July 2012

Dear Sir / Madam,

Chemical Safety Update (July 2012)

This latest issue of our update bulletin will provide you with information on key developments in the area of chemical safety.

The attached summary of news items details the areas covered in this bulletin. Clicking on the associated links will take you directly to the relevant material.

I hope you find the information provided helpful and informative. Feedback on whether you would find continuation of the update helpful would be appreciated. Please send any comments to: **Benjamin.nketiah@foodstandards.gsi.gov.uk**

Yours faithfully,

Michael Wight
Head of Chemical Safety Division

CHEMICAL SAFETY UPDATE: July 2012

SUMMARY OF NEWS ITEMS

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Materials Contact Materials (Science & Policy)	• Science (Research) • Policy	
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	• Regulation (EU) 274/2012, amending Regulation (EC) 1152/2009	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:090:0014:0016:EN:PDF
	• Regulation amending Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins in figs.	http://www.efsa.europa.eu/en/efsajournal/pub/2567.htm
	EFSA Developments • Scientific opinion on the risks for animal and public health related to the presence of phomopsins in feed and food	http://www.efsa.europa.eu/en/supporting/pub/214e.htm
	• Survey on ergot alkaloids in cereals intended for human consumption and animal feeding	http://www.efsa.europa.eu/en/efsajournal/doc/2605.pdf
	• Scientific Opinion on the risks for public and animal health related to the presence of citrinin in food and feed	
	• EFSA opinion on ergot alkaloids	http://www.food.gov.uk/science/research/contaminantsresearch/mycotoxins/mycotoxinsresearch/c03061/
	FSA Publication of New Research Requirement	

	• C03061 - Investigation of the loss of parent fumonisin mycotoxins during food processing	
Nitrate	• Consultation on European Commission Regulation (EU) No. 1258/2011, as regards maximum levels for Nitrate in Foodstuffs, Amending Regulation (EC) No. 1881/2006	
Coccidiostats and Histomonostats- undesirable carry – over from feed to food	• Commission Regulation (EU) No 610/2012 amending Regulation (EC) No 124/2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:178:0001:0003:EN:PDF
Food Allergy Update	• Food Information Regulation • Allergen management thresholds • Food Allergy research programme	
Novel Foods	**Genetically Modified (GM) Foods** • European Court of Justice (ECJ) opinion on GM pollen in honey • Formalising data requirements for GM food application dossiers • Low level presence of unauthorised GM materials in food • Consumer research on GM labelling **Novel Foods** • New EU regulation on novel foods • Advisory Committee on Novel Foods and Processes (ACNFP) **Nanotechnologies** • Intelligence gathering on nanotechnology in food production	

Food Additives	• Specifications • Sunset Yellow, Quinoline Yellow and Ponceau 4R • Food additives containing aluminium • Amendments to Annex II to Regulation 1333/2008 • Food Enzymes • Flavourings • Consolidation of legislation on food additives, flavourings, enzymes and extraction solvents	

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Food Contact Materials (Science & Policy)

1) Science (Research)

Set off report published

A research project ("Screening tests for visible and non-visible set off") commissioned by the Agency was published in June 2012. Set off is defined as "the unintentional transfer of substances used in printing inks from the printed (outer) surface of packaging to the inner food contact surface." The work developed a scanner for measuring the total surface area of patches of visible set off on the food contact surface of packaging. Exposure techniques and analytical methods for the measurement of individual ink components which may be present on the food contact surface of packaging, as a result of set off were developed. Finally migration experiments were undertaken on a variety of foodstuffs using specially prepared test films.
Further information and a copy of the final report can be accessed via the following link;

http://www.food.gov.uk/news/newsarchive/2012/jun/research-may12

2) Policy

FSA guidance on glitters and dusts as cake decorating materials

In November 2011, following enquiries, the Agency wrote to enforcement authorities with advice for food business operators on the use of glitters and dusts as cake decorating materials. The letter set out the need for these products to meet the requirements of food additives and food contact materials legislation, and also advised on the appropriate labelling of the glitters and dusts. The advice to enforcement authorities raised awareness of this issue and resulted in a number of enquiries to the Agency from food businesses and the public. In response to these

enquiries, the Agency published guidance on its website in April (see link below) to help food businesses use “edible” and “non-toxic” glitters and dusts appropriately on foods.
http://www.food.gov.uk/multimedia/faq/edibleglitter/

Environmental Contaminants (Inorganic)

EU Commission proposed revisions to Cadmium limits as set out in the annex to Commission Regulation 1881/2006 (as amended)

The Commission gave an update at the recent (29th May) Standing Committee Meeting on the Food Chain and Animal Health on the delayed cadmium proposal.
The Commission has received extensive feedback on the proposed revisions to the maximum limits and as a result is considering the best way forward. The Commission has indicated that it now intends to revise the draft proposal to focus on those commodities which do not already have maximum levels set (e.g. chocolate and cocoa products and baby foods) and will for the time being leave the majority of the other maximum limits that are already in place unchanged (e.g cereals, vegetables). However, the previously indicated amendments to maximum levels for certain fish species are still intended to be included as are the changes for specific vegetables (e.g. parsnips and salsify).
The Commission has indicated that it will draft a Recommendation addressed to the Member States to ensure that mitigation methods for the reduction of cadmium in food are fully used and promoted to farmers and also to encourage further research. The effects of the Recommendation will be reviewed after some time and the possibility to lower existing maximum levels re-assessed.
The Commission had also provided for new occurrence data for cadmium in cocoa products to be sent by 26th May for consideration.
This issue will be further discussed at the next Expert Committee on Environmental and Industrial Contaminants expected to be held in September 2012. Although it remains to be seen what the details are of this new approach and the revised proposal, it is anticipated that the FSA will be broadly supportive as what has been indicated appears more in line with UK thinking. The FSA will continue to argue that any new or revised maximum levels should be proportionate and justifiable.

