



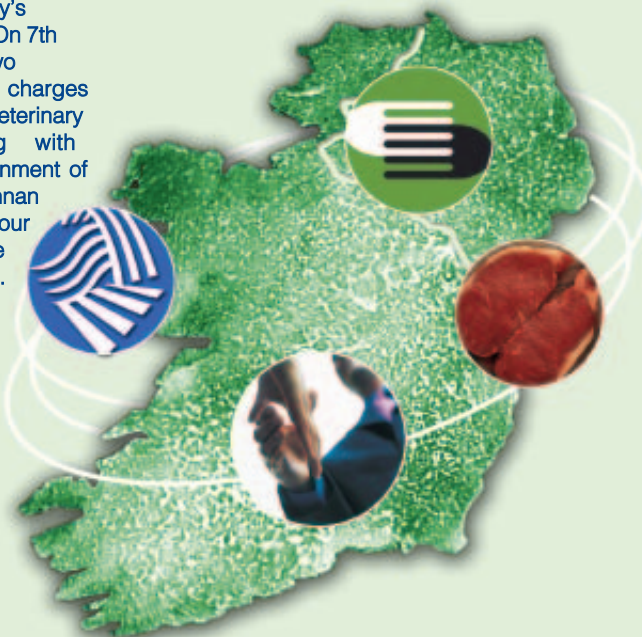
## food alert results in legal action on both sides of the border

A food alert issued in November 2005 resulted in an extensive investigation by food safety bodies on both sides of the Irish border into the use of illicit meat labels and the repackaging, relabelling and distribution of meat. The investigations involved substantial co-operation between enforcement officials on the island of Ireland and culminated in legal action in both jurisdictions.

The FSAI brought a case against D'Arcy Foods Limited, Ballybay, Co. Monaghan, Xxxxxx Xxxxxx and Ann McCabe, both of Castleblayney, Co. Monaghan regarding the company's breach of food safety legislation. On 7th June 2007, the company and the two directors were convicted on all charges relating to the illegal use of a veterinary control label and tampering with documents in relation to a consignment of beef cheek meat. Judge Flann Brennan imposed prison sentences of four months on both directors, which he said would not be suspended. He also imposed fines and expenses totalling €18,650 on D'Arcy Foods Limited. Notice of appeal has been lodged.

The Authority welcomed Judge Brennan's verdict and is particularly pleased with his comments that the offences were very serious and showed a high level of recklessness and

irresponsibility towards public health. The case involved a lengthy investigation and resulted in the destruction of over 23 tonnes of meat. The investigation would not have been possible without the assistance of the Department of Agriculture and Food, the Local Authority Veterinary Service, the Health Service Executive and the Food Standards Agency Northern Ireland. The outcome points to the very practical need for organisations involved in food control to co-operate fully, if consumers' health and interests are to be properly protected.



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# national microbiological surveillance

## microbiological safety of dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age

### Background

The World Health Organization (WHO) recommends that infants are exclusively breastfed for the first six months of life and thereafter continue to be breastfed in combination with suitably nutritious complementary foods for up to two years of age or beyond. There are however situations where breast milk is not available, where the mother is unable or has made an informed decision not to breastfeed or where breastfeeding is not appropriate. In these instances breast milk substitutes are required.

Breast milk substitutes are commercially available in both liquid and powdered form. Although liquid, ready-to-feed infant formula is a commercially sterile product, powdered infant formula (PIF) is not (using current manufacturing technology, it is not possible to produce sterile PIF). PIF may occasionally contain pathogens, and has been implicated, both epidemiologically and microbiologically, as the source and vehicle of infection in infants. *Enterobacter sakazakii* and *Salmonella enterica* are the organisms of most concern.

PIF undergoes a pasteurisation step during its manufacturing process and although *S. enterica* and *E. sakazakii* do not survive the pasteurisation step, recontamination may occur during handling and filling, i.e. via:

- 1) the raw materials and in particular the heat sensitive nutrients (e.g. vitamins, minerals etc.) added after pasteurisation
- 2) the processing environment (i.e. equipment and processing lines).

Although *E. sakazakii* and *S. enterica* cannot grow in PIF, they can survive for a long period of time in the powdered product and therefore pose a potential risk after rehydration if the product is temperature abused.

### Aim

The aim of this study was to investigate the microbiological safety (*E. sakazakii* and *Salmonella* spp.) of 'dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age' (hereafter referred to as PIF) on retail sale in the Republic of Ireland.

### Methodology

Samples of PIF were obtained by environmental health officers (EHOs) during April, May & June 2006. Samples were obtained from retail premises (supermarkets, grocery shops and pharmacies) and hospitals. 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. and
- *E. sakazakii*

Results were compared at a 95% confidence interval using the Z-test for two proportions.

### Results

*E. sakazakii* and *Salmonella* spp. were absent in all 719 samples (Table 1).

**Table 1: Prevalence of *E. sakazakii* and *Salmonella* spp. in PIF (n=719)**

	No. of samples (%)	
Result	<i>E. sakazakii</i> / 10g	<i>Salmonella</i> spp. /25g
Absent	719 (100%)	719 (100%)
Present	0 (0%)	0 (0%)

Food safety criteria are laid down in Commission Regulation (EC) No. 2073/2005 on Microbiological Criteria for Foodstuffs for *E. sakazakii* and *Salmonella* spp. in 'dried infant formula and dried dietary foods for special medical purposes intended for infants below six months of age'. Although these criteria are laid down for batch samples (n=30), single samples are permitted when official samples are taken for monitoring or surveillance programmes. All single samples (n=719) analysed in this survey meet the limits specified in Commission Regulation (EC) No. 2073/2005 for *E. sakazakii* (absence in 10g) and *Salmonella* spp. (absence in 25g).

Other surveys have been undertaken to investigate the prevalence of *E. sakazakii* and *Salmonella* spp. in PIF. Data relating to the prevalence of *E. sakazakii* in PIF are outlined in Table 2. There is a significant difference ( $p=0.05$ ) between the prevalence of *E. sakazakii* reported in these surveys (2 to 23%) and this Irish survey. However, it should be noted that the results of these surveys were generated using a variety of cultural and DNA based techniques and discrepancies between techniques have been reported.

**Table 2: Surveys of *E. sakazakii* in PIF**

(Table adapted from the FAO/WHO 2006 risk assessment on *E. sakazakii* and *Salmonella* in PIF <sup>[1]</sup>)

Reference	Year of publication of survey	Number of samples analysed	Number of samples with <i>E. sakazakii</i> present (%)
3	1988	141	20 (14.2)
4	1997	120	8 (6.7)
5	2003	22	5 (22.7)
6	2003	101	2 (2)
7	2004	40	5 (12.5)
2	2004	82	2 (2.4)
8	2006	98	12 (12.2)
This study	2007	719	0 (0)

Compared with *E. sakazakii*, *Salmonella* spp. are rarely found in PIF.



## Conclusions

The findings of this study are very encouraging, i.e. *E. sakazakii* and *Salmonella* spp. were absent in all samples (719 single samples). In recent years manufacturers of PIF have implemented strategies to control *E. sakazakii* and *Salmonella* spp. This may explain the absence of these pathogens in this survey compared with earlier surveys.

Control strategies are required not only during manufacture but also during the rehydration, use and handling of PIF as *E. sakazakii* and *Salmonella* spp. (if present) can survive for a long period of time in the dehydrated product. These pathogens can pose a potential risk after rehydration (particularly if the rehydrated product is temperature abused). In addition, extrinsic contamination can occur

from the preparation environment or from contaminated utensils (e.g. spoons, bottles etc) used for preparing or feeding PIF.

Guidelines on the preparation, use and handling of PIF in care settings and in the home have been published by the FAO/WHO. In Ireland, information relevant to the development of guidance material for the safe feeding of reconstituted powdered infant formula have been prepared by the Food Safety Authority of Ireland.

