



welcome to our new chairman

Mr. Eamonn Ryan has been appointed as the new Chairman of the FSAI by Ms Mary Harney, TD, Minister for Health and Children.

Prior to this appointment, Mr. Ryan was Executive Director of IDA Ireland. In a career spanning three decades of Ireland's economic transformation, he played a pivotal role in shaping and implementing strategy for the phenomenal growth of the Irish economy. He has a long and distinguished career in Ireland's public sector and has a wide knowledge and experience of business in the domestic and international arena.

Mr. Ryan was Executive Director International of IDA Ireland's global operations based in New York where, under his leadership and management, the agency attracted substantial levels of the most technologically-advanced foreign direct investment from the USA, Europe and Asia Pacific.

Eamonn Ryan is a graduate of University College Dublin, with further academic pursuits in Columbia University and Carnegie Mellon. He is a Board Member of the National Cancer Screening Service and a Board Member of Georgia Tech Ireland.

Mr. Ryan's strong business management experience will be of great benefit to the FSAI in the coming years. The CEO and staff look forward to working with our new chairman and wish him every success in his role.



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HACCP

A FOOD SAFETY MANAGEMENT SYSTEM

What is HACCP?

guidance note no 11 on assessment of haccp

Background

The FSAI has recently issued a revision of Guidance Note No. 11 which deals with the assessment of HACCP compliance in premises inspected by environmental health officers (EHOs). The revised guidance note takes account of the more flexible HACCP requirement under the new hygiene of foodstuffs Regulation (EC) No 853/2004. It was developed by the FSAI HSE National HACCP Steering Committee and is based on the European Commission's guidance document on HACCP and HACCP Flexibility.

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf

HACCP compliance options

Article 5 of Regulation (EC) No 853/2004 requires food business operators to put in place, implement and maintain permanent procedures based on the HACCP principles. The Regulation however, allows for a degree of flexibility in the application of these principles and the complexity of the procedure(s)/system developed. It recognises that in food businesses undertaking low risk activities the prerequisite hygiene requirements (outlined in Article 4 and Annex II of the Regulation) are sufficient to control food safety without the need to develop a HACCP based system. Additionally, the Regulation allows businesses to follow recognised guides to good practice where typical hazards and controls have been identified. Compliance with the HACCP requirement may therefore be achieved in one of three ways:

1. Implementation of the prerequisite hygiene requirements where this ensures that all hazards are effectively controlled
2. Use of a recognised guide to good practice where the hazards and controls have been identified
3. Development of a food safety management system by applying the seven principles of HACCP.

1. Implementation of the prerequisite hygiene requirements where this ensures that all hazards are effectively controlled

Businesses using this compliance option can be divided into two types:

- i. businesses where it is 'presumed' due to the nature of the business that prerequisite hygiene requirements alone are sufficient, in which case, a formal hazard analysis is not needed;
- ii. businesses who, upon applying the principles of HACCP, find through their own hazard analysis that the prerequisite hygiene requirements alone are sufficient.

In particular, this option is suited to food businesses where there is no preparation, manufacturing or processing of food (e.g. a small retail shop). However, it is possible that some businesses may be able to safely undertake simple food preparation when applying the prerequisite hygiene requirements correctly (e.g. portioning/slicing food).

Where required for food safety however, a food business operator using this option must ensure that the necessary monitoring, verification and possibly record keeping are carried out. For example, where a business stocks refrigerated food it is a specific legal requirement (Article 4(3) (d) of the Regulation) that the cold chain is maintained. This is best achieved through regular monitoring of the temperature and regular verification that the monitoring is actually taking place.

2. Use of a recognised guide to good practice where the hazards and controls have been identified

Businesses may choose to voluntarily follow a nationally recognised guide to good practice (as envisaged under Articles 7 and 8 of the Regulation) which has already applied the principles of HACCP (e.g. the National Standards Authority of Ireland (NSAI) hygiene standards). These guides can be applied by any food sector and are particularly suited to sectors where the handling of food is in accordance with procedures that are well known and that are part of the usual vocational training for that sectors (e.g. catering).

For such businesses it may suffice that the guides describe in a practical and simple way the methods to control hazards without necessarily entering into detail on the nature of the hazards and a formal identification of critical control points. These guides should nevertheless cover all significant hazards in a business and should clearly define procedures to control these hazards and the corrective action to be taken in case of problems.

Before implementing a guide, food businesses must first ensure that the guide is appropriate to the business. This is done by assessing whether the guide covers all the operations in the business. Where operators identify activities not covered by the guide, they should apply the principles of HACCP to these additional activities.

3. Development of a food safety management system by applying the seven principles of HACCP

Businesses may choose to develop their own HACCP based procedures by applying the seven principles. Annex I of the Commission's guidance document details the application of the seven principles according to the classical Codex Alimentarius approach.

[Note: The former national Irish standard for HACCP, IS 343, has been replaced by an international standard (EN ISO 22000:2005 Food Safety Management Systems - requirements for organisations throughout the food chain) and is available from the NSAI.]

Flexibility in the application of specific HACCP principles

In addition, to the overall flexibility in developing HACCP based procedures (as outlined above), the Regulation allows for flexibility with regard to specific HACCP principles. In the case of critical limits it recognises that they do not need to be numerical and in some cases may be chosen on the basis of accepted best practice (e.g. a chef relying on the change in the physical properties of food during cooking).

With regard to monitoring, the systematic temperature probing of food may not be necessary where standard calibrated equipment is employed. However, regular cross checking would be necessary to ensure that such equipment was achieving the desired temperature.

Documents and records should be appropriate to the nature and size of the business. In the case of a business using HACCP compliance option 2 for example, the guide to good practice would be acceptable evidence of HACCP documentation.

In the case of visual monitoring at critical control points the Commission advises that records could be limited to non-compliances, i.e. recording of critical limit which have been exceeded. In such cases it advises that the corrective action taken must also be recorded.

compliance

HACCP training

The Regulation introduces a specific requirement for HACCP training (Chapter XII, Annex II) but again with a degree of flexibility. Staff responsible for the development and maintenance of the HACCP based procedures or the operation of a relevant guide to good practice must have received adequate training in the application of the HACCP principles. This training does not have to be formal.

Regulatory assessment

The responsibility for choosing the most appropriate compliance option is that of the food business operator. If however, in the professional judgment of the EHO, hazards are not being controlled, they can recommend that the business use a different compliance option.

Where food businesses ensure food safety through prerequisite hygiene requirements alone, the EHO should verify the correct implementation of these requirements. Where a recognised guide to good practice is followed or a HACCP plan is developed, the businesses should be assessed against that guide or HACCP plan as appropriate.

National legislation

The European Communities (Hygiene of Foodstuffs) Regulations 2006 (S.I. No 369 of 2006) gives effect to Regulation (EC) No 853/2004 in premises inspected by EHOs. It outlines offences relating to the HACCP requirement and stipulates retention times for HACCP records.

residue meetings

The first bilateral liaison meeting for 2007 between the FSAI and the Department of Agriculture and Food (DAF) veterinary residues group took place in January. The meeting reviewed action taken when samples test positive for veterinary residues, in light of confirmatory testing now being available for an increased number of residues. The Authority is currently reviewing the procedures in place in conjunction with DAF. Work is progressing in DAF on the development of the 2007 residues control programme.

The FSAI hosted a cross agency meeting for all of the laboratories involved in the implementation of the national residues control programme. The purpose of this annual meeting is to provide a forum for residue laboratories to discuss the national control programme and issues regarding the implementation of the plan. Following this meeting, the FSAI are to commission a research project, to propose a risk based strategy to determine residue sampling and analysis. This project will be undertaken in conjunction with the FSAI scientific Sub-committee on food additives, chemical

contaminants & residues. It is anticipated that the results of this research project will feed into the national residues control programme. To further improve cross agency working, and to provide for better exchange of technical information between the laboratories, it was agreed to host a technical meeting for all laboratory staff in 2007. The Marine Institute will host this meeting.

The work programme for 2007 for the DAF pesticides group has been agreed between the FSAI and DAF. The information from the Irish children's diet study will be included for the first time in 2007, so the range of samples analysed should be more reflective of the total consumption patterns of the Irish population. The range of pesticides being analysed for has increased from 149 in 2006 to 246 in 2007. The laboratory will analyse 1,380 samples as part of the programme. The laboratory will continue, during 2007, to further validate the existing analytical methods used within the laboratory, with a view to extending the range of pesticides being determined in samples.

note from the editor

In this issue of the newsletter, you will find an additional feature, a supplement, which we will have in the newsletter from time to time; focusing on a specific topic. The supplement in this issue focuses on the work of the FSAI Scientific Committee and Sub-committees. It outlines the terms of reference, main tasks and membership of each Sub-committee. You will find it on pages 16-19.

The European Food Safety Authority (EFSA) is celebrating five years since its foundation in 2002, as an independent source of scientific advice on food safety. During this year, EFSA will be exploring its achievements and future direction in relation to three key themes: valuing high scientific standards in food safety, strengthening Europe, and the future starts now.



One of the supplements in the coming issues will be focusing on the work of EFSA. Further information on EFSA's fifth anniversary activities is available from the EFSA website: http://www.efsa.europa.eu/en/about_efsa/efsa_5th_anniversary.html

codex seminar

On the 21st March last, the Department of Agriculture and Food and the Food Safety Authority of Ireland hosted a half-day seminar on the functioning of the Codex Alimentarius Commission (CAC) in Dublin Castle. The seminar, which was chaired by Alan Reilly, FSAI and officially opened by Mr. Brendan Smith, T.D., Minister for Food at the Department of Agriculture and Food, was addressed by a range of top level speakers from the Food and Agriculture Organization (FAO), the World Trade Organization (WTO), and the EU Commission. Delegates included relevant policy and enforcement officials from a number of government departments and agencies together with key regulatory compliance personnel drawn from a diverse range of Irish food companies and organisations.

Minister Smith paid tribute to the important role played by Codex and also stressed the Government's commitment to the food sector as evidenced by resources provided in the recently launched National Development Plan, particularly for R&D.

