

EFSA sends firm message to food industry

The European Food Safety Authority sent a firm message to the food industry this week when it published a negative risk assessment after a company withdrew the application for a product that had been on the EU market.

An EFSA scientific panel was poised to adopt a negative Opinion in April on a smoke flavour used in processed foods known as FF-B. The panel had concluded the flavour was “weakly genotoxic in vivo” and that the panel “cannot establish its safety when added to food” on the basis of all the scientific evidence available. But the petitioner, US-based Forest Flavors International Inc, withdrew the application at the eleventh hour. This meant that technically the draft Opinion could not be adopted by the written procedure as the panel had intended to do.

The AFC panel, whose remit includes flavourings, is evaluating 16 smoke flavours used in the EU to provide scientific advice to the Commission, which will adopt a positive list. It received a dossier from Forest Flavors International Inc, based in Glasgow, Kentucky, for FF-B which is made from sawdust from oak, white oak, maple, beech and hickory trees.

It seems that the genotoxicity tests provided by the company showed that the smoke flavour primary product FF-B damaged DNA in animal testing.

The company said in the application that the smoke flavour was used in a range of food products including meat and meat products, fish and fish products, salts, spices, soups sauces, salads protein products, ready-to-eat savouries, alcoholic drinks and composite products such as casseroles and meat pies. The amounts ranged from 0.1g/kg in alcoholic beverages to 3.5 g/kg in meat and meat products. The petitioner estimated exposure at 3 mg/kg a day. EFSA said the company had informed it on 23 April of the decision to officially withdraw the application and to stop all activities shipping the product FF-B or derived products to the EU.

The AFC was going to adopt the negative Opinion on FF-B at its panel meeting of 17-19 April in Parma but the panel was not quorate during the discussion so it was decided to adopt the Opinion by written procedure. However, EFSA was then informed a few days later that the manufacturer had withdrawn the product and the application. EFSA “no longer has a formal mandate to give an opinion according to the smoke regulation,” says a note of the meeting.

Under Regulation 2065/2003, a flavour can only be authorised if it is sufficiently demonstrated that it does not present risks to human health. It is for EFSA to conduct the risk assessment and for the European Commission to propose a positive list.

EFSA said in a statement that it had sent the risk assessment to the European Commission to “help inform their consideration of the necessity of any further measures.” Two officials from DG SANCO heard the discussions in April at the panel meeting on the smoke flavour.

Philip Tod, spokesman for Health Commissioner Markos Kyprianou said that as the company had stopped shipping the flavour to the EU, there was no need for any further measures. He told EU Food Law that the product had been lawfully put on the market and that the company had undertaken to ship back any product not yet on the shelves. With regard to products on sale containing the flavour, he said the risk “is limited given that EFSA says it (the smoke flavour) is weakly carcinogenic.” A recall was not proportionate to the risk, he concluded.

Of the 16 applications for smoke flavours, a further three are not proceeding to an Opinion because of a lack of scientific data to demonstrate safety. It is understood that lack of information is the reason for the applications being withdrawn rather than safety concerns from the panel. However, it is not absolutely clear how EFSA deals with risk assessments for products on the EU market which it is unable to complete because of lack of data, or how this is communicated to the risk managers.

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The AFC panel chair Susan Barlow told the EFSA management board in March that the panel often did not proceed to an Opinion because the application was withdrawn by the company. She said the AFC hardly ever published negative Opinions because if there was a lack of information or a safety concern the company was informed and the Panel stopped work on the dossier. She stressed that this applied to applications for products which are not on the EU market (ie authorisations) and so she felt there was no risk to public health (see *EU Food Law* March 30 2007). The case of the smoke flavour is different because the product was on the market.

The management board suggested that if a risk assessment for an authorisation did not proceed to an Opinion then this should be noted in the Register of Questions published on EFSA’s web site. However, the Register of Questions is not yet up and running so it is not possible to do this yet.

EU Food Law was unable to contact the petitioner before going to press.

The full risk assessment from the AFC is published on the EFSA web site. EFSA has also published a statement to explain the issues. The risk assessment was conducted by a working group and was then endorsed by the panel by written procedure on 7 June. The panel has also published guidance for companies setting out the information it requires for the dossier.

Wall tells Trade Commissioner to stop dumping GMO problem on EFSA’s desk

The European Commission should stop dumping the GMO problem on the desk of the European Food Safety Authority, its management board chair Patrick Wall told trade Commissioner Peter Mandelson last week.

“Science won’t resolve the issue,” said Wall, who saw no solution in the Commission continuing to “keep dumping” the problem on EFSA by “asking for more Opinions” on GMO food and feed.

He pointed out that so far there had been no qualified majority of Member States in favour of a GMO approval and that some of them wanted to become GMO free states.

He suggested that some Member States used “pseudo science” to object to EFSA risk assessments. Under new procedures, EFSA has to take account of scientific points raised by Member States in an annex to GMO Opinions. Often the comments from Member States “clearly indicate that they don’t support GMOs,” said Wall.

Industry blamed

Wall also criticised the biotech industry in his remarks at their trade association EuropaBio Open Day in Brussels, saying “industry must take some of the responsibility” for consumer hostility to GMO food. They had not told the public what they were doing although they had been working on the science

since 1967. “There was an information gap and then the media take over.”

Wall made the comments with good-humour, cracking jokes including one about an Elvis clone. The result was that Mandelson and the biotech companies warmly applauded the criticisms and challenges that he put at their doors.

Wall set out why consumers were hostile to GMO food, saying they saw no benefit in it for them in contrast to the benefits from GM medicines. Consumers feared the biotech corporations were there to make short term profits, working on a three month timescale for share prices and bonuses; that US corporations wanted to own the food supply and that the real motive of the biotech industry was to sell more chemicals.

Delays

He said that the biotech industry complained about the time it took EFSA to deliver an Opinion but argued that six months at least was inevitable given that EFSA used lay volunteers who had to be flown into Parma for meetings. An EFSA Opinion had to be given by the panel, this was set out in the Regulation, which was prescriptive about what EFSA could do, he explained. If scientific advice rather than an Opinion was requested, the time frame could be much quicker because the secretariat could give the advice.

“There are time delays because for one of these panels we have to get 19 to 25 people together in Parma,” he said.

With a picture of an enormous ship as a back-drop, he told Mandelson that it was increasingly difficult to guarantee GMOs not authorised in the EU did not come into the EU. “You can’t sterilise a ship. It is not an operating theatre,” he said. Analytical chemists were getting down to lower and lower levels of detection, parts per billion, he said.

“That is not EFSA’s problem, EFSA has enough problems without taking on yours,” he said.

At the beginning of his presentation, he stressed that he was prepared to go to meetings hosted by organisations both in favour and against biotechnology. He also told the industry that EFSA’s job was strictly risk assessment and that promoting technology is “not our job.”

Given the strong criticism from some Member States and NGOs such as Greenpeace on EFSA’s GMO risk assessments, some eyebrows were raised when

Wall’s name appeared on the programme of the EuropaBio day, sponsored by companies such as Dupont and Bayer. In the event, Wall doled out criticism in almost equal measure to the biotech industry and the Commission.

Mandelson criticises risk managers who fail to defend GMO science

Trade Commissioner Peter Mandelson said the EU’s risk management system on GMO food and feed was in danger of being undermined by politicians and risk managers who did not defend the science on which safety assessments were made, in a speech to the European Biotechnology Open Day in Brussels last week.

He acknowledged public concern about GMO foods, saying that while most Europeans were enthusiastic about applications for biotechnology, the one exception is food. “Something like six in ten Europeans say they oppose GM food,” he said. However, half would be ready to buy GMO food if it were healthier or more environmentally friendly. “Which suggests that the advocates of biotechnology need to do a lot more to explain what biotech is, and what its real risks and benefits are.”

The process of assessing GM foods took time and risk managers were right to be thorough. “But it is also reasonable to insist that when the process has run its course, and the scientific issues have been thrashed out, we stand by the science,” he said. “And that applies to the technical experts and the politicians they report to. A rigorous system means approving GM imports when the science is on their side just as we take a firm line when precaution is justified.”

He said: “It is hard enough to communicate the outcome of complex scientific assessments to people in a simple, clear manner. If politicians and risk managers undermine their own system it becomes almost impossible. We devalue objective science as our most important benchmark.”

He expressed concern that Europe might soon not have reliable supplies of animal feed if it did not approve new GM varieties approved in other regions.

“Unless we can close the gap between GMO approvals in the EU and feed-exporting countries such as the US, Argentina and Brazil, we may have hungry cows and struggling farmers,” he said.

Eurofreeze conviction “voided”

The conviction against Eurofreeze (Ireland) has been “voided” because its company secretary made a declaration to say that she was unaware of the summons or proceedings relating to the case.

Eurofreeze (Ireland) was found guilty on 13 summonses at Enniskillen Magistrates Court last month (see *EU Food Law* May 11 2007). The company directors did not attend the court so the Magistrate determined the case in their absence.

The court fined the company £1,000 for each offence. The case centred on the company’s premises in County Fermanagh where meat and poultry products were repacked and relabelled contrary to the terms of the licence and in contravention of hygiene rules, the court said.

However, on 1 June 2007, the UK Food Standards Agency was advised by letter from the Court Service that the conviction against Eurofreeze (Ireland) had been voided by the Court following the declaration from the Company secretary.

FSA Northern Ireland officials have been in discussion with the Public Prosecution Service to consider how to proceed further on the matter.

A spokesperson for the Northern Ireland Court Service told *EU Food Law* that the summons was listed on the basis of information on the Royal Mail web site which indicated that it had been delivered to the defendant through the Royal Mail Recorded delivery system.

“Voided in this case means that the conviction was unsafe because the defendant made a statutory declaration that they were not aware of the summons or proceedings,” she said.

“The issue of further proceedings is now a matter for the Public Prosecution Service,” she confirmed.

The owner of Eurofreeze (Ireland) was George McCabe. The name of the company secretary who submitted the Statutory Declaration form as company secretary was Ann McCabe, she said.

The investigations began in autumn 2005 and involved at one stage the Food and Veterinary Office, part of the European Commission. In August 2006, magistrates in Northern Ireland condemned 254 pallets of meat and poultry from Eurofreeze (Ireland). The court found meat and poultry which were foul

smelling, green, stuck to cardboard and in many cases had no health mark at all or a bogus health mark. Some beef contained specified risk material, which should have been removed (see *EU Food Law* September 1 2006). There was a second condemnation hearing in March this year when 41 pallets were condemned, 162 were voluntarily surrendered and 214 were released back to the owners.

Meanwhile, the Food Safety Authority of Ireland has been rather more successful in its prosecution of a cold store at D’Arcy Foods Ltd where it secured a four month prison sentence for Ann McCabe and Ciaran McCabe, both of Castleblayney Co Monaghan. The judge said the sentences would not be suspended. They were convicted on all charges relating to illegal use of veterinary control label and tampering with documents in relation to a consignment of beef cheek meat. Fines and expenses of nearly €19,000 were imposed on the company. Notice of appeal has been lodged.

Commission seeks to balance flexibility with prescription for front-of-pack labels

Front-of-pack labelling is found useful by consumers and the European Commission is looking to propose a solution which would achieve the right balance between flexibility and prescriptiveness, Basil Mathioudakis, senior official at DG SANCO said last week.

Speaking at the Food Labelling and Food Safety conference on nutritional labelling, he said one possibility under discussion is a “governance” solution which would set up a system of basic rules but be flexible so that at a national level different possibilities could be tried.

“Operators would be under the control of national authorities,” he said. This would give time to see how different schemes worked and whether it would be worth having a scheme at Community level, he said. The idea would be to have Best Practices retained, he said, and for Member States to quickly feed back to Brussels any developments so that there could be “a quick revision of the rules,” if necessary. He stressed that the idea remained “sketchy” at the moment and was subject to discussion both within the Commission and with Member States.

During the panel discussion, he made clear that the Commission was hesitant about favouring one

scheme over another at this stage, perhaps because of the controversy of schemes such as traffic lights, recommended by the UK Food Standards Agency, versus the industry-supported Guideline Daily Amounts.

Timeframe

He said his unit felt under considerable pressure to have a proposal on labelling adopted by the Commission by the end of the year and that the timescale was ambitious given the issues which need to be resolved.

DG SANCO has so far not even pronounced on whether it considers nutritional labelling should become mandatory or not, leaving this question open in the recent White Paper on nutrition and obesity. Mathioudakis said there were arguments in favour of keeping a voluntary approach (at the moment it is voluntary unless a claim is made) because voluntary information is provided on most products, costs of a mandatory scheme might be a problem for small and medium-sized businesses and that a voluntary approach would be consumer driven and would be flexible and innovative.

However, there were strong arguments for making it mandatory because many considered this to be “fundamental to encourage healthier choices” and consumers wanted the information and had a right to the information.

Mandatory nutritional labelling could also prove an incentive to the food industry to reformulate products, he said. There could be exemptions for products where it was not relevant such as tea, coffee, spices, alcoholic beverages, single ingredient products (such as raw meat, raw fruit, vegetables, sugar, flour etc), individual portions and food sold in bulk which was not for direct sale to consumers.

Need for political support

At this stage, deliberations were ongoing, he said, although he did express a personal preference for a mandatory scheme. He stressed that he could not, however, give an answer on the question because the Commission services were still “working on the issue.” He also indicated that the ultimate proposal would depend on soundings from the Council and the European Parliament because the proposal would be subject to the co-decision procedure. “The name of the game is finding a certain qualified majority,” he said.

He expressed some surprise at the recent attention the European Parliament has devoted to trans fat with the number of written questions on the issue. While he agreed that trans fat is not beneficial and detrimental to consumers if consumed in certain amounts, he argued that the greater risk for cardiovascular disease was saturated fat because people generally consumed too much of this and that efforts should go into reducing total saturated fat. He warned against eliminating trans fat only to replace it with saturated fat.

Nutrients

In terms of nutrients which might be labelled, he said that there had been no clear consensus in the consultation but that five most mentioned were energy, fat, saturated fat, sugar and sodium, and that salt was preferred to the term sodium.

