



fsai commits to closer collaboration with efsa

The members of the European Food Safety Authority (EFSA) Advisory Forum have signed a 'Declaration of Intent' with EFSA confirming their commitment to strengthen scientific cooperation and information exchange on risk assessment in the European Union. Such cooperation will help ensure appropriate allocation of resources against priorities; better co-ordination of work programmes, thereby avoiding duplication of activities; early identification and analysis of emerging risks; and increased coherence in scientific risk assessment and communications.

Strong and formal collaboration between Member States and EFSA is key to the overall success and effectiveness of the European food safety system, and to increased consumer protection and confidence. Advisory Forum members will continue to build on the scientific networks

and collaboration achieved to date, utilising all available legal, administrative and financial tools to reinforce cooperation in risk assessment across the EU.

Examples of possible activities within the scope of the Declaration of Intent are:

- To formalise the sharing of scientific data on specific dossiers
- Setting up of ad-hoc liaison groups on forthcoming risk assessments
- Sharing draft opinions under embargo on issues of particular importance
- Formalisation of communications channels.

Following this formal commitment, a roadmap for scientific co-operation will be adopted by the Advisory Forum by the end of 2006. The Declaration was signed during the 18th meeting of the EFSA Advisory Forum in Berne, Switzerland. The full text of the Declaration of Intent is available on the EFSA website at:

www.efsa.europa.eu/etc/medialib/efsa/advisory_forum/adv_meetings/af_18th_meeting.Par.0004.File.dat/af_declaration_intent_18thmeet_en_6a.pdf



Pictured signing the Declaration of Intent are Mr Alan Reilly, Deputy CEO, FSAI and member of the EFSA Advisory Forum and Ms Catherine Geslain-Lanéelle, Executive Director of EFSA.

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risk assessment of azaspiracids in shellfish

Relative to other marine biotoxins, azaspiracids (AZAs) are a new phenomenon that were first identified in 1995 in Ireland and in only a few other European countries since. Human intoxication, termed azaspiracid poisoning (AZP), is associated with the consumption of shellfish contaminated with AZAs. In Ireland, in September/October 1997, on Arranmore Island, Co. Donegal an AZP incident was recorded, involving 20 - 24 individuals. In 1999/2000 this toxin was responsible for the closure of many Irish shellfish growing areas for much of the season as a means of protecting consumers' health.

An updated risk assessment for AZAs in shellfish has recently been prepared by the FSAI's Sub-committee on Food Additives, Chemical Contaminants and Residues and adopted by its Scientific Committee. The report is the second risk assessment on azaspiracids conducted by the FSAI's Scientific Committee; the first was published in 2001. There have been three international risk assessments on azaspiracids since the publication of the 2001 Irish risk assessment, all of which have used, as a basis, the 'lowest observable adverse effect level' (LOAEL) determined in that work. The European Commission set a regulatory limit of 0.16mg/kg in raw mussels based on the data provided in the 2001 Irish risk assessment.

European legislation has been established to secure a high level of consumer protection with regard to food safety. As certain marine biotoxins pose a serious health risk when present above maximum permitted limits in bivalve molluscs, echinoderms, tunicates or marine gastropods, legislation has required the establishment of national marine biotoxin monitoring programmes. These

programmes are responsible for monitoring shellfish harvesting areas for the presence of toxins produced by marine phytoplankton, and have generated new and useful data for use in risk assessments. There has also been significant progress in standardising analytical techniques for azaspiracids since 2001 and this work underpins an increase in the scientific data concerning this emerging but rare biotoxin. The 2006 risk assessment reassesses the risk to human health posed by azaspiracids based on these new monitoring and analytical data.

There are still only limited *in vivo* toxicological data available for AZAs because of the scarcity of purified toxin available to conduct tests. However, since 2001, some further AZA *in vivo* toxicological data have become available on mice, using the oral route of administration plus repeated dose studies. Unfortunately, these studies are of very limited value in a risk assessment because of the very small numbers of animals studied and issues related to the appropriateness of the route of administration. The animal studies have not demonstrated a 'no observable adverse effect level' (NOAEL). The studies were not designed statistically to determine this toxicologically relevant parameter. *In vitro* data have become available identifying several different AZA effects on biological functions but these studies are in their infancy.

The consumption of shellfish by humans is variable and may be considered to be an infrequent event in the general population. The current limited epidemiological data for AZP indicates an acute response. As such, exposure assessment must focus on determining an Acute Reference Dose (ARfD) based on available epidemiological

data. The ARfD is defined as "an estimate of the amount of a substance in food and/or drinking water, normally expressed on a milligram per kilogram body weight basis that can be ingested in a period of 24 hours or less without appreciable health risk to the consumer, on the basis of all known facts at the time of evaluation".

To characterise the risk in this risk assessment, estimates of a LOAEL were calculated by dividing the estimates of AZA intake that caused the incident of AZP on Arranmore by the standard adult body weight of 60kg. The risk assessors considered that application of a safety factor of three to this LOAEL to derive an ARfD was justified, based on the toxicodynamic effects of AZAs and human epidemiological evidence in its broadest context, that includes, the absence of reported symptoms of AZP, following consumption of shellfish containing up to the current regulatory limit of 0.16mg/kg in raw shellfish.