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

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## recommendations on feeding of infant formula



Powdered infant formula (PIF) contaminated with harmful bacteria has been implicated as a source of illness in infants. In recent years, the emergence of disease associated with a bacterium, *Enterobacter sakazakii*, in PIF has necessitated a new risk assessment. The Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization (WHO) have hosted two joint risk assessments on the subject (FAO/WHO, 2004 & 2006). One outcome of these risk assessments has been a risk assessment model that has allowed for the examination of the relative risk to infants of different practices regarding the reconstitution of powdered infant formula and ensuing infant feeding practices. As a result of this work the WHO has issued new guidance on infant feeding (WHO, 2007).

The FSAI has received requests for guidance on safe infant feeding of powdered infant formula both from the Department of Health and Children as well as public health nurses and dieticians working with infants in care settings and with parents of infants in the home. The FSAI facilitated the development of these guidelines by hosting a seminar on 2nd October 2006 on the topic of *E. sakazakii* and infant feeding. A consultation document was circulated for comment to participants from the health and food safety community, interested academics and the infant formula industry. Submissions were received from 26 individuals or groups of individuals containing over 220 comments.

The FSAI has taken the results of the consultation process, the outcomes of the international risk assessments and the guidance from the WHO and has developed a series of recommended safe practices for preparing and feeding powdered infant formula to infants in Ireland. The new document is targeted at public health professionals and public bodies responsible for issuing clear and simple guidance literature in this area. This has enabled FSAI to include the detailed rationale underpinning the recommendations; something the public health community had requested.

The new document, entitled '*Information relevant to the development of guidance material for the safe feeding of reconstituted powdered infant formula*' contains recommended feeding practices for several different groups of people. These include, those working in medical care settings and child care settings, as well as parents. The greatest recommended change is advice to make up powdered infant formula with boiled water that has cooled to no less than 70°C. This ensures that any harmful bacteria in the powder will be killed which makes a considerable impact to reduce the risk of illness.

The FSAI is in discussions with safefood to produce a series of information leaflets based on these recommendations. It is also hoped that other stakeholders, particularly hospitals will take a similar approach and develop clear and simple literature for those responsible for making up infant formula and feeding it to infants.

For more information on *E. sakazakii* and infant formula see the supplement in this issue.





# aflatoxin exposure assessment

## Background

Aflatoxins occur naturally in foods such as nuts, figs and other dried fruits, spices and crude vegetable oils. They are produced by moulds that grow on plants before harvest or on the foods during storage. They are undesirable because they have been shown to cause cancer in animals and humans. Although the presence of aflatoxins is undesirable in food, it is in many cases unavoidable. Because aflatoxins are considered to be genotoxic and carcinogenic, it is not possible to identify an intake without risk. Harmonised maximum levels (MLs) for aflatoxins were established in the EU in 1998, and are laid down in Commission Regulation (EC) No 1881/2006, setting maximum levels for certain contaminants in foodstuffs. For groundnuts, nuts, dried fruit, cereals and their processed products intended for direct human consumption or as an ingredient in foodstuffs, maximum levels of 4 µg/kg for total aflatoxins (aflatoxins B1 + B2 + G1 + G2) and 2 µg/kg for aflatoxin B1 (AFB1) have been set. For spices, corresponding levels have been set to 10 µg/kg for total aflatoxins and 5 µg/kg for AFB1. These levels were based on the ALARA (as low as reasonably achievable) principle. Higher MLs have been set for unprocessed products that are subject to further reduction methods prior to human consumption.

In recent years, discussions in the Codex Committee on Food Additives and Contaminants (CCFAC) and this year in the newly established Codex Committee on Contaminants in Food (CCCCF), have proposed setting, worldwide, a maximum level for total aflatoxins in processed almonds, hazelnuts and pistachios at a level higher than that currently in force in the European Union. Such a move has been supported by a large majority of the Codex member countries other than the European Member States and as a result, European countries have committed themselves to finding a common solution which would meet, to a large extent, the concerns and comments made by the different member countries. As part of the process, European countries tentatively agreed to a level of 8 µg/kg total aflatoxins in these tree nuts. However, at the same time, the EC expressed concern regarding the possible public health consequences of such an increase and the European Commission requested its scientific advisory body, the European Food Safety Authority (EFSA), to advise on the potential increase in risks to consumer health associated with a proposed change of the currently existing

EU maximum level of 4 µg/kg for total aflatoxins in almonds, hazelnuts and pistachios to 8 or 10 µg/kg.

In order to help progress the ongoing discussions CCFAC / CCCC, the WHO/FAO Joint Expert Committee on Food Additives and Contaminants (JECFA) was also asked to conduct an assessment of exposure to aflatoxins from tree nuts, in particular ready to eat almonds, hazelnuts, pistachios, and Brazil nuts, taking into account hypothetical contamination levels of 4, 8, 10 and 15 µg/kg. JECFA's assessment, which is expected to be completed at this year's meeting of the committee, will provide an estimate of exposure from tree nuts in the context of total human exposure to aflatoxins from all sources.

## EFSA assessment of potential increase of consumer health risk

Following the request by the European Commission, in January 2007 EFSA's Scientific Panel on Contaminants in the Food Chain (CONTAM) provided an opinion on the potential increase of consumer health risk by a possible increase of the maximum levels from 4 to 8 and 10 µg/kg for total aflatoxins in "ready-to-eat" almonds, hazelnuts and pistachios and derived products [1].

In order to assist EFSA in this task, European Member States provided data on the occurrence of these toxins in a range of foodstuffs. The FSAI compiled and submitted 1,765 analytical results that had been provided by the public analyst service in Ireland. In total, 34,326 analytical results for occurrence of aflatoxins in various foodstuffs were submitted to EFSA by 20 Member States, as well as 6,762 results from pre-export controls that were submitted by Turkey. Aflatoxin contamination was found in many food commodities including maize, peanuts, dried fruit and spices, as well as tree nuts, with Aflatoxin B1 the main aflatoxin found. The highest total aflatoxin levels were found in pistachios and Brazil nuts and these two food commodities also showed the highest percentage of lots which did not comply with the current EU maximum levels. The samples showed a broad range of contamination levels but overall, 74% of all samples were below the Limit of Detection (LOD), with the LOD varying considerably between laboratories.

Examination of the data indicated that increasing the ML for total aflatoxins for almonds, hazelnuts and pistachios from 4 to 8 or 10 µg/kg will only have a small

impact on the extra product that would be allowed onto the market (varying between 1.1-3.9%).

Data on consumption of almonds, hazelnuts and pistachios were available for only five Member States, of which Ireland was one. The GEMS/Food Consumption Cluster Diets database was used in estimating dietary aflatoxin exposure from foods other than almonds, hazelnuts and pistachios. The exposure assessment performed by the scientific panel on contaminants in the food chain used a precautionary approach to the uncertainties which means that the exposure is likely to be an overestimation.

The contribution from almonds, hazelnuts and pistachios was only a few percent of total dietary exposure to aflatoxins. Therefore, increasing the maximum levels from 4 to 8 or 10 µg/kg would result in an increase in estimated average total dietary aflatoxin exposure of about 1%. Estimated dietary exposures for children were within the range of estimates for adult populations, however these were predominated by exposure from foods other than nuts, for which data specific to children's diets were not available.

EFSA concluded that changing the maximum levels for total aflatoxins from 4 to 8 or 10 µg/kg in almonds, hazelnuts and pistachios would only have minor effects on the estimates of dietary exposure, cancer risk and the calculated margin of exposure. Exposure to aflatoxin from all sources should be as low as reasonably achievable, because aflatoxins are genotoxic and carcinogenic. The data indicate that reduction of total dietary exposure to aflatoxins could best be achieved by reducing the number of highly contaminated foods reaching the market and reducing exposure from food sources other than almonds, hazelnuts and pistachios.

The expected JECFA opinion will be considered along with the EFSA opinion at the next meeting of CCCC in April 2008 with a view to finalising discussions on establishing world-wide levels for aflatoxins in tree nuts.