Explaining that the CAC is an inter-governmental food standard setting body currently comprising 175 members that account for 90% of the world's population, the Codex secretary, Dr. Kazuaki Miyagishima, gave examples of activities undertaken in pursuit of its twin objectives - consumer health protection and ensuring fair practices in the food trade. He attributed its success to the transparency of its rule-based operation and the strong ownership sense of its members. He also drew attention to a number of future challenges including enhancing developing

country participation, achieving global consensus, and ensuring sustainable funding especially for the provision of scientific advice.

Mrs. Gretchen Stanton, Senior Counsellor at the WTO, focused on the origins, scope and functioning of the World Trade Organization's Sanitary and Phyto Sanitary and Technical Barriers to Trade agreements in the context of their recognition of and relationship with Codex. She detailed the rights and obligations these agreements conferred on members, their encouragement for the use of harmonised international standards, and their provisions in relation to assessing risks, recognising equivalence, ensuring transparency and procedures for conformity evaluation. Referring to some of the trade concerns raised by and against the EU under the SPS agreement since its inception in 1995, she explained the role of Codex standards in the settlement of some of the more notable food safety related disputes under WTO procedures.

Referring to the accession of the European Community to the CAC in 2003, Mr. Michael Scannell from the European Commission's DG SANCO, said this was an important step to ensuring that health and other EC interests are taken into account at Codex and that there is coherence between Codex standards and EC legislation. The EU is the biggest importer of food in the world and so has a real interest in the work of this international food standard setting body. He also went on to stress the importance of helping developing countries build robust food safety infrastructures.

Referring to the fact that Ireland is an export dependent food producing country, Mr. Hickey, from the International Dairy Federation, said that Codex was very important to the Irish food industry because it acted as a de facto shadow legislation as a consequence of its influence on the development of new EU food law. Stressing the need to raise concerns early on in the stepwise procedure, he explained how industry can get involved in Codex through national food representative organisations which may be affiliated to international NGO with observer status at Codex or participate in national Codex coordinating structures. He went on to explain the role of the International Dairy Federation in Codex and drew attention to some current issues under discussion at Codex of particular interest to the dairy industry.

Mr. Howell, the Irish Codex Contact Point, said Ireland participated actively in Codex with officials from a number of Government departments and agencies attending several committee meetings annually. Referring to the complexity of the system and the need to reconcile the interest of different stakeholders, he drew attention to the coordinating mechanisms in place in Ireland and in particular the role of the Irish Codex Advisory Committee.

Pictured at the Codex Alimentarius seminar are (l-r): Richard Howell, DAF; Michael Hickey, International Dairy Federation; Gretchen Stanton, World Trade Organisation; Alan Reilly, FSAI; Minister Brendan Smith, TD, DAF; Kazuaki Miyagishima, Codex and Michael Scannell, DG SANCO, EU Commission.



open consultation

There is currently one open consultation on the FSAI website:

National rules for on-farm production of small quantities of poultry meat for local supply

The introduction last year of new European Regulations on food hygiene established a “farm to fork” approach to food safety. This package of new legislation includes Regulation (EC) No. 852/2004 which lays down common rules for all food businesses, and Regulation (EC) 853/2004 which applies additional requirements to businesses handling foods of animal origin.

With regard to the slaughter of poultry, the general requirement of the regulations is that this activity takes place at approved slaughterhouses. However, there is acknowledgement of the close existing relationships between consumers and farmers slaughtering small quantities of poultry for local supply. That type of activity is exempt from specific approval requirements but Member States are required to draw up national rules regulating this activity to ensure protection of public health.

With this in mind, it is proposed to introduce national legislation in Ireland, in relation to the direct supply by the producer of small quantities of meat from poultry slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat.

The proposed national legislation sets out the scope of activities that will be permitted under the rules and it also includes definitions of:

- small quantities
- local
- on the farm.

The general hygienic requirements of such operations are also outlined along with provision for inspection.

The draft proposed rules and associated documents are available on our website at: <http://www.fsai.ie/consultations/index.asp>.

Comments and views on these proposed national rules, and in particular, comments in relation to scope and the definitions in the proposal should be submitted by 5pm on **Monday, 23rd April 2007**, as follows-

email: consultation@fsai.ie; fax: +353 1 8171301 or post: Consultations, Food Safety Authority of Ireland, Abbey Court, Lower Abbey Street, Dublin 1.

EU consultation on food labelling

The EU has opened a consultation in the form of a questionnaire on their website, which is intended for food business operators who operate in the EU and who label their products. The specific purpose of the questionnaire is to understand, and quantify, some of the costs the food industry might incur because of revisions in the Community general (horizontal) food labelling legislation (Directive 2000/13/EC) and Community nutrition labelling (Directive 90/496/EEC). These costs to food business operators are relevant, and important, in understanding the impact of revisions in general food labelling and nutrition labelling.

The questionnaire will inform two studies that the European Commission DG Health and Consumer Protection commissioned RAND Europe - a public policy research organisation - to undertake. These studies will assess the potential economic, social and environmental impacts of different policy options in food labelling.

The survey consists of five sections:

- i. general information
- ii. questions related to the options for the revision of Directive 2000/13/EC, relating to the labelling, presentation, and advertising of foodstuffs
- iii. questions related to the options for the revision of Directive 90/496/EEC, on nutrition labelling for foodstuffs
- iv. questions related to the legibility of labels
- v. closing questions.

The consultation is available at <http://www.foodlabelsurvey.eu/index.htm>

The closing date for submissions is 16th May 2007.



The following Regulations have been introduced over the last few months in Ireland:

S.I. No. 654 of 2006 European Communities (Pesticide Residues) Regulations, 2006

S.I. No. 56 of 2007 European Communities (Food and Feed Hygiene) (Amendment) Regulations, 2007

S.I. No. 67 of 2007 Abattoirs Act 1988 (Veterinary Examination and Health Mark) Regulations, 2007

S.I. No. 80 of 2007 European Communities (Plastics and Other Materials) (Contact with Food) (Amendment) Regulations, 2007

S.I. No. 84 of 2007 European Communities (Agriculture) (Accession of Bulgaria and Romania) Regulations, 2007

S.I. No. 85 of 2007 Health (Country of Origin of Beef) (Amendment) Regulations, 2007

S.I. No. 103 of 2007 European Communities (Avian Influenza) (Protection Measures Relating to Third Countries) (Amendment) Regulations, 2007

S.I. No. 104 of 2007 European Communities (Pesticide Residues) (Amendment) Regulations, 2007

S.I. No. 106 of 2007 European Communities (Drinking Water) Regulations, 2007

S.I. No. 114 of 2007 Abattoirs Act 1988 (Veterinary Examination) (Salmonella in Pigs) Regulations, 2007



vitamin D deficiency in Ireland

Dietary deficiency in Ireland today is remarkable given that diseases caused by excess and over-nutrition have been the focus of public health nutrition in recent times. However, there is accumulating evidence that vitamin D intakes are inadequate across all age groups of the population and that vulnerable groups (infants, children, pregnant women and the elderly) are at risk of deficiency.

Vitamin D is a fat-soluble micronutrient which plays a vital role in bone health, via its regulation of calcium metabolism. There is also accumulating evidence that it may play a role in the prevention of serious chronic diseases which affect the Irish population, including cardiovascular disease; diabetes mellitus; some inflammatory and autoimmune disorders; as well as some types of cancer.

Vitamin D is an unusual vitamin. Unlike other vitamins that are only available from food and supplements, vitamin D is primarily produced in the body via the action of sunlight (specifically ultraviolet B rays) on the skin. The problems of inadequacy and deficiency arise due to the geographical position of Ireland, which means we receive very little of this sunlight, especially in winter.

Looking at dietary sources, there is growing evidence that most people in Ireland fail to obtain enough vitamin D from food and supplements. Recent studies show that most population groups (from infants through to the elderly) do not achieve the recommended intake level (200IU (5µg) per day).

Other recent studies confirm that low levels of vitamin D are prevalent among various age groups in Ireland. The reasons for this are numerous and are outlined below:

Ireland's geographical position

Ireland lies at a northerly latitude (just above 52° North), which means that at this location very little UVB light reaches the earth's surface during the six months from October to March, resulting in no production of vitamin D. This means that Ireland's population is totally reliant on body stores and diet to maintain vitamin D status for 6 months of the year.

Skin pigmentation and cultural dress

Dark skin requires much longer exposure (10-50 times) to UVB sunlight than light skin to manufacture an equivalent amount of vitamin D. Therefore, people with darker skin have greater difficulty in obtaining vitamin D from the sun. In recent years the numbers of people in Ireland that are vulnerable to vitamin D deficiency due to their dark skin colour has increased greatly.

Although adults wear clothes that conceal most of the skin's surface, some cultural and religious practices preclude any skin exposure when outdoors. Many Muslim women wear burkhas, which cover the head and face, while others wear full Islamic dress covering head, arms, and legs.

Sunscreen use

Historically, it was believed that adequate sun exposure during the summer months ensured sufficient stores of vitamin D during wintertime. However, to reduce the risk of sun-damage and skin cancer, people are strongly advised to use sunscreen. A sunscreen with SPF of 15 used appropriately can reduce the capacity of dermal vitamin D synthesis by more than 98%.

Office-work replacing work outdoors

Work practices have changed greatly in Ireland over the past 50 years where work outdoors in the sunlight has largely been replaced by office work. This means that people are indoors during the sunny daylight hours and there are limited opportunities for vitamin D synthesis from UVB exposure.

Increased dependency on dietary vitamin D intakes

Due to the stores of vitamin D being lost quite rapidly, there is an increased dependency on dietary intakes for maintenance of vitamin D status in winter. Rich dietary sources of vitamin D include oily fish (e.g. tuna, sardines, salmon etc.) liver, egg yolks and fortified foods (margarine, breakfast cereals, milk) and also vitamin D supplements. These foods are not commonly eaten by many people in Ireland.

This situation is similar to other countries in Northern Europe where usual vitamin D intakes are not sufficient to maintain adequate levels, especially during winter. As a consequence, inadequate vitamin D status in Ireland and other Northern European countries is quite common among the very young (where bone growth is very rapid), adolescents, pregnant women (who have increased needs) and the elderly (where outdoor activity is compromised).

