January 2012

Dea Sir / Madam,

Chemical Safety Update (January 2012)

Before introducing our January 2012 update, I would like to take this opportunity to introduce myself as the new Head of the Agency's Chemical Safety Division and to provide you with some information on the division's work and structure which I hope you will find useful.

The division comprises a mixture of policy and scientific staff supported by a small number of staff providing regulatory, financial and administrative support.

The division is responsible for policy, risk assessment and risk management of chemical safety issues in relation to food, including natural, environmental and process contaminants, radiological safety, food additives, GM and novel foods and food allergens. The division also manages a programme of scientific research projects in these areas and provides the secretariats for two independent scientific advisory committees; the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) and the Advisory Committee on Novel Foods and Processes (ACNFP).

The division's work is broken down into the following areas:

- Chemical Risk Assessment and Exposure Assessment (including COT Secretariat)
- Emerging Risks
- Radiological Safety
- Novel Foods (including Genetically Modified Foods, Nanotechnology and ACNFP Secretariat)
- Food Allergens
- Environmental and Process Contaminants
- Food Additives

- Regulation and Business Support

There is an organogram on the following page which provides a top level overview of the division's structure which I hope you will find helpful.

Turning to the December 2011 update, this will provide you with information on key developments in the work areas detailed above, with the exception of food additives where developments merit the issue of a dedicated letter to relevant stakeholders on this occasion which has been issued.

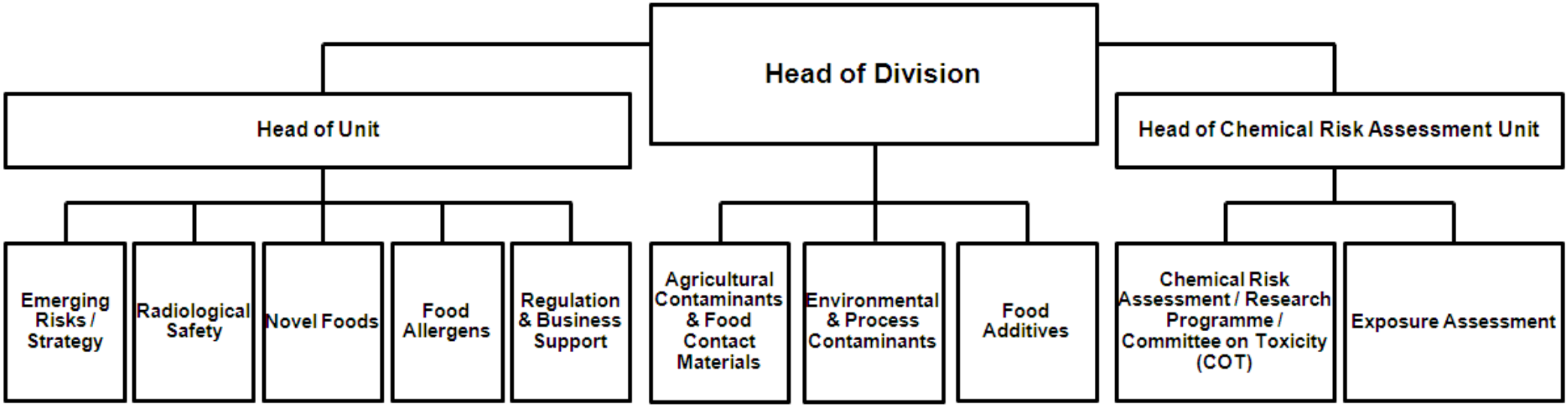
Directly after the organogram, there is a table that summarises the items covered in this update by subject area. Clicking on the associated links will take you directly to the relevant material.

I hope you find the update helpful and informative.

Yours faithfully,

Michael Wight
Head of Chemical Safety Division

Chemical Safety Division



CHEMICAL SAFETY UPDATE: NOVEMBER 2011

SUMMARY OF NEWS ITEMS

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Materials and Articles in Contact with Food	• The Materials and Articles in Contact with Food England Regulations 2012	
Environmental Contaminants (Inorganic) **Process Contaminants**	• EU Commission proposed revisions to Cadmium limits • Mercury • Lead • Arsenic • Cadmium in brown crab meat • Acrylamide • Acrylamide and Furan Survey	
Environmental Contaminants (Organic)	• Dioxins and PCBs • Dioxins in sheep liver • Brominated flame retardants (BFRs) • Polycyclic Aromatic Hydrocarbons • Marine Strategy Framework Directive (MSFD) • Summary of calls for data	
Mycotoxins and Plant Toxins	**EU** • Approval of pre-export controls for OTA in Canadian wheat **EFSA Developments** • Opinion on alternaria toxins in food and feed • Opinion on opium alkaloids in poppy seeds • Opinion on pyrrolizidine alkaloids in food and feed • Continuous call for data	http://www.efsa.europa.eu/en/efsajournal/pub/2407.htm http://www.efsa.europa.eu/en/efsajournal/pub/2405.htm http://www.efsa.europa.eu/en/efsajournal/pub/2406.htm www.efsa.europa.eu/en/data/call/datex101217.htm http://www.food.gov.uk/science/research/contaminantsresearch/mycotoxins/mycotoxinsresearch/c03044/