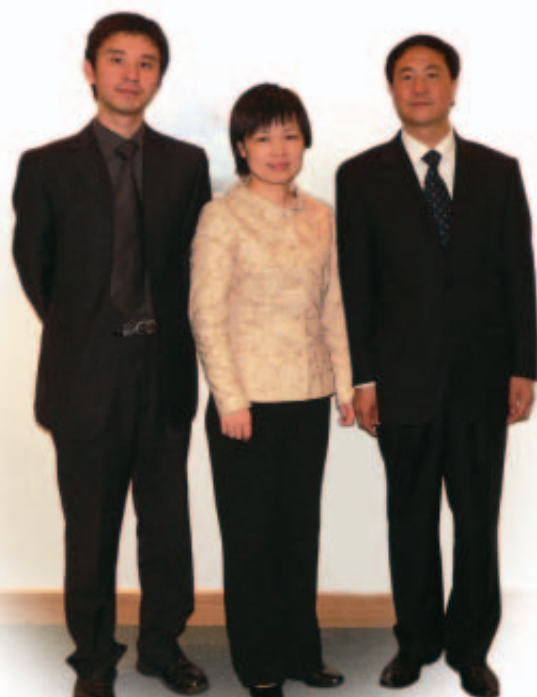
The median value for an ARfD from this risk assessment, is 0.63µg/kg body weight. This is comparable to the maximum intake value of 0.67µg/kg body weight for a 60kg person consuming 250g mussels contaminated with AZAs at the current regulatory limit of 0.16mg/kg. The validity of the proposed ARfD is supported by the absence of reported incidents of AZP since the adoption of the 0.16mg/kg maximum regulatory limit for AZAs in shellfish and strengthening of national biotoxin monitoring programmes to enforce it. Consequently, the current regulatory maximum limit for AZA in raw shellfish would seem appropriate.

chinese visit fsai

The FSAI recently played host to a delegation of food safety experts from the State Food and Drug Administration, Beijing, China. The objectives of the visit were to exchange experiences on the advantages and disadvantages of food safety regulations and management systems for food hygiene inspection, and to learn the process of formulating regulations, food hygiene standards and policy in terms of food safety

control in order to help China to perfect its food safety regulations and management system for food hygiene inspection.

Pictured here are (l-r): Mr Xiangyu Wang, Interpreter; Ms Min Huan, Director, Division of Information Analysis, Department of Food Safety Coordination, State Food and Drug Administration, Beijing; and Dr Zhenbin Mao, National Food Safety Supervisor, Department of Food Safety Supervision, State Food and Drug Administration, Beijing.



global meeting to address spread of harmful enterohaemorrhagic *escherichia coli* infection

The development of appropriate risk management interventions at both national and international level to address the spread of Enterohaemorrhagic *Escherichia coli* (EHEC) in meat and meat products, was top of the agenda at a meeting of international food and health experts, held at the FSAI from 4th to 7th September. The FSAI hosted the meeting on behalf of the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO) which was attended by international food safety and medical experts from Argentina, Australia, Canada, Denmark, Ireland, Mexico, the Netherlands, Serbia, the United Kingdom and the United States.

Enterohaemorrhagic *Escherichia coli* (EHEC) are a group of harmful bacteria that include *E. coli* O157 and related species. *E. coli* are generally harmless bacteria commonly found in gastrointestinal tracts of man and animals. A small number of *E. coli* have developed as toxin-producing dangerous pathogens and cause severe illness in humans after digestion. These include *E. coli* O157 and related species that are classified as enterohaemorrhagic strains because they typically cause bloody diarrhoea. Other symptoms include hemolytic-uremic syndrome (kidney failure) and neurological complications which are sometimes fatal, particularly in children.

The global meeting followed a recent increase in Ireland of cases of EHEC infection. Data from the Health Protection Surveillance Centre (HPSC) show that between 2004 and 2005 the number of EHEC cases increased from 67 to 135, and to date in 2006, 98 EHEC cases have been reported compared to just 53 in the same period last year. Similarly, HPSC data show that the number of EHEC outbreaks involving food or water has also increased, with seven outbreaks recorded in 2005 compared to two in 2004. Ireland's largest ever *E. coli* O157 outbreak occurred in 2005, involving 18 people, including nine children.

The purpose of the meeting was to highlight the threat posed by the spread of EHEC and to consider the need for both national and international risk-based control of the issue. An effective risk management strategy is required to halt the spread of

these harmful bacteria in the food chain and the aim of the meeting was to put such measures in place. The meeting was the first step in the development of a roadmap for future risk management in relation to this important public health hazard.

Dr Peter Ben Embarek from the WHO in Geneva addressed the delegates at the meeting. He stated that we are seeing a worldwide increase in the number of people infected with these dangerous pathogens, particularly *E. coli* O157. These are the most serious group of harmful bacteria that are being transmitted through the food chain and can cause severe illness, including blood poisoning and kidney failure which can be fatal. A recent multi-state outbreak in the USA resulted in 199 people becoming ill after eating fresh spinach; of these 103 required hospitalisation and three people died. Dr Sarah Cahill from the FAO reported that, in addition to the human health costs, the economic costs arising from product recalls, interruption to trade and legal actions are enormous, noting that legal costs arising from just one outbreak in the USA amounted to in excess of \$30 million.

The meeting marked the first step taken by the FAO and WHO in developing their microbiological risk assessment activity in the area of EHEC infection. The Codex Committee on Food Hygiene (CCFH), a subsidiary body of the joint FAO/WHO Codex Alimentarius Commission, expressed the need for scientific advice on this issue. The meeting established the current knowledge status on EHEC and reviewed information available on risk assessments already undertaken in a number of EU Member States. The key objective was to provide recommendations to the FAO and WHO on the development of risk management guidance documents on EHEC and on future risk assessment activity in this area.