He also warned against having too high an expectation of mandatory labelling, saying that in the US some 14 nutritional elements were labelled but obesity remained.

Commission calls on industry to speed up work on portion sizes

The European Commission called on the food industry last week to define a food portion for key food categories. In the run-up to the proposal on nutritional labelling, the European Commission is considering whether information should be given per 100g or per portion, Basil Mathioudakis from DG SANCO explained. However the problem in expressing information per serving was that there is no clear agreement on serving size.

The issue of how to make different foods easily comparable for the consumer came up several times at the conference on Food Labelling and Food Safety.

Breakfast cereal manufacturers cannot yet decide on a portion size, the meeting heard, with some arguing it is 30g while others say 45g. Furthermore, some companies give nutritional information based on added milk while others just give the values of the dry cereal, making it hard to make direct comparisons.

The CIAA, representing food and drink industry at a European level, is working on the issues but has yet to announce a consensus, the meeting was told.

Food industry poised for pan-European GDA ad campaign

The European food industry is poised to launch a major advertising campaign to promote Guideline Daily Amounts for front of pack nutritional labelling.

Major companies have joined together to use one scheme, recommended by the CIAA, which uses a front-of-pack logo to give the number of calories, which is the key recommendation.

“There will be TV advertising, point of sale and work with the media,” Lyn Trytsman-Gray, public affairs manager of Kraft said last week at the Food Labelling and Food Safety conference in Brussels.

“This will be underway shortly.”

She said the campaign would be along the lines of the one already launched in the UK which uses the theme “What is inside you?”

“There will be a similar approach,” she said.

Industry needed to explain to people about the GDA labelling and the campaign would be launched as products carrying the labels were rolled out into the market, she said.

She said that one icon front of pack giving the number of calories was being rolled out because of its simplicity. The CIAA recommendation also gives other GDA icons for sugar, fat and salt.

The GDA campaign is more advanced in the UK because much of the food industry prefers this labelling to traffic lights. Jane Holdsworth, campaign director at the Food and Drink Federation on GDAs, explained the www.whatsinside.com approach taken on advertising and marketing.

Critical mass on 50% products

In just over a year, the food industry had developed a consistent label, with some minor variances being ironed out, she said. There is already critical mass with the scheme now adopted by 32 food manufacturers, eight retailers and two food service companies, she said. GDA “is the most widely available scheme with high consumer usage and awareness,” she said. “We have critical mass, we think it is on well over 50 per cent of packaged food labels,” she said.

She claimed that GDAs, which some critics have said are hard to understand because they rely on

percentages, were appropriate for lower socio economic groups with lower levels of literacy and numeracy. GDAs were simple and helped consumers make choices without being dictatorial, she argued.

As well as TV advertising, the food industry had used advertorials in women’s magazines, press advertising and booklets to inform consumers. “In terms of awareness, 75 per cent have heard of GDAs and 80 per cent of consumers have seen our GDA labels.” She said research showed that 84 per cent find the labels easy to understand; that 54 per cent of consumers say they have already used them to aid food choices and that 82 per cent would like to see them on more brands. This data comes from Millward and Brown tracking carried out in March 2007, she explained.

“We have had very positive results, will continue to focus on driving awareness, usage and understanding and will work with the Food Standards Agency to evaluate,” she said.

Red Light – but consumers still buy it, says Waitrose

Putting a red traffic light on a food product does not stop consumers buying it – sometimes sales have increased, Jean Feord, Merchandise Legislation Manager at Waitrose told the conference on Food Safety and Food Labelling in Brussels last week.

Waitrose, an upmarket UK supermarket group, has adopted the traffic light scheme recommended by the Food Standards Agency.

With some categories, such as sandwiches, it saw a big surge in sales of healthier products when traffic light labels were first introduced and there has also been an impact on ready meals. But consumers saw a low fat but high sugar yoghurt as a “healthy indulgence” product, she said, and would buy it even though it was labelled with some ambers or reds. “For burgers, we have seen an increase in sales despite the red traffic light,” she said, speculating that as this was a seasonal line for the store, consumers felt they could still eat them because they were not eating them frequently.

“For certain category meals like ready meals or sandwiches traffic lights could persuade a change in purchase habits.

“However, if consumers want to indulge, they will buy it regardless, such as a pudding or a yoghurt.”

Her evidence appeared to suggest that traffic light labelling could work to change consumer behaviour in some food categories but not in all.

“For the Waitrose sandwich category, sales are up 30 per cent and the biggest growth is in wraps and the perfectly balanced sub brand,” she said. In its Traditional British ready meals, which tended to be high in fat and salt, there has been some decrease in lines labelled red and some increase in products labelled amber or green.

“But there have been no major swings in other Waitrose categories.”

She also stressed that none of this happened in isolation and that price and promotions would also clearly have an impact.

She said that as well as using the labels on the front of pack, Waitrose explained the system in store, telling customers to “choose mainly amber and greens with occasional reds for those indulgent days.”

She said research showed that customers in the UK wanted one scheme only but that she personally felt there was “too much blood on the carpet” now for this to happen.

She felt that a combination of GDAs and traffic lights could be useful.

One claim made by food companies which use GDAs, rather than traffic lights, is that for GDAs now there is “one consistent system” but for traffic lights there are lots of different schemes with different companies using differing models. “GDAs are much more consistent,” argued Andreas Kadi, in charge of EU regulatory affairs at Coca-Cola.

“The CIAA is driving consistency.”

GIs – no regulation for their use as ingredients

There is a problem when products with a Geographical Indication (GI) are used as ingredients in other foods, Bernard O’Connor from O’Connor and Company told the conference, because this is not specifically regulated.

A pizza might claim to be made “with Parma ham” but it was unclear if all the ham had to be Parma ham or if just some could be Parma ham. Similarly, if

there was a Champagne mustard”, could it use this name if it contained only trace elements of protected product?” he asked.

“The use of GIs as ingredients or for product names is a key question for producers,” he said at the Food Labelling and Food Safety conference in Brussels last week.

Some Member States have adopted their own rules and under Italian Decree 297/04 “tortellini with Parma ham” can only contain Parma ham and no other ham, he explained. The consent of the association for protection of the GI of Parma ham is also required. However, if the reference to the GI is only made in the list of ingredients then a consent is not required.

With the increase in the number of GIs, applications were also coming from third countries such as coffee from Columbia or Darjeeling tea, he said.

Evidence of consumption for Goji berries

There is sufficient evidence to show that Goji berries were being consumed to a significant degree in the UK before May 1997, the UK Food Standards Agency said this week.

This means that Goji berries will not require a full risk assessment under the Novel Food Regulation.

Goji berries (Chinese wolfberries) are small red fruits from the *Lycium barbarum* tree which grows in China, Tibet and other parts of Asia.

Goji berries have been marketed in major supermarkets including Tesco in recent months so retailers were keen to know the verdict of the FSA. As well as selling the berries, some companies are marketing other products containing them such as fruit drinks.

The FSA considered import data, evidence of the trees growing in the UK since the 18th century, evidence from Chinese restaurants, evidence of the use of the berries in a supplement plus evidence of consumption in Germany, the Netherlands and France.

One of the most important factors was the evidence from Chinese restaurants that they had been using them for up to 20 years and a recipe which includes them published in a magazine in 1994. There is no

legal definition of consumption “to a significant degree” required if there is to be no novel food assessment so it is decided on a case-by-case basis.

Food firms warned of the dangers of omission

An omission to provide material information which the consumer needs can be considered as misleading under the Unfair Commercial Practices Directive, lawyer Bernard O’Connor from O’Connor and Company has warned the food industry.

He said that because it was a general piece of legislation, the food industry had perhaps not given the UCP Directive the attention it deserved.

What was omitted could be as important as what was included under the legislation, he said at the Food Labelling and Food Safety conference in Brussels last week. In answer to a question, he said that if a company made a “low fat” claim on a product but omitted to say that the product was high in sugar then it could face a challenge under the UCP Directive. Similarly, a product claiming no added sugar but failing to say it contained sweeteners could also be accused of omitting information.

“You cannot be economical with the facts, that is omission,” he said.

EVIRA looks at 625 health claims

The Finnish Food Safety Agency Evira has received more than 625 health claims which companies want to be included on the Article 13 lists (these exclude disease risk reduction health claims).

Evira first asked companies to fill in a questionnaire on the claims they used and justification in March of last year and by August had received 575 responses, Sirpa Sarlio-Lahteenkorva from Evira said.

Evira then published the list of claims already received last autumn and gave companies a further opportunity in October 2006 to submit claims, during which time 50 more responses were received, she told the Food Labelling and Food Safety conference in Brussels last week.

Vital functions

Of the 625 responses the vast majority – more than 88 per cent – are on vital functions. Some 4.8 per

cent relate to behaviour or psychology and some seven per cent are on weight loss or weight maintenance. There are 34 products whose trademarks include a claim and 39 products which use a symbol or picture that is a claim.

Some 20 per cent of responses are on cardiovascular system claims, about 13 per cent on weight control and carbohydrate metabolism, ten per cent on gut health and immunity, seven per cent on mental state and performance and about six per cent on bones, musculo-skeletal system.

In terms of the evidence submitted, about 22 per cent report clinical trials conducted on the product.

“There are actually more studies that I would have expected, although we have not looked at the quality,” she said.

Some six per cent report in vitro and/or animal tests on the product. Some 53 per cent report clinical trials on a similar product and 36 per cent in vitro and/or animal tests on the product. Some 65 per cent quote other research such as evidence carried out on the ingredient and 48 per cent say the information is publicly available. Some 0.6 per cent say there is no knowledge of research.

Problems in classification

She said the key challenges now were how to classify the claims, how to evaluate scientific evidence and how to consider consumer understanding of the claims.

“Many claims are difficult to classify, such as claims on cholesterol, hormones, blood sugar and mental health,” she said. “There is also the issue that some active ingredients have medicinal effects in high doses. There may also be studies which show the prevention, treatment or even curing of human disease, even if the claim is under Article 13.”

A risk reduction claim must go for full assessment by the European Food Safety Authority while claims about treating or curing disease are banned on food.

“There is also the question of how to decide what claims are about children’s health and development. There is the definition of a child, the wording of the claim and the nature of the evidence.”

“Some definitions say a child is up to the age of 12, but others say you should have 18 because there is growth and development up to that age.”

Some of the other problems were:

- * Claims which rely mostly on epidemiological data
- * Claims where the active ingredient is incompletely characterised
- * Claims where the health effects are statistically significant but small, perhaps bringing a benefit to only a small part of the population
- * Claims where the substantiation is based on traditional knowledge
- * Claims relating to a biomarker where there is a dispute about the relevance of this biomarker for human health.

“You have to ask if epidemiological evidence is acceptable.”

She also said that on the issue of consumer understanding, which everyone agrees is complex, that the type of product could influence consumer interpretation of a claim, and there could be a difference between food supplements, traditional versus new foods or fortified products versus natural sources of an ingredient.

It is also vital that the conditions applying to claims should be analysed to ensure they are not misleading. It had to be clear the amount required for the effect and the bioavailability had to be evaluated, she said.

The work is now moved to the Ministry of Trade and Industry, which is responsible for compiling the national list. The working group includes Evira’s health claims expert group, however, and it will apply principles agreed in the Commission’s working group and guidelines from EFSA. A summary list of claims accepted and rejected by Evira is set out on p.12.

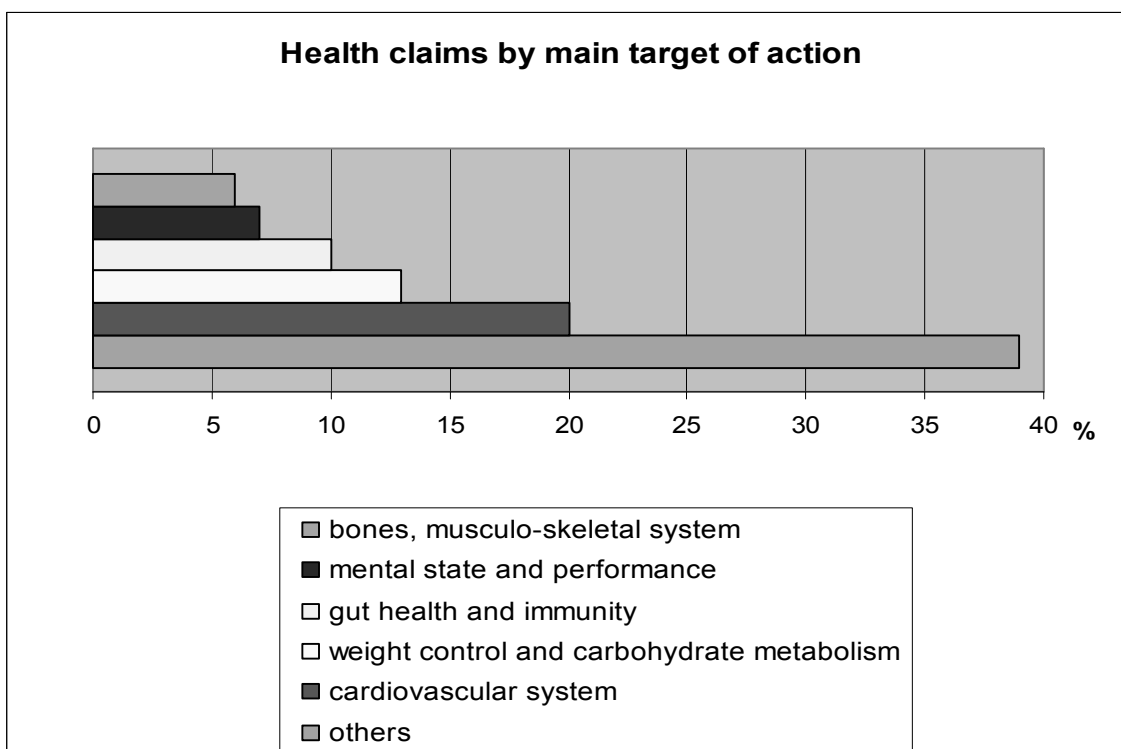
Examples of accepted claims by Evira

- Improvement of gut health and gut immune function (probiotics in fermented oat drink and yoghurt-type of product)
- Control and/or lowering of cholesterol (oatfibre+oatmeal cereal, 6g/100g beta-glucan)
- Promotes intestinal function (oatfibre+oatmeal cereal)

Examples of rejected claims and reasons for rejection

- Improves physical function + recovery (colostrum powder), amount/frequency tested
- Increases elimination of alcohol from blood (high fructose soft drink), totality of evidence, own unpublished studies with low quality
- Lowers blood homocysteine levels (fortified fruit juice/ fortified water), relevance for health unclear
- Calcium reduces the risk of dental erosion (fortified juice for children), the product contains fermentable sugars
- Contains iron that carries oxygen in blood (oatfibre+oatmeal cereal), no data on absorption/ bioavailability
- Lower cholesterol (fermented oat product), literature-based only

Source: Evira



Ramazzini publishes second study on aspartame

The artificial sweetener aspartame causes cancer in rats and there is a dose response in rats fed twice the acceptable daily intake (ADI) recommended in the United States, according to the research results published last week by the European Ramazzini Foundation in the peer-reviewed *Environmental Health Perspectives* journal.