	FSA Research News • C03044: The analysis of urine samples for biomarkers of exposure to Fusarium toxins **FSA Survey News (Food Survey)**	http://www.food.gov.uk/multimedia/pdfs/fsis0211.pdf
Nitrate	• New EU Regulation on nitrate in green leafy vegetables	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:320:0015:0017:EN:PDF
Food Allergy and Food Intolerance	• Food Information for Consumers Regulation • Rules on claims on foods for people with gluten intolerance • Allergen management thresholds • The Agency's food allergen and food intolerance research programme	
Emerging Risks	• Emerging Risks Programme	
Novel Foods	• European Court of Justice opinion on GM pollen in honey • Evaluation of GM food and feed legislation • Consumer research on GM labelling • Alternative protein sources • New EU regulation on novel foods • Animal Cloning • Intelligence gathering on nanotechnology in food production • EU definition of "nanomaterial" • Labelling of "engineered nanomaterials" in food • ACNFP meeting (24 November 2011)	

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Materials and Articles in Contact with Food

The Materials and Articles in Contact with Food England Regulations 2012

The proposed Materials and Articles in Contact with Food (England) Regulations 2012 will provide for the execution and enforcement, in England, of European Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food. The Regulations also revoke and re-enact nearly all food contact materials legislation within the Food Standards Agency's remit (with the exception of The Plastic Kitchenware (Conditions on Imports from China) England Regulations 2011)), into a single consolidated Statutory Instrument.

The Regulations will:

- Designate competent authorities for the purpose of the Regulation;
- Provide for offences of contravening certain provisions of the PIM Regulation and for defences against prosecution for committing an offence in particular circumstances; and
- Specify the penalties that the Courts may impose upon conviction for an offence.

The proposed Regulations will also revoke and re-enact all existing national legislation within the Food Standards Agency's (FSA) remit on materials and articles intended to come into contact with food, with necessary amendments; thus implementing or enforcing all EU food contact materials legislation in one consolidated instrument (with the exception of The Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011[1]). This is part of the FSA's intention to introduce a simplified system of food safety legislation in response to the Westminster Government's Red Tape Challenge initiative.

There are currently three separate principal SIs (and one amending SI) which contain the rules on food contact materials, which can be difficult for those that need to cross-refer to their various provisions; having all the rules in one SI will benefit stakeholders and make it more convenient for businesses and others that have to refer to the Regulations and obviate the need for cross-referencing between different sets of national Regulations – which is currently the case.

The national Regulation being revoked are:

- The Plastic Materials and Articles in Contact with Food (England) Regulations 2009[2]
- The Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011[3]
- The Materials and Articles in Contact with Food (England) Regulations 2010[4];
- The Ceramic Articles in Contact with Food (England) Regulations 2006[5], which implement the provisions of Council Directive 84/500/EEC[6], as amended by Commission Directive 2005/31/EC[7]

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[1] SI 2011 No. 1527
[2] SI 2009 No. 205
[3] SI 2011 No. 231
[4] SI 2010 No. 2225
[5] SI 2006 No. 1179
[6] Council Directive 84/500/EEC on the approximation of laws of the Member States relating to Ceramic articles intended to come into contact with foodstuffs

The Consultation on the proposed Regulations will be launched in the first week of January 2012 for a period of 12 weeks.

Environmental Contaminants (Inorganic)

EU Commission proposed revisions to Cadmium limits

The EU proposal on Cadmium limits across a range of food commodities was discussed at the Commission Expert Committee on the 10th October 2011. The Commission attempted to continue these discussions at the Standing Committee meeting on the 23rd November. Some member states including the UK pointed out that it was not appropriate to have technical discussions at a Standing Committee, so discussions will be ongoing at the next Expert Committee meeting in the New Year. Ahead of the Standing Committee meeting the Commission circulated its latest draft of the proposal can be found at:

http://www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/contaminantsnov2011

Please note that this is a working document circulated to member states to aid discussions and not a formal proposal from the Commission. The UK was surprised to note that the new proposal lists **reductions in the offal categories** which had not previously been included and for which stakeholders have not yet been consulted; therefore we are particularly keen to have feedback on these.
The UK is keen that any changes to the current limits should be proportionate, achievable and justifiable. The UK expects the Commission to propose suitable transitional periods for any new limits.

