he also has more specific duties:

- to provide relevant information to enable consumers to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use where such risks are not immediately obvious to the user. This should include information on the precautions to be taken to avoid those risks (for example, the need to wear protective gloves)
- to adopt measures commensurate with the characteristics of the products which he supplies, to enable him to be informed of the risks which these products might present and to take appropriate action, including, where necessary, withdrawing the product in question from the distribution chain.

A distributor is also required, within the limits of his activity, to participate in monitoring the safety of products that he supplies and pass on information on the product risks. In practice this will mean:

- passing on to consumers information provided by producers about product risks
- passing back to producers safety complaints and information and experiences on safety related matters which he obtains from customers
- co-operating with the authorities and others in the supply chain in taking action to avoid or remove those risks.

6. Rapid information system - RAPEX

- producers and distributors who discover that they have placed an unsafe product on the market, or distributed such a product
- notify the competent authorities of the fact and what action they have taken to remove the risks to consumers
- such notifications should also be transmitted to the enforcement authorities of all the Member States in which they believe the product has been marketed

How? - send these notifications to the appropriate national contact point (Department of Trade and Industry or Inspectorate or others) who will then pass the information on for onward transmission to other Member States.

7. Inspection, supervision - role and obligations of national authorities

Each country participating in the RAPEX system nominates a single national RAPEX Contact Point which submits to the Commission detailed information about dangerous products found on its own market. There are a list of the national Contact Points. They have to respect their obligation to place only safe products on the market and must designate.

- competent market surveillance authorities with necessary powers
- to take measures to prevent or restrict the marketing or use of dangerous products.

They must take appropriate measures if they find dangerous consumer products on the market. These measures must be proportionate to the risk and to the category of consumers. For example, in the case of toys containing small parts that can be swallowed by small children, the authorities generally require withdrawal of the product from the market or recall it from the consumers as these products pose a choking hazard to a very vulnerable category of consumers.

Producer and distributor notifications, procedure

Producers and distributors who discover that they have placed an unsafe product on the market, or distributed such a product notify the competent authorities of the fact and what action they have taken to remove the risks to consumers such notifications should also be transmitted to the enforcement authorities of all the Member States in which they believe the product has been marketed.

Inspection, supervision notification form

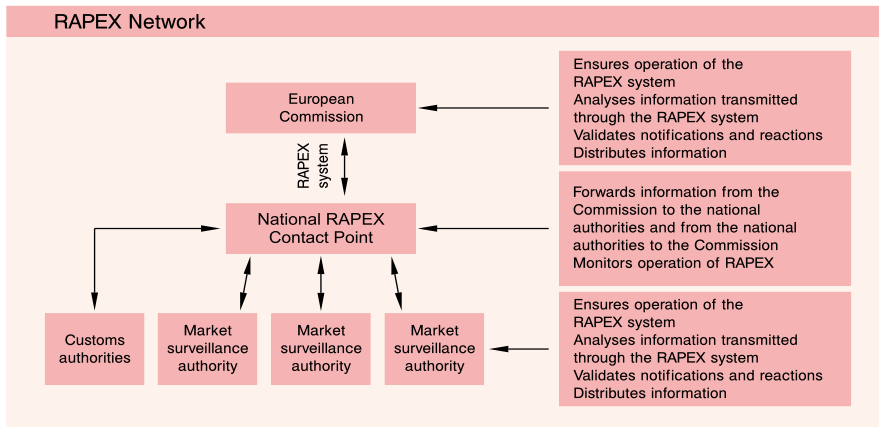
Information is submitted via a standard notification form, which includes details on: product identification (name, brand, model, description, picture); risks posed by the product (type of risk, results of laboratory tests); measures adopted to prevent risks (type of measures, scope, duration, date of entry into force); distribution channels of the notified product (manufacturer, exporter, importer, distributors, countries of destination) and photography of the product. The authorities will advise on actions aimed at removal of the risk and work with the producer or distributor.