*1. Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to the potential increase of consumer health risk by a possible increase of the existing maximum levels for aflatoxins in almonds, hazelnuts and pistachios and derived products: [http://www.efsa.europa.eu/etc/medialib/efsa/science/contam/contam\\_opinions/ej446\\_aflatoxins.Par.0001.File.dat/CONTAM%20\\_op\\_ej446\\_aflatoxins\\_en.pdf](http://www.efsa.europa.eu/etc/medialib/efsa/science/contam/contam_opinions/ej446_aflatoxins.Par.0001.File.dat/CONTAM%20_op_ej446_aflatoxins_en.pdf)*



# local authority veterinary service

## national meeting

The regional meetings for the local authority veterinary service (LAVS) took place in Mullingar in May in the form of a two day national meeting, with over 30 local authority veterinarians from across the country.

The meeting was opened by Ray Ellard, acting Director of Services Contracts, welcoming all those attending and setting the main themes for the meeting ahead.

Helen Crowley and Noeleen Murtagh gave presentations on the work of the FSAI advice-line and Information Resources available within FSAI as well as manning a busy stand promoting publications and detailing support available to the LAVS.

Dr Chris Thomas of the National Standards Authority of Ireland presented on the development of a quality management

system within the LAVS, outlining the ISO 9000 requirements and opening discussion on the potential benefits to the service of a national quality management system within the service.

Micheál O'Mahony, Aiden Scanlon, Tim Camon and Ciaran O'Sullivan updated the meeting on issues concerning FSAI veterinary public health and the LAVS such as the development of national rules on small poultry, *Trichinella* testing, national rules on wild game and training for temporary veterinary inspectors.

John Coady spoke to the group on the work of the FSAI audit division, discussing ongoing and forthcoming activity, FVO missions and generating discussions on the role and nature of audits of official controls on food products of animal origin.

Other topics discussed included the work of the cross agency hygiene package working group, legislation updates and the provision of regional cover. Roger Moore, LAV, led a comprehensive discussion of the work of the LAVS standardisation working group.

This was the first time the bi-annual regional meetings had been held as a single national meeting and it was greeted as a great success. Participants felt that more time was available for detailed discussions of the main agenda items but also the evening provided a relaxed atmosphere allowing attendees discuss topical issues and develop stronger, and more personal, working relationships.

# dairy produce inspectors and dairy science laboratory regional meeting

The FSAI met with the Department of Agriculture and Food (DAF) dairy produce inspectors and representatives from the dairy science laboratory at a regional meeting in Tullamore in April. These annual meetings provide FSAI with the opportunity to meet with field staff from DAF to update them on food safety developments that

impact on their work area. The group were updated on FSAI surveys, training and audits. Other topics discussed included the hygiene package, FSAI information services available to official agencies, approval of establishments under the hygiene package, a recent national reference laboratory workshop and genetically modified, novel

and functional foods. The analysis of data returns from dairy science laboratories and dairy produce inspectors for 2006 was also discussed. Dr Amanda Forde, Relay Research (UCC) updated the meeting on dairy food safety research activities.

# world health organization

## international health regulations



**World Health Organization**

The revised International Health Regulations (IHR 2005) of the World Health Organization (WHO) entered into force on 15th June 2007, with the aim of preventing national public health emergencies from spreading internationally. Under the revised Regulations Member States are required to report to the WHO any "public health emergency of international concern". For the first time, major food incidences are included in this category of events to be reported to the WHO. Speaking at a technical briefing session on the IHR 2005 at the recent World Health Assembly in Geneva (from l to r) were Mr Alan Reilly, Deputy Chief Executive FSAI; the Honourable Monsieur AK Remi, Minister of Health Cote D'Ivoire;



Dr D Heyman, Assistant Director General WHO; Dr M Chan, Director General WHO and the Honourable Dr T Clements, Minister of Health of Canada.

# legislation update

The following legislation has recently been published in the European Union Official Journal

## Beef labelling

*Commission Regulation (EC) No 275/2007 (OJ L76, p12, 15/03/2007) of 15 March 2007 amending Regulation (EC) No 1825/2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products.*

This Regulation makes a number of amendments to the detailed rules for the application of the European Union rules concerning the labelling of beef and beef products, in particular it introduces:

- measures for beef trimmings similar to those conditions set down for minced meat,
- new provisions for pre-packaged cut meat, where comprised of meat from a group of animals. Size and composition of a "group" is defined,
- simplified labelling rules for sale of non pre-packaged cut meats to the final consumer.

## Imports of animals and animal products

*Commission Decision 2007/275/EC (OJ L116, p9, 04/05/2007) of 17 April 2007 concerning lists of animals and products to be subject to controls at border inspection posts under Council Directives 91/496/EEC and 97/78/EC.*

This Decision lays down rules regarding the animals and products which are subject to veterinary checks at border inspection posts (BIPs). It provides that all composite products containing meat products should be subject to veterinary checks, while different criteria should be applied to composite products containing other animal products. It also sets out rules concerning composite products that may be exempt from veterinary checks under Directive 97/78/EC.

In general terms the Decision requires that the following composite products are subject to veterinary checks:

- composite products containing processed meat product,
- composite products containing half or more of their substance of any one processed product of animal origin other than processed meat product,
- composite products containing no processed meat product and less than half of their substance of processed milk product where the final products do not meet the requirements of Article 6 of Decision 2007/275/EC.

By way of derogation, the following composite products or foodstuffs intended for human consumption, not containing any meat products, are not generally subject to veterinary checks at a BIP:

- composite products containing less than half of their substance of any other processed product provided such products are:
  - (i) shelf-stable at ambient temperature or have clearly undergone in their manufacture a complete cooking or heat treatment process throughout their substance, so that any raw product is denatured,
  - (ii) clearly identified as intended for human consumption,
  - (iii) securely packaged or sealed in clean containers,
  - (iv) accompanied by a commercial document and labelled in an official language of a Member State, so that the document and labelling together give information on the nature, quantity and number of packages of the composite products, the country of origin, the manufacturer, and the ingredient.
- composite products or foodstuffs listed in Annex II of Decision 2007/275/EC.

## Spreadable fats/milk and milk products

*Commission Regulation (EC) No 445/2007 (OJ L106, p24, 24/04/2007) of 23 April 2007 laying down certain detailed rules for the application of Council Regulation (EC) No 2991/94 laying down standards for spreadable fats and of Council Regulation (EEC) No 1898/87 on the protection of designations used in the marketing of milk and milk products (Codified version)*

Regulations (EC) No 2991/94 and (EEC) No 1898/87 cover composite products of which an essential part is butter. The scope of paragraph Article 2(3) of Regulation (EEC) No 1898/87 needed to be defined more clearly with regard to composite products of which an essential part is butter. Regulation No 445/2007 states that the designation 'butter' may be used for composite products of which an essential part within the meaning of Article 2(3) of Regulation (EEC) No 1898/87 is butter if the end product contains at least 75% milk fat and has been manufactured solely from butter within the meaning of Part A(1) of the Annex to Regulation (EC) No 2991/94 and the other added ingredient(s) mentioned in the description.

The second subparagraph of Article 2(2) of Regulation (EC) No 2991/94 provides that

the sales descriptions listed in the Annex thereto are to be reserved for products which meet the criteria set out in that Annex. Therefore, trade marks which employ those designations may continue to be used in the future solely for products which meet those criteria.

## Foods for particular nutrition uses

*Commission Directive 2007/26/EC (OJ L118, p5, 08/05/2007) of 7 May 2007 amending Directive 2004/6/EC to extend its period of application*

At the time of the adoption of Directive 2001/15/EC on substances that may be added for specific nutritional purposes in foods for particular nutritional uses, a number of chemical substances added for specific nutritional purposes to some foods for particular nutritional uses, which are marketed in some Member States, could not be included in the Annex to that Directive because they had not been evaluated by the Scientific Committee on Food.

