

REGULATORY APPRAISAL

FOOD, WALES

THE CONTAMINANTS IN FOOD (WALES) (NO. 2) REGULATIONS 2006

MAXIMUM LIMITS FOR FUSARIUM TOXINS IN CERTAIN FOODSTUFFS

Background

1. European Community (EC) legislation on contaminants in food is made under the contaminants in food framework Regulation, Council Regulation 315/93/EEC. The Regulation lays down Community procedures for contaminants in food and applies to those contaminants that are not covered by other specific Community legislation. In view of the disparities between the existing laws of Member States in regard to the maximum limits for contaminants in certain foodstuffs and the consequent risk of distortion of competition, Community measures controlling specific contaminants (Commission Regulation 466/2001) were introduced under Council Regulation 315/93/EEC to ensure market unity while complying with the principle of proportionality. The provisions and requirements of Commission Regulation 466/2001 have applied across the EU since April 2002.
2. The intention of Commission Regulation 466/2001 is to provide consumers with an increased measure of protection by setting EC maximum levels for mycotoxins and undesirable process and environmental contaminants in those foodstuffs that are significant contributors to the total dietary exposure of consumers to those contaminants. The Regulation aims to exclude grossly contaminated food from entering the food chain and harmonises Member States' existing measures, thus facilitating trade. Maximum levels for lead, cadmium, mercury, dioxins (all environmental chemical compounds), polycyclic aromatic hydrocarbons (PAHs), nitrate, 3-MCPD (a process contaminant), aflatoxins, ochratoxin A (both mycotoxins, which are undesirable natural chemicals produced by moulds on certain foodstuffs. Mycotoxins are known carcinogens, which can cause cancer in humans), patulin (contaminant in many mouldy fruits including apples) and inorganic tin have already been set under this legislation.
3. In view of the requirement to protect public health by keeping contaminants at levels that are toxicologically acceptable, the European Commission investigates whether limits should be set for additional contaminants and/ or foods and also reviews the maximum limits for those contaminants currently in the legislation.
4. Fusarium toxins belong to a group of chemicals called mycotoxins, produced by moulds. There are a variety of *Fusarium* fungi, which produce a number of different mycotoxins of the class of trichothecenes (name of a group of toxins) such as deoxynivalenol (DON), T-2 toxin and HT-2 toxin as well as other toxins such as zearalenone and fumonisins. The *Fusarium* fungi are commonly found on cereals grown in the temperate regions of America, Europe and Asia. Several of the toxin-producing *Fusarium* fungi are capable of producing to a

variable degree two or more of these toxins. *Fusarium* species infect the grain pre-harvest although toxin production may also take place during storage of improperly dried grain. In connection with *Fusarium* infection and mycotoxin formation several risk factors have been identified. Climatic conditions during the growth, in particular at flowering, have a major influence on the mycotoxin content. The toxins produced by *Fusarium* fungi cause a variety of illnesses in animals and humans. These are detailed below.

5. It is important for the protection of public health that maximum limits are set on unprocessed cereals in order to prevent highly contaminated cereals entering the food chain and to encourage and ensure that all measures are taken during the field, harvest and storage stage of the production chain. The Commission has produced a draft Recommendation, which should be published in the near future, on the "Principles for the prevention and reduction of fusarium toxin contamination in cereals, zearalenone, fumonisins and trichothecenes, including deoxynivalenol" for general use by Member States, which it anticipates should provide a means of reducing the risk of contamination of cereals. Maximum levels are set at a level taking into account the current human exposure in relation to the tolerable intake of the toxin in question and which can be reasonably achieved by following good practices at all stages of production and distribution. Such an approach ensures that food business operators apply all possible measures to prevent or reduce the contamination as far as possible in order to protect public health. Accordingly, businesses involved in the cereal production and supply chain should be encouraged to adopt good practices to prevent and reduce fusarium toxin contamination.
6. Both industry and the Department for the Environment, Food and Rural Affairs (Defra) were consulted on the draft Commission Recommendation. Based on the principles in this Recommendation the UK is producing a Code of Practice, which will be specifically relevant to the UK. This should be available later in the year. Additionally, The Codex Alimentarius Commission adopted in 2003 a "Code of Practice for the prevention and reduction of mycotoxins contamination in cereals, including annexes on ochratoxin A, zearalenone, fumonisins and trichothecenes.
7. Trichothecenes are acutely toxic to humans causing sickness and diarrhoea and in some very extreme cases death. Acute exposure to deoxynivalenol causes gastrointestinal effects (particularly vomiting) in humans. This mycotoxin has also been shown to cause increased susceptibility to infections, growth retardation and reproductive effects in laboratory animals. Acute exposure to T-2 toxin is a suspected cause of alimentary toxic aleukia (ATA) in humans. Symptoms include gastrointestinal effects and leukopenia. Furthermore, this mycotoxin has been shown to effect the growth, reproduction and immune systems of laboratory animals.
8. The EU's Scientific Committee on Food (SCF) concluded in 2002 that the available data did not support the establishing of a group Tolerable Daily Intake (TDI) for the trichothecenes evaluated, and established a TDI of 1 µg/kg body