Pictured during the global meeting are (l-r): Mr Alan Reilly, Deputy Chief Executive, FSAI; Dr Sarah Cahill, Food and Nutrition Division, FAO; Dr John Cowden, Consultant in Health Protection, Health Protection Scotland and Chair of the meeting; and Dr Peter Karim Ben Embarek, Department of Food Safety, Zoonoses and Foodborne Diseases, WHO.

professor patrick wall appointed as chair of the efsa management board

Professor Patrick Wall was recently appointed Chair of the new Management Board of the European Food Safety Authority (EFSA). Professor Wall is the Associate Professor of Public Health at the UCD School of Public Health and Population Science, and is the former Chief Executive of the FSAI.

EFSA was established in 2002 on the back of a number of food scares which had undermined consumer confidence in the

safety of the food chain and is now the keystone of European Union risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provide independent scientific advice and clear communication on existing and emerging risks.

The EFSA Management Board ensures that the Authority functions effectively and efficiently, delivers its mandate and meets

the expectations of European and National institutions, stakeholders and the public. As Chair of the Management Board, Professor Wall will have a major influence on EFSA's strategy and future direction and on monitoring and implementation of their work programmes.

This appointment is a great honour for Professor Wall and comes in recognition of his contribution to consumer protection and food safety over the past decade.

2005 national residue monitoring programme

EU Member States (MS), including Ireland, are required under Directive 96/23/EC to draw up an annual National Residue Control Plan (NRCP). This plan outlines the official testing that MS will carry out on foods of animal origin to check for the presence of residues of veterinary medicines such as antibiotics, banned substances (e.g. hormones) and environmental contaminants (e.g. pesticides). This includes testing of over 11 domestic food producing species at farm level, at primary processing and of food imported directly from non-EU countries.

The NRCP is implemented mainly by the Department of Agriculture and Food (DAF), with sampling carried out by the Local Authorities; the Department of Communications, Marine and Natural Resources (DCMNR) implements the plan for aquaculture, with sampling and analysis carried out by the Marine Institute. All analyses are carried out in officially approved laboratories.

As part of the 2005 plan more than 45,000 samples, well in excess of the minimum requirement, were tested following sampling on both a targeted and suspect basis. Foods sampled included meat, milk, eggs, honey, aquaculture and imported foods. With regard to food produced in Ireland, the overall level of positive samples was 0.2%; 94 positives from 45,827 samples. This shows a downward trend in the number of positives from 2004 (0.39%). During 2005, as in previous years, no residues of growth promoters were found. Six of the positive samples related to the presence of banned substances from two farms. In these cases, DAF carried out follow up investigations. 0.2% of samples taken for antibiotic residues were positive which represented a continued decline on previous years.

In the poultry sector, 16 samples tested positive for residues of anticoccidials which again represented a downward trend from the previous year. Following risk assessment, the FSAI is satisfied that a risk to consumers

from poultry meat does not arise from these incidences. However, both the FSAI and DAF are anxious that industry deal effectively with this issue. To address this, DAF has carried out full investigations and is providing appropriate assistance.

In the aquaculture sector, over 700 tests were carried out on 181 farmed finfish samples. Two farmed salmon samples were positive for an unauthorised sea lice treatment. DCMNR is carrying out the appropriate follow up action on the farms in question.

As part of the Irish NCRP, imported food from non-EU countries is sampled where it enters the EU for the first time through an Irish designated import point, a Border Inspection Post. No samples of imported food tested positive for residues.

The annual plan for 2006 was submitted to the European Commission on 31st March, as required, and is currently well underway.

delegation from jordan visit the fsai

The FSAI recently organised a study visit for a delegation from the Aqaba Special Economic Zone Authority (ASEZA) in Jordan. ASEZA is working on a project to develop a food control laboratory to the best modern standards.

While Jordan is comparable to Ireland in terms of land size and population, in Ireland we export approximately 75% of the food we produce, whereas Jordan imports 75% of its food requirements.

Pictured here during a visit to the Department of Agriculture and Food, Central Meat Control Laboratory at Backweston, Celbridge, County Kildare are (l-r): Ms Mai Adnan Abdullah, Mr Ziad Ezz Deen Bashiti, Mr Khaled Qtaishat, Mr Samer M Tarawneh, EU IS-ASEZA Deputy Programme Coordinator and Mr Joe Murphy, Senior Laboratory Technician, Department of Agriculture and Food, Central Meat Control Laboratory.



Our Mission

Our mission is to protect consumers' health and consumer interests by ensuring that food consumed, distributed, marketed or produced in the state meets the highest standards of food safety and hygiene.

10th November 2006 - 10 November

Press Release

29 October 2006
The Government Commits Itself to

The Government Commits Itself to

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open consultation: food improvement agents package

There is currently one open consultation on our website:

EU package of proposals for new legislation on food additives, flavourings and enzymes

This package of legislative proposals, adopted by the European Commission and referred to as the Food Improvement Agents Package, aims to upgrade the legislation governing food additives and flavourings and it introduces for the first time harmonised legislation on food enzymes. It also proposes the creation of a common approval procedure for food additives, flavourings and enzymes, based on scientific opinions from the European Food Safety Authority (EFSA).