The results of the study, which fed rats aspartame from the beginning of fetal life, was met by a resounding silence from the media, consumer organisations and the sweetener industry. Although there was media interest when the ERF's Prof Soffriti presented results in New York last month, there was virtually no coverage in Europe of the publication of the study results.

The second ERF study fed one group of rats aspartame at doses of 2000 ppm, equivalent to 100 mg/kg bw, or twice the ADI in the US (which is 50 mg/kg bw) and two and a half times the ADI in Europe (which is 40 mg/kg bw). A second group was fed 400 ppm, equivalent to 20 mg/kg bw or half the European ADI recommended by the European Food Safety Authority. There was also a control group.

Commenting on why these doses were chosen, a spokesperson for ERF told *EU Food Law* that the experiment was designed to "better quantify the risk" given that the first study showed aspartame could cause cancer. Some critics argue that there are insufficient different doses and therefore no proper dose response.

The conclusions of the study, which was carried out with aspartame from Ajinomoto, was that there is a significant dose-related increase of malignant tumours in the male and female rats.

"The results of our second long-term carcinogenicity bioassay on aspartame not only confirm but also reinforce our first experimental demonstration of aspartame's multipotential carcinogenicity at a dose level close to the human ADI.

"Furthermore, the study demonstrates that when lifespan exposure to aspartame begins during fetal life, its carcinogenic effects are increased," concluded the study.

"On the basis of the present findings, we believe that a review of the current regulations governing the use of aspartame cannot be delayed. This review is

particularly urgent with regard to aspartame containing beverages heavily consumed by children."

The European Food Safety Authority (EFSA) dismissed the first Ramazzini study on aspartame in May 2006, saying the rats had lung infections and that the lymphomas and leukaemias were unrelated to aspartame.

In this second study, the ERF claims that its latest experiment disproves the alternate hypothesis from EFSA that the cancers were caused by high background incidence of chronic inflammatory changes in the lung.

The ERF experiments are unusual in that they allow the animals to die rather be culled at a certain age. The researchers argue that infectious pathologies are part of the natural dying process in rodents and humans. They also say that in the rats with lymphomas/leukaemias, the neoplastic tissue was observed not just in the lung but also in the liver, spleen and other lymph nodes.

Increase in cancers

EFSA criticised the first ERF aspartame study arguing that there was no dose-related response and that this would be expected if aspartame caused the cancers. In the second experiment, the differences between the male rats fed half the EU ADI and those in the control in some respects are not so great but there seems to be an increase in cancers in those male rats fed more than two and a half times the EU ADI (see table on p.15).

The percentage of tumour bearing male rats in the control and at 20 mg/kg bodyweight are similar (around 25 per cent tumour bearing animals for both and about 27 per cent total tumours.) But for the male rats fed 100 mg/kg bw, this rises to more than 40 per cent tumour bearing animals, more than 44 per cent total tumours. For lymphomas/leukaemias, the rise is from 9.5 per cent for the control, to 15.7 per cent for those fed half the EU ADI and for just over 17 per cent for those fed two and a half times the EU ADI or twice the US ADI.

In this second experiment, for the females total tumours rise from 50.5 per cent for the control, to 62.9 per cent for rats fed half the EU ADI and up to 85.7 per cent for rats fed two and a half times the ADI in Europe or twice the US ADI. For total lymphomas/leukaemias, these were found in 12.6 per cent of the female rats in the control, 17.1 per cent of rats fed half the EU ADI and 31.4 per cent of the female rats fed two and a half times the EU ADI.

Breast cancers increased from 5.3 per cent for the control, to 7.1 per cent for those fed half the EU ADI and then to nearly 16 per cent of those fed two and a half times the EU ADI.

Sweetener industry criticises study

However, the sweetener industry argues that with just two doses given, plus the control, there is “no defined dose response”. A spokeswoman for the International Sweeteners Association told *EU Food Law*: “From reading the article in Environmental Health Perspectives, we would say that with just two levels of treatment they have no defined dose response.”

She argued that the second study was similar in design to the first one which EFSA had criticised. “In general, the methodology used is similar to the one EFSA criticised last year and the FDA criticised in April,” she said. “They said that the conclusions Ramazzini had drawn were not reflected in the science and from talking to independent scientists we would expect the same conclusions to be drawn about this second study,” she said.

She argued that the same colony of rats had been used as in the first experiment, which was criticised by EFSA for not being healthy. However, *EU Food Law* could not find a specific reference in the paper saying the same colony was used. “They also did not use OECD guidelines in conducting the study.

“It seems to be the same sort of science as used in the first study which was criticised for being poor science,” she commented.

Call for EFSA to get data

She expressed concern that Ramazzini had not already handed over its data to EFSA.

“If you (Ramazzini) make these statements you should have to prove the science to back-up what you have said,” she commented.

She stressed that the Ramazzini studies went against the large number of studies, including recent studies on humans rather than rats, which showed aspartame to be safe.

The second ERF study points out that aspartame is in more than 6,000 food and drink products but does not go into detail on likely human doses. However, on its web site, where it has set up an interactive question

and answer page, Soffritti argues that it is quite easy for humans to exceed the current ADIs set in the US and the EU, particularly for children who have a relatively low body weight. He argues, in answer to a web question, that someone might easily in a day drink two cans of diet drink, one light yoghurt, one diet dessert, four packets of aspartame in coffee and perhaps ten candies or pieces of chewing gum containing aspartame. “The aspartame content in the above is 910g,” he concludes. For a woman weighing 50 kg, the consumption is just under half the EU ADI at 18.2 mg/kg body weight. For a child weighing 20 kg, the aspartame content would exceed the ADI in Europe, coming in at more than 45.5 mg kg body weight. “It is important to note that in both studies conducted by the European Ramazzini Foundation, carcinogenic effects were observed very close to the ADI for humans,” he said.

EFSA executive director Catherine Geslain- Laneelle has already written to ERF, before the results were unveiled in New York, asking for the full data.

EFSA invited to ERF

A spokesperson for ERF said it had invited Geslain-Laneelle to come to see the ERF laboratories and the work that it was doing. She said ERF’s experience of EFSA over the first experiment was that EFSA had been very onerous and staff had had to spend countless hours compiling data. “We had to do all the documentation with no support. This is not possible. It is not possible to make this request of a small, independent foundation. We want open dialogue with EFSA.”

A spokesperson for EFSA told *EU Food Law* that EFSA “considers carefully any new evidence that was not available at the time an Opinion is adopted.” She stressed that EFSA had already requested the data but that the ERC would not consider providing it before publication of the study. “Now that the study has been published, EFSA will re-iterate its request and will decide on the level of priority to review the data as soon as these become available.”

For the industry side, the Aspartame Information Service says that there are 200 studies which demonstrate the safety of aspartame; that EFSA has reconfirmed the safety of aspartame in 2006; that in the first ERF study the laboratory the rat colony was in-bred and not germ free and that ERF does not reveal the source of its funding.

Average Daily Intake of Aspartame		
Substance	Quantity/day	Concentration of aspartame consumed
Diet soda (200 mg/can)	2 cans	400 mg
Yogurt (125 mg/yogurt)	2 yogurts	250 mg
Diet custard/pudding (75mg/mousse)	1 serving	75 mg
Coffee with sweetener (40mg/packet)	4 cups	160 mg
Candy/chewing gum (2.5/candy)	10 candies	25 mg
Totals		910 mg

Equivalent to:	
Woman weighing 60 kg	= 15.1 mg/kg body weight
Woman weighing 50 kg	= 18.2 mg/kg body weight
Child weighing 30 kg	= 30.3 mg/kg body weight
Child weighing 20 kg	= 45.5 mg/kg body weight

Source: ERF

Lifespan exposure to low Doses of aspartame beginning during prenatal life increases cancer effects in rats. Morando Soffritti, Fiorella Belpoggi, Eva Tibaldi, Davide Degli Espostic, Michela Lauriola.

Commission concerns over Benecol Olive Oil

The problem of over-dosing on plant sterols looks set to be discussed next week at the Standing Committee for the Food Chain and Animal Health when the launch of Raisio's Olive Oil with Benecol will be considered.

Raisio has launched the olive oil with phytosterols, which can reduce cholesterol, into the Portuguese market. The product is sold, however, in a large bottle with no portion sizes. Given the copious amounts of olive oil consumed by the Portuguese, there are fears that some consumers could exceed the recommended maximum of 3g a day, particularly if they combine it with other phytosterol products.

It seems that Raisio has launched the product without going through the normal novel food authorisation procedure generally required for a product containing phytosterols. It is understood that as Benecol was on the market prior to May 1997, Raisio has launched the olive oil product into the market even though Benecol was not used in olive oil prior to the May date set out in the Novel Food Regulation but in a yellow fat spread. However, a spokesman for Raisio refused to answer any of the questions put to the company by **EU Food Law** apart from to say that the product was marketed legally on the Portuguese market. He declined the opportunity to discuss the letter from Raisio to the Commission, which first wrote to the company to express its concerns.

There is scientific evidence that phytosterols added to foods can lower cholesterol and authorisations have been granted for their use in products such as yellow spreads and milk type products. However there is concern that consumers could overdose on phytosterols if food manufacturers try to put them in everything on the market and that they are not suitable for certain sectors of the population such as pregnant women, babies and young children.

Recently, Coca-Cola has applied to use plant sterols in soft drinks. The issue was referred to the European Food Safety Authority which concluded that it had no means of knowing if consumption of these drinks would lead to the 3g a day being exceeded and that risk management measures were recommended to prevent a cumulative intake of more than 3g a day. It called for quantitative data in order to provide a risk assessment on the risk of over-consumption (see **EU Food Law** March 23 2007). In April 2007, the director general of DG SANCO Robert Madelin described the data on phytosterol consumption as "lousy."

Geslain-Laneelle offers EFSA scientists a new deal

The management board of the European Food Safety Authority will consider increasing the daily rate paid to scientists on the panels and committee at its meeting in September and giving higher amounts to the chairs and rapporteurs, who do more of the work.

Executive director Catherine Geslain-Laneelle proposed a package of improvements at the board meeting this week to help facilitate the work of the unpaid scientists who agree the EFSA Opinions.

In future, up to 40 per cent of the meetings will be outside Parma, which is difficult to get to, and video and conference facilities will be developed. There would be clarification over what went to the panels and which questions could be answered by EFSA staff, she said. However, some panels such as GMO, NDA and the animal feed panel were required in some legislation to provide Opinions, which could only be done by the panels. However EFSA staff could do more of the preparatory work, she said.

Creation of new panel

The management board will also consider a proposal in September to split the work of the AFC panel which deals with additives, food contact materials and flavourings, as outlined by the chair Sue Barlow at the March board meeting.

Geslain-Laneelle said she was also looking at having advisory experts to help with the work load of the Scientific Committee, who would not be full members of the Committee but would help in some of the tasks.

“We need to make the work conditions optimal,” she said, describing an increasing work load with 2,500 Opinions on feed additives alone required by 2010.

Her plans were welcomed by the board. Chair Patrick Wall said: “Scientists are the back-bone of EFSA” and that there must be “a process of continuous improvement.”

Questions over journal

The only real question came on her proposal to have an EFSA scientific journal, as a means of better recognising the work of the scientists along with letters of recognition sent to their employers. There were queries over how it would fit-in with the existing scientific literature from DG SANCO Director General Robert Madelin and questions from Bart Sangster on how peer review of articles would work and whether there would be sufficient articles to publish.

Diminishing the work load

Madelin said it was important that the heavy work load on individuals should diminish and that the pool of scientists should be increased so that the pressure was decreased. Deirdre Hutton said that with some scientists spending 20 per cent of their time on EFSA work, EFSA was at least “a shared employer”. This should be a maximum and steps taken to reduce it, she said. She was in favour of other scientists being invited to working groups but called for clear criteria on their appointment.

Geslain-Laneelle said EFSA was working to improve the transparency of the working groups.

Recognition

She also outlined plans to give greater recognition to scientists who spend time on EFSA work to make clear to their employers that this is important work and not holidays in Parma. She will look at ways to build awareness and appreciation of the work carried out.

Board members stressed the need to have the best scientific advice available to EFSA, recognising that some scientists at the cutting edge did not have sufficient time to be a member of a panel but could be involved in another way.

The EFSA executive will take forward these ideas coming back to the board in September. Some issues, such as the payment of a daily fee, have to be voted on by the board, which in the past has been reluctant to increase this.

Cloning: ethics versus the science

The European Food Safety Authority will make very clear to its stakeholders what is outside its remit in the forthcoming Opinion on cloning, executive director Catherine Geslain-Laneelle told the management board this week.

The Opinion on cloning will look at food safety, animal health, animal welfare and the environment but she stressed that there were many ethical issues which are outside’s EFSA’s brief. She said EFSA would hold discussions with stakeholders.