Mercury

EFSA have been requested by the Commission for an updated opinion on inorganic mercury/ methyl mercury in all food commodities. The Joint WHO/FAO Committee on Food Additives (JECFA) established a new provisional total weekly intake (PTWI) of 4µg/kg b.w. for inorganic mercury. The PTWI for methyl mercury remained unchanged at 1.6µg/kg b.w). EFSA published a call for occurrence data for inorganic and methyl mercury with a deadline of 1st October 2011 to which the UK contributed.

Lead

EU Discussions on the review of lead limits are on hold while cadmium is dealt with, but this is expected to progress rapid in the early part of next year, so please be ready for comment on this issue and to provide data if you wish.

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[7] Commission Directive 2005/31/EC amending Council Directive 84/500/EEC, as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs.

Lead Ammunition Group (LAG)

The Lead Ammunition Group (LAG) was set up in the UK to advise the Agency on the use of lead ammunition, in response to the issue of lead in game meat and whether or not this poses a risk to human health. The Agency awaits the advice of the group.

Arsenic

Preliminary discussions on limits for EU maximum limits for arsenic in food will probably begin early in 2012. If you are able to provide useful data for arsenic in any products (particularly cereal products, seaweed and vegetables) that may help inform future discussions on limits, please do so as soon as possible.

Cadmium in brown crab meat

Levels of cadmium in brown crab meat vary but can often be higher than those in the white meat as the brown meat includes the crab's internal organs which can accumulate contaminants.

The EU Commission has produced an information note on cadmium in brown crab meat, with the expectation that individual Member States will produce bespoke consumption advice relevant to their consumers. There are no plans to try to set a limit for cadmium in brown crab meat or to prohibit its sale.

In May 2011 the Agency requested data from the industry on cadmium levels in brown crab meat. Unfortunately, the information provided was not sufficient on which to base consumption advice. Consumption advice based on this data might have been overly conservative, as we cannot be sure that the high values measured are 'outliers' and not representative of cadmium levels in brown crab meat on sale in the UK.

In order to ensure that consumption advice is representative and proportionate, the Agency is planning to carry out a survey of the levels of cadmium in brown crab meat on sale in the UK.

Process Contaminants

Acrylamide

At the Commission Expert Committee working group meeting in October member states were invited to provide feedback on the ongoing investigations. Most member states reported that investigations were ongoing as planned. One early piece of feedback was that it seemed there may be an issue relating to SMEs awareness of the 'toolbox'. Member states agreed that there is no need to consider Measurement Uncertainty for investigations of exceedance as the indicative values are not maximum limits and the purpose of investigations is to obtain useful data, it is not enforcement activity.

Acrylamide and Furan survey

The Agency's latest acrylamide and furan survey got underway this November. The results of last year's survey will be published shortly in a food survey information sheet by the Agency.

Environmental Contaminants (Organic)

Discussions from the Expert Committee on Persistent Organic Pollutants, 19 July and 13 September 2011.

Dioxins and PCBs

The revised limits for dioxins and dioxin-like PCBs and the new limits for non dioxin-like PCBs were approved at Standing Committee on 4 July 2011. They were published on 3 December as Commission Regulation 1259/2011. The finalised values are unchanged from those set out in the previous bulletin (May 2011).

FOODSTUFFS		MAXIMUM LEVELS		
		Dioxins (WHO-PCDD/F-TEQ)	**Sum of dioxins and dioxin-like PCBs (WHO-PCDD/F-PCB-TEQ)**	**Sum of PCBs 28, 52, 101, 138, 153 and 180 (ICES–6)**
5.1	Meat and meat products (excluding edible offal) of the following animals: - bovine animals and sheep - poultry - pigs	 2.5 pg/g fat 1.75 pg/g fat 1.0 pg/g fat	 4.0 pg/g fat 3.0 pg/g fat 1.25 pg/g fat	 40 ng/g fat 40 ng/g fat 40ng/g fat
5.2	Liver of terrestrial animals referred to in 5.1. with the exception of sheep, and derived products thereof.	4.5 pg/g fat	10.0 pg/g fat	40ng/g fat
5.3	Muscle meat of fish and fishery products and products thereof, with the exemption of - wild caught eel - wild caught fresh water fish, with the exception of diadromous fish species caught in fresh water - wild caught char originating in the Baltic region - wild caught river lamprey originating in the Baltic region - wild caught trout originating in the Baltic region - fish liver and derived products - marine oils	3.5 pg/g wet weight	6.5 pg/g wet weight	75 ng/g wet weight