Vitamin D policies in other countries regarding supplementation and food fortification

Other countries with latitudes similar to that of Ireland (e.g. UK, Canada, USA) have already identified and addressed the problem of vitamin D deficiency by putting in place supplementation and/or food fortification programmes (see Table below).

From this table it can be seen that vitamin D supplementation programmes are in place even in countries at latitudes less than that of Ireland e.g. France, Germany.

Geographical Location	Vitamin D supplementation	National Vitamin D Fortification Policy	Latitude
<i>Ireland</i>	No	No	51°N - 55°N
Canada	Yes	Yes	45°N - 75°N
USA	Yes	Yes	38°N - 77°N
UK	Yes	No	Average 53°N
France	Yes	No	48°N
Finland	Yes	Yes	60°N
Germany	Yes	No	37°N - 52°N



Adverse effects of low vitamin D status

If the supply of vitamin D is restricted, bones become the main target organ for calcium release, which leads to increased bone turnover and risk of bone loss in the long term. It is well established that prolonged and severe vitamin D deficiency leads to rickets in children (bowed legs and arms, delayed closure of the fontanels in the skull, deformed rib-cage) and osteomalacia in adults. The long term risks include osteoporosis and, according to recent reports, hypertension, diabetes mellitus, some inflammatory and autoimmune disorders (including multiple sclerosis), as well as common cancers (colon, breast and prostate cancers).

Those most at risk

Although vitamin D deficiency is a concern for all population groups in Ireland, the groups most at risk are those experiencing rapid growth i.e. infants and young children. Even when maternal vitamin D status is optimal, newborns will have no more than 50-60% of their mothers vitamin D stores at birth. There is no doubt that breast milk is the optimum food for babies between birth and 6 months. However, exclusively breastfed infants are more vulnerable to low vitamin D status than those who are formula fed, as infant formula is fortified with vitamin D, to take into account the need to supplement this age-group. However, all infants aged 0-12 months would benefit from having extra vitamin D, as foods containing vitamin D are rarely included in weaning diets.

What is being done?

The Nutrition and Novel Foods Sub-committee under the aegis of the Scientific Committee are aware of the issue of vitamin D inadequacy in Ireland. A multidisciplinary working group on Vitamin D has been reviewing this in relation to infant nutrition (infants are the most at risk group of vitamin D deficiency). A report from this group will be available shortly.

7th Irish shellfish safety scientific workshop

A large and representative gathering, from regulatory agencies, universities, research laboratories and industry, attended the 7th Irish Shellfish Safety Workshop at the Marine Institute, Galway. The specific objectives of the workshop included presenting the Irish shellfish monitoring system and the results during 2006. An assessment of key developments relating to biotoxins since the last workshop in December 2005 was also provided.

During the course of the workshop, the current Irish research work in harmful algal blooms, gene probes, isolation and toxicology of azaspiracids was summarised. The workshop also aimed to strengthen the focus on shellfish microbiology, including viruses, water quality and risk management.

A review of the events surrounding the oyster closures in France in 2006 was presented by Aoife Ni Rathaille and Robin Raine in their presentation entitled "Predicting Alexandrium Blooms in Cork Harbour".

Additional to the workshop was a forum to discuss and debate some of the key questions which have been investigated in Irish research. Some of the research discussed included:

- seasonal patterns and toxicity trends in mussels & oysters;
- prediction of the start of PSP toxicity in Cork harbour;
- use of gene probes for rapid screening of phytoplankton;

- toxicity of azaspiracids;
- development of early warning systems and management of the risks of viruses affecting humans in shellfish.

Micheal O'Connide closed the workshop by concluding that "the Irish shellfish industry has continued to show its resilience and potential in the past five years. The Price Waterhouse review of the rope mussel sector has made valuable recommendations for the industry. The Marine Institute, Bord Iascaigh Mhara and other agencies will support the ongoing development of the shellfish sector to develop new markets, with no product recalls."

peter departs the fsai

Peter Whelan joined the Authority in 1999 as Contracts Manager, and in 2002 was appointed Director of the Service Contracts Division. Peter's hard work and dedication to the Authority were key in the development of service contracts with the official agencies. The good working relationship he holds with our colleagues in the official agencies, as well as FSAI staff, are testament to his approachable and

supportive work ethic. Peter leaves us to take up his post as Chairman of the newly established Sea Fisheries Protection Authority (SFPA). As the SFPA will be an official agency of the FSAI, we look forward to working with him again in the near future. The staff of the FSAI wish Peter every success in his new role and thank him for his hard work, commitment and friendship over the last eight years.





draft risk management standard

The International Organisation for Standardisation (ISO) have been developing, through one of its working groups, a draft international standard on risk management. ISO 31000 "*Guidelines on the principles and implementation of risk management*" is now in its fourth draft and the Irish input into the development of the standard is being co-ordinated by the National Standards Authority of Ireland (NSAI).

Throughout the world, organisations of all types and sizes, including the food industry, face a range of risks that may affect the achievement of their objectives. Risk, therefore, influences almost all forms of decision making. Risk management aids decision making, by taking account of uncertainty and the possibility of future events or circumstances, intended or unintended, and their potential effects. Risk management aims to assist in achieving an organisation's objectives. The management of risk involves applying logical and systematic methods for communicating and consulting, establishing context, identifying, analysing, evaluating, treating and monitoring risk associated with any activity, product, function or process and to report the results appropriately.

Risk management can be applied across many areas, to various functions and levels of an organisation. When implemented and sustained in accordance with the published ISO 31000 standard, risk management should enable an organisation to achieve:

- A more confident and rigorous basis for decision making and planning
- better corporate governance
- better identification of opportunities and threats
- effective allocation and use of resources for risk treatment
- improved compliance with relevant legislation
- improved incident management and reduction in losses
- improved stakeholder confidence and trust
- increased awareness of the need to treat and manage risk in organisations
- proactive rather than reactive management.

To be effective within an organisational context, risk management should be developed within the organisation's overall governance, management, and reporting processes, policies, philosophy and culture. Indeed, the use of risk management can be expected to strengthen these and other areas of activity, within an organisation. Within a specific context, such as a project or defined function, product or activity, exactly the same risk management approach can be used.

The draft ISO 31000 standard recognises the variety of the nature, level and complexity of risks and provides generic principles and guidelines for risk management and its implementation. It sets out how risk management can best be employed in the context of an organisation to manage risk.

ISO 31000 it is intended will be used by:

- those who need to ensure that an organisation manages risk;
- those within an organisation who need to manage risk within a more specific area or activity;
- developers of other standards, guides, procedures, and codes of practice that, in whole or in part, set out how risk is to be managed within the specific scope and context of their documents.

Although risk management has developed over time and across many sectors to meet diverse needs, it is now understood that a generic approach consisting of a set of essential elements can ensure that risk is managed effectively and coherently across an organisation. The generic approach described in the draft standard provides guidance on implementing these essential elements so as to manage risk, within any scope and context, with transparency and credibility.

Each specific sector or application of risk management brings with it distinctive needs, audiences, perceptions and criteria. One of the novel features of ISO 31000 will be its description of the activity of "establishing context" within this generic process. This feature is designed in particular, to capture this diversity of criteria as well as the nature and complexity of risk and other factors, that need to be considered and managed in each case.

Risk management within the area of food safety imposes criteria that may be highly defined, but may or may not be captured in legislation and international norms. The application of the risk management approach described in ISO 31000 ensures that those criteria are identified and applied. Therefore, the implementation of *Guidelines on the principles and implementation of risk management* can also be an aid to the management of compliance and performance.

Ms. Linda Hendy is the technical secretary of the NSAI - Risk Management Consultative Committee. Further information on the development of the standard can be sourced by telephoning the NSAI on 01-8073800.

food safety consultative council meeting

The food safety consultative council of the FSAI, under the chair of Ms. Veronica Campbell, held its second meeting in Drumshanbo, County Leitrim recently. The Council developed its work plans for the year and had updates on avian influenza and nutrition labelling.

It also agreed that the results of its survey on consumer and industry attitudes to food safety, jointly conducted with *safe food* - the Food Safety Promotion Board, should be published. Organic food was the main item of discussion and the Council listened to presentations from three speakers: - Pascal Gillard representing the Irish Organic Farmers and Growers Association, Lorcán Bourke of Bord Bia and Siobhán Morris representing the Leitrim Organic Farmers Co-operative. The Council are planning to host an open meeting for October 4th 2007, in Dublin and organic food is one of the topics under consideration for that meeting.





national microbiological surveillance: safety and quality of raw mushrooms

Background

Mushrooms are the edible fleshy fruiting bodies of certain fungi. The most commonly cultivated mushroom species is *Agaricus bisporus*, although many other species are now gaining importance.

The mushroom industry has been one of the big success stories of the Irish food industry. However, in recent years the Irish mushroom industry has experienced problems including increased production costs (e.g. labour, packaging and insurance), downward price pressures, investment issues and environmental issues. The future viability of this sector depends not only on commercial/economical issues but also on the safety of Irish mushrooms.

Mushrooms (like many fruit and vegetables) are eaten in their raw and cooked form and therefore it is important that they are free from contamination (both microbiological and chemical). In 2001, the viability of the Irish mushroom industry was threatened when *Salmonella Kedougou* (an uncommon serovar of *Salmonella* spp.) was isolated from Irish commercially grown mushrooms on sale in the United Kingdom. Investigations revealed that the contamination originated from sugar beet lime, an alkaline material used in the casing soil. To address the problem all casing manufacturing sites underwent a thorough sanitisation programme and a code of practice was developed for casing manufacturers. In addition, the FSAI issued advice to commercial caterers and consumers to cook all mushrooms ^[1]. These activities resulted in the elimination of the contamination ^[2].

Aim

The aim of this study was to investigate the microbiological safety (*Salmonella* spp., *Listeria monocytogenes* and *Staphylococcus aureus*) and the microbiological quality (*Escherichia coli*) of raw mushrooms on retail sale in the Republic of Ireland.