A working group of 14 people will prepare a draft Opinion which will go out to consultation in the autumn, according to her Progress Report tabled at the meeting. EFSA has already launched a request for relevant peer reviewed data.

Cloning of animals is hugely controversial and experts argue that the ethics and emotional response of consumers will have far more impact than a scientific risk assessment. With cloning already given the green light by the Food and Drug Administration in the United States, it could become the next battleground for a US/European trade dispute.

The cloning issue was taken up by a number of board members including Giorgio Calabrese who forecast that there would be problems in producing meat

without animals in the laboratory. "We need to speak about this," he said.

In the field of ethics, he suggested EFSA should engage with Christian representatives and people from other religions.

He also light-heartedly suggested cloning the chair Patrick Wall and the executive director in order to have more ambassadors for EFSA.

Meeting with COREPER

In the 15 page Progress report presented by Geslain-Laneelle to the board, which only covers two months, she highlights meetings with the Portuguese authorities to discuss EFSA co-operation during their presidency (which begins on July 1) as well as her attendance at the COREPER (committee of permanent representatives) meeting on 13 June to present EFSA's strategy for networking and co-operation with Member States.

The EFSA press release on salmonella in broilers generated significant press interest but there appears to have been little or no coverage in Hungary or Poland, two countries with the highest Salmonella infection rates in Europe, says the Progress Report.

Calabrese criticises GMO threshold for organics

European Food Safety Authority management board member Giorgio Calabrese criticised the 0.9 per cent limit for adventitious GMO contamination in organics agreed by Agriculture Ministers last week (see *EU Food Law* June 15 2007). He called instead for a limit at 0.1, 0.2 or 0.3 per cent.

"If something is organic, then it is not GMO," he said.

Chair Patrick Wall appealed for the board to stick within the risk assessment remit of EFSA.

EFSA to contract out preparatory work on claims lists

The European Food Safety Authority is looking to contract out preparatory work on the lists of health claims being prepared by the Member States under Article 13, Albert Flynn, chair of the NDA panel on nutrition told the management board meeting this week.

Flynn said there could be 400 to 500 health claims on these lists, which are currently being considered by Member States before being sent to EFSA. Contracting out was one means of dealing with the increasing work of the NDA panel which will conduct the individual risk assessment on disease risk reduction claims and children's claims from July. The panel will also support EFSA in its nutrition strategy which will be launched later this year, he added.

Flynn said that on the draft guidance for Article 14 disease risk reduction and children's claims, EFSA had already received more than 280 responses. "This is a high profile area, there are many interested parties," he said. In addition there had been the meeting with stakeholders last week under the Stakeholder Consultative Platform which he described as "very, very useful." These disease risk reduction risk claims will be dealt with by the panel, ad hoc scientific experts and EFSA staff, he explained, as will the work on the nutrient profiles where there is no mention of out-sourcing any work.

Healthy choices

The work of EFSA in relation to the health and nutrition claims Regulation would be vital in helping people to make healthy choices, a key element of the Commission's white Paper on Nutrition and obesity, Flynn said. "It is important that there are incentives and that there are healthy options available."

The NDA panel expects to publish its final guidance on the disease risk reduction and children's claims next month and Flynn said he expected to start receiving dossiers from 1 July. Collaborating with Member States was seen as key in delivering within legal deadlines.

Bart Sangster, who retired from Unilever last month, stressed that the final responsibility remained with the panel even when working groups were used. Flynn said that on the draft guidance, which was developed by a working group, the draft had been significantly changed on going to the panel, which had seen it "with fresh eyes." He argued that this was an example where the panel did take final responsibility even if not all members were involved throughout in every aspect of the detail.

Kellogg's makes 12 the new six

Kellogg's became the latest food company to make 12 the new six last week with the announcement that

it would only market foods that meet a certain nutritional profile to children under the age of 12.

Kellogg's also announced that its Guideline Daily Amount labels, familiar in the UK and other European countries, will be rolled out globally to give consumers percentage information on key nutrients on the front of pack.

The company has devised what it describes as science-based Kellogg Global Nutrient Criteria, which it will use as the basis for advertising to under 12s in addition to its existing commitment not to advertise to children under six. Implementation will be immediate and will be completed by 2008.

The nutrient profiling that Kellogg's is using sets the following criteria for **each serving**, which it defines as 30g both for breakfast cereals and cereal bars:

- * Calories: No more than 200 per serving;
- * No more than two grams of saturated fat
- * No added trans fat (hydrogenated vegetable oil)
- * No more than 230 milligrams of sodium
- * No more than 12 grams of sugar as labelled (excluding any sugar a consumer might add themselves).

Almost half Kellogg's products marketed to children do not meet these criteria. They will either be reformulated to meet the nutrient criteria or they will no longer be marketed to children from the end of 2008.

Unilever announced last month that it would only advertise foods to children under the age of 12 which met its My Choice criteria. These criteria are based on no more than two per cent of energy coming from trans fat, no more than 15 per cent of energy from saturated fat and less than 33 per cent of total fat. However, the Unilever system also has product categories with some higher benchmarks for salt. For total sugar, the rule is no more than 25 per cent of energy and under 7g per 100g.

The Kellogg's nutrient profiling initiative will not have an impact in the UK on what is broadcast to children. Ofcom is already implementing rules which ban the advertising of unhealthy foods to children based on profiling developed by the Food Standards Agency which is much stricter than the Kellogg's model.

Internet commitment

Kellogg is also making a commitment on its brand web sites for products which do not meet these criteria to limit access to children under 12. On licensed characters, it will only use these on products which comply with its nutrient criteria starting with new foods introduced from 2008.

The GDA labelling gives information on calories, total fat, saturated fat, total sugars and salt.

David Mackay, President and Chief Executive Officer of Kellogg Company said: "The initiatives...further strengthen our commitment to help consumers make informed food choices and set a new standard of responsibility. In addition, we plan to increasingly emphasise products with enhanced nutritional value as well as find ways to stress the importance of healthy lifestyles in our marketing to children."

Werner van Katwijk, Secretary General of the European Parents Association (EPA), said he welcomed the initiatives and applauded the provision of "simple nutrition information on its products."

In the United States, the Centre for Science in the Public Interest said that as a result of the announcement it would not be proceeding with a lawsuit against the company which it had filed along with two Massachusetts parents and the Campaign for a Commercial Free Childhood.

Kellogg's has world sales of more than \$11 billion including products such as Frosties, Pop-Tarts and Special K.

It first introduced front of pack GDAs in the UK in 2005 and has since rolled out an updated scheme to other European markets including Ireland, Spain, Portugal, Germany, France, Belgium, Netherlands, Italy and Greece.

Later this year, GDAs will appear on read to eat cereals in the United States, Canada and Mexico.

Baobab set to get positive risk assessment

Baobab dried fruit pulp from the Baobab tree is set to be given a positive risk assessment as a novel food, Mike Gasson, chair of the Advisory Committee on Novel Foods and Processes (ACNFP) has said.

The ACNFP has been responsible for the initial risk assessment on the application from PhytoTrade Africa which will be sent to the European Commission and other Member States under the comment procedure in the Novel Foods Regulation.

Speaking in Brussels last week, Gasson said that there was evidence of a history of traditional use as a staple food in Africa and that the ACNFP had given weight to this in its Opinion, particularly because it was a staple food and not something occasionally consumed.

The Baobab tree (*Adansonia digitata*), also known as the upside down tree, produces fruit which PhytoTrade Africa wants to use in dried fruit pulp form in products such as smoothies and cereal bars. The applicant also intends to market a de-pectinated baobab fruit pulp as a novel food ingredient in other products such as biscuits, confectionery.

Under the current Novel Food Regulation, a product or ingredient has to have a safe history of use in Europe or a full evaluation under the Regulation. However, some third countries increasingly argue that safe history of use outside Europe should be taken into account and this issue will be considered as part of the forthcoming review of the Novel Food Regulation.

The ACNFP is also about to publish its opinion on Echium Oil, a vegetable oil rich in omega-6 and omega-3 polyunsaturated fatty acids, extracted from seeds. Croda Chemicals wants to use the oil in a range of food products including milk and yoghurt based drinks

Labelling review could bring new rules on labelling liability for retailers and producers

The implications of the Lidl Italia case, where the retailer was found to be responsible for inaccurate labelling by a supplier, will be considered as part of the labelling review, Health Commissioner Markos Kyprianou has said.

The Lidl Italia case hit the headlines because the European Court of Justice ruled that the Italian branch of the German retailer Lidl had responsibility for a German product from Jurgen Weber which stated alcoholic strength of 35 per cent when in fact the alcoholic strength was 33.91.

The case has left retailers across Europe concerned that they could be held liable for the labelling minutiae on every pre-packed item that they sell.

Italian national law provides for liability for distributors in these cases as well as other operators.

In a written answer to a Parliamentary question, Kyprianou said the Commission is aware of the concerns and noted, that without prejudice to the ongoing analysis, that the penalty system for infringement of obligations arising from Community legislation is normally determined by national law.

He said that in practice, liability is becoming much more complex because primary producers often have contracts with manufacturers and distributors, requiring them to meet quality and or safety standards. He said distributors increasingly sell own brand products.

“This results in greater joint liability for the various operators throughout the food chain,” Kyprianou concluded “in contrast to the individual liability which was previously the case.”

In any case, the efforts under way to revise Community legislation on labelling “provide an opportunity to study this issue and to determine, where necessary, the principles for avoiding the risks inherent in regulatory fragmentation which would arise from the proliferation of different national arrangements in liability.”

The MEP who asked Kyprianou the question, Glenis Willmot, said the judgement meant that a Member State could impose a responsibility on the retailer to verify statements on labels or products made in other EU countries and that this could considerably increase the administrative burden on retailers. She said it can cause barriers to trade because retailers will be encouraged to stop selling products made in other EU countries and could lead to an overall reduction in consumer protection. She called on the Commission to take advantage of the current revision of 2000/13/EC to clearly define who is responsible for the accuracy of the particulars in a prepacked foodstuff.

The ECJ ruled that it is for national law to lay down the methods by which a distributor may be held liable for infringement of labelling obligations. Directive 2000/13 does not specify who is liable.

Brussels based lawyer Bernard O'Connor of O'Connor and Company said that in applying the court's reasoning a Member State could consider that

the retailer be bound to verify the substance of the compliance with all the rules, including perhaps the veracity of nutritional information when a health claim appeared on the label.

The financial consequences for retailers may be high, he warned.

“The possibility of national decisions claiming the responsibility of retailers for the compliance with Community requirements applicable to foodstuffs made in other EU Member States may even result in retailers stopping selling such products because they are unable to assess the extent of the risk that they will have to assume.”

He called for a clear system of operators’ responsibility to be established under the revision of the labelling rules which would specify the respective responsibilities of various operators involved in production, processing and sale of foodstuffs.

Judgement of the Court of 23 November 2006 Case C-315/05

EU set to debate GM maize imports

Imports of genetically modified (GM) ‘maize 59122’ could be authorised by the EU next Monday if EU national food and feed experts vote in favour.

The maize, modified with a protein known as ‘Bt’ to resist the maize rootworm, has been assessed for potential use in food, feed and processing.

According to a spokesperson from Pioneer Hi-bred who produce the maize, it will become “increasingly difficult” for the EU feed industry to source GM-free maize at a “reasonable cost” if member states do not pass maize 59122.

There is concern that Europe could face an animal feed crisis unless it approves GM feed sold in the United States and other grower countries.

The industry official underlined that more than two-thirds of the EU’s demand for maize used for feed is met through imports -- mainly from the United States where it is processed from mixtures of GM and non-GM maize.

Moreover, ten non-EU countries have already authorised 59122.

‘Herculex RW’, as the maize is more commonly known, received a positive assessment from the European Food Safety Authority (EFSA) in March this year.

However, certain EU states such as Austria and Luxembourg known for their GM-scepticism may block the vote.

The maize must be voted through with a qualified majority (255 votes out of 345) by the EU Standing Committee.

Dutch MEP to be Parliament’s EFSA contact person

Left wing Dutch MEP Kartika Liotard has become the European Parliament’s contact person for the European Food Safety Authority (EFSA).

This is a new role that Parliament has introduced to ensure two-way communication between the assembly and the EU’s numerous agencies. Liotard told *EU Food Law* that it was not yet certain what these contact people would do as all of them were “a little bit in the dark”, but she has already been in touch with EFSA Executive Director Catherine Geslain-Lanéelle to carve out a plan of action for cooperation.

The main aim of the new system is to ensure one person from Parliament was in constant contact with the relevant agency. The plan for EFSA was to stream all communications between MEPs and EFSA through the Committee on the Environment, Public Health and Food Safety and Liotard. Liotard for her part will try and keep the Committee up to date with new projects or ongoing work in EFSA.

Liotard said she welcomed the new system of naming contact persons. “I hope it will lead to more communication before decisions are made by agencies.”

She said in the past EFSA would present its work programme for the following six months when it was already adopted. Now the plan that Liotard and Geslain-Lanéelle have mapped out is for the EFSA chief to come along to a Committee meeting and explain the programme before it is finalised, giving MEPs the chance to ask for changes. Liotard reported that Geslain-Lanéelle had been really enthusiastic about the idea because the Executive Director complained that EFSA was currently seen as just an

advisory body for the European Commission, when it was also there for Parliament.

Geslain-Lanéelle is due to appear before the Committee in October to set out EFSA's plans for its upcoming work programme. The early timing means Parliament will have a chance to discuss the programme and call for changes, Liotard explained. "I think that's a start to more cooperation together," she said.

Liotard acknowledged that she had been critical of EFSA in the past. "For them (EFSA) it was not a secret that I was critical," Liotard said, adding that she was sure when agency staff heard about her nomination "it was like our contact person."

The Dutch MEP said she did not know if the contact person system would work, especially her cooperation with EFSA. But she said after three meetings with Geslain-Lanéelle "I think the intention is there on both sides to make it work."

EPHA says guidance should show how EFSA assesses claims

The European Food Safety Authority (EFSA) should give more information about how its panel on dietetic products, nutrition and allergies (NDA) will assess applications to approve health claims under the EU Regulation on Health and Nutrition Claims, says the European Public Health Alliance (EPHA).