It is not necessary to make a notification where it is clear that the risk is related to a limited number of specifically identifiable products or batches, and the producer or distributor has solid evidence to conclude that the risk has been fully controlled and its cause contained and dealt with. Such problems might include the malfunctioning of a production line, errors in handling and/or packing etc.

Role and obligations of national authorities **RAPEX website**

The Commission publishes weekly overviews of notifications from national authorities of dangerous products posing a serious risk to consumers on web.

These are the European Commission consumer affairs internet pages which receive the highest number of visitors. These overviews provide information on the product, the nature of the risk it poses and the measures that were taken to prevent these risks. This information enables consumers to check whether the products they use or plan to purchase have been notified through the RAPEX system. The RAPEX website can be consulted at <http://ec.europa.eu/rapex>.



Measures available to enforcement authorities

Suspension Notices - Where there may have been a breach of the Regulations, these notices temporarily ban the placing on the market or the supply of a product while tests are undertaken and the results are being waited for.

Requirement to Mark and Requirement to Warn - these powers allow an enforcement authority to order the marking of a product with suitable warnings where it could pose risks in certain conditions, or require that specific warnings be given to certain persons considered to be at particular risk from a product (e.g. young children, the elderly etc).

Withdrawal Notices - enforcement authorities can issue a Withdrawal Notice to permanently prevent a person from further supplying a product that is believed to be dangerous where it is already on the market (if the voluntary action taken by producers and distributors is insufficient or unsatisfactory) or from placing it on the market if it has not yet been so placed.

Recall Notices - where an enforcement authority has reasonable grounds for believing that a dangerous product has already been made available to Consumers.

Forfeiture and Destruction - where products are dangerous the enforcement authority may apply to the court for an order for their forfeiture and destruction. However as an alternative to destruction the court may, on condition that any order to pay the costs and expenses of the proceedings is complied with, permit the supply of the product to a person for repair or reconditioning or for scrap.

Withdrawal Notices - enforcement authorities can issue a Withdrawal Notice to permanently prevent a person from further supplying a product that is believed to be dangerous where it is already on the market (if the voluntary action taken by producers and distributors is insufficient or unsatisfactory) or from placing it on the market if it has not yet been so placed.

Who is responsible for corrective actions?

Producers

For products made in the eu and branded by the manufacturer the responsibilities of the producer should be accepted by the manufacturer of the product.

For products made in the eu and branded by the distributor the responsibilities of the producer should be **shared** between the manufacturer of the product and the distributor.

Distributors should accept the following actions:

- collecting information about unsafe products and passing it on to the producer and competent authorities
- providing information to help trace the origin of products
- providing information about the purchase of products (relevant data)
- cooperating in publishing the corrective action notice
- isolating and withdrawal products and returning them to the producer
- contacting purchasers of products on the request of the producer
- checklist.

Corrective actions

Producer should assemble the team with knowledge of the following functions - design, production, product safety/risk management, quality assurance, purchasing, distribution, marketing and customer service, public and corporate relations, legal accounts, etc.

In SME more in one person or outside the organization.

One person should have overall responsibility for external communication.

Monitoring procedures

Collect the following information:

- reports of accidents involving your products
- complaints from customers
- warranty claims
- insurance claims or legal actions
- results of product testing
- information of service engineers
- any evidence of hazards arising from sales to unexpected user groups
- information need to be reviewed regularly, especially when the design changes or new component suppliers are used.

Responsibility for corrective actions?

Producers' and distributors' responsibilities for corrective action vary depending on the circumstances. The main responsibility for carrying out corrective actions have producers, the distributors also have a role to play.

Companies need to have agreements with their suppliers, which define their respective responsibilities for corrective action. These responsibilities are summarised below to help companies decide which parts of the procedure apply to them.

For the purposes of corrective action the producer is defined as:

- the manufacturer of the product, when he is established in the Community
- any other person presenting himself as the manufacturer (including another manufacturer) by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product
- the manufacturer's representative, when the manufacturer is not established in the Community or if there is no representative established in the Community, the importer of the product
- other professionals in the supply chain, if their activities affect the safety of the product.