	The maximum level for crustaceans applies to muscle meat from appendages and abdomen. In case of crabs and crab-like crustaceans (*Brachyura and Anomura*) it applies to muscle meat from appendages.			
5.4	Muscle meat of wild caught fresh water fish, with the exception of diadromous fish species caught in fresh water, and products thereof.	3.5 pg/g wet weight	6.5 pg/g wet weight	125 ng/g wet weight
5.5	Muscle meat of wild caught eel (*Anguilla anguilla)* and products thereof.	3.5 pg/g wet weight	10.0 pg/g wet weight	300 ng/g wet weight
5.6	Fish liver and derived products thereof with the exception of marine oils referred to in point 5.7	--	20.0 pg/g wet weight	200 ng/g wet weight
5.7	Marine oils (fish body oil, fish liver oil and oils of other marine organisms intended for human consumption).	1.75 pg/g fat	6.0 pg/g fat	200 ng/g fat
5.8	Raw milk and dairy products, including butter fat.	2.5 pg/g fat	5.5 pg/g fat	40 ng/g fat
5.9	Hen eggs and egg products.	2.5 pg/g fat	5.0 pg/g fat	40 ng/g fat
5.10	Fat of the following animals: - bovine animals and sheep - poultry - pigs	 2.5 pg/g fat 1.75 pg/g fat 1.0 pg/g fat	 4.0 pg/g fat 3.0 pg/g fat 1.25 pg/g fat	 40 ng/g fat 40 ng/g fat 40 ng/g fat
5.11	Mixed animal fats	1.5 pg/g fat	2.50 pg/g fat	40 ng/g fat
5.12	Vegetable oils and fats	0.75 pg/g fat	1.25 pg/g fat	40 ng/g fat
5.13	Foods for infants and young children.	0.1 pg/g wet weight	0.2 pg/g wet weight	1.0 ng/g wet weight

Action Levels previously set out in Commission Recommendation 2006/88 have been revised, largely as a consequence of the changes to TEFs. The changes were endorsed at the 4 July Standing Committee and the new Action Levels are set out in Commission Recommendation 2011/516.

It is important to understand that, although new limits are being introduced for the non dioxin-like PCBs, analysis of which can be considerably less expensive than analysis for dioxins and dioxin-like PCBs, the former must not be used as a surrogate for the latter. Not only can they arise from unrelated sources but the less expensive PCB analysis may lack the necessary sensitivity.

Dioxins in sheep liver

EFSA published its opinion ‘on the risk to public health related to the presence of high levels of dioxins and dioxin-like PCBs in liver from sheep and deer’ on the morning of the 19 July POPs Working Group. The opinion can be found at:

www.efsa.europa.eu/en/efsajournal/doc/2297.pdf.

The CONTAM Panel concluded that the frequent consumption of sheep liver, particularly by women of child-bearing age and children, may be a potential health concern. Nevertheless, in general there was low concern and consensus has now been reached that the limit for

sheep liver should be relaxed, although the actual level and basis have yet to be agreed. The Commission has indicated that it expects the matter to be resolved within months.

Brominated flame retardants (BFRs)

EFSA published several opinions on BFRs during the summer. In the case of polybrominated biphenyls (PBBs) it found that levels were very low and, in view of the fact that manufacture and use were phased out several decades ago, PBBs are of no further interest. For polybrominated diphenyl ethers (PBDEs), in general there were no concerns but a possible adverse neurodevelopmental effect in young children was linked to BDE 99. EFSA noted that, although PBDE production and use have being phased out, many products containing PBDEs are still in use and concluded that there was a need for further data on occurrence as well as toxicology and epidemiology. Similarly, although no health concerns were identified for hexabromocyclododecanes (HBCDDs), as production and use are continuing, EFSA recommended that data collection should continue, particularly for levels in food for infants and toddlers. The three EFSA opinions can be found at:

PBBs – www.efsa.europa.eu/de/scdocs/doc/1789.pdf

PBDEs – www.efsa.europa.eu/en/efsajournal/doc/2156.pdf

HBCDDs – www.efsa.europa.eu/en/efsajournal/doc/2296.pdf

Polycyclic Aromatic Hydrocarbons

Commission Regulation 835/2011 amending Commission Regulation 1881/2006 with regard to the limits for PAHs was published in August, together with Regulation 836/2011, which amends the analytical criteria for PAHs. The two new regulations can be found at:

eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:215:0004:0008:EN:PDF.
eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:215:0009:0016:EN:PDF

Among the recitals in 835/2011, the Commission has mentioned the foods for which further data is of particular interest: cocoa beans and derived products, coconut oil, vegetables, cereals and food supplements. Although not referred to explicitly in the recitals, reports of high levels of PAHs in herbs and spices also continue to be of concern.