EPHA's comments came in response to draft guidance that the agency published last month (see *EU Food Law*, May 18, 2007), covering claims related to disease risk reduction and children's health and development, which have to seek prior authorisation under the Regulation.

While broadly welcoming the draft guidance as providing "a well-structured framework for gathering and assembling most of the information relevant to the substantiation of a health claim", EPHA called for greater clarity about how the NDA Panel will evaluate applications. Ideally, EPHA says this should be set out in a separate document, but if this is not possible then the organisation says the evaluation process should be set out in the draft guidance "in a way that distinguishes it from the process of gathering and assembling the information."

EPHA noted that the draft guidance attempts to distinguish between the information gathering process and the evaluation, but says the separate

nature of these two processes should be made clearer: "We think that the first task is the primary responsibility of the applicant and that the second is primarily the responsibility of the NDA Panel."

The Brussels-based grouping of health lobbies went on to lay out a four-point wish list for any future document on how the NDA Panel will evaluate applications. EPHA says the document should give details of:

- What counts as sufficient evidence to substantiate a claim.
- How the NDA Panel will weigh evidence from observational studies against evidence from intervention studies. EPHA argues that there should be at least some evidence from intervention studies for a disease risk reduction claim to be substantiated.
- How the NDA Panel will use evidence from studies involving bio-markers, including details of which bio-markers the NDA Panel considers to be established surrogates for health outcomes.
- How the NDA Panel will weigh evidence from clinical studies (human studies carried out in controlled conditions) against evidence from studies carried out on free-living human populations.

Pre-existent systematic reviews

Another criticism was that the draft guidance does not give enough weight to pre-existent systematic reviews, including systematic reviews that have meta-analyses, pertinent to the claim. EPHA points out that "in most 'hierarchies of evidence' used for assessing the effectiveness of interventions, systematic reviews and meta-analyses are considered to provide good quality evidence (similar to large individual studies)."

The organisation argues that "should there be a good-quality systematic review relevant to the claim then this would provide a good starting point for an application and might obviate the necessity of the applicant providing information about individual studies if they are included in the review."

The guidance should therefore encourage applicants to provide a synopsis of pre-existent systematic reviews, says EPHA showing the final date for included literature, the search strategy as well as inclusion and exclusion criteria.

EPHA goes on to argue that applicants should be encouraged to provide information about the source of funding for studies. Although the guidance encourages applicants to provide information about conflicts of interest for study authors, EPHA holds that this should be extended to funding “because we note that source of funding for studies are can influence the findings of studies.”

FVO finds poor EU compliance with hygiene rules in 2006

The European Commission’s Food and Veterinary Office (FVO) found Member States failing to apply EU hygiene rules throughout the bloc in a series of inspections carried out last year.

The latest FVO annual report covering activities in 2006 reveals that the office visited all of the then 25 Member States to assess application of hygiene regulations covering red meat and milk that took effect on 1 January last year. Inspectors found “limited application of the basic hygiene rules” throughout the EU.

“A wide range of shortcomings was identified in structures and maintenance, operational hygiene, inspection procedures and official supervision,” the report said. The situation was so bad in seven Member States that inspectors asked them to take immediate remedial action. These Member States, which were not named, were all due to be re-visited in the first half of this year.

In 2006 the FVO started a new series of inspections - in France, Poland, Spain and the UK - to assess risk of Salmonella infection in table eggs. The FVO found a mixed picture but the Member States visited were trying to reduce contamination levels in laying flocks further and all guaranteed that corrective measures were taken after the inspection.

The FVO inspected eight Member States - Austria, Germany, Greece, Ireland, Italy, the Slovak Republic, Spain and the United Kingdom – to assess control systems for the prevention, control and eradication of Bovine Spongiform Encephalopathy (BSE). A separate Polish inspection focused on official controls on the total feed ban and organic fertilisers. The inspectors found BSE control systems “were largely satisfactory apart from minor shortcomings regarding epidemio-surveillance.” The team also found minor failings in controls on removal of specified risk material (SRM) and while official

controls on the total feed ban were satisfactory on the whole, “there was still some room for improvement.”

Checks on official controls for compliance with food and feed hygiene requirements in Belgium, Denmark, Portugal and the Netherlands revealed the systems in place to be largely satisfactory. But there were minor problems when it came to approval and registration of feed business operators and primary feed producers.

There were five visits to follow-up previous animal by products (ABP) inspections in 2006. In Germany, Greece, Portugal, Spain and the United Kingdom inspectors found all had “adequate arrangements and sufficient infrastructures in place to handle most of the ABP in accordance with the ABP Regulation.” The FVO also noted progress in implementing previous recommendations but there was still some work to do. In particular, the report said Member States “need to improve the effectiveness and/or uniformity of official control of the ABP chain by ensuring:

- Availability of adequate staff resources;
- A clear definition and distribution of responsibilities amongst the competent authorities involved; and,
- More guidance and training, and better cooperation between the various competent authorities responsible for these official controls.

Other countries

In the run up to EU accession both Bulgaria and Romania saw FVO inspections to assess progress made in applying EU legislation, particularly hygiene requirements for products of mammalian origin. In Bulgaria, FVO found the situation in red meat and milk production and processing did not meet EU requirements. In both countries, the majority of raw milk did not meet EU requirements. The FVO also found deficiencies in both countries in the identification and registration of farm animals. Both countries pledged to correct the deficiencies found and there are to be follow-up inspections this year.

“Very little progress had been made since the previous mission in 2005,” the inspectors said after visiting Croatia, to assess animal health and veterinary public health controls on mammals and products of mammalian origin. The inspection, which looked at Croatian compliance in the light of its bid to join the EU found: “Most of the relevant EU legislation remained untransposed, no extra resources had been allocated to the competent authority and

little progress had been made in upgrading establishments or setting up the necessary animal disease programmes.”

The FVO visited some 31 countries worldwide to check health conditions for export of fishery products. The report said, while “huge differences exist between the countries visited, ... most of the countries inspected do not comply with all relevant conditions for exporting fishery products to the EU.” In some countries, the deficiencies were so significant that the Commission had to impose trade restrictions. As in previous years, the FVO found problems with laboratory testing capacities and a shortage of sufficiently trained and motivated officials to supervise the production chain. “This, combined with the poor hygiene conditions of fishing vessels and landing sites, led to situations where a potential risk for the EU consumer could not be ruled out,” the report said.

2006 statistics

Most inspections that the FVO carried out in 2006 covered food safety, although following the farm-to-fork approach means inspectors often also checked animal health or welfare at the same time.

The report shows some 68 per cent of the 255 inspections carried out last year were in the food safety field, 14 and 13 per cent for animal health and welfare respectively, with just 5 per cent covering plant health.

Some 26 per cent of inspections checked food of animal origin, 12 per cent import controls, while 7 per cent were for transmissible spongiform encephalopathies and animal by products. General horizontal issues, feed and food and pesticides each accounted for 5 per cent of inspections, with veterinary medicines and residues taking up 3 per cent. Inspections covering contaminants and additives and to check compliance with food hygiene hazard analysis critical control points (HACCP) both accounted for 2 per cent and ‘other’ 1 per cent.

FVO inspectors visited 78 different countries worldwide last year. The report shows that 159 of the 255 visits were in the then 25 Member States, 31 in accession and candidate countries and the remaining 48 elsewhere in the world. The UK was the most visited Member State with 16 visits, followed by Germany and Italy with 11 each, Poland with 10, then France and Spain nine each.

In their final year as accession countries before joining the EU this year, Bulgaria and Romania each had 13 inspections.

CLARIFICATION: The European Parliament’s vote last month to liberate pack sizes (*EU Food Law*, June 1, 2007) does not exclude pre-packaged bread across the EU. Only wines and spirits will continue to be sold in standard EU sizes, while Member States can continue to allow national sizes for the next five years for domestic producers of milk, butter, coffee, dried pasta and rice, and six years for white sugar. However, a recital to the new directive does state that British bakers can continue to sell pre-packaged bread in existing sizes.

Russian restrictions threaten Brazilian meat exports

Russia’s health service (SCVF) has suspended 16 Brazilian meat suppliers, citing “serious irregularities” in shipments originating in Brazil.

“It is evident that Brazilian companies benefiting from the recent increase in beef shipments to Russia are not subject to adequate veterinary service controls,” SCVF director Sergei Dankvert warned in a statement last month. He stressed Brazil’s inability to field enough inspectors to keep track of the world’s largest cattle population, consisting of about 200 million animals spread over vast and often remote regions.

The Russians echoed earlier European Commission complaints regarding inadequate control over cattle movement stemming from deficiencies in the national cattle traceability system. They cited evidence that some of the cattle and beef destined for Russia originate in regions at high risk for foot-and-mouth disease, which violates one of the SCVF’s primary conditions for allowing Brazilian beef imports. In addition, the SCVF accused its Brazilian sister agency of covering up an outbreak of FMD in Mato Grosso do Sul state last year.

Dankvert alluded to 40 instances in which Brazilian veterinarians had falsified documentation in order to cover up potential sanitation deficiencies in products destined for Russia. Although full details were not revealed, it emerged that the incidents involved multiple levels of the supply chain, including basic production, shipment, and meat processors.

Major downturn forecast

The SCVF said this month it would remove the 16 Brazilian meat suppliers from its eligibility list for an indefinite period. Because those companies are unlikely to be replaced by others anytime soon, the

level of beef shipments to Russia is likely to decline as the year wears on. Exporters in Chile and Uruguay are already developing strategies for filling the void, but neither nation has enough export capacity to offset a major downturn in Brazilian supply.

The SCVF invited Brazilian sanitation officials and beef exporters to travel to Moscow to refute the accusations against them. There was no immediate response, because it is difficult to counter the findings of multiple European Commission and Russian inspection teams.

Yet the Brazilians can't afford to ignore the underlying problems that threaten their foreign sales. Russia is by far the largest foreign market for Brazilian meat products, with purchases valued at approximately \$1.5 billion annually.

President Lula da Silva's regime is again scrambling to overcome sanitation deficiencies in the agricultural livestock sector. However, his cabinet's chances of success are limited by lack of cooperation on the part of Brazil's highly autonomous state governments and producers who have a long tradition of ignoring federal policy with impunity.

Former agriculture minister appointed to EFSA

A former Minister of Agriculture, Forestry and Food from Slovenia was appointed this week to the board of the European Food Safety Authority.

Milan Pogacnik is appointed for one year from July 1 2007 until 30 June 2008. He was chosen by the European Council and is not the first choice of the European Parliament, which wanted the Czech consumer association's Libor Dupal.

Pogacnik is a former dean of the veterinary faculty in Ljubljana, and set up the veterinary faculty in Ljubljana as an independent high school institution. He became Agriculture Minister in April 2004.

Pogacnik was picked from a list of five candidates which included British consumer champion Sue Davies, Jiri Ruprich, head of the Czech Institute of National Health and Margarita Arboix Arzo, from the Spanish national medicines agency (see EU Food Law April 27 2007).

The European Parliament wanted Dupal because of criticism that the EFSA board lacks consumer representation but its opinion is only advisory. So far, the European Council has taken little or no notice of the European Parliament views when selecting board members.

The reason the appointment is only for one year is because that is all that is left of Catherine Geslain-Laneelle's term, whom he replaces.

Conference Report

What is the evidence for GDAs or traffic lights? Will the Commission study on salt next year recognise the companies that have already made cuts? These were some of the issues discussed last week at the Food Labelling and Food Safety conference. Kate Trollope reports

GDA data – peer review publication being considered

The UK supermarket chain Tesco is looking at publishing peer-reviewed data to show the impact on consumer choices of its Guideline Daily Amount nutritional labelling which has now been adopted by seven other retailers and at least 32 food manufacturers.

Basil Mathioudakis from DG SANCO called on food retailers and manufacturers to provide data on front-

of-pack labelling schemes to date to help the Commission as it considers the options for its labelling review later this year.

Jim Murray from the European Consumers' Organisation BEUC criticised the supporters of GDAs for failing to publish proper, full studies to show its impact. Quoting a recent report by Which? in the UK, he said GDAs were "PR (public relations) dressed up as evidence" and "spin dressed up as science."

“Much of the evidence has not been published or not been published in full,” he said, “companies have not given a full report.”

“Kellogg’s and Cadbury’s gave summaries only of research details,” he said.

At the meeting, Jane Holdsworth from the Food and Drink Federation presented some of the Tesco results but these are not new – they are the very early examples on sandwiches and ready meals that Tesco released.

Amid calls for data, Karen Tonks from Tesco, who was a delegate the meeting, said Tesco was looking at publishing some sales data where you could see clear changes over time and that this would need to be peer reviewed. However, she, and others at the meeting, warned that such data did not always tell the whole story. With the huge reformulation work done by Tesco recently some products had changed a lot and so direct comparisons could not be made, she pointed out.

Others said that front-of-pack labelling was only one factor in any change in sales and that you had to consider price promotions, other promotions and other activities in the mix.

Food industry concern over Commission salt study

Food companies which have already removed salt from processed foods are concerned that the study which the European Commission is to carry out next year might not take account of what they have achieved and raise the bar too high.

The Food and Drink Federation in the UK has said that the Commission would have to go back as far as seven years in any such study to get a proper picture of salt content and to take account of reductions already made by some manufacturers.

Lyn Trytsman- Gray, public affairs director at Kraft, which has already made salt reductions, said one problem was that different companies kept the information in different formats. “Not all companies keep the data in the same format. We are not able to crunch it all together. Our information is not in the same format as that from Nestle or Coca-Cola.

“We need to be able to show effective monitoring.”

EFSA to publish more detailed declarations of interest

Improved and more detailed declarations of interest by experts on European Food Safety panels and the scientific committee will start to be published this month, Herman Koeter, deputy executive director and head of science said last week.

EFSA has been criticised, particularly by MEPs, for failing to have sufficiently detailed declarations of interest and for failing to scrutinise them.