Key elements of the proposal are outlined as follows:

Additives

The new legislation on additives proposes to simplify and streamline the food additive approval system. Currently the rules on additives are laid down in Directive 89/107/EEC and the procedure for the approval of food additives requires co-decision (i.e. approval from both Council and Parliament of a proposal from the Commission), which is time consuming. Under the new proposal, changes to the legislation will be made by comitology, allowing the Commission to update and add to the EU positive list of food additives, following Member State approval in the Standing Committee on the Food Chain and a right of scrutiny for the European Parliament. In this new piece of legislation all approvals of food additives will be based on a safety evaluation carried out by EFSA. The proposal also sets out a re-evaluation system for food additives currently on the EU market and the labelling rules for food additives sold as such are also updated.

Enzymes

This new proposal will introduce harmonised EU legislation on enzymes for the first time. The harmonised legislation will cover the evaluation, approval and control of enzymes used in food. Currently food enzymes used as processing aids are not covered by EU

legislation. This draft Regulation foresees the establishment of a positive list of all food enzymes used in food for a technological purpose, based on favourable scientific opinions from EFSA. The inclusion of a food enzyme in the Community list will be considered by the Commission on the basis of the EFSA opinion taking into account other general criteria such as the technological need and consumer benefit. The proposal also includes requirements for the labelling of food enzymes other than those used as processing aids. Food enzymes with a technological function in the final food will have to be labelled as ingredients with their function (e.g. stabiliser) and name.

Flavourings

The new proposed legislation on flavourings aims to update the general rules as set out in Directive 88/388/EEC in order to reflect technological and scientific developments in the area. The new legislation sets out clearer rules on maximum levels for undesirable substances, in line with EFSA opinions. Definitions of flavourings (e.g. flavouring substance, flavouring preparation, thermal process flavouring) are clarified and stricter conditions are also introduced for the term 'natural' when describing flavourings.

Common Authorisation Procedure

This proposal introduces a single common procedure for the approval of food additives, flavourings and enzymes. This approval procedure includes a safety evaluation by EFSA. This will lead to simplified legislation and more consistency in the procedures used to approve additives, flavourings and enzymes.

The draft proposals are currently available on our website at www.fsai.ie/consultations. Further details are also available on the site.

Comments and views on this consultation should be submitted by 5pm on **Monday, 6th November 2006**, 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.

midlands food forum

The Midlands Food Forum, organised by the Department of Agriculture and Food in conjunction with Bord Bia, is a unique opportunity for local food producers and support agencies to come together. The evening, which took place at the Heritage Hotel, Portlaoise, featured presentations on marketing opportunities and regional food ingredients and a questions and answers session with local food entrepreneurs. It also provided the opportunity for producers to meet the development agencies and to showcase their products.

Pictured at the Food Forum were (l-r): Mr Tom Parlon T.D., Minister of State at the Department of Finance with special responsibility for the Office of Public Works; Ms Ann Goodwin, Laois Leader; Mr Brendan Smith T.D., Minister of State with responsibility for Food and Horticulture; Dr John O' Brien, CEO, FSAI and Mr Muir Kennedy, Director of Marketing Services, Bord Bia.





nutrition and health claims made on foods: compilation of a national list of generally accepted

Introduction

In May 2006, a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods was agreed, following difficult detailed negotiations between the European Parliament, the Council of Ministers and the European Commission. It is expected to be legally adopted in October 2006. This legislation is comprehensive and wide in scope and has implications for regulators and food business operators alike. One immediate task now facing Member States and Food Business Operators (FBOs) is the compilation of a national list of well-established health claims under Article 13, a task which must be completed within a year of adoption of the Regulation. Before addressing that particular issue it is necessary to detail some of the background to this Regulation.

Background

Existing EU rules on general food labelling and nutrition labelling do not define conditions for the use of nutrition claims and do not allow health/disease reduction claims to be made. In July 2003, the European Commission adopted a proposal for a Regulation on nutrition and health claims made on foods in response to the increase in the number and type of nutrition and health claims appearing on food labels in the EU, and also to harmonise the different rules introduced by some Member States.

The aim of the Regulation is to ensure that consumers receive accurate and meaningful information and to allow FBOs to use serious and scientifically substantiated claims as a marketing tool. It covers nutrition and health claims used in the labelling, presentation and advertising of foods and only claims that are in conformity with the provisions of the Regulation will be allowed to be used on foods marketed within the EU.

Since 2003, detailed discussions spanning six EU presidencies, including the Irish Presidency in 2004, have been ongoing. The Department of Health and Children (DoHC) has led on these discussions for Ireland, with input from the FSAI and stakeholders.

What is a Claim?

The Regulation defines nutrition and health claims and the conditions for their use. A *claim* is any message or representation

(pictorial, graphic or symbolic) which states, suggests or implies that a food has particular characteristics.

A *nutrition claim* is any claim which states, suggests or implies that a food has particular beneficial nutrition properties due to the energy, nutrients or other substances provided, not provided or provided in reduced/increased amounts. The Regulation contains a list of nutrition claims in the Annex (e.g. low energy, low fat, high fibre) which can be used and specifies the conditions for their use.

A *health claim* is any claim that states, suggests or implies that a relationship exists between a food and health. Under the claims Regulation, health claims are divided into two categories: a) generally accepted/well established claims (Article 13) and b) claims referring to reduction of disease risk and to children's development and health (Article 14). Different authorisation procedures apply to each category.

Conditions for Using Claims

In order to be used, nutrition and health claims must be:

- truthful and reliable (based on scientific evidence)
- clearly worded and understood by the average consumer
- accompanied by full nutrition information (energy/protein/carbohydrate/sugars/fat/saturates/fibre/sodium).