To take into account the time needed for the completion of the evaluation of the substances by the European Food Safety Authority (EFSA) and for the transposition of the associated measures into the national legislation, an extension of the period of application of Directive 2004/6/EC to 31 December 2009 has been granted in Commission Directive 2007/26/EC.

## Materials and articles intended to come into contact with foods

*Commission Regulation (EC) No 372/2007 (OJ L92, p9, 03/04/2007) of 2 April 2007 laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with foods*

Commission Regulation (EC) No 372/2007 sets transitional specific migration limits (SML) for the sum of certain plasticisers used in gaskets in lids contacting fatty foods, so that the free circulation of those products is not endangered, the lids and foods that pose a significant risk are immediately excluded from the market and, at the same time, industry has sufficient time to finalise the development of gaskets that are compliant with the SML laid down in Directive 2002/72/EC as amended by Directive 2007/19/EC. The transitional SML is set at a level ensuring that the tolerable daily intake (TDI) will not be exceeded, taking into account the average consumption of the foods concerned and the opinion issued by EFSA on 16 March 2006.



In this edition of *fsainews* we have launched our guidance note outlining recommended safe feeding practices for powdered infant formula. In this supplement we are taking the opportunity of providing some insight into why FSAI has taken such a measure. Here we focus on Ireland's infant formula industry and the emerging hazard of a bacterium called *Enterobacter sakazakii*. The presence of these bacteria in powdered infant formula and their association with a small but significant number of infant illnesses around the world has elicited a robust response from the formula manufacturers and the Irish research community to reduce the risks.

## Ireland - a natural source of infant nutrition

Over the last two decades, Ireland has become one of the world's leading producers of infant nutritionals with the presence in Ireland of leading infant nutrition manufacturers - Wyeth, Abbott and Nutricia. The combined output from these companies accounts for almost 15% of the world's powdered infant formula. Ireland's unique grass-based production system makes it a natural location for the industry, and enables close collaboration between dairy producers and industry.

Ireland's formula manufacturers invest significant resources in researching and understanding infant nutrition, improving and developing ingredients, and in improving product and processing capabilities. Infant formula is made using a range of processes, from liquid processing such as sterilisation or ultra heat treatment, to spray drying and dry blending. Manufacturers use a wide range of formulations, processes and knowledge to produce safe and effective infant formula to meet the infant's nutritional requirements.

All infant formulas are manufactured and tested under strict regulatory requirements that require manufacturers to operate under Good Manufacturing Procedures (GMPs), assuring that their products, ingredients, processing conditions and packaging meet all applicable safety and quality requirements at every stage of the manufacturing operation. All formulations are carefully developed and evaluated before



they become commercial, and extensive analytical and microbiological testing is designed around individual processes and products, with validated test methods and statistical sampling plans implemented at each stage of the process. This ensures that formulations and processes are carefully controlled and monitored to assure compliance with all regulatory requirements.

## Infant formula manufacturers' measures to control *E. sakazakii*

The primary concern of infant formula manufacturers is to ensure the highest level of quality and safety of their products. Manufacturers recognise the serious risk posed by *E. sakazakii* and have invested significantly in upgrading and re-engineering their manufacturing facilities to mitigate against this risk. Recognising that *E. sakazakii* is a ubiquitous organism, efforts have focused on the implementation of strict control measures to ensure the safe production of infant formula. Control measures implemented include hygienic "zoning" of facilities, to control personnel and material movements into and through critical areas of the factory. Together with the implementation of specific food safety control measures (HACCP), microbiological monitoring, strict controls on raw material quality and adherence to hygienic manufacturing conditions, these measures have proved extremely successful in controlling microbial contamination. Food safety and quality

systems are under continuous review. Personnel are provided with continuing education to ensure that hygiene principles and practices are followed.

Formula manufacturers have long recognised the importance of appropriate labelling that provides clear instructions on how to correctly prepare and use infant formula. Manufacturers believe that explicit warning statements are not effective communication tools. Effective labelling provides simple messages that clearly communicate what should be done to prevent risk. In light of new authoritative guidance from the FSAI and the World Health Organization, manufacturers' have updated preparation instructions and strongly recommend fresh preparation before each feeding. Evaluation of the effects of formula reconstitution with high water temperature on nutrient content and product quality is ongoing.

## Enterobacter sakazakii in profile

Name:	Enterobacter sakazakii (formerly known as yellow pigmented Enterobacter cloacae)
Family:	Enterobacteriaceae
Environmental source:	Soil, water
Food isolation:	Vegetables, cheese, milk, powdered infant formula, meats, herbs, spices
Main disease concern:	Fatal meningitis, necrotising enterocolitis and bacteremia in infants
Vulnerable group:	All infants (defined as persons less than 12 months of age)
Most vulnerable group:	All infants less than 2 months of age and all immunocompromised infants irrespective of age

## Enterobacter sakazakii and its relationship to infant disease

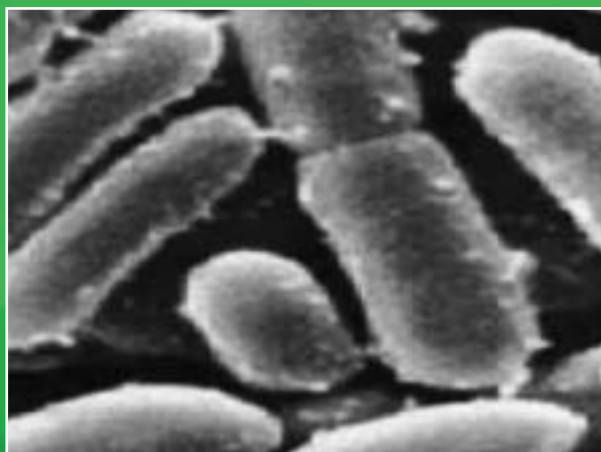


Figure 1: Electron micrograph of *E. sakazakii*

Invasive *E. sakazakii* disease is rare in infants. The first case of neonatal meningitis attributable to *E. sakazakii* was reported in England in 1958 [1] and since that time there have only been 111 reports of *E. sakazakii* infections worldwide. However, there have been at least 26 deaths and there is concern that it has been under reported. In 2003, a United States FoodNet survey estimated the annual rate of invasive *E. sakazakii* infection to be 1 per 100,000 infants (children less than 12 months of age) (U.S. Centres for Disease Control and Prevention (CDC) unpublished data). In infants of very low birth weight (less than 1,500g) the incidence was estimated to be 9.4 per 100,000 in a study of 19 neonatal intensive care units [2]. Children greater than 12 months of age and adults are thought to be a much lower risk group than infants. *E. sakazakii* has been associated with neonatal meningitis, necrotising enterocolitis (NEC), bacteraemia and necrotising meningoencephalitis [3] [4]. Reported mortality rates are high; NEC 10-55% and meningitis 40-80% [4].

A U.S. Centres for Disease Control and Prevention (CDC) report investigated the risk factors relating to ingestion of *E. sakazakii* in infants [5]. Forty-six cases were analysed (12 with bacteraemia, 33 with meningitis and one with a urinary infection). The infants with meningitis tended to be near-term infants (median 37 weeks) of normal birth weight (median 2,454 g) where infection tended to occur soon after birth (median six days after birth). The infants with bacteraemia tended to have very low birth weight (median 850 g), were pre-term (median 27.8 wks) and developed infection after the first few weeks of life (median 35 days). Bowen and Braden concluded that their findings suggested that all neonates (infants  $\leq 28$  days) as well as premature infants should be included in the 'high-risk' infant category. FAO/WHO concluded that the high-risk group are all infants in the first two months of life [6] based on the knowledge that infants up to about two months are known to be at elevated risk for meningitis (Dr. A. Bowen CDC, pers. comm.).