weight/day for deoxynivalenol (DON)¹ and a combined temporary TDI of 0.06 µg/kg body weight/day for T-2 and HT-2 toxin². The TDI is an estimate of the amount of contaminant expressed on a bodyweight basis that can be ingested daily over a lifetime without appreciable risk to human health.

9. Fumonisin are observed primarily on maize and in maize-based products and have been shown to cause kidney and liver damage in laboratory animals. High levels of exposure to fumonisin, which include fumonisin B₁, B₂ and B₃, have been observed to cause liver and kidney damage in animals if consumed over long periods. It is possible that they could have the same effect on humans given similar levels of exposure. The SCF has designated a TDI of 2-µg/kg body weight/day for both fumonisin B₁³ and in combination with fumonisin B₂ and B₃⁴.
10. Zearalenone has been shown to have oestrogenic (effects on human sex hormones) effects on laboratory animals, as well as having carcinogenic effects at higher doses. Apart from a possible incidence of precocious (early) puberty associated with zearalenone in Hungary, there have been no recent reports of human mycotoxicoses in Member States of the European Union. The SCF has established a temporary TDI of 0.2 µg/kg body weight/day⁵.
11. In the framework of Council Directive 93/5/EEC of 25 February 1993 on assistance to the Commission and cooperation by Member States in the scientific examination of questions relating to food, a scientific cooperation (SCOOP) task 'Collection of occurrence data on fusarium toxins in food and assessment of dietary intake by the population of EU Member States'⁶ was performed and finalised in September 2003.
12. The results of that task demonstrate that fusarium mycotoxins are widely distributed in the food chain in the Community. The major sources of dietary intake of fusarium toxins are products made from cereals, in particular wheat and maize. The report also demonstrated that the dietary intakes of fusarium toxins for risk groups like infants and young children are close to or exceed the TDI for the respective toxin.
13. The UK has carried out some work on the occurrence of fusarium toxins in the food chain previously. A survey of trichothecenes and zearalenone was reported in 2003⁷. In the vast majority of the 377 samples analysed, the levels

¹ European Commission Scientific Committee on Food. Opinion on *Fusarium* toxins: Part 1. Deoxynivalenol, 2 December 1999.

² European Commission Scientific Committee on Food. Opinion on *Fusarium* toxins: Part 5. T-2 and HT-2 toxins, 30 May 2001

³ European Commission Scientific Committee on Food. Opinion on *Fusarium* toxins: Part 3. Fumonisin B₁, 17 October 2000.

⁴ European Commission Scientific Committee on Food. Opinion on *Fusarium* toxins: Total Fumonisin, 4 April 2003.

⁵ European Commission Scientific Committee on Food. Opinion on *Fusarium* toxins: Part 2. Zearalenone, 22 June 2000.

⁶ Report available on the web-site of the European Commission, DG Health and Consumer Protection (<http://europa.eu.int/comm/food/fs/scoop/task3210.pdf>)

⁷ Food Standards Agency, Food Survey Information Sheet 35/03, March 2003.

of the mycotoxins were low. The highest levels of both trichothecenes and zearalenone were found in breakfast cereals from the first part of the survey where samples were traced to the 1999 UK cereal crop, where there was a high incidence of *Fusarium* ear-blight, which also highlighted the dependency of formation of *Fusarium* species on climatic conditions. *Fusarium* ear-blight is a fungal disease in plants. It is one of the major cereal diseases. It represents a threat to human health because infected plants can be contaminated with mycotoxins, which can result in infected cereals and cereal products.

14. In 2005, a survey of maize-based retail products for various mycotoxins was completed and reported⁸. Although levels were low in the majority of samples analysed, concentrations of fumonisins in two of the maize meal products were high and these were withdrawn from sale. A short, follow-up survey also identified several more of these types of products that were contaminated with high levels of fumonisins. The results of this survey, together with details of the action taken by the Agency are available at:

<http://www.food.gov.uk/news/newsarchive/2003/sep/moremaize>.