Methodology

Raw mushrooms were sampled by environmental health officers (EHOs) during January, February and March 2006. Samples were obtained from retail premises, catering premises and distributors/packers. Samples included whole and sliced mushrooms, loose and pre-packed mushrooms, washed and unwashed mushrooms, Irish and imported mushrooms. Mushrooms of all varieties, size and quality were sampled. Sample information was recorded on a questionnaire at the time of sampling.

The samples were analysed in one of the seven official food microbiology laboratories (OFMLs) using approved/standard methods. Samples were analysed for:

- *Salmonella* spp.
- *Listeria monocytogenes* (qualitative and quantitative analysis)
- *Staphylococcus aureus* and
- *Escherichia coli*

Results

Where applicable, the microbiological results were assessed against the criteria laid down in European legislation (harmonised microbiological criteria are laid down in Commission Regulation (EC) No 2073/2005 ^[3] for some food/pathogen combinations). Otherwise, the results were assessed against the national microbiological guidelines for ready-to-eat foods sampled at the point of sale (Food Safety Authority of Ireland, Guidance Note No. 3 ^[4]). The following were the main findings:

- *Salmonella* spp. were not detected in any sample, thus:
 - all sliced mushrooms were classified as satisfactory for *Salmonella* spp. when assessed against the microbiological criterion specified in Commission Regulation (EC) No 2073/2005 and
 - all whole mushrooms were classified as satisfactory for *Salmonella* spp. when assessed against the national microbiological guidelines.
- *L. monocytogenes* was detected in 1.1% (8/727) of samples but was not quantified at levels >100 cfu/g in any sample. Therefore, all samples were classified as satisfactory for *L. monocytogenes* when assessed against the microbiological criterion specified in Commission Regulation (EC) No 2073/2005.
- 99.2% of samples were classified as satisfactory when assessed against the national microbiological guidelines for *S. aureus*.
- all samples were classified as satisfactory when assessed against the national microbiological guidelines for *E. coli*.

These findings are very encouraging as mushrooms (like many fruit and vegetables) are eaten both in their raw and cooked form and therefore it is important that they are free from microbial contamination.

The report of this survey and other national microbiological surveys are available on the FSAI website
<http://www.fsai.ie/surveillance/index.asp#food>

1. Food Safety Authority of Ireland. 2001. Press releases 12th April & 21st May 2001:
http://www.fsai.ie/news/press/pr_01/pr20010412.asp,
http://www.fsai.ie/news/press/pr_01/pr20010521.asp
2. Doran, G, Sheridan, F, De Lappe, N., O'Hare, C., Anderson, W., Corbett-Feeney, G., and M Cormican. 2005. *Salmonella enterica* serovar Kedougou contamination of commercially grown mushrooms. *Diag. Microbiol. and Infectious Disease*. 51, 1, 3-76
3. Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L338, p1, 22/12/2005).
http://www.fsai.ie/legislation/food/eu_docs/Food_hygiene/Reg2073_2005.pdf
4. Food Safety Authority of Ireland. 2001. Guidance Note No. 3. Guidance Note on the Interpretation of Results of Microbiological Analysis of Some Ready-To-eat Foods Sampled at the Point of Sale.
http://www.fsai.ie/publications/guidance_notes/gn3.pdf

legislation update

Regulatory committees and the European Commission standing committee on the food chain and animal health

An integrated "farm to fork" approach is a general principle for EU food safety policy. This is reflected in the creation of food legislation which aims at ensuring a high level of protection of human life and health, while taking into account the protection of animal health and welfare, plant health and the environment.

Regulatory committees assist the European Commission in the development of food safety measures at all stages of the food chain, and they play a key role in the EU decision making process. In order to ensure a more effective and comprehensive approach to the food chain, the Standing Committee on the Food Chain and Animal Health (SCFAH) was established under Regulation (EC) 178/2002. The SCFAH replaced the Standing Veterinary Committee, the Standing Committee for Foodstuffs and the Standing Committee for Feedingstuffs.

Standing committee on the food chain and animal health (SCFAH)

The Standing Committee on the Food Chain and Animal Health (SCFAH) is comprised of representatives of the EU Member States and is chaired by a European Commission representative. It has eight sections:

- General Food Law;
- Biological Safety of the Food Chain;
- Toxicological Safety of the Food Chain;
- Controls and Import Conditions;
- Animal Nutrition;
- Genetically modified Food and Feed and Environmental Risk (2004);
- Animal Health and Animal Welfare and
- Phytopharmaceuticals.

The number of meetings varies between committees. For example, for 2007 the provisional list of meetings, which is available on the EU website at http://ec.europa.eu/food/committees/regulatory/planning_sc_meetings_2007.pdf, has programmed three meetings for the Committee of General Food Law and five for the Committee on

Toxicological Safety of the Food Chain. The Committees on the Biological Safety of the Food Chain, Animal Nutrition and Animal Health and Animal Welfare have 11 meetings provisionally booked.

The agendas and meeting reports are also available on the EU website of the European Commission at http://ec.europa.eu/food/committees/regulatory/index_en.htm.

At recent meetings the following issues of particular interest were agreed:

Toxicological safety of the food chain

Spinach extract containing high levels of nitrate used in sausages

It has been reported that some manufacturers of meat products were using standardised spinach extracts containing high levels of nitrates. Furthermore such products are labelled to imply that they contain no added preservatives. It has therefore been questioned whether such use should be considered as that of a food additive as it may exert a preservative and/or colour fixing effect.

Member States considered that such a practice would be a deliberate use of a food additive, if used for the intended technological purpose of preservation in the final food. Consequently, such a use of a food additive should comply both with the food additive legislation and also be labelled in compliance with the appropriate food labelling legislation.

The Commission has stated that it would write to the appropriate European trade associations to make them aware of this issue.

Criteria for the use of microbial cultures as food additives

The issue of cultures as food additives has been discussed a number of times in Commission working group meetings, at which time there was strong support that the use of cultures when used as preservatives should be considered as food additives. A draft paper describing when the use of cultures would be considered as food additives was tabled. The updated draft criteria are given below:

Draft criteria for determining status of culture use

Cultures are used for a variety of purposes from traditional use in food production, to more novel and targeted applications for food preservation. Such uses can be divided between ingredient/processing aid and food additive uses. To aid in this interpretation the following draft criteria have been developed.

- Cultures which are added at the beginning or early stages of manufacture, and which contribute to the characteristic nature of the food would not be considered as food additives. Examples would be starter cultures used in cheese, yoghurt or dried sausage production.
- Cultures which are used during the manufacture of foodstuffs and which contribute to the characteristic nature of the food would not be considered as food additives. An example would be cultures applied to the surface of a ripening cheese which contributes to the development of the characteristic nature of the cheese (production of cheese rind).
- Cultures which are added for a specific technological effect (such as preservation) would be considered as food additives. Examples could be the use of cultures on cooked or raw meat/shellfish etc. Also included in this example would be the addition of cultures to prepared foodstuffs whereby the culture is intended to act as a preservative.
- Cultures which are added to food, but which are not added for a technological function, would not be considered as food additives. An example would be the addition of cultures to a yoghurt or dairy drink whereby the cultures are added for a probiotic effect in the consumer.

These draft criteria will be circulated by the Commission to stakeholders for comment, and it will be discussed further and endorsed at a future meeting of the Standing Committee after consideration of any further comments from Member States and stakeholders.

Committee on general food law

Labelling of a cocoa product containing sweeteners

A question was raised regarding whether a cocoa product containing no added sugars would be in compliance with the definition of chocolate as set out in Directive 2000/36/EC and could be labelled as such. The Commission stated that chocolate products in which the added sugar has been totally or partially replaced by sweeteners are not prohibited by Directive 2000/36/EC, in so far that they comply with requirements of Directive 94/54/EC on sweeteners.

Labelling of products which contain chocolate as an ingredient

A question was asked regarding whether it was necessary to declare the dry cocoa solids of a chocolate product when the chocolate product is an ingredient of another foodstuff. The Commission, referring to an interpretation note issued in 2001, stated that the declaration requirements of Directive 2000/36/EC on

cocoa and chocolate products apply in addition to the general labelling requirements of Directive 2000/13/EC, as the percentage of cocoa solids gives an indication of the quality of the chocolate products. Since Article 2(1) of the general labelling Directive (2000/13/EC) provides that the labelling and methods used must not be such as could mislead the purchaser to a material degree, including as to the characteristics of the foodstuffs and its composition, the indication of ingredients has to be done in such a manner as to be clear to the consumer to what the indications are related and what information they provide.

The Commission provided the following as an example:

The indication of a chocolate with hazelnuts should be as follows:

Ingredients: Sugar, cocoa butter, hazelnuts (25%), cocoa mass, emulsifier (soya lecithin), flavouring (vanillin)

Chocolate part contains: Cocoa solids 35% minimum.

Labelling of water content in fish and fishery products

The Committee exchanged views on the question of the labelling of added water in glazed deep frozen fish. A question was raised on whether water retained by water retention agents (polyphosphates) could be considered as added water if the amount of these agents contained in the final product does not exceed the maximum limit set by the legislation and whether or not it should be labelled as an ingredient.

The Commission stated that according to the labelling provisions, a distinction has to be made between glazing water, which must be taken into account for the calculation of the drained net weight, and added water, considered as ingredient.

The Committee concluded that any addition of water, that results in the presence of water in the final product, entails an obligation to include water in the list of ingredients, provided that its amount exceeds 5% by weight of the finished product.

Currently being discussed

Simplification of milk marketing rules

The European Commission adopted a proposal in mid February 2007 that aims to simplify the common market organisation for milk and dairy products. The milk package contains amendments of the following three pieces of legislation:

- Council Directive 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption.

The amendment includes a proposal for the standardisation of the rate of proteins in preserved milk.

- Council Regulation (EC) No 1255/1999 on the common organisation of the market in milk and milk products.

The amendment includes a Community definition of butter quality, which it is proposed will replace the 27 national quality classes for butter with a single quality definition.