Also,

- the nutrient/substance for which the claim is made must be present/absent in an effective amount and in a form that is available to be used by the body.

As the use of these claims is voluntary the responsibility rests entirely on FBOs to ensure that, if they are making a nutrition or health claim for their product, it can be supported by reliable scientific evidence.

Nutrient Profiles

To ensure that a nutrition or health claim does not mask the overall nutritional status of a product, the Regulation provides for nutrient profiles which are conditions for the use of nutrition and health claims (Article 4). The nutrient profiles will be

based on the quantities of certain nutrients contained in the food that affect health - fat, saturated fat, trans fatty acids, sugar and salt, the overall nutritional composition of the food, the role and importance of the food and its contribution to the diet. The European Food Safety Authority (EFSA) is to advise on nutrient profiles within a year of adoption of the Regulation and the nutrient profiles will be set with input from the food industry and consumer groups. Some of the issues EFSA will consider are whether profiles will be adopted for all foods or categories of foods, the choice and balance of nutrients to include the reference quantity, the calculation of the profile and the feasibility and testing of a proposed system.

Article 13 Claims - Immediate Task for FBOs and Member States:

One of the main tasks now facing Member States and FBOs is the compilation of a national list of well-established health claims under Article 13; this task must be completed within a year of adoption of the Regulation.

Article 13 allows health claims, other than those referring to the reduction of disease risk and to children's development and health, to be authorised by being placed on a Community list of permitted claims. The first step in establishing such a Community list is the submission of a national list from each Member State. The type of health claims which will be included on this list are claims referring to the role of a nutrient or of another substance in:

- growth, development and bodily functions
- psychological and behavioral functions, or
- slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety.

These claims must be based on generally accepted scientific evidence and be well understood by the average consumer. This Community list will be based on lists provided to the Commission by Member States and will be adopted after consultation with EFSA.

pted claims

List of Article 13 Claims in use in Ireland

The DoHC has requested the FSAI to draw up a list of claims falling under Article 13 currently in use in Ireland, for submission to the European Commission. This list will be based on information submitted by FBOs and the onus is on FBOs to submit appropriate scientific evidence to the FSAI in support of their claim. This is a difficult task given the tight time frame involved and preparatory work has already been undertaken at EU and national level involving officials and stakeholders.

The preparatory work at EU level has focused on how best EU Member States can undertake a co-ordinated approach to the compilation of the list of Article 13 health claims. Food industry stakeholders have also been involved in the process. At national level the DoHC and FSAI have had a series of meetings on the issue, also involving stakeholders. As a result of these discussions a tabular format for FBOs to use when submitting information regarding claims has been agreed as below.

This tabular format will be used by all EU Member States.

On receipt of the information regarding claims, competent authorities in Member States (the FSAI in Ireland), will undertake a preliminary screening of claims to assess whether the scientific evidence provided is sufficient to allow examination of the claim or not. However, examination of the claim and the scientific evidence will be undertaken by EFSA. Each Member State must submit its list of Article 13 claims within one year of adoption of the Regulation, which gives a provisional deadline of the end of October 2007. Following examination of the Member States lists by EFSA, the Commission, in consultation with Member States, will adopt a Community list of permitted claims within three years of the entry into force of the Regulation.

Number of Article 13 Claims to be Processed in Ireland

At this stage it is estimated that approximately 1,000 food products on sale in Ireland carry health claims. Claims on food supplements, also covered by this Regulation, are estimated to be in the region of several thousand.

Over the coming months, the DoHC and the FSAI will strive to ensure that all stakeholders in the food and food supplements industries are aware of the responsibilities placed on them by this Regulation, if they choose to make a health claim about a particular product.

FBOs will be invited to submit their claims for consideration in the format detailed below and relevant information will be advertised in the national press, posted on the DoHC and FSAI websites and forwarded by direct contact with stakeholder representatives.

The submissions from FBOs will form the basis of the list to be submitted to the Commission by Ireland, for consideration for inclusion in the Community list of authorised generally accepted, well established, health claims.

Any addition of claims to the Community list based on newly developed scientific evidence will be subject to a separate accelerated authorisation procedure. Health claims referring to disease risk reduction and child development and health are subject to a full authorisation procedure.

Food/Food Category/ Food Component	Diet and Health Relationship	Any Conditions for Claim to be Valid	Source and Nature of Evidence	References*	Examples of Wording	Remarks

*References - this refers to the scientific evidence required to support the claim i.e. independent, peer-reviewed studies carried out with regard to the health claim.



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

S.I. No. 356 of 2006

European Communities (Avian Influenza) (Amendment of Regulations) Regulations (No.2) 2006

S.I. No. 379 of 2006

European Communities (Avian Influenza) (Control on Imports of Avian Products from Romania) (Amendment) (No. 2) Regulations, 2006

S.I. No. 464 of 2006

European Communities (Pesticide Residues) (Products of Plant Origin including Fruit and Vegetables) (Amendment) (No. 3) Regulations, 2006



national ploughing championships

The National Ploughing Championships and The National Ploughing Association celebrate their 75th anniversary this year, and to mark the occasion hosted the 53rd World Ploughing Contest. A four day event, the championships were held in Tullow, Co. Carlow. The national event was opened by the Minister for Agriculture and Food, Mary Coughlan TD, on Wednesday 27th September and President Mary McAleese opened the world event on Thursday 28th.