Cadmium in the brown meat from crabs

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. As such there is a maximum limit for cadmium in white meat in Commission Regulation 1881/2006 (as amended) but it has not been possible to set a limit for brown meat. The EU Commission produced an information note
http://ec.europa.eu/food/food/chemicalsafety/contaminants/information_note_cons_brown_crab_en.pdf on the issue of cadmium in brown meat and expects individual member states to produce bespoke consumer advice.

In order to ensure that UK consumer advice is proportionate and backed up with up to date evidence, the FSA is planning to carry out a survey of the levels of cadmium in the brown meat from crabs and crab products containing it on sale in the UK.

Sampling and analysis will take place during Summer 2012. The FSA will then produce consumption advice for brown meat and brown crab meat products for UK consumers.
It is expected that around 3-400 samples of brown crabmeat and brown crabmeat products (including pastes, pâtés and dressed crabs) will be taken from retail outlets such as supermarkets, fishmongers and market stalls at various locations around the UK.

Mercury

The European Food Safety Authority (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. It is anticipated that there will be discussions on revisions to maximum limits in due course.

Lead

EU discussions on the review of lead limits have been mostly delayed while cadmium is dealt with, but it is expected that there will be some discussion at the September expert committee meeting. **If you have data that will be of use in formulating UK policy for any revisions to lead maximum limits then you should provide this to us at your earliest possible convenience**.

Lead In Game Meat

Food Standards Agency in Scotland (FSAS) have recently completed a study of habits and behaviours of high-level consumers of lead-shot wild-game meat in Scotland. The FSA intends to publish this shortly and is producing consumption advice based on the findings and other data sources.

Arsenic

The Commission has indicated that it is considering whether a maximum limit of 0.2 mg/kg for inorganic arsenic in rice is appropriate, based on the current data. However, this is pending further occurrence data being submitted and discussion at the expert Committee and therefore is subject to change.

If you are able to provide useful data for arsenic (total and/or inorganic) in any products (particularly all cereal products, seaweed and vegetables) that may help inform future discussions on possible limits for these categories, please do so as soon as possible.

A survey of arsenic in muscle and kidneys from cattle and sheep was published on the Food Standards Agency website on the 25 April 2012.
The survey comprised of 207 samples of muscle and kidney sampled from cattle and sheep at slaughterhouses in various locations across England and Wales.
Further information and a copy of the survey can be accessed at the following link;
http://www.food.gov.uk/science/surveillance/fsisbranch2012/arsenic

A research study of arsenic in UK grown fruit and vegetables was published on the Food Standards Agency website on the 29 June 2012. The study mainly comprised of 630 samples of basket produce and 174 samples of field produce and associated soil. The levels and distribution of arsenic and other metals e.g. cadmium, lead, copper and zinc was investigated in a range of selected fruits and vegetables.
Further information and copies of the research reports can be accessed at the following link;
http://www.food.gov.uk/science/research/contaminantsresearch/chemicalcontaminants/c01bprogramme/c01b_list/fs241003/
The Agency is considering whether to expand this study to investigate the level and distribution of these and other metals in UK grown fruits, vegetables and cereals.

Nickel and Chromium (trivalent and hexavalent)

EFSA (CONTAM) is planning to assess dietary exposure to nickel, chromium and chromium VI.
EFSA has published on its website a call for occurrence data of nickel and chromium (trivalent and hexavalent) in food. The deadline for data submission to EFSA is 1st October 2012. If you are able to submit occurrence data to the Agency please do so as soon as possible.
http://www.efsa.europa.eu/en/data/call/120426.htm

Planned Consultation on the Revocation of the Arsenic in Food and the Chloroform in Food Regulations

In April 2011 the Westminster Government launched the Red Tape Challenge (RTC) initiative[1] with the purpose of getting comments from business and the public on the stock of legislation. On 6th May 2011 most of the Food Standards Agency's (FSA's) legislation was published on the RTC under the Hospitality Theme and remained on the site until 2 June 2011. In line with our better regulation principles and in response to the RTC, the FSA will be developing a simplified system of food safety legislation, including the consolidation and revocation of a number of domestic Statutory Instruments. As such, the FSA will be launching a formal consultation by end of August 2012 to revoke The Arsenic in Food Regulations 1959 and The Chloroform in Food Regulations 1980.