- Council Regulation (EC) No 2597/97 laying down additional rules on the common organisation of the market in milk and milk products for drinking milk.

Council Regulation (EC) No 2597/97 currently provides that only three categories of drinking milk may be produced and marketed in the Community:

- skimmed milk (0.5% fat or less);
- semi-skimmed milk (between 1.5% and 1.8% fat);
- whole milk (3.5% fat or more).

In order to respond to changes in nutritional habits (tendency towards consumption of dairy products with less milk fat), as well as to comply with the general objective of encouraging the production of agricultural products which are demanded by the market, it is proposed to allow production and marketing in the EU of milk with fat contents outside the three abovementioned categories, provided that clear and readable information on the fat content is provided on the label.



water, water everywhere...

Water, which comes from rivers, lakes or aquifers, not naturally pure, but treated to reduce contaminants to a safe level, is classed as potable water. Potable water, that is, tap water, and packaged water are regulated by EU Directive 98/83/EC on the quality of water intended for human consumption. This Directive is implemented into Irish Law by:

- Statutory Instrument No. 106 of 2007, European Communities (Drinking Water) Regulations, 2007 and
- Statutory Instrument No. 79 of 2005, European Communities (Natural Mineral Waters, Spring Waters and other Waters in Bottles or Containers) Regulations, 2005.

Naturally pure water, that is, natural mineral water and spring water, from underground sources that are safe to drink, are regulated by EU Directive 80/777/EEC as amended by Directive 96/70/EC and Directive 2003/40/EC, and implemented into Irish Law by Statutory Instrument No. 79 of 2005.

The FSAI has a service contract with the National Standards Authority of Ireland (NSAI), and in this regard the NSAI is an official agency of the FSAI.

The NSAI as the nominated 'responsible authority' has the following official control responsibilities:

- formal recognition of waters extracted from the ground as 'Natural Mineral Water';
- permitting companies to exploit (bottle and place on the market) the natural mineral water from named bore hole exits / extraction points;
- continual recognition of the Natural Mineral Water by means of surveillance inspections confirming the water continues to satisfy the requirements of the Directive;
- ongoing renewal of permission to exploit by means of surveillance inspections;
- permitting companies to exploit from additional bore hole exits /extraction points and confirmation of originating source.

cyprus to adopt irish model for food safety regulation

The Food and Agriculture Organization (FAO) and World Health Organization (WHO) recently jointly published their Food and Nutrition Paper Number 76 entitled "Assuring Food Safety and Quality - Guidelines for Strengthening National Food Control Systems". The guidance has been well received across the globe. One noteworthy aspect from an Irish perspective is that the guidance uses Ireland, and the establishment of the Food Safety Authority of Ireland, as an example and case study of good practice in the reform of national food control services. Cyprus has recently decided to

reorganise its own national food control services and is looking to the "Irish Model" as the basis for its reformed services. Staff from the FSAI recently travelled to Cyprus at the invitation of its Government. The purpose of the visit was to brief the Cypriot Minister for Health and senior management officials from government departments and agencies including health, agriculture and the municipalities on the operation of food control systems in Ireland. We await developments with interest.

new requirements for caterers to declare origin of beef

In June 2006, new legislation (Health (Country of Origin of Beef) Regulations 2006 - S.I. 307 of 2006) was introduced, requiring certain catering food businesses selling beef such as roast joints, and steak, to inform customers where the beef originates from.

Following an amendment to the legislation, in March 2007, which further clarified the types of businesses involved and the types of products covered, the FSAI has produced guidance for caterers on the requirements.

'Origin of beef' in the legal sense of the Regulations is the country (or countries) where an animal was born, reared and slaughtered. Where this is all in the same country, such as Ireland, a simple declaration such as '**Origin of Beef: Ireland**' is sufficient. Where different countries are involved, these all need to be indicated.

Caterers must display this information on a menu, a menu board, window display or some other means which is **clearly visible** to the customer and easy for them to read and understand.

The requirements will be enforced by environmental health officers of the Health Service Executive. In addition to leaflets designed for caterers, guidance has also been provided to the environmental health officers on enforcement of the Regulations.

Copies of the information leaflet for caterers and the guidance document for enforcement officers can be downloaded from the FSAI website www.fsai.ie or by calling our advice-line on 1890 33 66 77.



local authority liaison meetings

The first round of liaison meetings between the FSAI and local authorities have been taking place between January and April. In this round of meetings, a new initiative is being piloted whereby an FSAI veterinary officer also attends one liaison meeting per local authority per year. This initiative is being piloted to allow the LAVS raise and discuss veterinary issues arising at local level and more detailed discussions on technical issues raised in notes and updates presented at the liaison meetings.

Topics being discussed at these meetings include: service contract issues, updates on hygiene package legislation, updates on the approval of establishments and ongoing sampling and surveillance

programmes. The issue of regional cover within the service and continual professional development of veterinary officers is also being discussed.

The FSAI local authority standardisation committee have approved the recently amended ante mortem/post mortem standard operating procedure (SOP) and forms and updated books of the forms have been distributed. The SOP on approval of local authority supervised meat establishments has been reviewed by the group. Other SOPs developed include slaughterhouse inspection/audit, animal by-products and transport SOPs. A priority for the group is to develop an SOP on risk assessment.

nutrition and health claims

Introduction

The recent introduction of a new European Regulation (Regulation (EC) No 1924/2006) on nutrition and health claims made on foods marketed within the European Union, has caused much discussion among food business operators (FBOs).

The Regulation places the responsibility onto FBOs to ensure claims they make on foods are authorised. Claims that are not authorised under this new European Regulation (Regulation (EC) No 1924/2006) will not be permitted.

In order to assist FBOs, the FSAI has developed a new section regarding nutrition and health claims on our website (www.fsai.ie). This new section of the website is designed to help inform FBOs about the new legislation and the tasks they must undertake to ensure the claims they make in relation to food are compliant. All FBOs who make any claims about the nutritional or health benefits of their foods should refer to the nutrition and health claims section of the website, which provides information on:

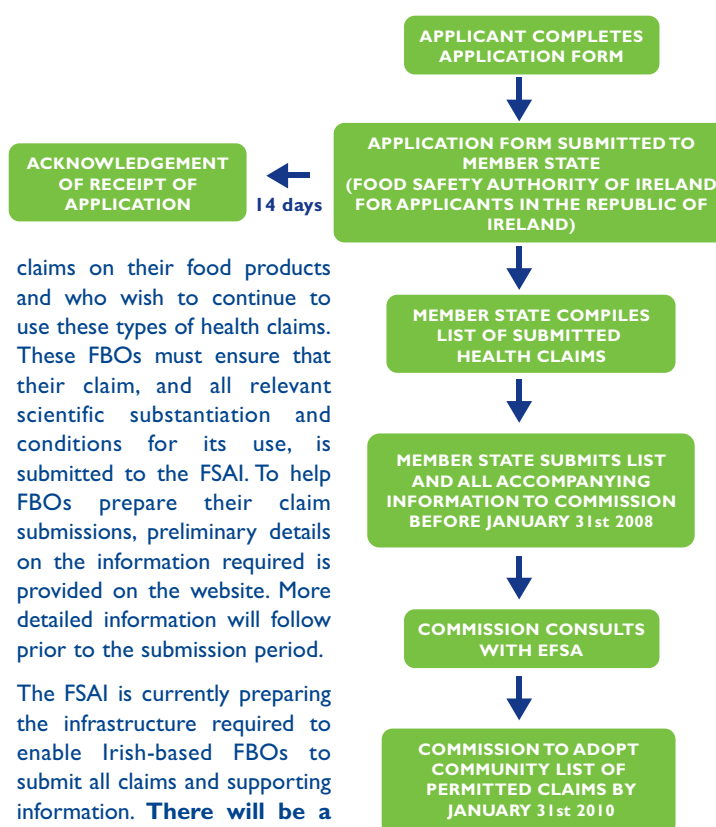
- general information on claims;
- conditions for the use of nutrition and health claims;
- transitional measures;
- an outline of the various procedures that FBOs must follow to have their health claims authorised (this varies depending on the type of claim involved);
- an update on the process being developed by the FSAI to compile the national list of health claims under Article 13. This information will be updated regularly to provide details on the data that will be required from FBOs to substantiate their claims;
- frequently asked questions.

The nutrition and health claims section of the website will be continuously updated to keep FBOs fully informed of the period for submission of health claims for the Article 13 list and of the information they need to provide and procedures to be followed.

Health claims other than those referring to the reduction of disease risk and to children's development and health (Article 13)

In Ireland the FSAI, with support and input from the Department of Health and Children, will compile the Irish national list of Article 13 claims. This has immediate implications for Irish FBOs who have

PROCESS FOR AUTHORISATION OF HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH - Article 13 claims



claims on their food products and who wish to continue to use these types of health claims. These FBOs must ensure that their claim, and all relevant scientific substantiation and conditions for its use, is submitted to the FSAI. To help FBOs prepare their claim submissions, preliminary details on the information required is provided on the website. More detailed information will follow prior to the submission period.

The FSAI is currently preparing the infrastructure required to enable Irish-based FBOs to submit all claims and supporting information. **There will be a three month period whereby the FSAI will be accepting submissions from FBOs.** The time period for submissions to be made will be advertised to ensure that relevant FBOs are alerted.

An on-line application, which will be made available on the FSAI website (www.fsai.ie), will be used to accept submissions for Article 13 claims in Ireland. It is envisaged that FBOs will complete their submissions on-line as this information will be directly added to the list for the European Commission. In the case of an FBO not having internet access, a paper version of the submission form can be completed.

nutrition and health claims

Health claims based on newly developed scientific evidence and/or applications which include a request for the protection of proprietary data (Article 13(5))

An FBO wishing to add a health claim, based on newly developed scientific evidence and/or which includes a request for protection of proprietary data, to the Community list of permitted claims, may apply for inclusion of the claim in that list.