Marine Strategy Framework Directive (MSFD)

The Marine Strategy Framework Directive (Directive 2008/56/EC, published in June 2008) is a European initiative intended to facilitate cooperation between Member States to improve the quality of the marine environment around Europe by 2020. Strategy, progress and targets will be based around a series of descriptors of 'Good Environmental Status' (GES). These descriptors, 11 in all, cover a broad range of parameters including biodiversity, levels of fish stocks, litter and noise. Two descriptors are associated with chemical contamination – Descriptor 8, which relates to pollution in general, and Descriptor 9, which relates directly to fish and other seafood for human consumption. One consequence of the latter is that there is likely to be a greater emphasis on linking chemical contaminant levels in fisheries products to specific marine sub-regions.

UK strategy with regard to the MSFD is being prepared by a Defra-led Steering Group comprising members with relevant expertise from various government departments and agencies as well as the Devolved Administrations. FSA is represented on the Steering Group for its particular expertise in relation to Descriptor 9.

Defra intends to put the proposed UK approach out to formal consultation in February/March 2012. Stakeholders, particularly those with an interest in fish and fisheries products, are strongly encouraged to participate in the consultation process.

Summary of calls for data

- PAHs in cocoa beans and derived products, coconut oil, cereals and cereal products, vegetables and vegetable products and marine and plant-based supplements.
- Dioxins and PCBs in all currently-regulated food groups, particularly ovine and bovine liver and pig meat.
- Non-dioxin like PCBs.
- Polybrominated diphenyl ethers (PBDEs) and hexabromocyclododecanes (HBCDDs) in all foods
- PFOS and related compounds in any foods (outstanding from previous bulletins)

Mycotoxins and Plant Toxins

European Union

The Standing Committee on the Food Chain and Animal Health (SCoFCAH) approved the Canadian application for pre-export checks with regards to OTA in wheat (common and durum) and certain derived products (flour). The pre-export agreement will be similar to the relevant controls for aflatoxins in peanuts from USA as described in Commission Decision 2008/47/EC.

EFSA developments

The European Commission requested the European Food Safety Authority (EFSA) to assess the risk of certain contaminants to public health. In response, EFSA recently published scientific opinions on:

- **Risks to animal and public health related to the presence of Alternaria toxins in feed and food**

Alternaria toxins are produced by the fungal species *Alternaria* which cause plant diseases. The plants mainly infected are wheat, sorghum and barley. Infection has also been reported in oilseeds (e.g. sunflower and rapeseed), tomato, apples, citrus fruits, olives and several other fruits and vegetables. More than 70 alternaria toxins are known, some of which can have harmful health effects in animals, including fetotoxic and teratogenic effects.
The EFSA contaminants panel decided to perform a limited dietary exposure assessment focusing on adults (≥18 to ≤65 years old) due to limited availability of occurrence data. The adults' exposure assessment was estimated for a limited number of alternaria toxins and it should be regarded as indicative only.

EFSA established a Threshold of Toxicological Concern (TTC) of 2.5 ng/kg b.w. for the genotoxic alternaria toxins AOH and AME. The estimated chronic dietary exposure to those toxins exceeded the TTC, indicating a need for additional compound-specific toxicity data.

A TTC of 1500 ng/kg b.w. was established for the non-genotoxic TeA and TEN. The estimated dietary exposures to those toxins were lower than the TTC value and were considered unlikely to be a human health concern.

- **Risks to public health related to the presence of opium alkaloids in poppy seeds**

Poppy seeds, obtained from the opium poppy, are used as an ingredient in bakery products, cakes and desserts as well as for decoration on dishes or as condiment. The seeds can become contaminated with opium alkaloids, naturally present in the plant, during harvest or due to insect damage. The principal opium alkaloids are morphine, codeine, thebaine, papaverine and noscarpine. Consumption of foods containing poppy seeds that are contaminated with opium alkaloids can lead to adverse health effects.

Morphine is the predominant alkaloid in poppy seeds and EFSA based its exposure assessments on the occurrence and intake values for this toxin. An acute reference dose (ARfD) of 10µg/kg morphine/kg body weight was established for which a person consuming poppy seed-containing foods would not be expected to experience effects following consumption of one meal or total consumption within a day. This is valid for adults and children.

EFSA concluded that if poppy seeds are consumed as condiments or decoration on bread and fine bakery wares, it is possible that some consumers, particularly toddlers, will exceed the ARfD for morphine on rare occasions (based on consumption data from high consuming countries such as Germany).

However, EFSA noted that the uncertainties involved in this risk assessment were significant and more information is required, including information on consumption of poppy seeds and variance of poppy seeds available on the market.