*E. sakazakii* has been isolated from many foods and environmental sources and can be considered ubiquitous [7]. The role of these sources in neonatal infection has not been determined. However, of the 27 infection studies cited by Iversen and Forsythe (2003) [4], eight cite infant formula milk as the suspected source of the *E. sakazakii* infection (the source was unknown or not specified in the remaining 19 studies). Bowen and Braden (2006) [5] found that of 26 infants where feeding patterns were specified, 24 (92%) were fed on PIF. Formula samples associated with 15 (68%) of 22 of these cases yielded *E. sakazakii*. In 13 (87%) of these cases the clinical and formula strains were indistinguishable. *E. sakazakii* has been isolated from infant formula milk powder on many occasions [7] [8], although contamination can be considered as low and sporadic.

1. Mullane N.R., Iversen C., Healy B., Walsh P., Whyte P., Wall P.G., Quinn T. Fanning S. (2007) *Enterobacter sakazakii*: an emerging bacterial pathogen with implications for infant health. *Minerva Pediatr* 59: 137-148
2. Stoll B., Hanson N., Fanaroff A., Lemons A. (2004) *Enterobacter sakazakii* is a rare cause of septicemia or meningitis in VLBW infants. *J. Pediatr*, 144, 821-823
3. Muytjens H.L., Zanan H.C., Sonderkamp H.J., Kollee L.A., Wachsmuth I.K., Farmer J.J. (1983) Analysis of eight cases of neonatal meningitis and sepsis due to *Enterobacter sakazakii*. *J. Clin. Micro.*, 18, 115-120
4. Iversen C., Forsythe S.J. (2003) Risk profile of *Enterobacter sakazakii*, an emergent pathogen associated with infant milk formula. *Trends in Food Sci. & Technol.* 14, 443-454
5. Bowen A.B., Braden C.R. (2006) Invasive *Enterobacter sakazakii* disease in infants. *Emerg. Infect. Dis.* August Publication <http://www.cdc.gov/ncidod/EID/vol12no08/05-1509.htm>
6. FAO/WHO (2006) *Enterobacter sakazakii* and *Salmonella* in powdered infant formula. Microbiological risk assessment series 10, ISBN:92-5-105574-2 [ftp://ftp.fao.org/ag/agn/jemra/e\\_sakazakii\\_salmonella.pdf](ftp://ftp.fao.org/ag/agn/jemra/e_sakazakii_salmonella.pdf)
7. Iversen C., Forsythe S.J. (2004) Isolation of *Enterobacter sakazakii* and other Enterobacteriaceae from powdered infant formula milk and related products. *Food Microbiol*, 21, 771-777
8. FAO/WHO (2004) *Enterobacter sakazakii* and other microorganisms in powdered infant formula. Microbiological risk assessment Series No 6, ISBN 92-4-156262-5 <http://www.who.int/foodsafety>



## firm funded project: detection and surveillance of *E. sakazakii* along the infant formula food chain

Project start date:	1/1/2006
Project end date:	31/12/2008
Partners:	University College Dublin Ashtown Food Research Centre Moorepark Dairy Research Centre Food Safety Authority of Ireland
Project deliverables:	<ul style="list-style-type: none"> <li>• Develop methods to detect and characterise <i>E. sakazakii</i>,</li> <li>• establish the prevalence and numbers of <i>E. sakazakii</i> along the infant food chain,</li> <li>• assess the effectiveness of current controls used in the infant formula manufacturing process,</li> <li>• assess the risk posed by <i>E. sakazakii</i> and make recommendations to facilitate the implementation of further future controls and</li> <li>• disseminate all research findings to all of the stakeholders.</li> </ul>

## project outcomes to date

### improving isolation and detection methods

Current isolation and culture methods for *E. sakazakii* have certain drawbacks. They are variously sensitive and specific for *E. sakazakii* and they take several days (up to five in the case of the FDA protocol) before results are available.

The FDA approved method is a presumptive, most probable number (MPN) test based on a “three-tube” enrichment, so that low levels of the organism, if present in the product, can be detected and quantified. However, the protocol is only selective for *Enterobacteriaceae* and is not specific for *E. sakazakii*. The final step requires the biochemical identification of any presumptive-positive *E. sakazakii* colonies.

Several media have been developed for specifically detecting *E. sakazakii*, rather than general *Enterobacteriaceae*, in powdered infant formula. Figure 2 shows a photographic plate of one of these differential media. These media take advantage of the key biochemical characteristic of this bacterium, the production of alpha-glucosidase. This enzymatic reaction was not found in any other *Enterobacter* spp. Chromogenic agars use chromogens that are cleaved by alpha-glucosidase to produce a characteristic colony colour.

The ISO method (DTS 22964) for *E. sakazakii* uses the chromogenic agar ESIA (AES Laboratoire) after enrichment. ESIA is incubated at 44°C for 24 hours and resultant colonies are green to blue-green in colour (figure 3). The selective agents are sodium desoxycholate and crystal violet. Presumptive *E. sakazakii* colonies are confirmed by pigment production on TSA at 25°C with enhanced light exposure.

As part of the FIRM funded project on *E. sakazakii*, the UCD Centre for Food Safety under Professor Shea Fanning have developed and published an alternative method that can detect between one and five CFU in 500g of powdered formulae, following sample pooling, in less than 24 hours [1]. The homogenised sample of infant formula is circulated over coated paramagnetic beads marketed under the brand name Pathatrix™ (Matrix Microscience Ltd., Newmarket, UK).

These positively charged magnetic beads electrostatically attract the negatively charged membrane chemicals on the

surface of Gram-negative bacteria. Captured *E. sakazakii* are plated directly onto DFI agar (Oxoid, Hampshire, UK) and incubated at 37°C for 18 hours. A same-day method combining cationic capture and real-time polymerase chain reaction (rt-PCR) technology is also being developed by the UCD group. This approach will further reduce the time to detection.

I. Mullane N.R., Murry J., Drudy D., Prentice N., Whyte P., Wall P.G., Parton A. and Fanning S. (2006) Detection of *Enterobacter sakazakii* in dried infant milk formula by cationic magnetic bead capture. *Appl. Environ. Micro.* 72:9, 6325-6330.

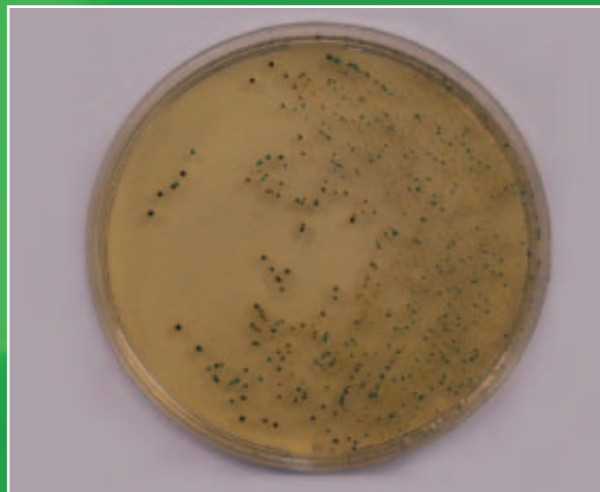


Figure 2 Appearance of *Enterobacter sakazakii* NCTC 11467 (blue green colonies) and *Salmonella Typhimurium* DT104 (black centred colonies) on DFI culture media.

## ISO Detection Protocol (-6 days)

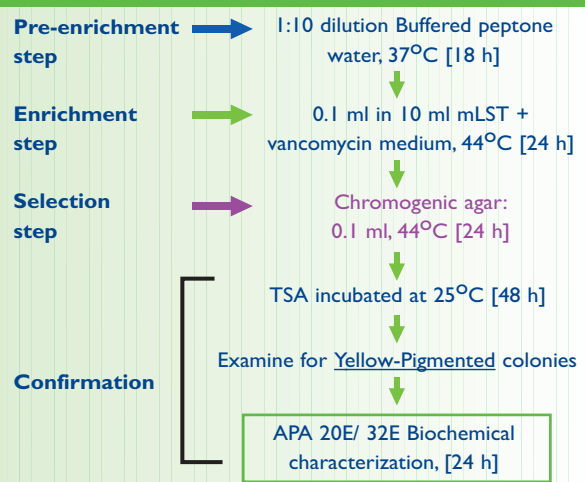


Figure 3: (A) ISO method protocol for detection of *E. sakazakii*



Figure 3: (B) *E. sakazakii* on ESI agar after enrichment. Photo courtesy of AES Chemunex.