Submission procedure (Article 18)

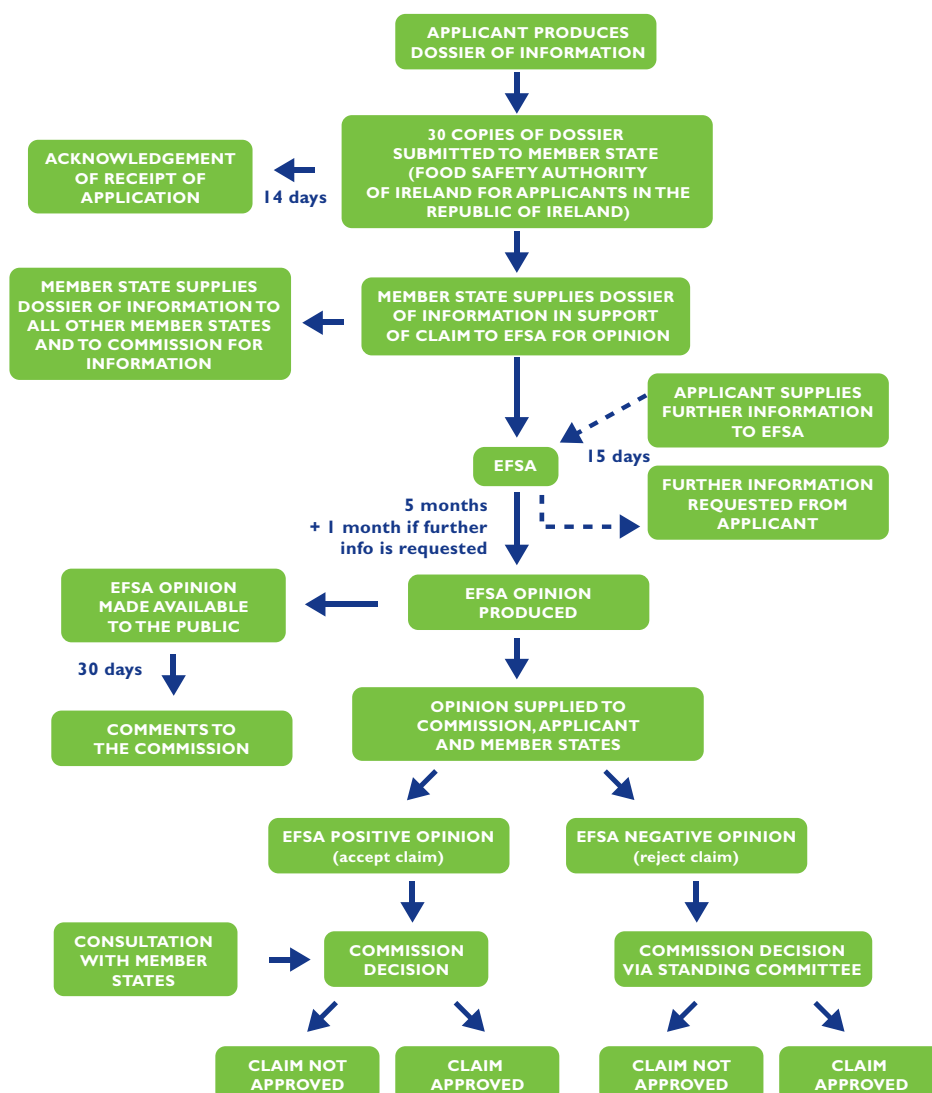
The Commission will adopt a list of permitted health claims by 31st January 2010 at the latest. This procedure relates to the addition of claims to that list; therefore, this procedure will not be applicable until after that date. Guidance regarding the submission of claims under Article 13(5) will be issued by EFSA and the FSAI website will be updated accordingly, when the guidance document becomes available.

The application must include the following information:

- the name and address of the applicant;
- the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics;
- a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in Regulation (EC) No 1924/2006 on nutrition and health claims;
- where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;
- a copy of other scientific studies which are relevant to that health claim;
- a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;
- a summary of the application;
- the reasons for the request.

PROPOSED PROCESS FOR AUTHORISATION OF HEALTH CLAIMS BASED ON NEW OR EMERGING SCIENTIFIC EVIDENCE

Article 13(5) claims



Claims referring to reduction of disease risk and to children's development and health (Article 14)

Under the new Regulation, reduction of disease risk claims and claims referring to children's development and health may be made where they have been authorised in accordance with the procedure laid down in Articles 15, 16, 17 and 19 of the Regulation. Once authorised, they will be included in a Community list of permitted claims together with all the necessary conditions for their use. The prohibition in Article 2(1)(b) of the general labelling Regulations (Directive 2000/13/EC) which prevents the labelling of a product attributing to any foodstuff the property of preventing, treating or curing a human disease, or referring to such properties, also applies.

Submission Procedure (Article 15)

FBOs should submit their application to the FSAI who will acknowledge receipt of the application in writing within 14 days of its receipt, stating the date of receipt of the application. Application forms are available to download from the website or by contacting the FSAI advice-line on 1890 33 66 77, after July 1st 2007.

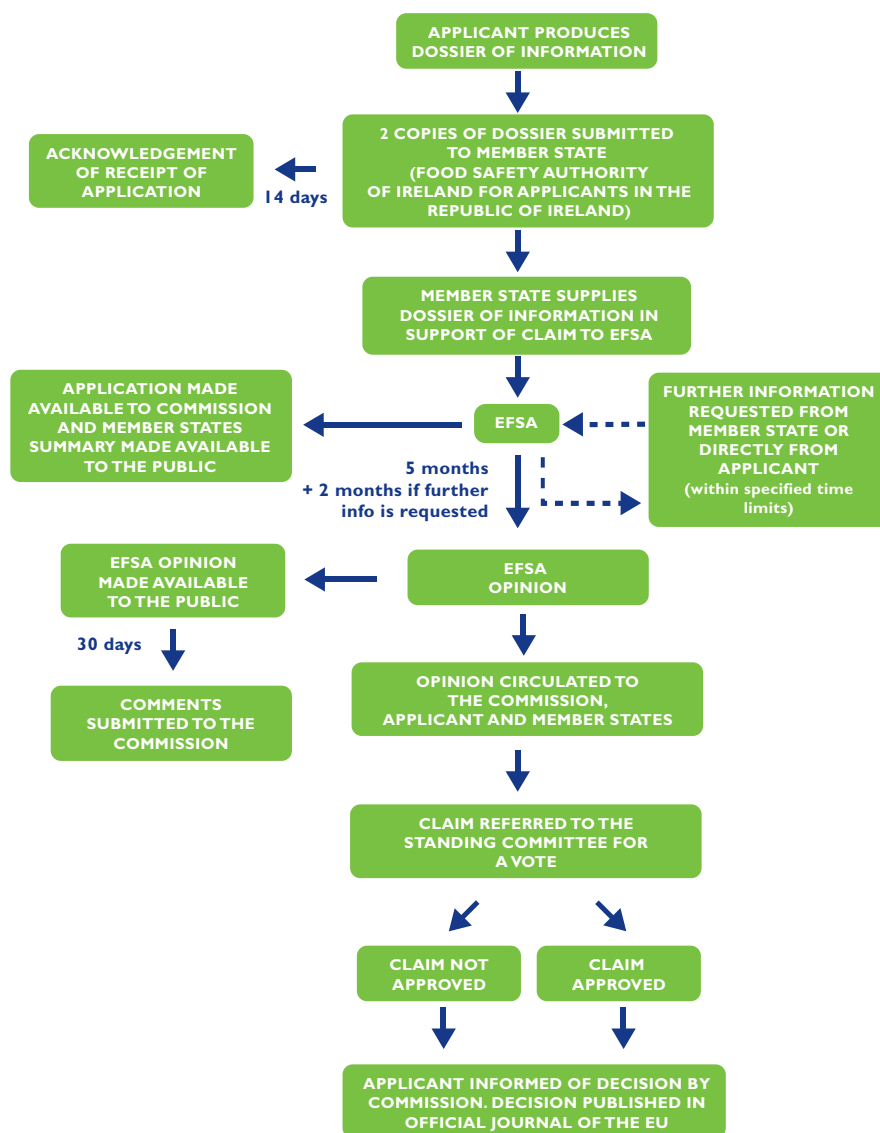
Two paper copies and two electronic copies (e.g. cd, memory stick etc.) of the dossier are required to comply with the requirements of Article 15(2)(a)(iii), to circulate the dossier to EFSA. The paper copies will be considered the formal application. Electronic copies should use common electronic formats, such as MS Office type documents or Adobe Acrobat Reader. The files should be searchable using the search facilities of standard software packages.

Specific details regarding submission of dossiers will be posted on the fsai website.

The application must include the following information:

- the name and address of the applicant;
- the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics;
- a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to

PROCESS FOR AUTHORISATION FOR DISEASE REDUCTION CLAIMS AND CLAIMS REFERRING TO CHILDREN'S DEVELOPMENT AND HEALTH Article 14 claims



demonstrate that the health claim complies with the criteria provided for in Regulation (EC) No. 1924/2006;

- where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;
- a copy of other scientific studies which are relevant to that health claim;
- a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;

g. a summary* of the application (which will be made public by EFSA).

*The summary should be presented in an easily comprehensible and legible form and should not contain any confidential material. An electronic version of the summary should be provided.

The FSAI advice-line (1890 33 66 77) will be available Monday to Friday from 9am to 5pm to answer questions and deal with queries, FBOs may have relating to nutrition and health claims.