Koeter told the Food Labelling and Food Safety conference in Brussels that EFSA had revised the declaration of interest form to ask more detailed questions in a drastic change.

This enabled EFSA secretariat properly to scrutinise the declarations.

The panels were reformed last June so some of the new declarations for this year should start appearing on the web site shortly, he said.

EFSA says that an interest in an issue does not necessarily mean a conflict of interest but wants to be able better to demonstrate if there is bias or not.

“Independence has to be managed,” said Koeter

He held up the melamine advice (see *EU Food Law* last week) as an example of how EFSA could provide scientific advice more speedily rather than always have panel Opinions, which take much longer. He said EFSA had received the request on 21 May and been ready to deliver on 7 June. “That is two and a half weeks and it proved very effective,” he said.

McDonald’s – the automated approach

McDonald’s fast food chain is trying to make food safety as automated and foolproof as possible, Bizhan Pourkomainian told the meeting. With young people aged late teens to early 20s largely working in the restaurants, robust procedures were needed so that “You don’t have to think about food safety. You just do it.”

He described the automated burger cooking procedure and how washing chemicals were supplied in automated amounts from dispensers or into the

sink so that they could be no mistake in using too much or too little. Milk shake machines stop working if the temperature rises too much or if there is any pasteurisation failure. “They are automated and they just stop.” Staff have to clean them out and start again.

He regarded salad as the “highest risk” item sold by the restaurants, which it is increasingly putting on the menu in an effort to offer healthier choices.

“It is not sterilised or pasteurised, you just wash it.” McDonald’s was making checks through the supply chain to ensure safety. “You don’t want to find it is being grown where there is run-off water from an abattoir,” he commented. One of its suppliers could trace back salad to a three-metre-square area of land, he revealed. On beef, McDonald’s could trace back the name of the cow within three hours, he said.

Support for co-ordinated approach on obesity

The European Commission has limited regulatory competence in the area of obesity and should focus on co-ordinating an approach across the EU and complementing national policies, Noelle Vonthron from EuroCommerce, representing retailers said.

Labelling alone is not the solution but could help however it must be kept flexible so that it could change as required to meet consumer needs, she argued.

Offering healthier options is a must in the fight against obesity, she said, and there were already regulatory measures such as the one on trans fat in Denmark, the initiative on salt in the UK and voluntary actions by the food industry.

She highlighted, however, that because Member States do have the competence to legislate on obesity, there is increasing national legislation which could lead to trade barriers. She gave the examples of the ban on vending machines in secondary schools in France, restrictions on advertising of junk foods in the UK and Spain and the outright ban in Sweden as well as restriction of trans fats in Denmark.

“Legislation can be justified at national level but too many different approaches would create barriers to trade.

“There is a need for a co-ordinated approach.

She welcomed the Commission White Paper on obesity saying it gave self-regulation a chance, setting the 2010 deadline by which time operators had to prove that they were acting responsibly and proactively.

German scepticism on front-of-pack labels

The German Federal Ministry of Food, Agriculture and Consumer protection (BMELV) expressed scepticism about front-of-pack labelling.

Heinrich von Uechtritz from BMELV said: “I am not sure about front-of-pack labels; it is not proved until now. We have to look at the labelling of products to see if it helps solve the problem. I think we need a lot of research.”

Dutch Socialist MEP Dorette Corbey said there had been “a lot of research done, particularly in the UK” She said: “It is proven that front-of-pack labelling helps consumers make choices.”

Lower fat cheese is now the best seller, says Kraft

A lower fat version of Kraft’s Philadelphia cream cheese has become the best seller, Lyn Trytsman- Gray, public affairs director told the meeting. A 12 per cent fat version of Philadelphia now outsold the original version of the product. The company had also launched an even lower fat version at five per cent.

She argued that European markets were diverse in terms of consumer preoccupations with healthy eating. Research showed that consumers in the UK, Italy and Spain were most concerned about fat but that in France this was not such a pressing issue and consumers were more concerned about sugar and alcohol.

Reformulation had to be gradual rather than drastic because otherwise consumers could reject the product. “There has been a 35 per cent reduction in salt in Dairy Lea but we have done it incrementally,” she said.

The European Commission is promoting reformulation in its White Paper on obesity but she said. “You have to promote consumer acceptance. There can’t be drastic changes.”

Manufacturers could also produce products with a limited and stated calorie content, such as the 75 calories bars of Milka, she said.

There were limits to reformulation because some products, such as chocolate, were defined by law and could not be completely changed. In those instances resealable packs and portion sizes were used.

Individual responsibility: Dutch Socialist MEP Dorette Corbey said she agreed that consumers had a personal responsibility for what they ate. But she argued that healthier choices needed to be made easier by having a voluntary front-of-pack labelling scheme so consumers can quickly identify better choices. She is in favour of a star system and argues that such a scheme would encourage the food industry to reformulate because then they could display more stars.

Spain focuses on additive intake monitoring

There must be much more work done on monitoring the real consumption of additives, Victorio Teruel Munoz from the Spanish Food Safety Agency ASESAN said.

“The real intake of additives is very important,” he told the meeting.

Spain was a member of the working group at EU level on this issue and saw this as a priority, particularly in the light of the forthcoming review of additives which is currently at first reading stage in the European Parliament.

Retailers criticised for removing additives

Food retailers which say they are not going to use additives “undermine the whole industry and undermine the food safety agencies in Europe,” a representative from Ajinomoto, which makes aspartame and monosodium glutamate, said.

He asked for the position of the Spanish food safety agency on this question but did not receive a direct reply, perhaps because it has been more of an issue in the UK than in Spain.

In the UK, many of the retailers have removed additives from children’s food and drink and a broader range of products.

UPSTREAM AND DOWNSTREAM

Bluetongue returns in Germany

A case of bluetongue disease has been discovered in a cattle herd in Hückeswagen in northwest Germany. The infected animal was one of the 1 600 cattle inspected monthly for the disease by the veterinary authorities in the state of North Rhine-Westphalia.

The case proves that some of the flies that carry the disease have survived the warm winter of 2006/07, says *DLZ Agrarmagazin*.

Since the disease first hit northern Europe in August 2006, North Rhine-Westphalia has seen a total of 944 cases – in cattle, sheep and a few deer. Compensation totalling €300 000 has been paid for 191 cattle and 224 sheep.

Romania rejects GM seed accusations

The Romanian ministry of agriculture has responded to French media reports expressing concern about controls over GM seed and other material in the country by claiming that the situation is “under full control of the relevant public authorities.”

In a recent press release, the ministry claimed the backing of the European Commission evaluation mission carried out in April, which said that Romania had put into practice “a functioning control system for genetically modified food, fodder and seeds.”

The ministry stressed that the GM soya cultivated in Romania prior to the country’s accession to the EU at the start of the year was no longer authorised, and that control measures undertaken in 2006 to eliminate unauthorised GM soybean crops were continuing this year.

It also underlined, however, that some EU-authorised GM maize was being cultivated in Romania this year, in line with EU principles. A register of farmers cultivating GM maize had been drawn up and transmitted to the relevant authorities.

The ministry took the step of issuing the press release after the French newspaper *Le Monde* published an article expressing concern about the degree of control being exercised over GMOs in Romania.

COUNTRY REPORT

BELGIUM

Delhaize recalls sardines

Belgian supermarket chain Delhaize, parent company of the US Food Lion group, has recalled canned sardines in soya oil due to raised histamine levels. The sardines, of the brand 365 bear the batch number UV 307 V and have a use by date of 12/2011.

Histamine is an amino acid that occurs naturally in fish muscle, with some species such as sardines, mackerel and tuna, containing more than others. Symptoms of histamine poisoning in people that have consumed the allergen include headaches, hot flushes, reddening of the face and circulatory problems. The symptoms are temporary but anyone experiencing them should consult a doctor, the Belgian federal agency for the safety of the food chain (AFSCA) is advising.

GERMANY

Germany pressing EU for dioxin standard for cod’s liver

Germany is calling on the EU to bring in a dioxin standard for canned and otherwise processed cods liver as current standards only cover fresh or chilled liver.

Germany has been fighting for a cod liver standard since 2004 but the European Commission and several other Member States are resisting the move, citing lack of data. Germany does not intend to give up and will again push for the limits at an upcoming meeting in Brussels, one German regulatory source told us. “We are of the opinion that we need a regulation,” the source said.

Even the limits for fresh or chilled cod’s liver are apparently due to an oversight in the drafting process as the threshold levels were only supposed to cover muscle meat. All fish livers were meant to be left out. The source said the Commission had written to Germany saying that inclusion of fresh or chilled livers was a mistake and like fried or otherwise processed cod’s liver should have been deleted from the EU standards.

In the absence of an EU standard the Federal Institute for Risk Assessment (BfR) is to draw up national recommendations for consumers, which a spokeswoman said would include advice about not eating cod liver more than X times a week. The BfR is also concerned about dioxin intakes for people consuming cod liver oil capsules as food supplements.

At the same time as the German government is pushing other member states for an EU standard on canned cod's liver, campaign group Foodwatch continues to insist that there is a standard in place and that four products it checked were not in compliance (see **EU Food Law**, last issue). A ministry of health letter to Foodwatch is understood to state that there is only a standard for fresh or chilled cod's liver.

However, some confusion could come because the oil in the can with the liver would have to comply with maximum limits.

Without a legally binding limit for cod liver, German food control authorities would have no right to remove the canned products that Foodwatch found to contain high dioxin limits, the source told us. Commercially, supermarket chain Metro might find it difficult not to announce a recall when its competitors have done so, "but legally they are in the right," the source said.

BVL asks Brussels for clarification

Meanwhile, the confusion in Germany prompted the Federal Agency for Consumer Protection and Food Safety (BVL) to ask the Commission for a clarification over the legal situation.

BVL said: "The assessment done by the German consumers organization "Foodwatch" is based on my opinion that the current legal basis (Regulation (EC) No 1881/2006) includes maximum levels set for dioxins for fish livers, with the exclusion which refers to fresh or chilled fish livers.

"However, this situation allows different ways of interpretation: from the legal point of view and from the point of view based on the intention of the legislator. Therefore I have asked the European Commission to provide a clarification of the corresponding legal basis (Regulation (EC) No 1881/2006).

"The European Commission provided the information that the intention by setting maximum levels for the sum of dioxins and the sum of dioxins and dioxin-like PCBs in muscle meat of fish and fishery products and products thereof (Regulation

(EC) No 1881/2006) was linked to an exclusion of fish liver in general and products derived thereof. Anyway, a final clarification will be provided by the European Commission as soon as possible."

Poisoning risk with bitter apricot kernels, BfR warns

The German Federal Institute for Risk Assessment (BfR) is warning about a poisoning risk linked to bitter apricot kernels and calling for the packaging to carry warnings.

Bitter apricot kernels are sold in health food stores and, more recently, to an increasing degree on the Internet, says a BfR statement.

The BfR says bitter apricot kernels have a high natural level of amygdalin, a substance that releases hydrocyanic acid during digestion, which can lead to severe, acute poisoning. At high doses it can even prove fatal.

Eating just a few kernels can already lead to the onset of acute poisoning symptoms, says the BfR, which advises consumers not to eat more than one or two bitter apricot kernels a day "or even none at all for precautionary reasons."

Andreas Hensel, BfR President said in the statement that either way "consumers should be informed about the dangers of poisoning through warnings on the packaging."

In some cases it is claimed that bitter apricot kernels can help to fight cancer, says the agency, noting that "there is no scientific evidence to back this claim." The agency hits out at these unsubstantiated health claims, "which could encourage desperate sick people to buy them," calling them "irresponsible." It underlines that products to treat cancer cannot be sold as foods and must be authorised as medicines. "Amongst other things, efficacy must be proven," says BfR.

Bitter apricot kernels are also sold as foods for immediate consumption. The packs on sale differ in size and only some carry information about health risks. In recent months some state (laender) food control authorities have banned the sale of products which were not adequately labelled. However, bitter apricot kernels are also sold on the Internet, the BfR says, noting that it is difficult for the authorities to control this distribution channel.

The BfR says that measures to regulate the direct consumption of bitter apricot kernels are currently being discussed at EU level. The UK has also issued warnings about the risks so is likely to back Germany in pressing for EU limits.

BfR raises alarm about cadmium levels in chocolate

Children that eat a lot of chocolate could be consuming unsafe levels of cadmium, the German Federal Institute for Risk Assessment (BfR) is warning.

The BfR says that people, especially children, eating the average estimated intake for chocolate of 100 g a week, would already be close to 10 per cent of the World Health Organisation's provisional tolerable weekly intake (PTWI) for cadmium of 0.007 mg/kg and that is without chocolate spread or drinking chocolate, let alone other food sources.

The International Agency for Research on Cancer (IARC) has classified cadmium a category 1 carcinogen, the highest risk class for cancer causing chemicals. The heavy metal is also toxic to the kidneys, which is the main target organ when cadmium is consumed orally (as opposed to for example smokers who inhale cadmium).

Cadmium is naturally present in soil and therefore in plants but the amount present in the cocoa seed used to make chocolate varies depending on source. African cocoa seeds tend to have less cadmium than their South American counterparts but a BfR spokeswoman told *EU Food Law* that is not much help to consumers because they do not know where the ingredients for their chocolate are sourced.

The BfR is concerned that chocolate could be a risk and points to studies suggesting harmful effects even at lower amounts than the PTWI.

As part of an EU review of upper limits on heavy metals, the BfR recommended a maximum level for cadmium in chocolate of between 0.1 mg/kg and 0.3 mg/kg chocolate. The spokeswoman explained that the BfR always had to recommend more than one option but that the agency advised 0.3 mg/kg would only give a minimum amount of consumer protection, while 0.1 mg/kg would offer the highest level of protection.

However, the European Commission has set the new limits without one for cadmium in chocolate, because it said the intake data used was not sound. BfR is not

recommending a national German limit because it fears that could break international trading rules under the World Trade Organisation.

Instead, the BfR is waiting for new intake data that it expects to have by the end of the year. Based on that data the institute will confirm or change its recommendations for chocolate.