8. Liability for damaged product - council directive 85/374/eec of 25 july 1985

Without prejudice to the liability of the producer, any person who imports into the Community a product for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a producer within the meaning of this Directive and shall be responsible as a producer.

Where the producer of the product cannot be identified, each supplier of the product shall be treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product. The same shall apply, in the case of an imported product, if this product does not indicate the identity of the importer referred to in paragraph 2, even if the name of the producer is indicated.

The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.

Where, as a result of the provisions of this Directive, two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the rights of contribution or recourse.

8.1 A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account

Including:

- the presentation of the product
- the use to which it could reasonably be expected that the product would be put
- the time when the product was put into circulation.

8.2 A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation

The producer shall not be liable as a result of this Directive, if he proves:

- that he did not put the product into circulation, or
- that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards, or

- that the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business, or
- that the defect is due to compliance of the product with mandatory regulations issued by the public authorities, or
- that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered, or
- in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.

Dangerous products resembling foodstuffs council directive 87/357/eec

The Directive applies to products which are not edible but could easily be confused with foodstuffs by their appearance, smell or packaging those which, although not foodstuffs, possess a form, odour, colour, appearance, packaging, labelling, volume or size, such that it is likely that consumers, especially children, will confuse them with foodstuffs and in consequence place them in their mouths, or suck or ingest them, which might be dangerous and cause, for example, suffocation, poisoning, or the perforation or obstruction of the digestive tract.

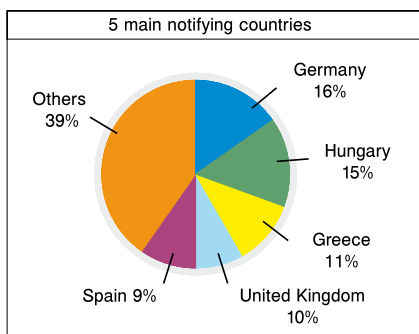
Member States must take all the measures necessary to prohibit the marketing, import and manufacture of such products.

Checks must be carried out to ensure that no such products are marketed.

If a Member State bans a product under the terms of this Directive it must inform the Commission and provide the details needed to inform the other Member States.

9. Statistic notifications by notifying country

Notifications by notifying country



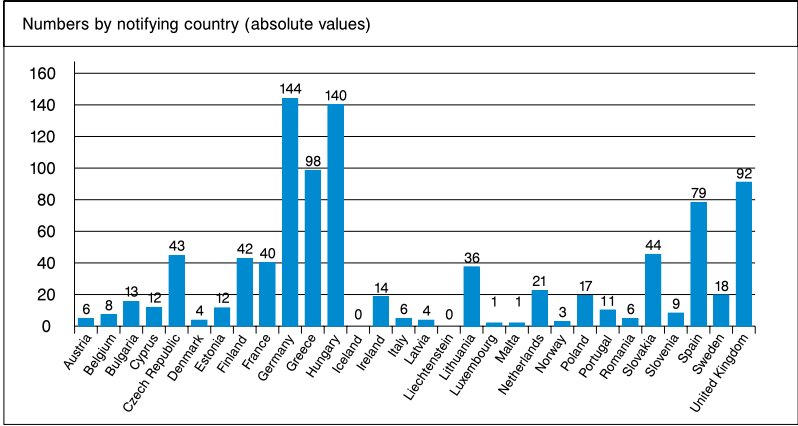
Situation in 2006

In 2006, all member states of the EU (including Bulgaria and Romania) were active in the RAPEX system.