The Scientific Committee of the FSAI is composed of scientists from a range of disciplines working in a voluntary capacity. Their role is to assist and advise the FSAI Board on scientific matters. In practice, food safety issues can require specific knowledge and it is often more appropriate to form a Sub-committee of specialists to tackle specific scientific tasks.

terms of reference

The FSAI is legally obliged to base its opinions on scientific grounds and to develop food standards on the basis of the best, most up-to-date scientific advice available. To aid the FSAI in risk assessment, which underpins risk management decisions, the Scientific Committee was established in 2000 in accordance with Article 34 of the Food Safety Authority of Ireland Act, 1998. The Committee is made up of independent scientists, from a variety of disciplines, appointed in their personal capacity and who serve a five year term. The Scientific Committee is required by the FSAI Act to provide advice in three areas:

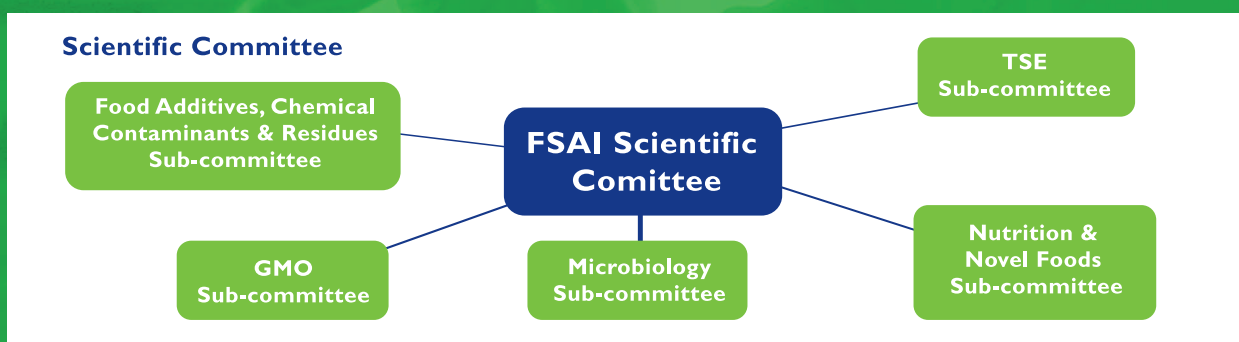
- the implementation and administration of food inspection services,
- the nutritional value of food and
- matters of food safety and hygiene.

In addition to advising the FSAI, the Scientific Committee also provides overall strategic direction to its Sub-committees (of which there are five) and approves their work programmes.

members

The members of the FSAI Scientific Committee are:

Prof. Albert Flynn (Chair), University College Cork
 Dr. Catherine Adley, University of Limerick
 Ms. Paula Barry Walsh, Department of Agriculture and Food
 Prof. Dan Collins, University College Dublin
 Dr. Eibhlin Connolly, Department of Health and Children
 Prof. Martin Cormican, University College Hospital Galway
 Dr. Philip Hess, Marine Institute
 Prof. Colin Hill, University College Cork
 Mr. Cathal Kearney, Health Service Executive
 Dr. Mark Lynch, Department of Agriculture and Food
 Prof. Brian McKenna, University College Dublin
 Dr. Paul McKeown, Health Protection Surveillance Centre
 Dr. Michael O'Keeffe, Ashtown Food Research Centre
 Prof. Michael Ryan, University College Dublin



gmo sub-committee

The GMO Sub-committee provides the FSAI with expert advice on the safety to humans, animals and the environment, of genetically modified organisms (GMOs) and derived food and feed. In particular, this Sub-committee assesses applications to market GM food and feed within the EU under Regulation EC No 1829/2003 along with the safety assessments carried out by the European Food Safety Authority (EFSA). In 2006, the GMO Sub-committee considered five GM maize and one GM potato applications, while an application and EFSA safety assessment for GM sugar beet is currently being examined. The GMO Sub-committee is also consulted on various issues related to developments within the field of food biotechnology as required by FSAI.

terms of reference

The terms of reference of the Sub-committee cover the following areas:

1. To provide advice to the FSAI on specific aspects of applications to market GMOs, GM food and GM feed within the EU.
2. To provide advice on specific aspects of new EC and national legislative proposals related to GMOs and their use in the production of food and feed.
3. To provide advice on new developments within the area of biotechnology that may impact on food safety, human health or the environment.

reports

Genetically modified foods leaflet

Food safety and genetically modified foods

members

Prof. Colin Hill (Chair), University College Cork
 Mr. Michael Burke, Department of Health and Children
 Prof. Philip Dix, National University of Ireland, Maynooth
 Dr. Thomas F. Gallagher, University College Dublin
 Prof. Matthew A. Harmey, University College Dublin
 Dr. Liam Hyde, Department of Agriculture and Food
 Dr. Brendan Lynch, Teagasc
 Dr. Thomas McLoughlin, Environmental Protection Agency
 Dr. Ewen Mullins, National Crops Research Centre
 Dr. John O'Neill, Department of Environment, Heritage & Local Government
 Dr. Paul Ross, Teagasc
 Dr. Douwe van Sinderen, University College Cork
 Dr. Edward J. Walsh, University College Dublin

nutrition and novel foods sub-committee

The 13 members of the Nutrition and Novel Foods Sub-committee all have backgrounds in nutritional science but their work covers a diverse range of areas pertaining to public health. The main role of this Sub-committee is to provide advice on issues relating to nutrition and develop scientific recommendations that form the basis of the FSAI's nutrition policy. Recently, the Sub-committee has been updating aspects of the Recommendations for a National Infant Feeding Policy (1999). Other infant feeding issues that have been reviewed include FOS and GOS (fructo-oligosaccharides and galacto-oligosaccharides) in infant formulae as well as the duration of milk feeding in infants. In addition, a significant project on the risk benefit analysis of mandatory fortification of flour with folic acid in the Republic of Ireland has been completed.

The Nutrition and Novel Foods Sub-committee plays an important role in the FSAI's safety assessment of novel foods under Regulation EC No 258/97. Any company wishing to market a novel food within the EU must submit a dossier of scientific information which is assessed, initially, by one Member State Competent Authority. Eventually, all Member States submit an opinion on the application, along with the initial assessment, and to this end the FSAI utilises the best scientific advice available, as provided through its Nutrition and Novel Foods Sub-committee. In 2006, applications assessed included an oil extracted from *Allanblackia* seeds, a synthetic lycopene, an oil rich in arachidonic acid to be used in infant formula, capsulated clinoptilolite, which is a crystalline aluminosilicate mineral food supplement, and CardiaBeat™, which is an oil-based food supplement containing phytosterols, phytosteranols and their esterified forms. This Sub-committee is currently assessing an application to market oil extracted from antarctic krill that was assessed initially by the competent authority of Finland.

Future work involves the revision of the healthy eating guidelines for Ireland. This work will also include revision of the Recommended Dietary Allowances for Ireland (1999).

terms of reference

The terms of reference of the Sub-committee cover the following areas as requested by the Scientific Committee, or as a result of self-tasking following consultation with the Scientific Committee:

1. To advise on the nutritional value and content of food to include:
 - a. food supplements;
 - b. food fortification;
 - c. nutrition labelling;
 - d. health claims;
 - e. PARNUTS;
 - f. food for special medical purposes;
 - g. novel foods.
2. To advise the Scientific Committee on any dietary and nutritional question directed to them by FSAI.
3. To advise the Scientific Committee on the collection and assessment of data relating to public health arising from nutritional value and content of food.
4. To advise the Scientific Committee on the update and revision of Dietary Guidelines in Ireland, including those relating to special subgroups such as infants and the elderly.
5. To advise on nutritional and related human health aspects of applications to market novel foods and where applicable, GM foods within the EU (in conjunction with the GMO Sub-committee).
6. To advise on EU food legislation relating to nutrition.
7. To advise on research needs in the area of diet and nutrition.
8. To advise the Scientific Committee on the risk assessment work of international organisations, including the following:
 - the European Food Safety Authority (EFSA)
 - World Health Organization / Food and Agricultural Organization committees.
8. To support the Scientific Committee in the drafting and publication of scientific reports related to nutritional aspects of food.

members

Prof. Albert Flynn (Chair), University College Cork
Dr. John Kearney, Dublin Institute of Technology
Dr. Mairead Kiely, University College Cork
Dr. Sinead McCarthy, Trinity College Dublin
Dr. Maureen McGowan, Health Service Executive
Dr. Helene McNulty, University of Ulster, Coleraine
Dr. Celine Murrin, University College Dublin
Ms. Ursula O'Dwyer, Dept of Health and Children
Prof. Ivan Perry, University College Cork
Dr. Helen Roche, Trinity Centre for Health Studies
Dr. Ita Saul, Our Lady's Hospital for Sick Children
Prof. John Scott, Trinity College Dublin
Dr. Emer Shelley, Dept of Health and Children

reports

Report on the mandatory fortification of flour with folic acid for the prevention of neural tube defects

Recommendations for a national infant feeding policy

Recommended dietary allowances for Ireland 1999

Recommendations for a national food and nutrition policy for older people



food additives, chemical contaminants & residues sub-committee

The Sub-committee, which consists of 13 members with expertise in a variety of backgrounds, operates under the aegis of the Scientific Committee of the FSAI and was re-established in 2005.

The Sub-committee has recently produced an updated risk assessment on a group of naturally-occurring marine biotoxins known as azaspiracids. The report updated the previous risk assessment produced by the Committee using recently available data, and concluded that the current regulatory limits for these toxins in raw shellfish were appropriate.

The Sub-committee has also contributed to an FSAI report on the health implications for coeliacs of gluten in the diet, particularly arising from the current composition and labelling of gluten free foods. Members of the Sub-committee are also assessing risks to the food chain of spreading animal and human waste products on land.

Work planned for the future includes the publication of a series of fact sheets on contaminants in foods covering dioxins, mycotoxins, veterinary drug residues, heavy metals and PAHs. A sub-group of members of the committee and additional experts will also be established to examine the application of a risk-based approach to the development of the national plan for monitoring residues in food.

terms of reference

The Sub-committee operates under the aegis of the Scientific Committee of the FSAI and the terms of reference of the Sub-committee cover the following areas:

1. To provide advice on possible risks to the health of consumers arising from exposure to food additives, food contact materials, processing aids and chemical contaminants in food including pesticides and veterinary drug residues, and to advise on risk management strategies for such chemicals.
2. To support the carrying out of detailed risk assessments of specific chemicals in food and feed as required.
3. To advise on the assessment of any dossier submitted in support of a request for the temporary authorisation of a food additive at national level, including the carrying out of an independent risk assessment.