Finally, it was concluded that food processing can reduce morphine in poppy seeds by up to 90%, thus reducing the exposure considerably.

- **Pyrrolizidine alkaloids (PAs) in food and feed**

PAs are toxins produced by plants as a defence against herbivores. They can contaminate cereal crops, legumes, herbal teas, food supplements, honey and animal derived products such as milk and eggs.

EFSA assessed the risk of exposure to PAs through consumption of retail and bulk honey, as occurrence data was only submitted for these products. EFSA concluded that 1,2-unsaturated PAs are genotoxic and carcinogenic in animals and although no epidemiological studies were available, EFSA considered those PAs as human carcinogens as well. Based on a Margin of Exposure (MOE) approach, a health concern for toddlers and children who are high consumers of honey was identified. Additionally, high consumers of locally produced honey might be at risk although lack of adequate data prevented a full risk assessment.

The $BMDL_{10}$ (benchmark dose lower confidence limit) of 70 µg/kg b.w. per day was calculated using one of the most toxic PAs (lasiocarpine) as the reference point for the MOE calculation. It should be noted that lasiocarpine was not found in honey.

Overall, the data on PA occurrence in feed were too limited to undertake a reliable estimate of the animal exposure.

The impact of the uncertainties on the risk assessment of human and animal exposure through consumption of food and feed was considered substantial and further information is required, especially on exposure through sources other than honey.

EFSA continuous data collection

As previously communicated by the Agency, EFSA issued a call for data on certain contaminants in food and feed, on a continuous basis, after a relevant request by the European Commission. The current call for data includes mycotoxins, process contaminants, organic and inorganic contaminants. The deadline for transmitting data is 1 October each year

The call can be found at: www.efsa.europa.eu/en/data/call/datex101217.htm

FSA research news

The final report of the project code C03044 - The analysis of urine samples for biomarkers of exposure to Fusarium mycotoxins – has been published. The project aimed to investigate whether urinary deoxynivalenol (DON) can be used as a biomarker to assess consumers' exposure to DON. The results indicated that urinary DON is correlated to DON intake (via consumption of contaminated food products) and hence can be used as a biomarker of exposure. Using estimated DON intakes and the estimated DON transfer to urine, 2/300 individuals in the UK were predicted to exceed the Tolerable Daily Intake (TDI) for DON. It should be noted that this figure was derived from a small stratified sample based on cereal consumption.

The project report can be found at:
www.foodbase.org.uk/results.php?f_category_id=&f_report_id=724

FSA Survey news

The Food Survey Information Sheet (FSIS) on the results of the second year of the 4 year mycotoxins survey has been published. The survey looked at mycotoxins in foods for infants and young children, ergot alkaloids in cereal products and patulin in apple juice.

Link: http://www.food.gov.uk/multimedia/pdfs/fsis0211.pdf

Nitrate

A new EU Regulation on changes to rules and maximum levels for nitrate in green leafy vegetables has now been published and applied from 23 December 2011. Further details can be found on the Agency's website at
http://www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/nitratesept11.
The new Regulation can be found via the following link:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:320:0015:0017:EN:PDF.

Food Allergy and Food Intolerance

Food Information for Consumers Regulation

The European Council of Ministers has now formally agreed the EU Regulation for provision of food information to consumers. This regulation, which brings together general food

labelling and nutrition requirements into one European-wide piece of legislation, is expected to be published before the end of 2011. There will be a transition period or 3 or 5 years before businesses need to meet the new requirements. The main points are:

- Country of origin – subject to further discussion, the introduction of mandatory origin information for most fresh and frozen meat. Also, the origin of main ingredients will have to be given if different from where the final product is made.
- Nutrition labelling will be required for most foods. Simplified information may be provided voluntarily on front of pack.
- Labelling clarity – a minimum font size has been set for all mandatory information on labels.
- Allergen information will have to be provided on all food (whether prepacked or loose). Allergens will have to be highlighted on the ingredient list for prepacked foods.
- Drinks with high caffeine content will have to be additionally labelled as not recommended for children or pregnant and breastfeeding women, with the actual caffeine content quoted.
- Meat and fish products that look like a cut, joint or slice and contain more than 5% added water will have to show this in the name of the food.
- The types of vegetable oil used in food, such as palm oil, must be stated.

In addition to the need to highlight allergenic foods in the ingredients lists on pre-packed foods, there is the new requirement to provide allergy information for sold non-prepacked, covering sandwich bars, bakeries, deli counters, cafes and restaurants, etc. Individual Member States will be putting national measures in place to help food businesses meet these new requirements.