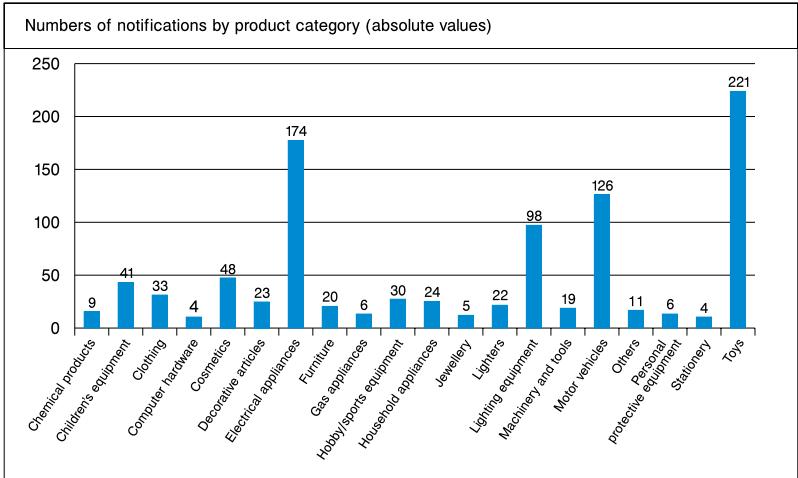
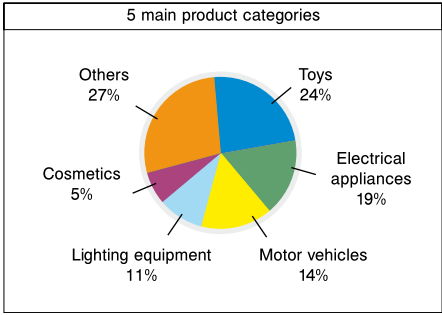
The following 5 countries accounted for 60 % of all notifications:

- Germany (144 notifications, 16%)
- Hungary (140 notifications, 15%)
- Greece (98 notifications, 11%)
- United Kingdom (92 notifications, 10%)
- Spain (79 notifications, 9%).

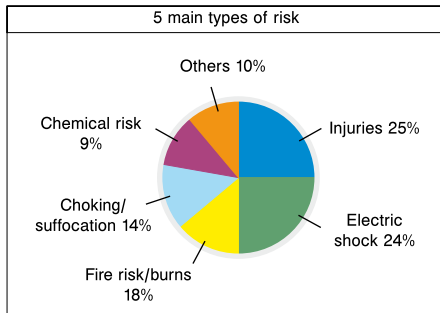
Uneven participation of countries in the system continued in 2006. This is an issue that is being addressed by the Commission. However, when consulting these statistics the varying size of the countries as well as the different production and market structures within the EU should be taken into account.



Notifications by product category



Notifications by type of risk



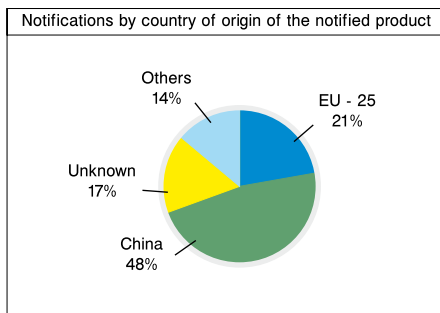
Some notifications concern products presenting more than one risk, therefore, the total number of notified risks is higher than the total number of notifications. In 2006, 148 notifications reported more than one type of risk. The total number of notified risks was 1095 for 924 notifications (or 1.2 risks per notification).

The five main risk categories were:

- injuries (274 notifications, 25%)
- electric shock (270 notifications, 24%)
- fire risks/burns (194 notifications, 18%)
- choking/suffocations (157 notifications, 14%)
- chemical risk (95 notifications, 9%).

These results confirm previous years' trends, whereby the risk of getting injured and the risk of getting an electric shock have been the main types of risks to which consumers have been liable to exposure over the last few years.

Notifications by country of origin



China was indicated as the county of origin of the notified product in almost half of all cases (440 notifications, 48%). This is mainly due to the great amount of products imported to the European Union from China.

The 25 EU countries (EU-25) accounted for 195 notifications (21% of the notifications).

The number of notifications concerning products of which the country of origin was unknown was fairly high, totalling 159 notifications (17% of all notifications). This high percentage of products of unknown origin is a limiting factor in assessing the presence of dangerous products in the EU. However, a slight improvement can be noted compared to the previous year when 20% of notifications concerned products of unknown origin.