The FSAI had an information stand at the event again this year; the 8th year participating. The theme of the stand was 'Clean Livestock - Your Contribution to Clean Food'. With over 65 acres of exhibition space and 20 acres of demonstration arena, the 2006 event attracted over 220,000 visitors, proving still to be Ireland's most popular farming festival and the biggest agricultural event in Europe. The event therefore provides the FSAI with an excellent opportunity to meet with those working in the farming sector, to answer their queries and discuss any issues they may have.

fsai hosts meeting of efsa working group

The FSAI recently played host to a meeting of the EFSA Advisory Forum Working Group on Information Technology. The aim of the Working Group is to consider the practical aspects of building links between EFSA and national agencies in Member States.

The main points in the terms of reference of the working group are as follows:

1. To discuss the feasibility of undertaking common projects, taking into consideration the requirements and technical limitations of the projects.
2. To develop a collaborative tool for Advisory Forum document sharing.
3. To develop links between websites of the member organisations of the Advisory Forum.



Pictured are members of the EFSA Advisory Forum Working Group on Information Technology during the eight meeting of the group, hosted by the FSAI.

fsai student placements win awards

The FSAI has, for the past three years, facilitated a student placement through the University of Limerick Cooperative Education Programme. As part of the programme, students are required to undertake relevant work experience, normally for a duration of eight months.

Two of the students on the programme, Ms Deirdre Kennedy and Ms Ruth Morrissey,

who were on placement in the FSAI in 2004 and 2005 respectively, have been awarded the Cooperative Education Award, for the most outstanding student within the College of Science. The University of Limerick introduced the Cooperative Education Awards to show special recognition to students who had excelled during their work placement. In overall

terms, some 170 nominations from employers were received for this year's awards.

Congratulations to both Deirdre and Ruth on their awards; we wish them continued success in their careers.

seminar on enterobacter sakazakii

Enterobacter sakazakii is an emerging pathogen whose prevention and control is a high priority at both national and international level by all stakeholders in the food chain.

Pictured are the speakers at the recent FSAI seminar on Enterobacter sakazakii (l-r): Professor Séamus Fanning, Centre for Food Safety, University College Dublin; Ms Ita Saul, Our Lady's Children's Hospital, Crumlin; Dr Andrée Bronner, Special Dietary Foods Industry, France; Dr Peter Karim Ben Embarek, World Health Organization, Switzerland; Dr Mary Flynn, FSAI; Dr Anna Bowen, Centres for Disease Control and Prevention, USA; and Mr Alan Reilly, FSAI.



surveillance of infant food for pesticide residues

The FSAI has carried out a surveillance study of infant food and infant juices available on the Irish market for the possible presence of pesticide residues, in order to establish levels of compliance with existing legislation in this area. This survey follows on from a previous study carried out in 2004. The legislation on processed food for infants and young children requires that these products generally contain no, or extremely low levels of pesticide residues, in order to ensure maximum health protection for this vulnerable group of the population. Pesticide residue levels in processed food for infants and young children should not exceed a Maximum Residue Level (MRL) of 0.01 mg/kg (0.01 parts per million (ppm)) for the majority of individual pesticides and even lower levels apply to certain specified pesticides.

Fifty samples of baby food, comprising juices, jars and boxes (cereal/meat/fruit/vegetable based) were analysed in this survey. Samples purchased were 'ready-to-eat', and were analysed as such, or sold in the dry form, requiring reconstitution before use. In the case of the latter, samples were reconstituted in accordance with the manufacturers' instructions and analysed in this form. A total of 386 pesticides were included in the survey.

Of the 50 samples tested for the 386 pesticide compounds, representing a total of 19,300 individual results, 10 positive results for the presence of residues were obtained. These residues comprised o-phenylphenol, piperonylbutoxide, fenhexamide, maleic hydrazide, propylenethiourea/ ethylenethiourea (PTU/ETU) and diphenylamine. However, only two out of 10 residues detected were above the MRL established for these pesticides in baby food. The

two residues detected above the MRL were o-phenylphenol, found in one product, and maleic hydrazide which was detected in two separate products.

Follow up investigations in the case of o-phenylphenol showed that the presence of the residue was not as a result of its use as a plant protection substance but as a result of its presence in the packaging material of the baby food. In the case of the first product containing maleic hydrazide at 0.1mg/kg, investigations carried out by the manufacturer have revealed that the source of the residue was an onion powder used in the recipe. In the case of the second product found with residues of maleic hydrazide at 0.7 mg/kg, all suppliers of the raw ingredients for the product have indicated that they did not use maleic hydrazide during the production of the crops.

The FSAI considers that the residue levels found in the products concerned presented no risk to infants and young children. The manufacturers involved have taken appropriate follow up action and have put in place the relevant checks and safeguards in order to ensure that this problem does not occur in the future. The FSAI is satisfied that all necessary steps have been taken to ensure legal compliance with the requirements of the legislation as they relate to levels of pesticides. Overall the results of the study show good compliance with the existing legislation on pesticide residues in baby food and the FSAI will continue to monitor such products for pesticide residues and other chemical contaminants, in order to safeguard the health of Irish children.

The full report is available on our website,
www.fsai.ie/surveillance/food/infant_food_pesticides.pdf

study visit from malta

The FSAI and the Central Science Laboratory in York are partners in an EU funded Phare project in Malta. It has two aims; to re-equip and train the staff of the official food control laboratory and to train environmental health officers (EHOs) in food safety auditing. The FSAI was responsible for the audit training which was delivered by Teagasc, the Ashtown Food Research Centre. Some 21 EHOs in Malta undertook a two week training course (with practical elements) followed by an exam. Day seminars were organised for the sixty other EHOs who could not participate in the two week courses. The final part of the training programme was a study visit to Ireland to meet with colleagues, exchange experiences and witness the application and supervision of food safety control systems. The first group visited in September and were facilitated by the EHOs in the HSE in Galway and Dublin. The second group visited in October.