15. In addition, two out of the 292 samples from the main survey were found to contain deoxynivalenol above the limits (then under discussion) of 500 µg/kg for bread, pastries, biscuits, snacks and breakfast cereals and 750 µg/kg for cereal flour, including maize flour, semolina, maize grits and maize semolina, including polenta. The results of the survey underlined the importance of introducing regulatory limits for these toxins and the establishment of codes of practice to help the reduction and prevention of them from the food chain.

Purpose and intended effect of the measure

16. The first objective of these Regulations is to make provision for the enforcement, in Wales, of Commission Regulation 856/2005, which amends Commission Regulation 466/2001 and sets maximum limits for fusarium toxins in various foodstuffs. The Regulation will apply from 13 July 2006 and will only apply to products, which were placed on the market on or after 13 July 2006.

17. The second objective is to ensure that enforcement authorities act in accordance with a recently adopted Commission Regulation laying down the sampling methods and the methods of analysis for the official control of the levels of mycotoxins in foodstuffs. This will replace the existing Commission Directives on sampling methods and the methods of analysis for the official control of the levels of aflatoxins (98/53/EC, as amended), ochratoxin A (2002/26/EC, as amended), patulin (2003/78/EC) and fusarium toxins (2005/38/EC), all of which will be revoked.

18. The purpose of setting maximum levels for fusarium toxins in food is to provide consumers with an increased measure of protection against undesirable contaminants i.e. deoxynivalenol, zearalenone and fumonisins in those foods that contribute significantly to the total dietary exposure of consumers to those contaminants. The purpose of the sampling and analysis Regulation

⁸ Food Standards Agency, Food Survey Information Sheet 72/05, January 2005.

(401/2006) is to provide a consistent and harmonised approach for the enforcement of the maximum limits throughout the European Union.

19. Currently the maximum limits set in Commission Regulation 466/2001 are enforced in Wales under The Contaminants in Food (Wales) Regulations 2006. The associated Commission Directives on sampling and analysis for official control purposes are also currently implemented in these Regulations. Similar Regulations apply in Scotland, England and Northern Ireland due to come into force on 1 July 2006. These and preceding Regulations have previously been consulted on.⁹
20. New Regulations have now been drafted and will revoke and replace The Contaminants in Food (Wales) Regulations 2006. These Regulations will be The Contaminants in Food (Wales) (No. 2) Regulations 2006 and will extend to Wales only.
21. A review of the maximum limits for fusarium toxins is due to be carried out by 1 July 2008, including deoxynivalenol, zearalenone and fumonisins and with a view to including a maximum limit for T-2 and HT-2 toxins in cereals and cereal products.
22. This Regulatory Appraisal is concerned only with the enforcement of Commission Regulation (EC) No. 856/2005 and the implementation of Commission Regulation 401/2006. As part of this consultation, a separate RA addresses the enforcement of Commission Regulation (EC) 199/2006 amending Commission Regulation 466/2001 as regards dioxins and dioxin-like PCBs.
23. The purpose of Commission Regulation (EC) No 401/2006 of 23 February 2006 is to consolidate the existing Commission Directives on sampling methods and the methods of analysis for the official control of the levels of aflatoxins, ochratoxin A, patulin and fusarium toxins. Sampling plays a crucial part in the precision of the determination of mycotoxins in food. Thus, it is appropriate to apply whenever possible the same sampling procedure to the same product for the control of mycotoxins and to provide for the sampling provisions and performance criteria for the methods of analysis to be used for the official control of all mycotoxins into one legal text to simplify and improve the applicability.
24. The introduction of these harmonised statutory controls would reduce uncertainty or dispute in interpreting results against limits directly applicable to all Member States and would also reduce inconsistency or dispute of sampling

⁹ Consultations on Commission Regulation 466/2001 and the Directives were carried out under The Contaminants in Food (Wales) Regulations 2002 in July 2001 (aflatoxins in spices), December 2001 (ochratoxin A) and March 2002 (lead, cadmium, mercury, dioxins, 3-MCPD and nitrates), The Contaminants in Food (Wales) Regulations 2003 in February 2003 (dioxins sampling and analysis Directive), The Contaminants in Food (Wales) Regulations 2004 (patulin, aflatoxins in maize, dioxins and inorganic tin in canned foodstuffs), The Contaminants in Food (Wales) (Amendment) Regulations 2005 (nitrate, aflatoxins & ochratoxin A in foods for infant and young children) and under The Contaminants in Food (Wales) Regulations 2005 (ochratoxin A in certain foods, PAHs in certain foods, revised limits for lead & cadmium & revised fish species and updated Directive on sampling & analysis for lead, cadmium, mercury & 3-MCPD).