Process Contaminants

[1] http://www.redtapechallenge.cabinetoffice.gov.uk/home/index/

Acrylamide

The European Commission has published the updated / revised FoodDrinkEurope acrylamide minimisation brochures or pamphlets on the Commission website at http://ec.europa.eu/food/food/chemicalsafety/contaminants/acrylamide_en.htm . These may be of particular help to smaller businesses as they are sector specific and highlight key elements of the 'toolbox' on acrylamide minimisation.

Acrylamide and Furan survey

The 2010/11 acrylamide and furan survey was published on the Food Standards Agency website on the 17 April 2012. The survey comprised samples taken from 248 products and gives a snapshot of the range of acrylamide and furan levels in UK retail foods.
http://www.food.gov.uk/news/newsarchive/2012/apr/acrylamide
The 2012/13 acrylamide and furan survey is underway with retail samples from the various product groups being analysed.

Glycidyl esters

Glycidyl esters are process contaminants which can be formed during the refining of vegetable oils. In light of recently published scientific reports (such as the new toxicological study from the University of Palma '*Comparison between 3-MCPD and its palmitic esters in a 90-day toxicological study*' (E. Barocelli, *et al*.) and a report from BfR in Germany is due to be published in the next couple of months) it is expected that the European Commission will request a risk assessment by EFSA of 3-MCPD and *glycidyl* esters in due course. As such the FSA is keen for information and opinion from stakeholders on this issue, particularly regarding mitigation measures, in order to prepare our position for any forthcoming EU negotiations.

Benzalkonium Chloride (BAC)

On 25 July the European Commission issued guidelines on measures to be taken in relation to the presence of benzalkonium chloride (BAC) in or on food and feed. BAC has been found in samples of fruit and vegetables, as well as in dairy products, above the default MRL of 0.01 mg/kg set down in Commission Regulation 396/2005 for non-approved pesticides. Some of the levels found are considered to be a potential risk to health. The Standing Committee on the Food Chain and Animal Health (SCoFCAH) has established a guideline level of 0.5 mg/kg. Food and feed of plant and animal origin containing BAC above this level should not be placed on the market.

Food Business Operators who use BAC for cleaning or other purposes should review their procedures and conduct screening to ensure that the guideline value is not exceeded. Any exceedance of the new guideline value should be handled as a food safety incident in the normal way.

This guideline is temporary and will be reviewed in February 2013. More information will be available from the Chemical Regulations Directorate of the Health and Safety Executive, which has responsibility for monitoring residues (www.pesticides.gov.uk). Alternatively, you may contact Dr David Mortimer at FSA.

Environmental Contaminants (Organic)

Discussions from the Expert Committee on Persistent Organic Pollutants, 18 June 2012.

Dioxins and PCBs

Following the implementation of Commission Regulation 1259/2011 setting out revised limits for dioxins and dioxin-like PCBs and new limits for non dioxin-like PCBs, corresponding changes to the sampling and analysis criteria came into force in March through Commission Regulation 252/2012, which replaces Regulation 1883/2006.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:084:0001:0022:EN:PDF

Dioxins in sheep liver

In January the EURL published a report comparing the results for different extraction methods. This showed that results for the same sample of sheep liver varied considerably when expressed on a fat basis but not when expressed on a whole weight basis. Although this appears to support a move to a whole weight limit, the Commission wanted to investigate other food types. Results for this investigation did not show the same phenomenon and there was general agreement that other limits should remain on a fat basis.

The Commission tabled a number of options, with preference for a move to a separate, whole weight limit of 1.25 pg/g for dioxins, 2.0 pg/g for total TEQ and 3.0 ng/g for non dioxin-like PCBs in sheep liver. Limits in other liver would also be expressed on a whole weight basis, with levels of 0.5 pg/g, 1.0 pg/g and 2.0 ng/g respectively. This will be formally tabled at the next meeting, in the autumn, and the Commission indicated that it would expect a final position from every Member State.

Dioxins and PCBs in Organic Eggs

Dioxin/PCB contamination of organic eggs from facilities in Germany and Netherlands have been investigated recently. Levels were up to three times the limit and attributed mainly to PCBs. In both cases, the contamination source was building debris mixed into the soil where the birds were gritting. The Commission has asked all Member States to increase vigilance with regard to contamination of free range and organic eggs. Pending a more detailed investigation by the FSA, producers and enforcement bodies are encouraged to increase the level of compliance monitoring.

Brominated flame retardants (BFRs)

EFSA published its fourth BFR opinion, on brominated phenols, on 16th April. There was no data for occurrence in food. The opinion can be found at:

http://www.efsa.europa.eu/en/efsajournal/pub/2634.htm

The fifth and final opinion, covering new and emerging BFRs, is due for publication later in the year. Once this is available, the FSA will be able to finalise its strategy for further BFR investigations.

Polycyclic Aromatic Hydrocarbons

There have been no discussions on PAHs. However, this is a reminder that the recitals in Regulation 835/2011 mention the foods for which further data is of particular interest: cocoa beans and derived products, coconut oil, vegetables, cereals and food supplements, with levels of PAHs in herbs and spices also continuing to be of concern.

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.
- 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

Developments on EU policy

- **T2 and HT2 toxins**

Discussions are ongoing at Commission Working Group level regarding an EU recommendation on the presence of T2 and HT2 toxins in cereals and cereal products intended for human consumption. Recommendations on monitoring and levels at which further investigations would be considered appropriate are being discussed.