The *E. sakazakii* research team at a recent meeting in UCD (l-r): Seamus Fanning (UCD-CFS), Cat Molloy (post-graduate based at AFRC), Kieran Jordan (MDRC), Claire Cagney (research officer based at AFRC), Niall Mullane (post-graduate based at UCD-CFS), Benedict Arku (post-graduate based at MDRC), Ed Fox (research officer based at MDRC), Perrine Tissier (placement student at MDRC) and Ruth Henry (UCD-CFS), the project administrator. Geraldine Duffy (AFRC) is also linked to this group, but is not in the photograph.

## investigating the fate and ecology of *E. sakazakii* during manufacture of powdered infant formula

Research teams at Moorepark Dairy Research Centre under Dr Kieran Jordan and the UCD Centre for Food Safety under Professor Shea Fanning have been studying the survival of *E. sakazakii*, particularly during spray drying. Spray drying is the manufacturing process that turns the pasteurised liquid infant formula milk base into a powder. This process has been identified with a high potential for recontamination of powdered infant formula (PIF) with *E. sakazakii*. The researchers will shortly publish findings which show that four different strains of *E. sakazakii* inoculated into 35% reconstituted skim milk and spray dried in a Buchi mini spray drier at an inlet temperature 160°C and outlet temperature 90°C, survived the spray drying process and could be isolated from the powder (Arku et al. submitted). The results emphasise that the controls in place to prevent *E. sakazakii* from getting to the spray drier are not only necessary, but are essential in the manufacturing environment of PIF.

The UCD team have also conducted a detailed study of how *E. sakazakii* behaves during the colonisation of a powdered infant formula factory [1]. This included a detailed study by molecular techniques of the interrelatedness of isolates from different sites of the production process. The purpose of the monitoring programme was to locate points of contamination, investigate clonal persistence, and identify possible dissemination routes for *E. sakazakii* along the processing chain. A total of 80 *E. sakazakii* isolates were recovered from the manufacturing facility. The overall frequency of isolation of *E. sakazakii* in intermediate and final product was 2.5%, while specific locations in the processing environment were contaminated at frequencies up to 31%. All *E. sakazakii* isolates were characterised by pulsed-field gel electrophoresis (PFGE) (similar to that shown in figure 4). XbaI macrorestriction digests yielded 19 unique pulse-types that could be grouped into 6 clusters of between 5 and 32 isolates. The formation of large clusters was consistent with the presence of a number of clones in the manufacturing environment. While the majority of isolates were of

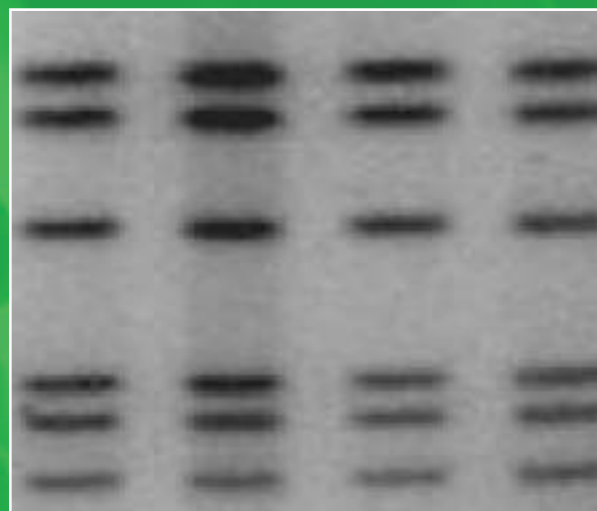


Figure 4 :Tracking *E. sakazakii* in a PIF factory by DNA fingerprinting: A picture of a PFGE gel where the genome of *E. sakazakii* has been cut up using a restriction enzyme. The different lanes show isolates from different factory locations that are genetically the same.

environmental origin (72.5%), no cluster was confined to one specific location and indistinguishable PFGE profiles were generated from isolates cultured from the manufacturing environment, sampling points along the processing chain and from intermediate and final product. These findings suggest that the manufacturing environment serves as key route for sporadic contamination of PIF. These data will support the development of efficient intervention measures contributing to the exclusion of *E. sakazakii* from the PIF processing chain.

I. Mullane N.R., Whyte P., Wall P.G., Quinn T. and Fanning S. (2007) Application of pulsed field gel electrophoresis to characterise and trace the prevalence of *Enterobacter sakazakii* in an infant formula processing facility. *Int. J. Food Micro.* 116: 1, 73-81

## *Enterobacter sakazakii* in the farming environment

The Food Safety Department at Ashtown Food Research Centre, Teagasc, Dublin, are conducting research on *E. sakazakii* in the farming environment. Research to date has established methods for the detection and enumeration of *E. sakazakii* from soil, water and cattle faeces. Ongoing research is examining the presence, persistence and survival characteristics of the pathogen in these environmental matrices on dairy farms. This research will establish if farms are a potential source of *E. sakazakii* and if control measures are needed to limit potential transmission into dairy or baby food manufacturing plants. The group involved in this research are Dr Geraldine Duffy, Ms Claire Cagney and Ms Cat Molloy.

## Acknowledgements

The following researchers are acknowledged for their collaborative contribution to the success of the FIRM funded *E. sakazakii* project: Dr Paul Whyte (UCD), Dr Amalia Scannell (UCD), Dr Francis Butler (UCD), Professor Patrick Wall (UCD) and Dr Denise Drudy (UCD).

## Contributors

Wayne Anderson  
Geraldine Duffy  
Sheamus Fanning  
Kieran Jordan  
IBEC- Irish Infant Formula Manufacturers





# new research on microbiological risk management in shellfisheries

Bivalve shellfish, such as oysters, contaminated with sewage can present a health risk to consumers when eaten raw or lightly cooked. In Europe and elsewhere in the world, regulatory controls rely on the use of bacterial monitoring to assess the sanitary quality of harvest areas. Despite these controls, on occasion viral illness associated with shellfish consumption continues to be documented. In Europe, the most common of these is gastroenteritis caused by norovirus (NoV).

The Marine Institute, in partnership with other European laboratories, has recently completed a three year EU funded project aimed at reducing the risk (REDRISK) associated with such shellfish. The project, part of the SEAFOODplus research programme, was carried out at sites in the UK, France, Spain and Ireland. The primary objective was to identify the conditions leading to NoV contamination in shellfisheries. The project was split in to two sequential phases.

Firstly, a sanitary survey of the selected study site was undertaken to determine the potential pollution source. The Irish study site was Clew Bay, County Mayo, which has a well established shellfish growing industry.

Secondly, microbiological and environmental monitoring of the study area was conducted. During this monitoring phase,

recently developed quantitative real-time PCR methods were used to determine virus levels in shellfish. This is the first time these procedures have been applied in a systematic approach to assess virus contamination in shellfisheries.

The conclusions from the Irish element of the study are:

- Recently introduced real-time PCR procedures provided an accurate and robust tool to determine the quantitative level of virus contamination in oysters.
- The sanitary survey accurately predicted the relative risk of NoV contamination in oysters at each site within the study area.
- Intermittent NoV contamination observed in two sites was associated with untreated sewage from storm overflows due to high rainfall. This influence was observed in sites up to 4.5km from a pollution source.
- The three major factors influencing NoV contamination were proximity to sewage input, season (epidemics in the population during winter representing a higher risk period) and the influence of untreated sewage inputs as result of overflows from the waste water treatment plant.

The information from the project identifies the potential to introduce risk management procedures to better control the health risks associated with bivalve shellfish. This could involve the use of sanitary surveys, improved communication with sewage treatment plant operators (overflows) and health professionals (epidemics). This, in conjunction with virus monitoring would make it possible to identify significant risk periods. During such periods, additional intervention steps could be introduced to reduce the risk.