4. To advise on the content of national surveillance programmes for food additives, chemical contaminants, pesticides and veterinary drug residues.
5. To advise on the appropriate use of food consumption and analytical data to provide assessments of the exposure of Irish consumers to food chemicals and possible implications for public health, in association with the Sub-committee on Nutrition and Novel Foods.
6. To advise on relevant aspects of new EC and national legislative proposals related to food additives and chemical contaminants, including the establishment or revision of maximum levels for such chemicals in food.
7. To advise the FSAI on the risk assessment work of international organisations, including the following:
 - the European Food Safety Authority (EFSA)
 - the Joint Expert Committee on Food Additives (JECFA)
 - World Health Organization / Food and Agricultural Organization committees.
8. To support the FSAI in the drafting and publication of scientific reports related to food additives, chemical contaminants and residues.

reports

Legislation, intake and usage of food additives in Ireland

members

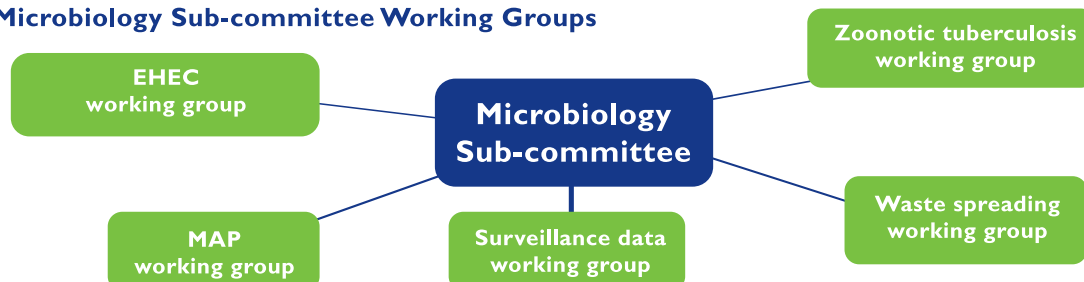
Prof. Michael P Ryan (Chair), University College Dublin
 Dr. Thomasina Barron, Dept of Agriculture and Food
 Dr. Padraig Burke, Public Analyst Laboratory Galway
 Dr. Claire Chambers, Consultant
 Dr. Edel Healy, Health and Safety Authority
 Dr. Philipp Hess, Marine Institute
 Dr. Liam Hyde, Dept of Agriculture and Food
 Dr. Sinead McCarthy, University College Dublin
 Dr. Evin McGovern, Marine Institute
 Dr. John Moriarty, Dept of Agriculture and Food
 Dr. Michael O'Keeffe, Teagasc
 Dr. Dan O'Sullivan, Dept of Agriculture and Food
 Dr. Liam Regan, State Laboratory

microbiology sub-committee

In its first five years the microbiology Sub-committee issued risk assessments and recommendations for action on *E. coli* O157, *Campylobacter* and *Listeria monocytogenes* in foodstuffs. Shorter opinions were provided on the risk of zoonotic tuberculosis in meat and dairy products and also on the food safety implications of *Mycobacteria avium* subsp. paratuberculosis (MAP) in milk and dairy products. The new membership of the Sub-committee started their five year term in early 2006 and are currently working on four projects. A working group is revisiting and updating the risk assessment on

E. coli O157 and broadening its content to address the risks from the wider group of Enterohaemorrhagic *E. coli* (EHEC). Another working group is addressing the risks to the food chain of spreading animal and human waste products on land. A further working group is updating the Sub-committee's opinion on MAP whilst the main Sub-committee is revising its opinion on zoonotic tuberculosis. Later in 2007 another working group will be formed to look at the outcomes of the microbiological official controls testing programme in the HSE with a view to examining its organisation, execution and data analysis.

Microbiology Sub-committee Working Groups



microbiology sub-committee

terms of reference

The terms of reference of the Sub-committee cover the following areas:

1. To provide advice on possible risks to the health of consumers arising from their exposure to micro-organisms, parasites and viruses in food.
2. To carry out detailed risk assessments on specific micro-organisms in food and evaluate risk management options.
3. To advise on the content and effectiveness of national surveillance and official monitoring of foodstuffs for micro-organisms.
4. To advise on emerging, newly emerged and re-emerging microbial hazards in foods.
5. To advise on relevant aspects of new EC and national legislative proposals related microbiological control in foods.
6. To advise on the scientific content, impact on food safety in Ireland and relevance to food safety in Ireland of microbiological risk assessment work carried out in other international and national organisations including the following:
 - European Food Safety Authority (EFSA);
 - World Health Organization / Food and Agricultural Organization committees;
 - Other food agencies;
 - Academic institutions.
7. To support FSAI in drafting reports on microbiological contamination of foods.
8. To advise the Scientific Committee on research gaps and needs in the area of food microbiology.

9. To undertake any other such work or investigations in the area of food microbiology that the Sub-committee sees fit after notification and approval from the Scientific Committee.

members

Prof. Martin Cormican (Chair),
University College Hospital Galway
Dr. Catherine Adley, University of Limerick
Ms. Paula Barry Walsh, Dept of Agriculture and Food
Dr. Tom Beresford, Moorepark Dairy Research Centre
Dr. Cyril Carroll, University College Galway
Prof. Dan Collins, University College Dublin
Ms. Helen Cowman, Health Service Executive
Dr. Bill Doré, Marine Institute
Dr. Geraldine Duffy, Ashtown Food Research Centre
Dr. Michael Fallon, Dept of Agriculture and Food
Prof. Seamus Fanning, University College Dublin
Mr. David Nolan, Dept of Agriculture and Food
Mr. Ray Parle, Health Service Executive
Dr. Neil Rowan, Athlone Institute of Technology

Reports

The prevention of *E. coli* O157:H7 infection:
A shared responsibility

The control and management of *Listeria monocytogenes*
contamination of food

Control of *Campylobacter* species in the food chain

tse sub-committee

Since its inception, the FSAI had a BSE Sub-committee, and in 2005 this group broadened its terms of reference to include all TSEs (transmissible spongiform encephalopathies) with potential food safety concerns.

This Sub-committee monitors emerging scientific understanding of this important group of diseases. It provides support for the Authority in re-assessing food-related risks, in the context of emerging knowledge.

The TSE Sub-committee continuously reviews the surveillance and epidemiology of TSEs in farm animals. Temporal and geographic trends are analysed and compared with other countries. The continued decreasing incidence of BSE in Irish cattle provides a reassuring index of adequacy of existing consumer protection measures.

The Sub-committee continuously re-appraises existing consumer protection measures. It directs the Authority in performing audits of the systems in Irish food business operations to ensure that specified risk materials are removed from the food chain. The extent and results of those audits are reviewed by the Sub-committee.

The Sub-committee monitors and reviews emerging legislation in the area of TSE control at European or national level. The general trend across the EU, as described by the Commission's TSE Roadmap, is for a gradual relaxation of controls in this area. The Sub-committee advises the Authority on the risk alterations associated with changes to TSE controls.

The Sub-committee remains abreast of activities and outputs of analogous groups nationally, such as the Department of Health and Children CJD (Creutzfeldt-Jakob disease) Advisory Committee, as well as international groups such as the TSE Biohazard Panel of the European Food Safety Authority and the UK Spongiform Encephalopathy Committee.

For 2007, the TSE Sub-committee is likely to devote resources to emerging knowledge in the area of BSE and atypical TSEs in small ruminants. The concept of background baseline prevalence of TSE in cattle will also require consideration. The emphasis of the FSAI audits will be adjusted to include retail outlets. Surveillance for TSE in wild ruminants will be a further consideration for 2007.

terms of reference

The Sub-committee operates under the aegis of the Scientific Committee of the FSAI and the terms of reference of the Sub-committee cover the following areas as requested by the Scientific Committee, or as a result of self-tasking following consultation with the Scientific Committee:

1. To advise the FSAI on hazards associated with TSEs and related risks.
2. To advise on monitoring and controls in place a national levels for consumer protection.
3. To advise on relevant aspects of new EC and national legislative proposals related to TSE.
4. To advise the FSAI on current and emerging issues of relevance.

members

Prof. Dan Collins, (Chair), University College Dublin
Ms. Paula Barry Walsh, Dept of Agriculture and Food
Dr. John Griffin, Dept of Agriculture and Food
Dr. Colm Henry, Mercy Hospital Cork
Dr. Margaret O'Sullivan, Health Service Executive
Mr. Sean O'Laoide, Westmeath County Council
Prof. Mark Rogers, University College Dublin
Mr. Michael Sheridan, Dept of Agriculture and Food



mailing list

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new board member appointed to the fsai



Mr. Pat O'Mahony, M.V.B., M.V.M., A.M.D., M.B.A., M.R.C.V.S., Chief Executive at the Irish Medicines Board, has recently been appointed to the Board of the FSAI.

Mr. O'Mahony spent a number of years in private veterinary practice, and as technical manager in the pharmaceutical industry in Ireland and the U.K. Following this, Mr. O'Mahony worked in public health and was Director of Consumer Protection at the FSAI, until taking up his current position in 2002.

Mr. O'Mahony has an MBA degree from the Michael Smurfit Graduate School of Business, University College Dublin in 2001.

He is a member of the Management Board of the European Medicines Agency and a member of the Board of the Irish National Accreditation Board.

recent publications

The following publications have recently been produced by the FSAI:

- Guidance Note No. 11 - Assessment of HACCP Compliance (Revision 2)
- Guidance Note No. 21 - Food Supplements Regulations and Notifications
- Leaflet - Advice for Caterers on the Country of Origin of Beef Requirements
- Report - Recommendations for a national policy on vitamin D supplementation for infants in Ireland.
- Food Safety Authority of Ireland Annual Report 2005

These publications are available on our website at www.fsai.ie/publications, or by calling our advice-line on 1890 33 66 77.

Editor:

Ruth Fitzsimmons

Contributors:

Anne Marie Boland

Fiona Byrne

Gail Carroll

John Coady

Raymond Ellard

Mary Flynn

Mary Friel

Kathleen Henshilwood

Eamon Horgan

Jeffrey Moon

Lisa O'Connor

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Abbey Court, Lower Abbey Street, Dublin 1

Tel: (01) 8171300

Fax: (01) 8171301

E-mail: newsletter@fsai.ie

Website: www.fsai.ie