The relevant EFSA opinion was published in December 2011 and did not identify a health concern based on the available occurrence data.

- **Temporary derogations for Fusarium toxins in cereals**

Discussions on amending the EU legislation in order to include a provision for temporary derogations for Fusarium toxins in cereal and cereal products are currently ongoing in Commission Working Group meetings. The current proposal includes an addition to article 7 of Regulation (EC) 1881/2006 to allow for a temporary derogation from the maximum level for a specified Fusarium toxin in a particular cereal or cereal product. This is foreseen during periods of extreme climatic conditions, and where the supply chain is seriously affected despite the use of Good Agricultural and Manufacturing Practices by the industry and provided that the temporary levels do not pose any risk to consumers' health.

The need for such a measure became apparent when elevated levels of ZON in wheat bran were seen in 2009 following adverse weather conditions during the 2008 harvest.

- **Alternaria toxins**

EFSA published an opinion on the risks to public health related to the presence of alternaria toxins in food and feed (please refer to the FSA January 2012 chemical safety update), recommending the collection of further occurrence data. As a result, the European Commission and Member States have agreed that representative data from monitoring across European countries should be generated and include at least alternariol (AOH) and alternariol monomethyl ether (AME). Tezuazonic acid (TeA), tentoxin (TEN) and altenuene (ALT) should also be monitored where possible.

Currently available analytical methods for alternaria toxins have not been subject to inter-laboratory validation yet although proficiency testing may be possible within the EU-RL framework. Liquid Chromatography (LC) methods have been found to have the widest application for determination in cereals, fruits and vegetables.

- **Pyrrolizidine alkaloids (PAs)**

EFSA published an opinion on the risk of exposure to PAs through consumption of retail and bulk honey as referred to in the FSA January chemical safety update. A number of recommendations were made by EFSA including monitoring and further development of analytical standards.

Further discussions have been held within the EU on this issue. Work on reduction and weed removal practices to reduce PAs in food has recently been accepted by the Codex Alimentarius Commission. This will be assisted by the EU with a view to developing an EU recommendation in the future. PAs also remain on the JECFA priority list to evaluate.

Work in developing analytical methods for the determination of PAs in foods is ongoing and the EU Reference Laboratory will shortly be undertaking some proficiency testing.

- **Opium alkaloids in Poppy seeds**

Following the publication of the EFSA opinion on opium alkaloids, which identified some health concerns resulting from the presence of opium alkaloids, including morphine, in poppy seeds and poppy seed containing products, discussions on possible risk management measures have been discussed at EU level. One option is the development of a code of practice taking into account the different production practices. At present, information is being collected and discussions will continue at Working Group level.

- **Possible amendment of Regulation (EC) 401/2006 on sampling and analysis methods for mycotoxins in foods.**

Regulation (EC) 152/2009 on sampling and analysis of animal feed is currently under revision in particular with regard to:

- The integration of the regulation on sampling large lots
- The alignment of sampling for heterogeneously distributed substances with that for mycotoxins.

The possibility of updating Regulation (EC) 401/2006 on sampling and analysis for mycotoxins in food is also being explored. Issues to be considered include:

- The number of determinations (i.e. how many times a sample should be tested for a particular analyte);
- Reporting issues – how should correction for recovery and measurement of uncertainty be reported in the analytical certificates; and
- Performance criteria for multi-methods and screening methods.

- **Regulation (EU) 274/2012, amending Regulation (EC) No 1152/2009 imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins has been published**

The amendment to the Regulation reflects changes to Combined Nomenclature (CN) codes for certain food categories, requires that all consignments of US almonds must be covered by a certificate under the Voluntary Aflatoxin Sampling Plan and reduces the frequency of physical testing on import to the EU of Brazil nuts in shell from Brazil from 100% to 50% and for consignments for each category of hazelnuts and derived products from Turkey from 10% to approximately 5 %

- **Commission Regulation 594/2012 amending Regulation(EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs as regards ochratoxin A**

For ochratoxin A, the new Regulation extends the period of time for which a maximum level of 30 µg/kg applies to Capsicum spp. including paprika from 1 July 2012 until 31 December 2014. It also sets a separate level of 8 µg/kg for ochratoxin A in wheat gluten not sold directly to the consumer. The Regulation enters into force on 26 July 2012.

- **Commission Regulation amending Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins in figs.**

The current EU regulation which sets a limit of 4 µg/kg for total aflatoxins in dried figs and a limit of 2 µg/kg for aflatoxin B1 is being amended in order to adjust the limits for aflatoxins in dried figs to the new limit of 10µg/kg for total aflatoxins in ready-to-eat dried figs which have been adopted by Codex. The new EU limits, which were agreed in the Standing Committee on 11 July in Brussels will be 10 µg/kg for total aflatoxins in dried figs and 6 µg/kg for aflatoxin B1.

EFSA developments

- **Scientific opinion on the risks for animal and public health related to the presence of phomopsins in feed and food**

Phomopsins are a family of mycotoxins produced by the fungus *Diaporthe toxica* (formerly referred to as *Phomopsis leptostromiformis*). Lupins are the main host for the fungus. The majority of lupin seed is used in animal feed, but lupin products might also be used for human consumption in the European Union.