and analytical procedures. This would provide benefits to industry and consumers in improved confidence in compliance testing. Failure to adopt harmonised sampling and analytical controls would undermine enforcement bodies' ability to enforce legislation effectively and efficiently

Risk Assessment

25. Not making these Regulations may maintain an unacceptable risk to human health and would leave the UK enforcement authorities without any domestic legislation for the enforcement and execution of Commission Regulation 856/2005. It would also leave the UK enforcement authorities without appropriate statutory sampling and analysis procedures in respect to mycotoxins in foodstuffs specified in Commission Regulation 466/2001, as amended. This would leave any results of sampling and analysis for enforcement purposes open to interpretation. Not making these Regulations may compromise consumer health.
26. Enforcing the new limits laid down in Commission Regulation 856/2005 for fusarium toxins in cereal and cereal products will provide consumers with an increased measure of protection by ensuring that enforcement authorities have sufficient means by which to prevent contaminated products from entering the market. To do nothing would leave enforcement bodies without adequate statutory powers to prevent the placing on the market of those commodities, which fail to meet the maximum limits laid down in Commission Regulation 466/2001, as amended, which are directly applicable to all Member States.

Options

27. In respect of this legislation, the "Do Nothing" option is not an option, as it would ultimately lead to infraction proceedings against the National Assembly for Wales by the European Commission. Therefore, the "Make the Legislation" option, to implement the changes required to comply with European legislation, is being proposed.

Benefits

28. Making these Regulations will provide enforcement authorities with the necessary domestic legislation for the enforcement and execution of Commission Regulation 856/2005. It will also provide UK enforcement authorities with statutory sampling and analysis procedures to ensure adherence with the limits. This option would harmonise standards across Member States and prevent any barrier to trade occurring as a result of existing or future legislation in place in individual Member States, indeed it may even facilitate beneficial trade creation. The potential benefits to health are difficult to quantify but are likely to include reducing the risk of illness through exposure to fusarium toxins. Fusarium toxins have been associated with various adverse effects on human health, including the potential to cause cancer. Making these Regulations may reduce the burden on the health service through prevention of serious chronic illness. A summary of costs and benefits is at Annex I.

Costs

Business Costs

29. Industry has been made aware of the maximum limits set by Commission Regulation 856/2005 since 2003. The Food Standards Agency is working with industry to produce a Code of Practice, which will help minimise the formation of fusarium toxins. Preliminary advice has been issued and industry may already be taking steps to assure themselves that their products comply with the maximum limits.
30. There are no specific requirements to test products under Commission Regulation 466/2001, as amended; however, it is the responsibility of individual food operating businesses to determine how they satisfy these requirements. For example, checks on food commodities are likely to involve sampling and analysis, to ensure that contamination is not in excess of legal limits or alternatively reliance on checks carried out by the supplier of the food commodity in order to satisfy compliance with the “due diligence” requirement under section 21 of the Food Safety Act 1990. The Agency’s research has shown that the occurrence of fusarium toxins in the UK is low. Therefore, firms already operating such risk based systems as standard are not expected to incur significant extra operating costs. Also, the costs related to product withdrawal will be minimised since there is no requirement for products already on sale before 1 July 2006 to comply.
31. A comprehensive list of trade associations representing bakers, millers, farmers, food and cereal ingredients manufacturers, grain and animal feed traders were contacted to ascertain the costs of the Regulations to the affected businesses. No comments or indication from industry suggested anything other than minimal changes in costs were expected. However, during the consultation some responders raised concerns regarding the costs of testing for traders and small businesses and commented that the impact of regulation may cause costs to be passed back up the food chain to growers, thereby affecting their business. A proportion of any increased cost, which industry may face as a result of the Regulations, may be passed on to the consumer in the form of higher prices for a small number of products likely to be affected. Whether this occurs or not will depend on the nature and demand for the product, the composition and level of competition in the market and the willingness of individuals to pay the premium to ensure the safety of the product. However, such costs are not expected to be significant.