Pictured are the Maltese delegation who visited in September; Hadrian Bonello, Graziella Borg, Helen Calleja, Mario Camilleri, Mark Cutajar, Alastair Lowell, Horace Micallef, Malcolm Micallef, Jason Mifsud, Aaron Simpson and Clive Tonna (all EHOs) with Mr Raymond Ellard, Director, Audit and Compliance Division, FSAI.



national microbiological surveillance: bacteriology

Background

Dietary trends and consumer demand for convenience foods have led to an increase in the availability of ready-to-eat foods such as pre-packaged salads. These are diverse products which may contain both raw (e.g. salad vegetables) and cooked (e.g. meat, seafood, pasta, egg) ingredients. The raw salad vegetables play an important role in determining the microbiological status of the overall product as they are not exposed to any microbial reduction step (e.g. heat treatment) prior to consumption. These products have a high nutrient and moisture content and if temperature abused can readily support microbial growth.

Listeria monocytogenes and *Salmonella* spp. are pathogens of particular concern. *L. monocytogenes* is ubiquitous in the environment and is present in many raw foods including fruit and vegetables. The presence of this pathogen in ready-to-eat foods raises concern as it is capable of growing slowly under refrigerated conditions (i.e. the typical storage conditions for pre-packaged salads). Levels of *L. monocytogenes* >100cfu/g at the point of consumption may cause a risk to consumers. (Listeriosis is the disease caused by *L. monocytogenes*). Salmonellae are bacterial pathogens which reside in the intestinal tract of infected animals and humans and are shed in the faeces. They are

one of the most common causes of foodborne illness. (Salmonellosis is the disease caused by *Salmonella* spp.).

Aim

The aim of this study, which was undertaken as part of the European Union Coordinated Programme for the Official Control of Foodstuffs 2005, was to investigate the prevalence of *L. monocytogenes* in pre-packaged mixed raw vegetable salads containing meat, seafood or other ingredients at retail level. The prevalence of *Salmonella* spp. was also investigated in this Irish study.

Methodology

Pre-packaged mixed raw vegetable salads containing meat, seafood or other ingredients were sampled from retail premises by environmental health officers (EHOs) during the period September to November 2005. The samples were analysed in one of the seven Official Food Microbiology Laboratories (OFMLs) using approved/standard methods. The samples were analysed for the following parameters:

1. *Listeria monocytogenes* (qualitative and quantitative test)
2. *Salmonella* spp.

Additional information about the sample was recorded on a questionnaire by the EHO at the time of sampling.

Results

Microbiological results:

A total of 715 samples from retail premises were analysed for one or more microbiological parameters.

- *L. monocytogenes* was detected in 19 samples (i.e. 2.7%; 19/714)*. It was present at levels >100cfu/g in two of these samples (i.e. 0.3%; 2/715) (Table 1). This finding initiated follow-up action by the relevant EHO, as levels of *L. monocytogenes* >100cfu/g may cause a risk to consumers. One of the products was withdrawn from the market. The other product was no longer available on the market; however, its ingredients were tested and *L. monocytogenes* was not detected in any ingredient. Inspections were also undertaken in the two premises where the samples were obtained.
- *Salmonella* spp. was not detected in any sample (n=714).

Questionnaire data:

Sample information (e.g. sample source, location of pre-packaging, type of ingredients etc.) was captured via questionnaires which were completed at the time of sampling. Questionnaires were returned for 550 samples, i.e. there was a 76.9% response rate (550/715).

a case of botulism in ireland

Foodborne botulism is caused by the ingestion of a preformed neurotoxin produced by *Clostridium botulinum*, an anaerobic spore forming bacteria. In September, a case was reported to the Health Protection Surveillance Centre (HPSC) of a Polish national who had eaten a home prepared pork product which originated in Poland. Foodborne botulism is a very rare form of illness in Ireland and this is the first recorded case in recent times. Similar cases have occurred in the UK over the past few years in Polish nationals consuming home produced imported meat products.

Foodborne botulism is a disease that has been recognised for over 1000 years and the canning industry uses the 'botulism cook' or 12-D heat process as the basis for thermal destruction of the microorganism. The disease was first reported to be associated with blood sausages and more recently with home-produced cooked and fermented foods of animal origin. It has also

been reported in canned vegetables and seafood products.

Seven types (A, B, C, D, E, F and G) of botulism are recognised, based on the antigenic specificity of the toxin produced by each strain. Types A, B, E and F cause human botulism. In the case reported to the HPSC, cells of *C. botulinum* type A and B were identified in the home prepared pork product.

While the incidence of foodborne botulism is low, the disease is of considerable concern because of its high mortality rate if not treated immediately and properly. Onset of symptoms in foodborne botulism is usually 18 to 36 hours after ingestion of the food containing the toxin, although cases have varied from four hours to eight days. Early signs of intoxication consist of weakness and vertigo, usually followed by double vision and progressive difficulty in speaking and swallowing. Difficulty in breathing, weakness of muscles and constipation may also be common

symptoms. Death can result from respiratory failure.

The Polish national in this recently reported case lived in the west of Ireland and was lucky that the botulinum anti-toxin was available from the manufacturer of 'Botox', located in Co Mayo. This manufacturer carried a supply of anti-toxins for *C. botulinum*.