The absence of toxicological studies associated with phomopsins or exposure/occurrence information did not allow EFSA to assess the risks for either humans or livestock. However, the severity of effects on liver and its generality among animal species suggest that human and livestock exposures should be kept as low as possible.

The EFSA Panel on Contaminants in the Food Chain concluded that, before meaningful progress can be made, validated analytical methods for the identification and quantification of the major toxic phomopsin congeners in foodstuffs, livestock feeds, and fluids/tissues from dosed animals must be developed. In addition, data on the presence of lupin-based foods and feeds, the extent of consumption by European populations and livestock, and contamination by phomopsins need to be collected.

- **Scientific Opinion on the risks for public and animal health related to the presence of citrinin in food and feed**

Citrinin is a mycotoxin produced by several species of the genera *Aspergillus, Penicillium* and *Monascus* and occurs mainly in stored grains. It was not possible to carry out a dietary assessment due to limited availability of occurrence data. Additionally, the derivation of a health-based guidance value was not considered appropriate due to the limitations and uncertainties in the data available to EFSA. However, a level of no concern for nephrotoxicity of 0.2 µg/kg b.w. per day was determined. Based on the available data a concern for genotoxicity and carcinogenicity could not be excluded at the level of no concern for nephrotoxicity.

In the absence of adequate exposure data, characterisation of the risk of citrinin as a food contaminant was based on the estimate of the citrinin concentrations in grains and grain-based products that would result in an exposure equal to the level of no concern for nephrotoxicity.

There is evidence that food commodities other than grains and grain-based products can also be sources of citrinin, but the overall contribution to human exposure could not be estimated.

- **Survey on ergot alkaloids in cereals intended for human consumption and animal feeding**

The report of the project CFP/EFSA/CONTAM/2010/01 “Survey on ergot alkaloids in cereals intended for human consumption and animal feeding” has been published. The project was designed to obtain representative data on the occurrence of the six most prominent ergot alkaloids (ergometrine, ergotamine, ergosine, ergocristine, ergokryptine and ergocornine) in rye, wheat and triticale food and feed samples in Europe, using a validated multi-toxin analytical method.

Products originating from a number of European countries, including the UK were purchased from the Belgian market and analysed for the presence of ergot alkaloids. Ergot alkaloids were present in 52 % of rye feed, 95 % of rye food, 34 % of wheat feed, 86 % of wheat food, 48 % of triticale feed and 76 % food products from the shops at total alkaloid levels ranging from 1 to 12340 µg/kg. Though the highest frequencies of contamination were observed for food samples, the feed samples and in particular the Swiss rye feed accounted for the highest levels of ergot alkaloids.

Only three samples of UK origin were tested. Total ergot alkaloid levels in those samples were found to be from 0 to 6µg/kg.

- **Opinion on Ergot alkaloids**

The European Commission requested EFSA to evaluate any potential risk to human health from the presence of ergot alkaloids in foods.

Ergot alkaloids are produced by fungi of all species of the *Claviceps* genus, most notably by *C. purpurea*, which parasitise the seed heads of living plants (mostly cereals and grasses) at the time of flowering. Typical signs of ergotism are gangrene and/or hallucinations and convulsions. At lower levels of contamination, ergot alkaloids can cause vasoconstriction and reproductive effects. Ergotism is not reported in humans nowadays but it is occasionally reported in animals.

The EFSA opinion has recently been published and can be found at www.efsa.europa.eu/en/efsajournal/pub/2798.htm.

FSA research projects

C03061 - Investigation of the loss of parent fumonisin mycotoxins during food processing

Previous research showed that certain food processes result in a reduction of the parent fumonisin levels (compounds that are originally present in the food ingredients before processing, e.g. in grains). After processing, an amount of the parent fumonisins are found in hydrolysed and bound forms (hidden fumonisins) which cannot be detected by conventional analytical methods. Therefore the toxin

levels detected in the final food products appear to be lower than the parental levels present in the foods before processing.

This study aimed to investigate the apparent loss of fumonisins during certain food processes and assess whether this has any food safety risk implications for consumers. The effect of single food ingredients such as salt, glucose, fructose and sucrose (and combinations of some of these ingredients), on the levels of parent fumonisins in naturally contaminated maize dough were studied. The effect of food processes focussing on fumonisin levels was also studied for the production of cornflakes breakfast cereals, extruded snacks based on maize flour and tortilla chips.

A decrease of parent fumonisin levels, detected by conventional analysis, after processing was noted. Furthermore, total fumonisins (the sum of parent and hidden fumonisins) were found to be higher than the parent fumonisins alone in all cases. However, all levels found were below the EC maximum legal levels.

The occurrence of higher levels of total detectable fumonisins in maize and maize based foods than shown by conventional analysis is of interest and worthy of further study to assess how plant metabolism, geographical location and climactic factors could also contribute to the loss of fumonisins prior to harvesting and food process. Industrial process variables may also be worthy of further investigation.