Rules on claims on foods for people with gluten intolerance

New legislation on the compositional and labelling standards for foods claiming to be either 'gluten-free' or 'very low gluten' (Commission Regulation (EC) No. 41/2009) will come into force on 1st January 2012. These levels are:

- 'gluten-free': at 20 parts per million of gluten or less
- 'very low gluten': at 100 parts per million of gluten or less - however, only foods with cereal ingredients that have been specially processed to reduce the level of gluten may make a 'very low gluten' claim.

These regulations apply to all foods, pre-packed or sold loose, such as in health food stores or in catering establishments. Foods not complying with these new rules will become illegal and will need to be taken off the market after that date. The new labelling standards are an important public health measure to help protect the long term health of coeliacs, enabling them to make informed choices about the foods that are safe for them to eat. Where caterers are unable to justify 'gluten-free' or 'very low gluten' claims because of the risk of cross-contamination, they will be able to indicate which foods do not have gluten-containing ingredients, if steps have been taken to control this contamination. This will allow coeliacs to make choices based on their individual levels of sensitivity. More information can be found at:

www.food.gov.uk/safereating/allergyintol/label/gluten/

Allergen management thresholds

There is a growing need for the determination of allergen thresholds for use in allergen risk assessment and by food businesses when making decisions on whether or not allergen cross contamination advisory labelling (such as 'May Contain X') is needed on food products. A symposium on 'Frontiers in Food Allergen Risk Assessment' that was co-funded by the Food Standards Agency, brought together key representatives in food allergy from across the world to discuss current and emerging data from clinical and analytical studies. International Life Sciences Institute (ILSI) Europe published a report on the symposium which can be found at: www.ilsi.org/Europe/Documents/Food%20Allergy%202011.pdf.

The Agency's food allergen and food intolerance research programme

The Food Intolerance Research Programme aims to investigate the causes and mechanisms underlying food intolerance, including food allergy. The work has in recent years focused on severe food allergy, in particular peanut allergy, and a major aim is to identify risk factors associated with the development of food allergy so that appropriate information can be provided for consumers.

The Food Intolerance research programme was established in 1994 and the current objectives are:

- To identify the risk factors (e.g. genetic, environmental, dietary and other risk factors) associated with the development of sensitisation to food proteins and the development of clinical food allergy, particularly in the early life stages of the individual.
- To investigate the immunological mechanisms of food allergy to understand, at the immunological level, what factors are important in determining/regulating the allergic versus tolerant status.
- To determine the prevalence of food allergy (both total food allergy and the prevalence of allergy to individual foods) in the UK in infants, children and adults, and whether prevalence is changing over time.
- To develop suitable methods for the detection of allergens in food.
- To determine what factors influence the severity of allergic reactions to foods.

For more information see:

www.food.gov.uk/science/research/foodcomponentsresearch/allergyresearch/t07programme/

The Food Information Regulation was published in the EU Official Journal on 22 November 2011 and is available here: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF

Emerging Risks

Emerging Risks (ER) Programme

Through the emerging risks team, the Food Safety Group is developing an intelligence-led, proactive approach to the identification of potential new and re-emerging risks that is capable of identifying patterns and trends in large amounts of food safety information.

This programme of work will support delivery of the FSA 2010-15 strategic plan by addressing the main priority to;-

"increase horizon scanning and improve forensic knowledge and intelligence on, global food chains to identify and reduce the impact of new and re-emerging risks – particularly around chemical contamination".

Much of the work to date has been focused on developing the necessary methodologies and these are now beginning to become operational. For example, the ER team are analysing incident data to establish variance from statistically-derived baseline levels, which has the potential to act as an early warning signal for emerging risks.

The team is also looking to see whether there are indications that the current global economic situation and changes in global food sourcing is impacting on food safety risks and subsequent incident reports that we receive. For example, the ER, Food Fraud and Incidents teams are working together to identify intelligence to help understand why an increase in incidents relating to fraudulent practices has been observed.

Work is being undertaken on **Global food chain analysis**, which involves assessing and mapping the potential risks associated with individual processes used to manufacture food products. The methodologies resulting from this work will enable the FSA to better understand where vulnerabilities may exist within food chains. In addition, by understanding the features and attributes of each chain and what can occur at each stage, any unexpected changes could give early warning of new issues, the elusive "unknown unknowns".

Methods for analysis of the **root causes** of food safety incidents have been developed in collaboration with industry partners. We are working to embed root cause analysis into the FSA's incident response procedures and to roll out the principles across industry and local authority enforcement to enable a far greater understanding of why issues happen and the most effective methods of preventing incidents from occurring. We are also currently developing an eLearning training module to assist industry and local authorities in carrying out root cause analysis.

EFSA Developments

The ER team are members of EFSA's Emerging Risks Exchange Network (EREN), which provides opportunities to exchange intelligence relating to potential emerging risks with Member States across Europe. Exchange of information also includes the identification and sharing of methodologies for the detection of emerging risks.