Government Costs

32. The maximum limits will be enforced by local authorities and in relation to imported products from countries outside the EU by port health authorities, as is the case at present with the current maximum limits enforced under the Contaminants in Food (Wales) Regulations 2006. There may be some extra costs to these authorities due to the additional sampling and associated staff time that will be required to check compliance with the new limits. The cost of bulk sampling at import would be approximately £200, although the number of imports overall is low. However, local authority costs for sampling would be expected to be very much lower. In conjunction with this there will also be the cost of the charges incurred for the analysis of the sample by a public analyst.

The estimated cost is anticipated to be approximately £100 - £150 per sample for each toxin depending upon the size of the sample submitted for analysis. However, the cost for each individual toxin would be less if multiple toxin analyses were carried out. There are no identified costs for the Assembly.

33. It is difficult to estimate the costs to the enforcement bodies without details of the precise regime that will operate; for example what proportion of an authority's budget may be allocated for checking compliance with the new limits. The decision to undertake sampling and analysis is made by each enforcement authority on a risk assessment basis and is not dictated by the Food Standards Agency. However, there will be some additional burden on resources to ensure compliance.
34. There may also be some additional informal monitoring costs, for example the Food Standards Agency regularly carries out surveys to help protect and inform consumers, monitor trends and assess dietary exposure. They also ensure that the legislation is effective in protecting customers from exposure to harmful contaminants, such as fusarium toxins.
35. As previously stated fusarium toxins have been implicated in a variety of detrimental health effects in humans. Any prevention of short or long term illness through introduction of the Regulations and, therefore, enforcement of the new limits may potentially avoid more significant related additional burdens on the health services and prevent loss of productivity and consumer welfare. Any indirect costs of illness, such as perhaps the loss of welfare of the families of the ill, may also be abated.

Consultation with small business – the Small Firms' Impact Test

36. Stakeholders including the Small Business Service, the Federation of Small Businesses and small businesses themselves, including those that are members of trade associations, have been consulted throughout negotiations on the legislation via interested parties' letters. Small businesses will continue to have the opportunity to put forward their views throughout the consultation procedure and their representation is welcomed from them and their representative organisations if not already contacted as part of the consultation process.
37. It is not anticipated that any potential additional costs arising from checking compliance with the maximum limits will be significant to small businesses. It is the responsibility of individual food operating businesses to show how they satisfy compliance with the "due diligence" requirement under section 21 of the Food Safety Act 1990. For example, this may require that businesses specify requirements to be met by their supplier prior to receiving the product to ensure that the products are not contaminated above the permitted limits.

Competition Assessment

38. Those involved in the cereals markets will be affected by the maximum limits as will those involved in markets for the products specified in Regulation 856/2005, including flour, bread, pastries, biscuits, breakfast cereals, pasta and foods for infants and young children. This will include growers, manufacturers,

importers, traders, processors, wholesalers and retailers of these commodities or products.

Cereals

39. Statistics from Defra indicate that in 2004, the total area of land in the UK producing cereals was approximately 3.1 million hectares, the production volume of which amounted to over 22 million tonnes at an estimated value at market prices of £1,675 million. Imports from the EU and from the rest of the world in 2004 amounted to almost 2 million tonnes and 465,000 tonnes respectively. In economic terms wheat is the most important cereal crop in the UK, typically comprising around two thirds of the value of total cereal output.
40. Geographically, cereals production within the UK is heavily concentrated in England; indeed over 80% of the total UK cereals area is in England. A further 15% is found in Scotland with the remainder in Wales and Northern Ireland. Correspondingly, cereals are an important sector in economic terms in England and Scotland only, with cereals output accounting for around 16% of total gross agricultural output in each country.

Bread

41. UK retail sales of bread by volume have fallen over the last few years from 2,110,000 tonnes in 1999 to an estimated 1,987,000 in 2004. According to the same report however, the same comparison by value shows an increase from £1,791 million to an estimated £1,961 million over the same period. The industry may be divided up into three main industry sectors: plant bakeries, in-store bakeries (ISB), and craft bakeries; the latter better known as high street retail bakeries or master bakers. The plant bakeries are accountable for the majority of bread production to the UK market, producing both finished product for retailers, as branded and own-label goods, and supplying bake-off to the in-store and craft bakeries. The share of retail value supplied by the plant manufacturers has, however, grown over recent years.
42. The majority of bread sold in the UK is baked here, with the exception of some imported long-life speciality products and a small amount of bread produced in France and imported on a daily basis, valued at less than 1% of the market. Over three-quarters of bread sold in the UK is wrapped factory-produced loaves, the majority of which originates from a small number of large plant bakeries; the remainder comes from medium and small plants, which offer standard, speciality and ethnic bread products to the retail market.
43. The Federation of Bakers, a trade organisation that represents the interests of plant bakeries with a turnover of over £10 million, lists ten member companies operating 55 plants throughout the UK. The largest of these are British Bakeries Limited with 15 sites, Allied Bakeries Limited with 13 sites, Warburtons Limited with 11 sites and Rathbones Kears Limited with three sites. Allied Bakeries, British Bakeries and Warburtons together account for half of the plant bread market by value.