C03068 – study to compare the aflatoxin content of Brazil nut kernels with that of the shell

The relationship between the levels of aflatoxin contamination in Brazil nuts kernels (edible portion) in comparison to that on the shell (non-edible portion) was investigated. The results of the project support the conclusion that initially aflatoxin contamination occurs on the shell, or more particularly on the surface of the kernel at the interface with the shell, with little contamination on the kernel. However, as the infection increases, the amount of aflatoxin on the kernel increases dramatically and the aflatoxin on the shell remains at a relatively low level. A conversion factor was determined that could allow the estimation of the level of aflatoxins in the kernel when the concentration in the whole nut is measured, further work will be required to validate the conversion factor.

Further information on the project can be found at:

http://www.food.gov.uk/science/research/contaminantsresearch/mycotoxins/mycotoxinsresearch/fs241008/

Nitrate

Consultation on European Commission Regulation (EU) No. 1258/2011, as regards maximum levels for Nitrate in Foodstuffs, Amending Regulation (EC) No. 1881/2006

In 2011, the Food Standards Agency (FSA) successfully negotiated more practical maximum levels (i.e. higher than proposed by the Commission originally) for nitrate in rocket. The maximum levels for nitrate have applied from 1 April 2012. The FSA will continue to engage with industry on reducing levels of nitrate in rocket and support the work being carried out by industry on agronomic practices to achieve this. The FSA will also commence a formal public consultation in due course to fully assess the impact of the changes to the nitrate legislation, including the introduction of maximum levels for rocket. Due to the ambulatory provisions contained in the Contaminants in Food (England) Regulations 2010 (SI 2010 No. 2228) (and equivalent legislation in Scotland, Wales and Northern Ireland) an amending Statutory Instrument (SI) will not be required. The purpose of the consultation is to provide stakeholders with an opportunity to comment on the maximum levels for nitrate in lettuce and spinach and the new maximum levels in rocket and the associated Impact Assessment.

Parallel consultations will also be running in Scotland, Wales and Northern Ireland.

Coccidiostats and Histomonostats- undesirable carry –over from feed into food

Commission Regulation (EU) No 610/2012 amending Regulation (EC) No 124/2009 of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed

The new EU Regulation amends the provisions for certain substances listed in Annex to Commission Regulation 124/2009, in particular for lasaiocid sodium, maduramicin, nicarbazin and diclazurilin. The Regulation enters into force on 30 July 2012.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:178:0001:0003:EN:PDF

Food Allergy Update

Food Information regulation

Now that the Food Information Regulation 1169/2011 (FIR) has been published (see the February 2012 IP letter) the Food Standards Agency is working with DEFRA (who lead on this piece of legislation) and with Department of Health and Devolved Administrations to put in place national provisions to provide the powers to enforce this directly applicable EU Regulation. It is expected that there will be a public consultation during late summer on the draft national Statutory Instruments, an Impact Assessment and a draft Guidance to Compliance document. Anyone who has questions on the food allergy aspects of this consultation should contact Olujuwon Adetokunbo (Olujuwon.Adetokunbo@foodstandards.gsi.gov.uk)

Allergen management thresholds

Work on the development of allergen management thresholds is continuing and a workshop will be held in September to discuss the outputs from the International Life Sciences Institute (ILSI) Food Allergy Task Force expert group which is addressing this issue. Key stakeholders (industry, consumers, health professionals and regulators) will be invited to discuss the work of the expert group and how the management thresholds that it is developing can be used. A paper summarising the work of the expert group and the outcome of the discussions at the workshop will be submitted for publication in a peer reviewed scientific journal.

Food Allergy research programme

The Food Standards Agency has recently commissioned Reading Scientific Services Ltd to conduct a survey of foods with allergen advisory label warnings and similar products without such warnings. The survey will investigate the types of warning used and will also include analysis of the foods to determine the levels of allergen present. This study is expected to be completed by mid 2013.
An Invitation to Tender call has been issued for research into the current extent of allergen information provision for foods sold non-prepackaged (such as in bakeries, sandwich bars, on deli counters and in all forms of catering) and to explore the barriers that currently prevent some businesses providing such foods from making allergy information available. The finding from this research will help the Agency develop appropriate guidance and advice for the food service sector so that they are able to meet the new requirements to provide allergy information when the Food Information Regulation comes into force in December 2014.

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.

Genetically Modified (GM) Foods

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

The ECJ advised in September 2011 that pollen from GM plants should be regarded as an "ingredient" if it is present in honey. This has implications 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 European Commission is working on amendments to the legislation that will clarify the situation but has not offerred a timescale for this work.

Formalising data requirements for GM food application dossiers

The European Commission has drafted a Regulation that sets out the information that applicants should provide when seeking authorisation of food and feed derived from GM plants. By and large this repeats the requirements set out in EFSA guidance but it aims to provide additional clarification and it defines some extra elements including a literature review of published papers relevant to the GM product. One controversial aspect of the proposal is a mandatory requirment for animal feeding studies on crops containing new GM events, which goes beyond EFSA's guidelines. This proposal is likely to be issued for consultation under WTO procedures[2] over the summer and could then be adopted in the Autumn.