Avoid jojoba as a precaution, BfR tells consumers

The German Federal Institute for Risk Assessment (BfR) is advising consumers to avoid eating jojoba due to a potential risk suggested by animal tests.

BfR says jojoba is not sold in any stores in Germany but German consumers can buy it over the Internet from other countries. An institute spokeswoman said that there were currently no indications that manufacturers wanted to put jojoba on the market as a food or ingredient. Any company doing so would have to seek approval as a novel food.

Concerns about jojoba safety come from rat and dog tests showing that the plant *Simmondsia chinensis* can suppress appetite and lead to weight loss. Jojoba liquid wax is indigestible and can destroy intestinal cells, while simmonsins, a key substance in jojoba appears to have effects on the nervous system, the spokeswoman said.

BfR says that human tests on jojoba are lacking so the institute cannot say with certainty that the plant does pose a danger. But the spokeswoman said, the BfR is advising people to avoid eating jojoba based on the precautionary principle "because we cannot say it is safe."

UK

Row over nutrient profiling

The Food Standards Agency's nutrient profiling model for foods which can be advertised to children has come under fire because the supermarket chain ASDA says its milk has too high a sugar content and falls foul of the rules.

Critics have taken issue with the nutrient profiling which they claim allows a soft drink such as Coke Zero to be advertised to children but not full fat milk.

The board of the FSA heard this week that in the original profiling done by the FSA, full fat milk definitely met the requirements nutritionally and could be advertised to children. Gill Fine, in charge of consumer choice at the Agency, said the definition of whole milk was taken from food tables which give reference values produced by Widdowson's, in common with the definitions for other types of food.

Now ASDA is saying that its milk and the milk from other supermarkets in the UK does not conform to the definition in these tables and in fact contains too much sugar to be advertised to children, the board was told. ASDA therefore removed a reference to full fat milk from one its recent advertisements.

Fine said the FSA was talking to ASDA about the analysis it had done. There were suggestions at the meeting that the tables were based on an "average" milk whereas in fact the nutritional content of milk varies from summer to winter and even from Spring to Autumn.

The issue was not discussed at the board meeting but questions are also being asked about whether the tables used for the profiling reflect the actual content of the foods or if further anomalies could be found.

The Ofcom advertising restrictions came into effect on 1 April and have been criticised by the food industry because products such as Marmite, raisins and honey can no longer be marketed to children.

The FSA hosted a meeting last week to discuss a review of the model, which will be overseen by a group of independent scientists. There will be an informal public consultation later this year followed by a formal public consultation next year. The FSA will consider recommendations made by the panel in 2009.

Folic acid – no verdict on bread or flour

The Food Standards Agency did not make any new decisions on fortification with folic acid at its board meeting last week. The previous board meeting decided to fortify either bread or flour, but did not reach a final conclusion, with some board members saying they could accept bread fortification but not flour. At the meeting last week, the board gave some steers to the executive but said it was for the secretariat to work out the finer detail.

The board decided to fortify flour or bread with folic acid to reduce neural tube defect births by up to 18 per cent. The questions now are whether to fortify just bread, and if so whether there would be exemptions for organic bread or wholemeal, for example. The policy is to label products which have been fortified and if flour for cakes and biscuits were to be fortified, they would need to be fortified.

Industry is concerned that importers in other countries might choose not to purchase fortified UK goods if labelling for folic acid is required.

The paper put to the board said fortifying wheat flour rather than bread had practical advantages.

The board stressed that in making recommendations the public health issues should be most important but every effort should be made to avoid problems for industry. Board members also stressed the need for controls on products which are voluntarily fortified with folic acid, as set out in its original discussion.

It specified that fortified products must be labelled.

Pureed baby food "unnecessary" expert claims

Spoon feeding babies pureed food is unnatural and unnecessary, a childcare expert has claimed. Gill Rapley, deputy director of Unicef's Baby Friendly Initiative said feeding babies in this way could cause problems later in life.

She said children should be fed only with breast or formula for six months and then weaned onto solids to improve control over how much they ate. This could prevent them becoming picky about food, she said.

Obesity the cause of child protection cases

Obesity has been the cause of 20 child protection cases this year, the BBC reported last week. It said paediatricians were involving child protection officers in cases where parents or carers were failing to tackle the obesity problem by improving diet, controlling food intake and exercise.

Dessert recall

Premier International Foods has recalled some batches of the dessert Angel Delight because there might be small pieces of metal in the product.

Salad recall over salmonella fears

The supermarket chain Morrisons has recalled some prepacked salads because salmonella contamination was found during routine testing. The products include two sizes of a Bistro salad, a cheddar, tomato and egg layered salad and a layered garden salad. The company has put up notices in store and the Food Standards Agency published a food alert.

Cadbury pleads guilty to food safety offences

The UK company Cadbury has pleaded guilty to three food safety offences after salmonella was found in its chocolate last year and faces a separate legal suit over alleged health and safety breaches at its production plant.

Last Friday 15 June, Cadbury pleaded guilty to three charges brought by Birmingham City Council about the problems at its Bourneville plant in the city. The same day Herefordshire Council launched separate legal proceedings over health and safety failings at Cadbury's Marlbrook plant.

The outbreak happened when a leaking pipe at the Marlbrook plant near Leominster in Herefordshire contaminated crumb mix that was then sent on to the production facility at Bourneville. Birmingham Council was the first to bring charges, at a case heard last Friday. The three charges to which the company pleaded guilty were:

- Contrary to the General Food Regulations 2004, that between 19 January and 10 March 2006 Cadbury placed on the market ready to eat chocolate products which were unsafe, in that they were injurious to health and unfit for human consumption due to the presence of Salmonella organisms.
- Contrary to the General Food Regulations 2004, that between 19 January and 18 June 2006 Cadbury failed to immediately inform the competent authorities that they had reason to believe that ready to eat chocolate

products, placed on the market, may be injurious to human health due to the presence of Salmonella organisms.

- Contrary to Food Hygiene (England) Regulations 2006, that between 19 January and 18 June 2006 Cadbury failed to identify hazards from ready to eat chocolate products contaminated with Salmonella and failed to identify critical control points and corrective actions in line with Haccp (Hazard Analysis and Critical Control Points) principles.

All three offences carry a maximum penalty of an unlimited fine or up to two years imprisonment. Birmingham Crown Court will sentence Cadbury on 13 July.

They send a strong message to the food industry that if they are aware of a food safety problem, they must notify the competent authorities.

Herefordshire Council is prosecute Cadbury on six separate charges involving health and safety at the Marlbrook plant. The six alleged offences, which could also each result in an unlimited fine or up to two years in prison, relate to: Good repair (leaking drainage pipe); good repair (damaged roof vents); layout of the premises (not permitting adequate cleaning and/or disinfection); provision of adequate drainage facilities; cleaning and/or disinfection of equipment (conveyors); and, cleaning and/or disinfection of equipment (storage silos).

Cadbury has been summoned to appear before Herefordshire Magistrates on July 24 to plead on the six charges. A statement says the summonses are "the culmination of nearly 12 months of extensive investigation by Herefordshire Council environmental health staff."

We made a mistake says Cadbury

Following the 15 June hearing in the Birmingham case Cadbury issued a statement confirming that it was pleading guilty. "Mistakenly, we did not believe that there was a threat to health and thus any requirement to report the incident to the authorities - we accept that this approach was incorrect," the statement said.

"Quality has always been at the heart of our business, but the process we followed in the UK in this instance was unacceptable," it added, going on to apologise for the shortfall and noting that the company has since spent over £20m in the UK "on new and rigorous quality control procedures."

The statement stressed: “The processes that led to this failure ceased from June last year and will never be reinstated.”

The statement also pointed to the Hereford Council case saying the company would examine the charges and respond “at the appropriate time.”

“We sincerely regret this lapse and are focused on ensuring that this can never happen again. A major review has taken place of our quality, health and safety procedures globally to learn lessons and ensure that our consumers can rely on the highest levels of processes and standards wherever we operate.”

The salmonella in chocolate problem led to a major product recall which cost the company £30 million.

Cadbury is also facing legal action from consumers who claim they were made ill by eating chocolate contaminated with Salmonella.

In a global management shake-up, Simon Baldry, UK managing director, is to leave the company this summer.

INTERNATIONAL

US

Ground beef recall totals 5.7 million pounds

What started as a recall of 75,000 pounds of ground beef on June 3 was expanded to a total 5.7 million pounds, FSIS announced on June 9. The expansion is the second for United Food Group, LLC of Vernon, Calif., which had already widened the recall on June 6.

The recalls by one of the country’s largest meat processors were spurred by an investigation conducted by the California Department of Health Services and the Colorado Department of Health in collaboration with the CDC, in which 14 people in six states came down with E. coli O157:H7 illnesses. Some of the patients were hospitalized, but all have since recovered.

The illnesses were linked through the CDC’s PulseNet system, a national network of public health and regulatory agencies that provide “fingerprints” of foodborne disease isolates from patients. The specific link to the meat was established through positive tests from products still in some of the patients’ refrigerators and freezers. So far, three recovered beef samples — from Arizona, California and Colorado — tested positive and matched the outbreak strain.

FSIS said the recall was expanded “out of an abundance of caution” after the sample of frozen ground beef from a patient in Arizona came back positive. Interestingly, the woman had made hamburgers out of the originally fresh ground beef with a patty maker, which prevented a lot of handling, thus preserving the integrity of the sample, said FSIS spokesman Steven Cohen. What’s more, the woman still had her retail receipt, which indicated that the beef she purchased was produced prior to the production dates corresponding to the two earlier recalls.

In the first two phases of the recall, investigators determined that illnesses were linked to products processed at United Food Group on April 13 and 20. There were a range of days that the beef from the Arizona woman’s freezer could have been produced, but the company chose the earliest possible production date of April 6, according to Cohen. The enormity of the recall reflects that the fact that it encompasses ground beef produced during a two-week period, between April 6 and April 20.

And while fresh beef produced in April has obviously already been sold — and the bulk of it consumed — the company wanted to make sure that consumers returned products they may have frozen. “The reason for the recall is that much of this product was in five-pound chubs,” United Food Group spokesman Lyle Orwig said. “A lot of people don’t buy and consume it [immediately].”

USDA issues pessimistic forecast on biotech in Europe

The current regulatory system and approval process for biotech products in the European Union is a barrier to trade, USDA’s Foreign Agricultural Service declared in a report prepared by the U.S. mission to the EU in Brussels and released June 8.

The EU has approved only nine biotech events since 1998 and currently has a backlog of about 35 products awaiting approval, FAS noted, commenting, “In view of the unwieldy and less than transparent process for application and approval, it is unlikely that this backlog will be reduced significantly in the short term.”

Although a World Trade Organization dispute panel ruled against the EU’s biotech approval system last fall, the European Commission “has not yet indicated how it plans to implement the panel’s decision,” FAS said, echoing a similar statement by the U.S. Trade Representative in April.

FAS said the Council of Ministers’ involvement in the biotech approval process is a dramatic departure from normal legislative procedures. Agriculture ministers normally meet to approve major agriculture policy reforms or trade policy positions in the WTO Doha Round. “Typically, working level officials drawn from the member-states meet in a regulatory committee to review technical issues and would make decisions on biotech events,” the report said.

Noting that an increasing number of the applications in the approval pipeline are for cultivation, the most politically-charged aspect of the biotech debate in Europe, “the approval process will likely continue at the current leisurely pace,” FAS said.

Traceability, labeling and coexistence FAS reported that traceability and labelling regulations, which took effect in 2004, “are frequently difficult to understand and comply with and have had an adverse impact on trade. The commission has been slow to provide guidance documents to help exporters interpret these new regulations.

“In particular, exporters have had difficulty determining if their product(s) are subject to the new labelling requirements. Finally, [commission officials] and the member-states decided that products (such as beer, wine and cheese) that are produced with genetically modified ‘processing aids’ are not subject to these regulations. This is inconsistent with the intent of the new regulations.”

In line with the commission’s regional policy on coexistence issues, several member-states — including Denmark, Germany, and three regions in Austria — have taken a “maximalist approach” to coexistence legislation, requiring extensive liability systems be put in place and mandating extremely low thresholds for adventitious presence, FAS said. The commission may initiate infringement proceedings against a member-state’s coexistence law if it is judged to be

incompatible with EU law, but there is no time limit on how quickly the commission must act.

Corn and other exports blocked

The breakdown in the EU’s approval process for biotech products has blocked most U.S. exports of corn and hindered trade in other products, FAS reported. Many food processors and exporters have either reformulated or sought out non-biotech sources in response to the implementation of mandatory traceability and labeling requirements in April 2004.

“Consumer-ready products have been particularly hard hit,” FAS said. “Most European retailers’ own-store brands are non-GM, while they may consider carrying private supplier brands containing biotech ingredients. Since labelling hasn’t been required for animal products such as meat and dairy, biotech feed ingredients have generally fared better. Reportedly, about two-thirds of the animal feed consumed in the EU is currently labeled as genetically modified. However, some consumer groups are pressuring retailers to carry meat and dairy products produced from non-biotech feed ingredients.”

Agricultural biotechnology continues to be more of a political than a scientific issue in Europe, and the prospects for improvement remain dim, FAS concluded.

European Commission disappointed

Wolf Maier, counselor for food safety, health and consumer affairs in the European Commission’s Washington delegation, expressed disappointment that the report came from a source that works closely with commission officials in Brussels. He characterized the report as “poorly informed and poorly balanced,” noting that a standing committee singled out for criticism makes technical rather than political decisions.

“We’re just applying the rules we have, which are science-based, risk-based and transparent,” Maier said. “The timelines are not that different from those in the U.S. We have to be careful to follow our procedures and respect sensitivities on both sides. We have very little flexibility; we can’t accelerate our procedures.”

Meat and poultry coalition launches web site on food and fuel

A coalition of meat, livestock and poultry trade associations last week unveiled www.balancedfoodandfuel.org, a web site aimed at

informing policy-makers, the media and the public about the impact of national ethanol policy on the food industry and consumers.