EFSA has also set up a data collection working group (DACO) to develop systems to evaluate data and information sources. As members of this working group, the team has identified specific methodologies for assessing data sources and has made recommendations that the selection of such sources should include a "gap" analysis to identify data types which are missing or under represented. The FSA is using the principles of this work to assess and map data sources that have been identified in order to identify and rank those that are most relevant to the FSG's emerging risks programme.

Novel Foods

The Novel Foods Unit in the Chemical Safety Division deals with the safety and labelling of genetically modified foods and the regulation and authorisation of novel foods. It also acts

as a co-ordination point within the FSA for issues associated with the use of nanotechnologies in food production. The Unit provides the Secretariat for the Advisory Committee on Novel Foods and Processes (ACNFP), a committee of independent experts who provide advice on all of these topics.

The following list provides brief details of the main issues that the Unit is currently working on. We would be grateful for feedback from readers whether they would find it useful to include details of the work in this area in future editions of this newsletter.

Genetically Modified (GM) Foods

European Court of Justice (ECJ) opinion on GM pollen in honey

The ECJ has recently advised that pollen from GM plants should be regarded as an "ingredient" if it is present in honey. This has imlpications for the labelling of honey in general and for the ability to market honey that contains traces of GM pollen that is not covered by an EU authorisation for food use. The FSA is working with Defra to minimise the potential disruption fo the supply of productrs that are both safe and accurately labelled.

Evaluation of GM food and feed legislation

The European Commission has engaged consultants to evaluate the EU legislation on GM food and feed, Regulation 1829/2003. The report of this evaluation was publsihed on 28 October and covers the authorisation procedures, labelling and public acceptance. The Euroepan Commission considers that no changes to the legisaltion are needed, and shortcomings can be addressed by improving the implementation of the Regulation. This report will be discussed at a meeting between the Commission and Member States on 12 December 2011.

Consumer research on GM labelling

The Agency is commissioning research to help understand consumers' responses to labelling of GM foods and their views on "GM-free" labelling schemes. The latter have been introduced in some European countries and may, in future, be harmonised across all Member States. This work should be complete in Summer 2012.

Novel Foods

Alternative protein sources

The Unit has recently presented a paper for the FSA Board describing two alternative sources of dietary protein, namely insects and meat producted "in vitro" using cell culture. The paper can be found at: www.food.gov.uk/multimedia/pdfs/board/fsa111110.pdf.

New EU regulation on novel foods

The EU regulation on novel foods (Regulation 258/97) is due to be updated and the Commission issues its proposal for a new regulation in January 2008. Negotiations between EU Member States and the European Parliament eventually failed in March 2011, primarily because it was not possible to find a suitable compromise on issues related to the cloning of animals for food production. We are awaiting a new proposal from the Commission, probably in early 2012.

Animal Cloning

As noted above, animal cloning was part of the discussions on the proposal to update the novel foods regulation. The Commission is expected to put forward a new proposal specifically covering the different aspects of the use of cloned animals in food production, including the marketing of food obtained from cloned animals. There is as yet no timescale for this proposal, which will cover a range of different issues that are within the remits of FSA and Defra.

Nanotechnologies

Intelligence gathering on nanotechnology in food production

We will shortly be putting out an open call to industry (via our website) to encourage them to contact us to share any relevant information about prospective uses of nanotechnologies in food production. We are also continuing to work on a register of nano/food applications and hope to have something early in the New Year.

EU definition of "nanomaterial"

In October the European Commission published a generic definition of the term "nanomaterial". This definition has no legal force but the Commission has suggested that it should be used as the basis for any future actions at EU or national level in the field of nanotechnology, incorporating any specific amendments that are necessary for a given field of application. It is not yet clear whether and how this definition will be applied in respect of food.

Labelling of "engineered nanomaterials" in food

The food information regulation was formally agreed in October and includes a requirement to label foods that contain "engineered nanomaterials". We are in discussion with Defra over how to interpret the definition in practical terms, to help with the preparation of guidance to operators and enforcers. The regulation will come into force in 2014 and Defra is the lead UK Government department.

Advisory Committee on Novel Foods and Processes (ACNFP)

The ACNFP met on 24 November and discussed a number of applications for authorisation of novel foods (DHA-rich algal oils, corander seed oil and synthetic vitamin K). The Committee will also advised on the implications of a recent study that examined the effect of micro-RNAs consumed in food on gene expression. Later the same day, the Committee held an open event where it discussed a range of topics, including nanotechnology and cloning, with members of the public.

More information about the ACNFP can be found at: acnfp.food.gov.uk/.