Low level presence of unauthorised GM materials in food

During 2011 the EU adopted a regulation that harmonised the enforcement of legislation regarding unauthorised GM materials in animal feed. The Regulation defines a "technical zero" of 0.1%, which is the lowest level where results are

satisfactorily reproducible between official laboratories when appropriate sampling protocols and methods of analysis are applied. This "technical zero" only applies in certain circumstances where the GM material is approved in the country of origin and its safety is already being assessed for approval in the EU.
In June, the Commission announced that it plans to issue a proposal for applying a similar approach to food. It is expected that this proposal will be circulated for discussion after the summer break.

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 completed by November 2012.

Novel Foods

New EU regulation on novel foods

The EU regulation on novel foods (Regulation 258/97) is due to be updated and we are awaiting a new proposal from the Commission, probably in early 2013.

Advisory Committee on Novel Foods and Processes (ACNFP)

The ACNFP met in February and April 2012 and discussed a number of applications for authorisation of novel foods (gamma-cyclodextrin, DHA-rich algal oil, chia seed Clostridium butyricum, calanus oil, isomalto-oligosaccharides, methylcellulose and the glucosamine salt of tetrahydrofolic acid): The Committee also advised on new techniques for modifying plant genetics and on current approaches for estimating exposure to novel ingredients.

Nanotechnologies

Intelligence gathering on nanotechnology in food production

The Agency has updated its web pages on nanotechnologies to (a) provide information on nanomaterials that may be used in food and food contact materials, and (b) encourage industry to contact us to share any relevant information about prospective uses of nanotechnologies in food production.
Links: http://www.food.gov.uk/safereating/nano/monitoring/ and
http://www.food.gov.uk/safereating/nano/regulatory-advice/

Food Additives

Specifications

Following agreement at the Standing Committee on the Food Chain and Animal Health on 4 July 2011, Regulation 231/2012 laying down specifications for food additives listed in Annexes II and III of Regulation 1333/2008 was adopted on 9 March 2012 and published in the Official Journal of 22 March 2012. The new Regulation, which consolidates and repeals the three existing purity criteria Directives, includes a number of technical changes and clarifications whilst specifications for additives which are no longer permitted have been removed (e.g. Red 2G). It will apply from 1 December 2012 – the transitional period has been included to allow industry to adapt to the changes. The Food Additives (England) (Amendment) and the Extraction Solvents (Amendment) (England) Regulations 2012 (and equivalent legislation in Scotland, Wales and Northern Ireland) provide for the execution and enforcement of the new Regulation.

The text of the Regulation can be found at:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:083:0001:0295:EN:PDF

Sunset Yellow, Quinoline Yellow and Ponceau 4R

Following agreement at the Standing Committee on the Food Chain and Animal Health on 9 September 2011, European Commission Regulation 232/2012 amending Annex II of Regulation 1333/2008 was adopted on 16 March 2012 and published in the Official Journal of the European Communities on 17 March 2012. This Regulation introduces reductions in permitted levels of Sunset Yellow (E 110), Quinoline Yellow (E 104) and Ponceau 4R (E 124) in a number of food categories, including soft drinks, confectionery, sauces and seasonings. The Regulation includes a use level of 20 mg/l for Sunset Yellow in soft drinks. The currently permitted limits for these three colours are set out in Annex V Part 2 of Directive 94/36/EC.

Regulation 232/2012, which is directly applicable in Member States' legislation, will apply from 1 June 2013. Foods already placed on the market that comply with the provisions of the current legislation can continue to be marketed until stocks are exhausted. Due to the ambulatory provisions in the Food Additives (England) Regulation 2009, (and equivalent legislation in Scotland, Wales and Northern Ireland), the new legislation will apply automatically in national legislation, without the need for an amending Statutory Instrument.

The text of the Regulation can be found at:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:078:0001:0012:en:PDf

Food additives containing aluminium

Following agreement at the Standing Committee on the Food Chain and Animal Health on 23 November 2011, Regulation 380/2012 amending Annex II of Regulation 1333 as regards conditions of use and use levels for aluminium conaining food additives was adopted on 3 May 2012 and published in the Official Journal of 5 May 2012. To take account of EFSA's 2008 opinion that some consumers are exceeding its reduced Tolerable Weekly Intake (TWI) of 1 mg/kg/bw/week, the new Regulation removes some aluminium containing additives from the list of approved additives and restricts the permitted use of E 541 Sodium Aluminium Phosphate (SALP) to one type of product only - the sponge parts of chequered sponge cakes (Battenberg-style cakes) at a maximum level of 0.4 g/kg. In addition, new restrictions on the permitted food uses and levels of aluminium lake colours have been introduced.

The new Regulation entered into force on 24th May 2012, but transitional periods for non-conforming products have been included (until 1 August 2014 for foods containing aluminium lake colours and 1 February 2014 for others, including products containing SALP). Foods not complying with the Regulation's new provisions that are placed on the market before these dates may continue to be marketed until their use-by date. Due to the ambulatory provisions in the Food Additives (England) Regulation 2009, (and equivalent legislation in Scotland, Wales and Northern Ireland), the new legislation will apply automatically in national legislation, without the need for an amending Statutory Instrument.