The Marine Institute works with partners in the Molluscan Shellfish Safety Committee (MSSC), including the Food Safety Authority of Ireland, the Sea Fisheries Protection Authority (SFPA), Bord Iascaigh Mhara, the Health Service Executive and the Irish Shellfish Association (ISA) to implement the programme of monitoring and management of microbiological risks from Irish shellfish.

The full report from the REDRISK project will be available shortly and can be obtained along with any further information from Bill Doré of the Marine Institute at [bill.dore@marine.ie](mailto:bill.dore@marine.ie).



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

**S.I. No. 143 of 2007** European Communities (Control of Animal Remedies and their Residues) Regulations, 2007

**S.I. No. 144 of 2007** European Communities (Animal Remedies) Regulations, 2007

**S.I. No. 171 of 2007** European Communities (Additives, Colours and Sweeteners in Foodstuffs)(Amendment) Regulations, 2007

**S.I. No. 178 of 2007** Consumer Protection Act 2007 (Commencement) Order, 2007

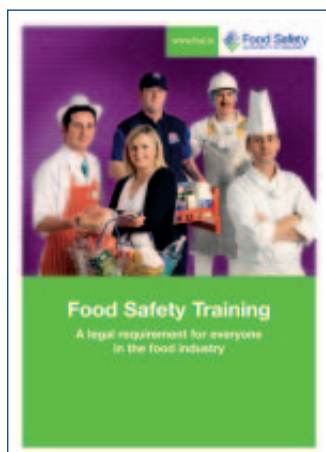
**S.I. No. 179 of 2007** Consumer Protection Act 2007 (Establishment Day) Order, 2007

**S.I. No. 202 of 2007** European Communities (Phytosanitary Measures) Regulations, 2007

**S.I. No. 225 of 2007** European Communities (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations, 2007



# food safety training



It is a legal requirement that staff involved in a food environment are trained and/or supervised, commensurate with their work activity. The responsibility for the supervision and training of staff lies with the proprietor of the food business.

The FSAI has recently published a food safety training information leaflet to provide practical advice and guidance to food business operators.

**Outlined below are some common questions and answers on food safety training.**

## Q: What course do food businesses have to do to meet their legal requirement?

A: There is no one specific course that you must do to meet your legal requirement. However the law states that food workers need to be trained and/or supervised '**commensurate**' with their work activity.

To assist food businesses meet their legal obligation, the FSAI, in consultation with industry representatives, enforcement officers and training providers, has produced guides to food safety training. These guides detail the food safety skills that food handlers and non-food handlers should be able to demonstrate at various stages of employment in the workplace.

There are two guides in the series:

- **Level 1 (Induction Skills) and Level 2 (Additional Skills)**
- **Level 3 (Food Safety Skills for Management)**

Level 1 outlines the basic food safety skills that all staff should demonstrate within the first month of employment while Level 2 outlines additional food safety skills that staff should be able to demonstrate within 3 to 12 months of commencing employment.

Level 3 outlines the food safety skills that managers and supervisors in food operations should demonstrate.

Food businesses can use the training guides to design and develop their own training programmes/in-house course for their food business. The food safety skills outlined in the guides provide the content that needs to be covered in a food safety training course. Additionally, these guides contain relevant information, checklists and records that can help businesses meet their legal requirements for food safety training.

## Q. How can employers help make training work for their food business?

Trainees should be given assistance to help them successfully implement food safety training in the workplace. It is only when the employee implements and demonstrates the knowledge and skills that an employer can be confident that the food being produced in their premises is being handled hygienically. The FSAI recommend that food handlers are encouraged and assisted to implement the information that they have learnt during a training session in the workplace.

## Q. Does the FSAI deliver any food safety training?

The FSAI delivers two training courses that have been designed to meet specific identified training needs for the food industry.

### 3 hour induction training programme 'Food Safety and You'

"Food Safety and You" is based on the skills outlined in the Guide to Food Safety - Level 1 - Induction Skills. The target group for this programme is **all employees** at induction level in all sectors of the food industry. The induction training programme takes 3 hours to deliver and has been designed to promote active learning and the application of training in the work environment. To formalise this, each employee completes a training application plan with the assistance of their manager or supervisor after the 3 hour training session. There are a variety of training aids to assist the trainer deliver training, in order to make it interesting, interactive and fun.

The induction training programme is available to managers/supervisors/trainers who want to train their staff and who have

- sufficient food safety knowledge to deliver induction food safety training
- experience in a management/training/supervisory role.

To avail of the training programme trainers/managers are required to complete the FSAI's two day Further Education and Training Awards Council (FETAC) certified **Food Safety Training Skills Workshop**.

### 'Training for Management in the Chinese Food Sector'

This programme has been developed specifically for management (owner/manager/head chef) in the Chinese food sector. The programme is delivered by Chinese nationals in Mandarin or Cantonese and has been designed to promote the application of training in the work environment.

Individuals who would like to avail of either of the above training courses must complete the relevant application forms which are available from the FSAI Training Compliance section.



## Q. What other resources are available from the FSAI to assist businesses meet their training requirements?

The FSAI has compiled a database of 'Food Safety Training Materials in Foreign Languages' which is available on the FSAI website at [www.fsai.ie](http://www.fsai.ie). This database provides information on food safety training materials, including publications, videos, posters, translation services and useful website addresses. The database gives a brief description of the item, the language(s) in which it is available and where it is available from.

There are also a number of other publications available to the food industry that will assist them to meet their training needs. A full list of publications is available on the FSAI website [www.fsai.ie/publications/index.asp](http://www.fsai.ie/publications/index.asp).

If you have any queries on training please contact the FSAI advice-line on 1850 33 66 77 or by e-mail: [info@fsai.ie](mailto:info@fsai.ie) or contact the Training Compliance section on 01-8171348 or by e-mail: [training@fsai.ie](mailto:training@fsai.ie).

# national peho meeting

The first of this year's National meetings of principal environmental health officers (PEHOs) and FSAI took place in April in Naas. Topics discussed included overviews of the new nutrition and health claims legislation as well as contaminants legislation. FSAI provided updates on the National control plan, audits, data management and

information services. The meeting was attended by 24 of the PEHOs from the Health Service Executive (pictured below). The group wished a fond farewell to Frank Menton and Gerry Heraghty who are due to retire this summer.



Front Row (l-r): Declan Hamilton, Jackie Kelly, Catherine Foye, Brendan Lawlor, Catherine Cosgrove, Frank Menton, Tony Christie, Ann-Marie Part, Tom Prendergast.  
Back Row (l-r): John Moynihan, Richard Fitzgerald, Frank Gleeson, Annette Fitzgerald, David O'Brien, Rita O'Grady, Brian McKeever, Declan Mulhare, Mari Greene, Sean Nagle, Mary Keane, Noel Donnelly, Al Donnelly, Cathal Kearney, Matt Grogan.

## fao/who guidelines on preparing powdered infant formula

One of the Authority's corporate goals is to participate in and influence the development of national, European and global food safety policy and standards. Collaboration with international agencies, such as the World Health Organization (WHO) and the Food and Agriculture Organization (FAO), is one way in which the Authority has achieved this goal. Recently, through successful collaboration, we have jointly completed new guidelines for the safe preparation, storage and handling of powdered infant formula (PIF).

PIF is not a sterile product and can contain harmful bacteria such as *Enterobacter sakazakii*. Inappropriate preparation and storage practices can exacerbate the problem. These guidelines provide advice on the safe preparation of PIF both in health care and home settings. The guidelines are risk-based and were developed on the basis of the outcome of the WHO/FAO risk assessment of *E. sakazakii* in PIF and in response to a request from the World Health Assembly (WHA resolution WHA/58.32).