Ireland is seeing an influx of nationals from Eastern Europe and a proliferation of new food products from these countries. Food inspectors should be aware of the possible increased risk of botulism among migrant workers from Eastern Europe who are importing home produced foods which may not always be stored under refrigerated conditions.

For further information, see:

www.ndsc.ie/hpsc/EPI-Insight/Volume72006/File,2000,en.PDF
www.hpa.org.uk/cdr/archives/2006/cdr4006.pdf
www.cfsan.fda.gov/~mow/chap2.html

Microbiological safety of pre-packaged mixed salads

The following were the main findings:

- 93.6% of samples were sourced in supermarkets, 65.1% were pre-packaged in manufacturing premises, 48.7% contained meat as the added ingredient and almost 75% contained salad dressing (e.g. mayonnaise, Caesar dressing, French dressing).
- Samples were stored at temperatures ranging from -1°C to 15.9°C (Table 2). Of particular concern was the finding that 23.8% (131/550) samples were stored at temperatures >5°C. (Salads should be stored under refrigerated conditions, i.e. at ≤ 5°C).

* Qualitative (i.e. presence/absence) tests were carried out on 714 samples. Quantitative (i.e. enumeration) tests were carried out on 715 samples.

Conclusions

In this study *L. monocytogenes* was detected in 2.7% (19/714) of samples and was present at levels >100cfu/g in 0.3% (2/715) of samples. *Salmonella* spp. was not detected in any sample (n=714). While these findings are encouraging it is imperative that the food industry does not become complacent as both pathogens can cause serious illnesses in susceptible members of the population.

Compliance with temperature control requirements and maintenance of the cold chain is a legal requirement for all food business operators (Article 4 of European Commission Regulation No 853/2004 of the European Parliament and of the Council of

29 April 2004 on the Hygiene of Foodstuffs). Ready-to-eat foods such as salads should be stored under refrigerated conditions (i.e. ≤5°C); however, this study revealed that 23.8% (131/550) of samples were stored at temperatures >5°C. This finding is unacceptable.

Refrigeration is necessary to prevent/minimise microbial growth; however, refrigeration alone cannot be relied upon to ensure product safety (this is particularly true for pathogens such as *L. monocytogenes* which are capable of growing slowly under refrigerated conditions). Strategies to avoid and control contamination must be implemented at all stages of the food chain, i.e. from farm to fork.

The report of this survey and other national microbiological surveys are available on our website at: www.fsai.ie/surveillance/index.asp#food

Table 1: Quantitative results for <i>L. monocytogenes</i> in pre-packaged mixed salads			
Number of samples (%)			
<20 cfu/g [1]	20-100cfu/g	>100cfu/g	Total
713 (99.7)	0 (0)	2 (0.3) [2]	715

Table 2: Storage temperatures				
Number of samples (%)				
No. of samples	Temperature range of storage unit (°C)	No. (%) of samples stored at the following temperatures		
		< 5°C	> 5°C	N/S
550	-1°C to 15.9°C	400 (72.7%)	131 [3] (23.8%)	19 (3.5%)

[1] OFMLs used a limit of detection of either 10 or 20cfu/g for the quantification of *L. monocytogenes*. More detailed information is available in the final report.

[2] *L. monocytogenes* counts of 400 and 1200 cfu/g were recorded for these 2 samples.

[3] >5°C - ≤6°C (n=50); >6°C - ≤7°C (n=26), >7°C - ≤8°C (n=13), >8°C (n=38), >5°C (n=4)

cooperation with the federal institute for risk assessment, germany

The Federal Institute for Risk Assessment, Berlin, Germany, is the scientific body of the Federal Republic of Germany with the responsibility to prepare expert reports and opinions on questions of food safety and consumer health protection on the basis of internationally recognised scientific assessment criteria.

The Federal Institute is engaged in scientific cooperation with other international institutions and organisations involved in consumer health protection and food safety. To develop communication and scientific cooperation with the FSAI, the President of the Federal Institute for Risk Assessment, Professor Dr Dr Andreas Hensel, recently visited the Authority.

Mr Alan Reilly, Deputy CEO, FSAI (right) welcomes Professor Dr Dr Andreas Hensel, President, Federal Institute for Risk Assessment, to the FSAI.





mailing list

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new board member appointed to the fsai



Ms Anne Nolan, B.Sc. (Pharm), MBA, MPSI, Chief Executive of the Irish Pharmaceutical Healthcare Association (IPHA) has recently been appointed to the Board of the FSAI. Ms Nolan has over 25 years experience in the healthcare industry, with particular expertise in the pharmaceutical sector.

From 1982 to 1987 Ms Nolan worked in retail pharmacy and pharmaceutical wholesaling and from 1987 to 1994 she was Healthcare Group Director and Company Secretary with the Federation of Irish Chemical Industries. She was a member of the Irish Medicines Board from 1996 to 2005. Ms Nolan is currently serving on the Board of the European Federation of Pharmaceutical Industries Association and the Association of the European Self-Medication Industry, and is a council member of the Pharmaceutical Society of Ireland and the International Federation of Pharmaceutical Manufacturers Associations.

In addition to her Board commitments in the healthcare sector, she serves on the Board of the Irish Aviation Authority, Smurfit Business School and KPL Limited. Ms Nolan is also a part-time lecturer in the School of Pharmacy at Trinity College, Dublin.

recent publications

The following publication has recently been produced by the FSAI:

- FSAI Customer Charter

This publication is available on our website at www.fsai.ie/publications.

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