The removal of permission to use SALP will impact upon those parts of the UK food industry which need to reformulate and the Agency has collected information concerning costs in order to complete an impact assessment, on which we will shortly be consulting. In addition, the European Commission has agreed to issue amendments to the Regulation which will permit aluminium lake colours to be used in certain additional food products requested by industry. The aim is that these amendments should come into force before 1 August 2014.

The text of the Regulation can be found at:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:119:0014:0038:EN:PDF

Amendments to Annex II to Regulation 1333/2008

Following agreement by Member States at the meeting of the Standing Committee on the Food Chain and Animal Health on 27th February 2012, three new Commission Regulations permitting additional food uses of three authorised additives were adopted on 4th June 2012 and published in the Official Journal of 5 June 2012. Details are set out below:

COMMISSION REGULATION (EU) No 470/2012 as regards the use of polydextrose (E 1200) in beer (energy reduced and low alcohol only)

COMMISSION REGULATION (EU) No 471/2012 as regards the use of lysozyme (E 1105) in beer (only those not subject to pasteurisation or sterile filtration)

COMMISSION REGULATION (EU) No 472/2012 as regards the use of glycerol esters of wood rosins (E 445) for printing on hard-coated confectionery products (personalised or promotional products only)

The texts of the Regulations can be found at:

http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2012:144:SOM:EN:HTML

Following agreement by Member States at the meeting of the Standing Committee on the Food Chain and Animal Health in March 2012, Commission Regulation 583/2012 permitting the use of polysorbates (E 432-436) in coconut milk has been adopted on 2 July 2012 and published in the Official Journal of 3 July 2012. The text of the Regulation can be found at:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:173:0008:0009:EN:PDF

The new Regulations are all directly applicable in national legislation and enter into force 20 days after their publication in the Offical Journal,. Due to the ambulatory provisions in the Food Additives (England) Regulation 2009, (and equivalent legislation in Scotland, Wales and Northern Ireland) the new legislation will apply automatically in national legislation, without the need for an amending Statutory Instrument.

Food Enzymes

Two new legal measures on food enzymes were agreed at a Standing Committee meeting in May. One of these will amend the Enzyme Regulation 1332/2008 to extend the period for making applications by 18 months. This extension was agreed to take into account delays in clarifying guidance from the European Food Safety Authority. The previous deadline was September 2013, but this will now be extended to March 2015. The measure will now be subject to scrutiny by the European Parliament and Council and we expect the amendment to be formally adopted by the Commission and published in the Official Journal towards the end of the year. A separate amendment to Regulation 234/2011 (which sets out the procedural elements of the Common authorisation procedure) was agreed by the Standing Committee to provide clarification on the data which should be provided for the risk assessment dossier. For example, it states that toxicity information is not required for enzymes produced from edible part of animals or plants. It also states when grouped enzyme dossiers can be submitted to EFSA. This amendment has subsequently been published in the *Official Journal* on 28 June and is available from the following link

http://eurex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:168:0021:0023:EN:PDF
The Commission has also initiated discussions with Member States and European stakeholders on the future categorisation of food enzymes and to clarify when an enzyme should be classed as a processing aid or a food ingredient and any associated labelling issues. When agreed this guidance should facilitate the development of the future positive list.

Flavourings

Positive list of flavouring substances
A Commission measure adopting the first positive list of flavouring substances was agreed at a Standing Committee meeting on 23 April. The Union positive list will harmonise the use of flavouring substances in and on food in the EU. A separate measure establishing transitional measures for foods containing flavouring substances and for the various types of flavourings (e.g. other flavourings) which are not yet regulated was also agreed which will allow time for the evaluation and authorisation of these flavourings and source materials. It is expected that the Regulations will be adopted and published in the Official Journal in September/October. During the vote on the positive list measure at Standing Committee the Commission noted that there was some ongoing discussion about the interpretation of the term flavouring substances with modifying properties and they are planning to develop further guidance in conjunction with Member States and Stakeholders on this issue which may ultimately alter the status of some substances in the positive list. It was also confirmed that the positive list only controls the use of substances when used for flavouring purposes, when used for other reasons these would remain subject to other legislation.

Smoke flavourings
The European Food Safety Authority is currently evaluating additional studies on two smoke flavouring primary products. Once the EFSA opinions have been completed the Commission, following discussions with Member States, will consider the next steps (e.g. maximum use levels for primary products in different foods) and we expect a draft proposal on the positive list of primary products towards the end of this year.

Consolidation of legislation on food additives, flavourings, enzymes and extraction solvents

In line with our better regulation principles and in response to the Government's Red Tape Challenge it has been decided to create a single statutory instrument for all food additive type legislation incorporating the provisions on food additives, flavourings, smoke flavourings, food enzymes and extraction solvents. Work to combine the elements of the relevant statutory instruments will begin shortly and a formal consultation is expected towards the end of the year. This work will also incorporate some necessary changes to the enforcement rules for flavourings rules arising from the new transitional provisions agreed at Standing Committee and also adapt the national rules on food additives to reflect the full entry into force of the annexes of Regulation 1333/2008 in June 2013.

Similarly the FSA is planning to consult in the coming months on plans for reviewing the Mineral Hydrocarbons in Food Regulations 1966.