In addition to the guidelines, easy-to-follow booklets and a poster for preparation in the home and in care settings were also produced. The new guidelines, booklets and poster were recently launched at the 60th World Health Assembly, in Geneva. The Guidelines are available in six languages from the WHO website at: <http://www.who.int/foodsafety/publications/micro/pif2007/en>

Pictured at the 60th World Health Assembly in Geneva where the guidelines were launched are Dr Jenny Bishop (WHO) and Dr Judith O'Connor (FSAI).





# survey on the marketing, advertising and distribution of infant formulae and follow-on formulae

A survey on the marketing, advertising and distribution of infant formulae and follow-on formulae was undertaken to determine compliance of the marketing of breast milk substitutes with the current Regulations, in particular with the legal requirements regarding:

- advertising
- the provision of information to health professionals
- the provision of information to mothers/mothers-to-be
- marketing practices.

During the course of the survey, 21 maternity units and three children's hospitals were visited. Key staff were interviewed by questionnaire regarding the interaction between the infant formulae manufacturing industry and hospitals. In addition, advertisements placed in specialist publications and women's magazines were

reviewed; the display of infant formulae and follow-on formulae in retail shops was examined and the websites of infant formulae manufacturers were checked for compliance.

The legal basis for this survey was the Commission Directive 91/321/EEC on Infant Formulae and Follow-on Formulae (as amended). This Directive is transposed into Irish legislation by the European Communities (Infant Formulae and Follow-on Formulae) Regulations, 2004 (S.I. No. 242 of 2004).

The results of the survey show differences in the level of compliance between the different areas of marketing, advertising and distribution of infant formula and follow-on formula. The level of compliance was generally good in hospitals, in retail shops and in women's magazines. On the other hand, the level of compliance was quite poor

in advertisements placed in specialist publications and in leaflets aimed at health professionals.

The survey also highlighted difficulties in assessing some aspects of the Regulations due to their subjective nature.

As a result of the survey, it is recommended that manufacturers amend some of their information leaflets, advertisements in specialist publications and websites, and only provide health care professionals with information on request (as required by the Regulations). In addition, a recommendation is made on the further investigation of consumers' knowledge regarding the difference between infant formulae and follow-on formulae.

Copies of the survey report can be downloaded from the FSAI website, [www.fsai.ie](http://www.fsai.ie), or by calling our advice-line on 1890 33 66 77.

## diet and health: an international challenge all-island conference

A recent conference, jointly sponsored by the Food Safety Authority of Ireland (FSAI), the Food Standards Agency Northern Ireland (FSANI) and the all-island agency *safefood* heard of the latest developments on key nutrition topics including obesity, nutritional deficiency, salt intake, fortification and food poverty. In addition, case studies presented show the importance of all-island partnerships in changing dietary habits.

Professor Albert Flynn, University College, Cork, called for a co-ordinated approach at EU level to tackle the obesity issue in a paper entitled 'Nutrition from an International Perspective'. While efforts are being made on a national level to beat obesity, Ireland is still shaped by European policy and greater changes will only occur if Member States co-operate and tackle the problem together. Ireland ranks in the middle on obesity levels in relation to other European countries. While physical activity levels have declined, people haven't changed their eating habits to accommodate this.

*At the recent diet and health conference were (l-r): John O'Brien, FSAI; Martin Higgins, safefood; Dame Deirdre Hutton, Food Standards Agency; Morris McAllister, Food Standards Agency, Northern Ireland.*







# fsai report on vitamin D deficiency in ireland

Further to the article in the last issue, the working group on Vitamin D supplementation for infants in Ireland has published their report entitled *'Recommendations for a national policy on vitamin D supplementation for infants in Ireland'*.

The report recommends the implementation of a national policy of vitamin D supplementation among infants aged 0-12 months in Ireland. This recommendation follows a review undertaken by the FSAI's Scientific Committee which highlights the re-emergence of rickets in infants in Ireland. The report identifies poor vitamin D status amongst infants, adults, adolescent girls and pregnant women living in Ireland.

The report recommends vitamin D supplementation during infancy to ensure healthy bone development and to prevent rickets. This is particularly important for dark skinned infants who are at the highest risk of vitamin D deficiency. According to the report, as many as 23 cases of rickets were reported in recent years at two Dublin-based paediatric hospitals. As rickets is the most extreme consequence of vitamin D deficiency, the FSAI expects the incidence of vitamin D deficiency in Ireland is underestimated.

The report examines recent studies which show that most people in Ireland are not eating enough of the foods naturally rich in vitamin D or of foods fortified with the vitamin. Low intakes of vitamin D are prevalent among all age groups throughout Ireland and that the recommended daily intake of 5µg of vitamin D per day is not being met. Babies are most susceptible to developing the bone deformities associated with rickets because of the rapid growth and development that occurs during the first year of life and the likelihood of having insufficient stores of vitamin D to meet their needs. It is therefore necessary to adopt a clear, simple and safe recommendation. The group concludes that all infants aged 0-12 months living in Ireland would benefit from vitamin D supplementation. The Scientific Committee suggests that strategies should also be put in place to increase vitamin D intake in different age groups of the population in Ireland.

The only currently available supplement for infants in Ireland, Abidec, also contains vitamin A, which when combined with infant formula, exceeds the safe upper limit of vitamin A. The report therefore recommends that before a national vitamin D supplementation policy can commence in Ireland, a new supplement containing only

vitamin D needs to be available for all Irish infants aged 0-12 months. The report recommends that all partially and exclusively breastfed infants should be supplemented with 0.3ml of Abidec per day (providing 5µg of vitamin D).

The deficiency in infants is caused by low Vitamin D status in mothers, no Vitamin D from sunlight in Ireland between October and March, the lack of Vitamin D rich foods in a normal Irish diet and the need to protect skin from sunlight to prevent skin cancer.

Therefore, the report concludes, as an interim measure, until a new vitamin D supplement is made available, that all breastfed and partially breastfed infants (excluding those who are fed in excess of 500ml of formula per day) should be supplemented with 0.3ml of Abidec daily. Until a supplement providing exclusively Vitamin D is made available, all infants regardless of how they are fed should be supplemented from birth to 12 months. The FSAI believe that breastfeeding combined with Vitamin D supplementation provides the optimum nutritional profile for infants.

Copies of the survey report can be downloaded from the FSAI website, [www.fsai.ie](http://www.fsai.ie), or by calling our advice-line on 1890 33 66 77.

## hygiene package training for laboratories

The FSAI provided a one day hygiene package workshop for staff from the official food microbiology laboratories (OFML) and public analyst laboratories (PAL) in April. This workshop aimed to provide an overview of Regulations 178/2002; 2073/2005; 882/2004; Regulation 852/2004 and Regulation 853/2004 as relevant to OFML and PAL staff.

The presentations were supported by interactive exercises which focused on the hygiene package legislation requirements and microbiological criteria. Feedback was extremely positive and attendees welcomed the interactive sessions which provided opportunity to raise and discuss issues. Pictured below are attendees discussing a training exercise.





## mailing list

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## visitors to the fsai



*Pictured outside the offices of the FSAI are (l-r): Mr. G Mohan Kumar; Mr. Elias Sait; Mr. Lars Herborg, EC Consultant; Ms Shashi Sareen; Mr. K S Money; Mr. Vijay Kumar and Ms. Bharathi S. Sihag.*

The European Commission under its Trade Investment and Development Programme (TIDP) is implementing a number of projects in India in relation to food control systems, laboratories, accreditation systems and related areas. The Export Inspection Council of India (EIC) is a main beneficiary of these. In April, a number of senior officials from EIC and other organisations came to Ireland as part of their study tour, to understand and get an insight on various systems being implemented by different EU countries. Accompanied by their EC Consultant, Mr. Lars Herborg, they visited the Food and Veterinary Office of the European Commission, food processing plants as well as the FSAI.

## recent publications

The following publications have recently been produced by the FSAI:

- Guidance Note No. 22: *Information Relevant to the Development of Guidance Material for the Safe Feeding of Reconstituted Powdered Infant Formula*
- Report - *Survey on the Marketing, Advertising and Distribution of Infant Formulae and Follow-on Formulae*

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

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