Breakfast Cereals¹⁰

44. After a downturn in the late 1990s, the UK breakfast cereal market recovered and has shown slow but steady growth in volume, with an estimated 409,000 tonnes sold in 2003, equivalent to a market value of £1,117 million, the majority of which were manufactured in the UK. The breakfast cereal market is characterised by global manufacturers operating in an oligopoly (controlled by several major manufacturers), with the largest four manufacturers in the UK estimated to share 77% of the market value. However, a variety of smaller manufacturers operate in niche sectors, with limited distribution. In 2003, accounting for 40% of market share, Kellogg was the largest manufacturer in the UK, with estimated sales of £447 million. Weetabix and Cereal Partners commanded a share of around 15% each, equivalent to around £170 million, whereas the fourth largest manufacturer was Quaker with around 6% share of the market. A further 17% of the market was comprised of own label manufacturers, of which supermarket chains had a strong presence.
45. Wheat and corn products are estimated to each account for 18% of the various types of breakfast cereals in the UK market, valuing both at around £190 million. A similar share of around 17% is held by bran cereals, with muesli products growing to about 10%. In the distribution side of the breakfast cereal market, the supermarkets dominate, possessing an estimated 93% share of the market in 2003. The remainder of the market incorporates convenience and independent trade channels.

Biscuits¹¹

46. Non-sweet biscuits - At 17% of the overall biscuit market, the non-sweet biscuit market incorporates crackers and crispbreads (77%) and savoury biscuits (23%). The largest three manufacturers of non-sweet biscuits in the UK share over two-thirds of the £285 million market. After acquiring the Jacobs brand in 2004, United Biscuits now accounts for 40% of the market, with Quaker and Ryvita accounting for 18% and 11% respectively. The majority of the remainder of the market includes supermarket own-label brands, although there are a large number of small artisan UK producers, and some international manufacturers competing in small niches. With regards the distribution aspect of non-sweet biscuits, the supermarkets dominate the market, accounting for 85% of sales in 2005. The remainder of the market incorporates independent and specialist stores.

Sweet biscuits

47. The total biscuit market represents a value of £1.7 billion, with sweet biscuits accounting for 83% of this market. It is more diverse than the non-sweet biscuit market, although the top four manufacturers enjoyed a 58% share of the sweet biscuit market in 2005. These included United Biscuits (23%), Burton's (15%), Nestle (11%) and Fox's (9%). Other brands made up 24% of the market, and supermarket own-labels accounted for the rest (18%). The supermarkets and co-ops account for around 86% of the sales volume in the UK, with the remainder including independent and specialist stores.

¹⁰ Mintel, Breakfast Cereals, Market Intelligence 2004

¹¹ Mintel, Sweet Biscuits, Market Intelligence 2005; Mintel, Non-Sweet Biscuits, Market Intelligence 2005; Mintel, Cereal Bars, Market Intelligence 2004

Cereal bars

48. The UK market of cereal bars nearly trebled between 1998 and 2003, to £182 million, of which the main players are Kellogg with a 32% market share, and Jordans with a 10% share. The rest of the market is very diverse, with a wide range of other brands, including supermarket own-label products. As with the biscuit market, the main distributors of cereal bars are the supermarkets and co-operatives, which account for about 83% of the market, with confectioners, tobacconists and newsagents and other independents accounting for the rest.

Pasta¹²

49. The UK market for pasta and pasta-based ready meals is diverse, with an estimated market volume of 206,000 tonnes in 2004, valued at £463 million. The market suppliers are heavily biased towards the supermarkets that produce their own-labelled products. In 2004, dry pasta accounted for £98 million in sales, of which 67% were supermarket own-label, with Buitoni being the only major branded manufacturer in this category, possessing a 17% share of the market. For chilled pasta and pasta ready meals, sales in 2004 were £79 million and £160 million respectively, with the supermarkets' own-label share being even more pronounced at around 93%. In the other major category of frozen pasta ready meals (sales of £109 million), some branded products were present, with Birds Eye taking 24% of the market and Heinz and Findus accounting for 13% and 8% respectively. As in the other categories, the own-labels represented a large portion of the market, with a 47% share.