The announcement coincided with a Government Accountability Office forecast that in five years nearly a third of the U.S. corn crop will be used to produce fuel ethanol. Assuming U.S. ethanol production continues to expand to the Energy Department's projected 11.2 billion gallons by 2012, about 30% of the corn crop will be needed for the fuel supply, according to a GAO report.

"The rising cost of corn has driven up the cost of feed and with it the cost of meat, dairy and poultry products, causing some producers to cut back production," the coalition said in a statement, adding that these economic shifts would affect consumer purchasing behaviour, potentially reducing animal protein consumption.

The new web site features economic analyses, charts, third-party experts, literature and basic facts about ethanol policy. Coalition sponsors include the American Meat Institute, National Chicken Council, National Cattlemen's Beef Association, National Meat Association, National Milk Producers Federation, National Pork Producers Council, National Turkey Federation and United Egg Producers.

"Our nation's current ethanol policy may be good news for petroleum blenders, but it's a raw deal for animal agriculture and consumers," the site says. "A more rational policy, however, can help avert the coming economic crisis."

The coalition says that food and fuel policy could be balanced by taking the following actions:

- Providing federal funds for broad-based applied research into renewable energy technologies, economics, and byproduct safety, quality, and usability
- Limiting new energy mandates to emerging bio-based sources (e.g., cellulosic, methane) that do not adversely affect animal feed availability
- Distributing subsidies and tax credits for agriculture-based energy sources among all forms of energy as a means to grow opportunities for all forms of energy. Fuel-based tax credits should function inversely to oil prices.
- Making infrastructure incentives source/feed stock and renewable energy neutral.

- Providing regulatory and legislative policy options that enable producers to opt out of the Conservation Reserve Program in response to market forces
- Supporting a "working lands" approach to reintroduce acres into crop production
- Exposing consumers to more renewable fuels choices by allowing the current ethanol tariff to expire in December 2008

US succeeds in delaying biotech standards

The United States succeeded in delaying for another year new work on criteria for methods of detecting bioengineered foods when the Codex Committee on Methods and Sampling met in March in Budapest, Hungary.

In a newly released meeting report, U.S. delegate Gregory Diachenko said the delegation had "fully participated on all agenda items and was successful in achieving its objectives and goals" at the CCMAS session. The U.S. delegation had gone to Budapest hoping to halt or delay further work on the biotech methods document.

At the CCMAS meeting, Germany, France, the United States, United Kingdom and European Commission revised a draft biotech methods document to take account of earlier comments. Germany proposed that the revised document be forwarded to the Codex Commission for approval as a new work item.

However, the United States, supported by several other delegations, stressed that the paper had been available only at the Budapest session and proposed that it be circulated to members of the electronic working group and revised as necessary for consideration at next year's CCMAS meeting. "Following some discussion, it was agreed that the electronic working group led by ... Germany and the United Kingdom would revise the current document and in addition would give consideration to the development of guidelines for governments and prepare a project document as a proposal for new work. It was further agreed to establish a physical working group to be hosted by Germany that would meet inter-session, if necessary," Diachenko reported.

Changing the committee's terms of reference

On a separate but related agenda item, the Netherlands presented a discussion paper on the need to amend the CCMAS terms of reference in order to develop or endorse methods of analysis for which there are no provisions in Codex standards, such as biotech detection methods. The Dutch delegation proposed new work to identify unwanted restrictions in the committee's terms of reference and to propose changes where necessary.

Several delegations supported the proposal, but the United States and several other delegations said the amendment was unnecessary because CCMAS had been able to provide advice on methods within its current terms of reference. Taking into account the divergent views, the committee asked the Netherlands to further develop the discussion paper, providing further evidence of restrictions, for consideration at the committee's next session.

On other agenda items, the CCMAS:

- Returned to Step 6 in the eight-step Codex approval process draft guidelines for settling disputes over analytical (test) results. The committee hopes to finalize the draft guidelines at its next session for adoption by the Codex Commission in 2008.
- Returned to Step 3 a draft guideline on analytical terminology proposed by the United States. The document will be redrafted by an electronic working group led by the United States for consideration at the next committee session.
- Endorsed several methods of analysis in Codex standards as proposed by an *ad hoc* working group, but with a few minor amendments and comments.

US calls codex contaminants generally satisfactory

The United States views the outcome of the inaugural meeting of the Codex Committee on Contaminants in Food in Beijing, China in April as "generally satisfactory," U.S. delegate Nega Beru said in a newly-released meeting report.

The CCCF returned to Step 2 in the eight-step Codex approval process a draft code of practice for reduction of acrylamide in food prepared by an electronic working group led by the United States and United Kingdom. The document will be redrafted

and circulated for comment and consideration by the committee at its next session.

Beru had told a public preparatory meeting in March that the acrylamide code of practice would likely "take a while" because the document needs to keep pace with mitigation measures developed to deal with the compound.

In a controversial decision, the CCCF forwarded draft maximum levels (MLs) for tin in canned foods and in canned beverages to the Codex Commission for final adoption next month. The European Commission and Switzerland recorded reservations about this decision.

The committee noted that the adoption of the ML for tin in canned foods would result in consequential changes to MLs for tin in certain canned products (i.e., products in tin-layered cans), which are currently included in Schedule I of the General Standard for Contaminants and Toxins in Foods (GSCTF).

Aflatoxins in nuts

On the controversial issue of aflatoxins in nuts, the CCCF held at Step 7 both the draft ML of 15 µg/kg for total aflatoxins in almonds, hazelnuts and pistachios for further processing, and the draft ML of 8 µg/kg for total aflatoxins in almonds, hazelnuts and pistachios ready-to-eat. The committee plans to resume discussion on these draft MLs at its next session in light of results from a forthcoming evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The committee also agreed to establish an electronic working group led by the European Commission to update a discussion paper on the issue.

The CCCF returned to Step 2 a proposed sampling plan for aflatoxin contamination in almonds, brazil nuts, hazelnuts and pistachios. An electronic working group led by the United States will redraft the plan for comments and consideration at the next committee session.

The CCCF asked Brazil to update a discussion paper on aflatoxin in brazil nuts, incorporating additional data that would become available on the contribution of the shell to contamination, for consideration at the next committee session.

On other agenda items, the CCFL:

- Agreed to forward to the Codex Committee on Methods of Analysis and Sampling the ranges for the determination of dioxin and PCBs as well as matrices for which these levels were to be applied.

The committee asked CCMAS to also indicate for the different methods the highest level that can be reliably analyzed.

- Returned to Step 2 proposed changes to the preamble of the General Standard for Contaminants and Toxins in Foods. An electronic working group led by the European Commission will redraft the proposed draft revisions for consideration at the next committee session.
- Retained at Step 7 a draft ML for Ochratoxin A (OTA) in wheat, barley and rye pending a reevaluation of OTA by JECFA this month. Work on this item is expected to be completed by 2009.
- Forwarded to the Codex Commission for fast track adoption at Step 5/8 a draft code of practice for prevention and reduction of Ochratoxin A contamination in wine
- Forwarded to the Codex Commission for adoption at Step 5 a draft ML of 0.4 mg/kg for 3-MCPD in liquid condiments containing acid-hydrolyzed vegetable proteins (excluding naturally fermented soy sauce)
- Forwarded to the Codex Commission for adoption at Step 5 a draft code of practice for the reduction of 3-Monochloropropane-1,2-Diol (3-MCPD) during the production of acid-hydrolyzed vegetable proteins (acid-HVPs) and products that contain acid-HVPs
- Returned to Step 2 a draft code of practice for the reduction of contamination of food with polycyclic aromatic hydrocarbons (PAH) from smoking and direct drying processes. An electronic working group led by Denmark will redraft the code of practice for consideration at the next committee session.
- Discontinued for the time being consideration of a discussion paper on deoxynivalenol (DON). Countries were encouraged to submit data on DON contamination to the GEMS/Food Databases electronically and in the prescribed format.
- Established an electronic working group led by Brazil to prepare a revised discussion paper proposing new work on a draft code of practice for Ochratoxin A in coffee for consideration at the next committee session
- Established an electronic working group led by Ghana to update a discussion paper on Ochratoxin

A in chocolate for consideration at the next committee session

- Forwarded to the Codex Executive Committee a project document proposing new work on aflatoxin contamination in dried figs. The committee also agreed to establish an electronic working group led by Turkey to draft a proposed code of practice on the topic.

Priority list of contaminants and toxins

The CCCF endorsed a priority list of contaminants and naturally occurring toxicants for JECFA evaluation that includes the following compounds: deoxynivalenol (DON), patulin (removed from list), phenyl hydrazine (low priority), furan, and perchlorate.

Codex panel advances 182 pesticide commodity MRLs

The Codex Committee on Pesticide Residues has advanced some 182 pesticide-commodity maximum residue limits (MRLs) for adoption next month by the Codex Alimentarius Commission.

The approved MRLs are based on consideration of 18 pesticides by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) last year. An additional four pesticide-commodity MRLs were advanced from Step 6 to Step 8 in the eight-step Codex approval process, according to a report on last month's meeting in Beijing, China by U.S. delegate Lois Rossi.

Eight pesticide-commodity MRLs from recommendations of the 2006 JMPR were held at Step 5 as a result of dietary intake concerns identified by the JMPR (e.g., endosulfan) or concerns registered and documented by national governments. The United States identified concerns for bifentazate and quinoxifen, which will be addressed by this year's JMPR and reconsidered at next year's CCPR meeting, Rossi said.

In considering the MRLs, the committee used a procedure proposed by the United States. Objections to advancement of recommendations from the JMPR must be based on science and related to possible errors of the JMPR or to information/data not reviewed by the JMPR. Such objections must be in writing on a prescribed "Concern Form." Prior to this procedure, MRL advancements had been denied for extraneous reasons such as lack of use by a particular country, Rossi said.

Approximately 125 pesticide-commodity MRLs were recommended for revocation for lack of use or other reasons. About 59 pesticide-commodity MRLs were returned to steps 7 and 4. These represent 13 chemicals with dietary intake or other issues previously identified and awaiting further review by the JMPR, either retrospective analysis or periodic review.

Some 66 pesticide-commodity MRLs for 13 pesticides were returned to Step 6 for future consideration by CCPR and/or possible retrospective analysis by the JMPR. Included in this group are MRLs for esfenvalerate and metalaxyl-M that await a revocation of the revoked limits for fenvalerate and metalaxyl, respectively.

Acute dietary intake concerns

The CCPR adopted a concept for the retrospective/prospective analysis of alternative Good Agricultural Practice (GAP) information and corresponding field trial data by the JMPR to identify a lower MRL when there appears to be an acute dietary intake concern.

The United States had prepared a paper on specific procedures to be used in this reanalysis process. The committee noted that the proposed procedure included several new activities involving the JMPR and decided to forward the U.S. paper to this year's JMPR for consideration.

For example, the paper requests the JMPR to indicate an acceptable MRL level when the MRL based on the highest residue has an associated apparent dietary intake concern and no available alternate GAP provides an acceptable MRL level. Based on input from the JMPR, the CCPR will further consider the U.S. proposal next year, Rossi said.

Classification of foods and feeds

An electronic working group co-chaired by the Netherlands and the United States provided recommendations for revision of two crop groups, bulb vegetables and fruiting vegetables (non-cucurbit). These revisions were adopted at Step 3 and circulated for comments and follow-up discussion at the next committee meeting, with final group revisions occurring in 2011.

The CCPR concluded that principles and guidance on the selection of representative commodities, needed for extrapolation of MRLs to commodity groups or subgroups, should be considered by the working group but be developed as a document separate from the classification. It was also agreed that no individual commodity group would be adopted until

all revisions had been completed and presented to CCPR, in order to avoid uncertainty about which MRL applies when a commodity changes groupings following the revisions.

Processed foods and feeds

The United States contributed to a work group led by the European Commission that addressed possible changes in the establishment of MRLs for primary processed commodities. The commission proposal basically endorsed the U.S. policy of establishing MRLs only where the residue concentrated appreciably from the raw agricultural commodity to the processed fraction.

The United States submitted a table of raw agricultural commodities for which processing studies should be mandatory. The relevant papers were referred to this year's JMPR. It was further agreed that the CCPR would decide next year whether to develop guidelines on the application of processing factors.

Analytical methods and uncertainty factors

The CCPR continued discussions on use of the estimation of uncertainty in analytical results from the determination of pesticide residues for use in enforcement actions. The United States does not apply an uncertainty factor in reporting pesticide residue values for enforcement purposes. The test values must exceed the U.S. tolerance or MRL for all reported values for the tested commodity to be in violation.

The committee decided to establish an electronic working group to develop a guidance document on the estimation of the uncertainty of results for the determination of pesticide residues. The United States presented numerous method references for pesticide residue analyses, and these will be added to an international repository of methods.

Compounds to be evaluated by JMPR

The *ad hoc* Working Group on Priorities had an unusually complex agenda, including many new compound nominations from the United States and a U.S. proposal to modify the criteria for nomination to allow the nomination of pesticide compounds with no residues on crops. The United States views this proposed change as critical to support use of inherently safe no-residue compounds on commodities in international trade, Rossi said.

All U.S. new compound nominations were added to the proposed future agendas of the JMPR, as were proposed new uses for several existing Codex compounds. While there were no negative comments

on the U.S. proposal per se, the committee decided to defer adoption until next year to provide all national governments with adequate time to consider the issue.

The CCPR adopted a new procedure proposed by the working group for establishment of the list of priorities, to be implemented at the next committee session. The process eliminates the Working Group on Priorities and establishes an electronic working group coordinated by Australia.

The priorities will be discussed as a plenary agenda item without a prior *ad hoc* meeting. Strict timelines

and rules will be enforced to yield a more efficient and open process. Submissions must be made to the electronic working group and the JMPR Secretariat no later than Nov. 30. A Circular Letter with a revised proposed priority list will be distributed to national governments for a two-month comment period with a March 1 deadline. An agenda item will be prepared that takes into account comments received.

The next CCPR session was tentatively scheduled for April 14-19, 2008 in Beijing.

EU FOOD LAW

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EU Food Law is published every week by Agra Informa Ltd.,
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