50. This market profile is reflected in the make-up of the distributors of dry and fresh pasta, of which the supermarkets accounted for 88% of sales value in 2004, with co-operatives, Marks and Spencer, and independent retailers accounting for the remainder.

Baby foods¹³

51. The total market for baby food and drinks can be split into four main areas: milks, meals, drinks and finger foods (rusks and cereal bars). The greatest value share of the market is taken up by milks (46%) and meals (44%), with drinks (6%) and finger foods (4%) taking up a relatively small proportion. UK retail sales of baby foods in 2002 totalled around £381 million with £184 million (48% of the total) accounted for by sales of baby meals and finger foods. Imports of baby and infant foods into the UK last year were valued at approximately £195 million per annum¹⁴. Baby meals come in two main types: wet foods including pre-cooked, pureed meals or chilled products and dry foods including meals and sauces requiring rehydration before consumption as well as cereals and baby rice. In 2002, wet meals accounted for 76% of the baby meals market compared with 24% for dry foods.

52. The supply structure for baby food in the UK is heavily concentrated, with a handful of manufacturers characterising the supply chain. The main companies involved are large multinational businesses with a selection of big brand names. In 2002, the three biggest companies accounted for 83% of the baby

¹² Mintel, Past and Pasta-Based Meals, Market Intelligence 2005

¹³ Mintel report on Baby Food Drinks and Milk, October 2002.

¹⁴ Information from Infant and Dietetic Foods Association, 6 Catherine Street, London. WC2B 5JJ.

meal and finger food market, with Heinz/Farley's accounting for 47% of the market, Cow & Gate with 20% and HiPP with 16%.

53. The baby foods and drinks sector is characterised by a broad pattern of distribution, with sales of these products being spread amongst supermarkets, chemists, garage forecourts and motorway service areas. In 2002, supermarkets were estimated to account for around £263 million (69%) of baby foods and drinks sales.

Effect on competition

54. The Competition Filter Test has been completed and it is not anticipated that the structure of the existing sector would be significantly affected by making provisions for the enforcement of Commission Regulation 856/2005.
55. There is no current requirement for industry to carry out sampling and analysis within Commission Regulation 466/2001, as amended. However, it may wish to do so (and may already be doing so) when carrying out its existing programmes of checks for contamination in excess of legal limits to gain the protection of the 'due diligence' defence under section 21 of the Food Safety Act 1990. This is applicable to all food operating businesses in the import, production, processing, storage, distribution and sale of food and in this respect is not disproportionate on any one business or group of businesses.

Consultation

With Stakeholders

56. Discussions on possible limits for fusarium toxins in foodstuffs began at the Commission Working Group of Agricultural Contaminants meeting on 13 and 14 January 2003, when the Commission tabled their initial position on limits for deoxynivalenol, nivalenol, T-2 toxin, HT-2 toxin, zearalenone and fumonisins in various cereals and cereal products. During the course of the negotiations with the Commission, the Food Standards Agency has regularly conveyed information to interested organisations including industry, enforcement authorities, research institutes, consumer groups and other interested parties. In addition, the Commission has held several stakeholder meetings during negotiations to consult, exchange views and formulate discussion with interested parties including industry.
57. In Wales, a four-week public consultation was carried out from 30 April 2006 to 4 June 2006. A list of the stakeholders consulted in Wales can be found at Annex II. Stakeholders in Wales were specifically invited to comment upon any likely additional costs, other than those identified in the draft Regulatory Appraisal, which might arise as a result of implementing the Regulations. The Welsh Consumer Council was the only organisation to respond in Wales and they had no substantive comments to make. In England, five responses were received three of these were substantive. These related to Fusarium toxins and the high cost of analysis for dioxins and the limited number of laboratories accredited to carry out this work.

58. The Agency acknowledges that analysis for dioxins is expensive and that Public Analysts Laboratories are currently unable to carry out the work themselves. The Agency highlighted these issues in earlier Regulatory Appraisals on The Contaminants in Food (Wales) Regulations 2002 and The Contaminants in Food (Wales) Regulations 2003 and the equivalent Regulations in the other parts of the UK. The Agency consulted widely throughout the negotiations on the maximum limits for dioxins and dioxin-like PCBs and requested information from enforcement authorities on the implications of these proposals but received no quantified information. Maximum limits for dioxins have applied since 1 July 2002 and the costs of analysis and the current situation with the Public Analyst service would apply irrespective of whether provisions were made for the enforcement of Commission Regulation 199/2006 or not.

With Subject Committee

59. These Regulations were notified to the Health and Social Services Committee via the list of forthcoming legislation on 5 October 2005 (HSS (2)-10-05 (p.5b) item no: FSA 22(05)) and have remained on the list ever since. The Regulations were not identified for detailed scrutiny.

Enforcement, Sanctions, Monitoring and Review

60. Local authorities and port health authorities are responsible for enforcing a large proportion of Regulations with respect to food safety and have done so in respect to the maximum limits for contaminants in food set out in Commission Regulation 466/2001, as amended, since 2002. Thus, enforcement will be carried out using existing systems, which are maintained in these Regulations.

61. The criminal sanctions in the current Contaminants in Food (Wales) Regulations 2006, would apply in the case of prosecution against those in breach of the Regulations. This is currently a fine not exceeding level 5 on the standard scale, i.e. £5,000.

62. The Food Standards Agency will continue to consult with enforcement authorities, industry and other stakeholders to evaluate the effectiveness of and experience with the legislation.

63. The Agency will consult with enforcement, industry and other stakeholders to evaluate the effectiveness of and experience with the legislation. As part of this process, the Agency meets regularly with representatives from the Association of Public Analysts (the APA Liaison meetings) to help inform this review.

64. As stated earlier, the European Commission investigates whether limits should be set for additional contaminants and also reviews the maximum limits for those contaminants currently in the legislation. The Agency will consult stakeholders for information to inform these investigations, including data available from enforcement or industry testing, and any data from surveillance the Agency may undertake on these contaminants in food.

Summary

65. European Community measures (Commission Regulation 466/2001) setting maximum levels for certain contaminants in foodstuffs have applied since 2002. The aim of the Regulation is to provide an increased level of consumer protection by keeping contaminants at levels that are toxicologically acceptable and to exclude grossly contaminated food from entering the food chain. It also harmonises Member States' existing measures facilitating trade.
66. In order to ensure a continued high level of consumer protection, the European Commission, in co-operation with Member States, investigates whether limits should be set for additional contaminants and also reviews the maximum levels for those contaminants currently in the legislation and the foods that are subject to control. Consequently, Regulation 466/2001 has undergone a number of amendments including most recently a new Commission Regulation setting maximum levels for fusarium toxins. The Regulation is supported by an allied Commission Regulation, which lays down the methods for sampling and analysis for the official control of those contaminants specified in the Regulation. Currently enforcement of Regulation 466/2001 is carried out under The Contaminants in Food (Wales) Regulations 2006.

Annex I

Summary Costs and Benefits Table

OPTION	Total benefit per annum: economic, environmental, social	Total cost per annum: • economic, environmental, social • policy & administrative
1 – Do Nothing	None	<ul style="list-style-type: none"> • Infraction proceedings against the UK government • Possible adverse report from the Commission’s Food & Veterinary Office • Possible financial costs to industry arising from lack of consumer confidence in the safety of the UK food supply
2 – Make provision for the enforcement & enactment of the EC measures under The Contaminants in Food (Wales) No 2 Regulations 2006	<ul style="list-style-type: none"> • Fulfils the UK’s legal obligations to make provision for the enforcement of EC Regulations • Continued high level of public health safety & consumer confidence in compliance testing • The new Regulations will ensure that measures, which are applicable to all Member States, are in place, thereby facilitating trade and ensuring a level ‘playing field’. 	<ul style="list-style-type: none"> • No quantified information received by the Agency in respect to costs arising from the EC legislation. There are likely to be some costs arising from the costs of sampling & analysis but these are expected to be minimal. The EC legislation does not specify the number of checks to be carried out to ensure compliance with the limits. • It was agreed that the new Regulation would apply from 1 July 2006 to allow industry time to implement the new measures.

It is recommended that **Option 2 is supported**.

The Contaminants in Food (Wales) No 2 Regulations 2006 will provide enforcement authorities with the necessary powers to effectively enforce the provisions and maximum limits set in Commission Regulation 466/2001, as amended. The Regulations will revoke and replace The Contaminants in Food (Wales) Regulations 2006. The Agency is developing Guidance Notes on the legislation.

Annex II

INTERESTED PARTIES IN WALES

Organisation
Ruddock & Sherratt
Good Food Distributors
Gwynedd CC
Meridian Foods
Co-operative Group (CWS) Ltd
Kwik Save Group Ltd
Wales Young Farmers' Club
Peters Food Service Ltd
T/A Source Foods
G C Hahn & Co Ltd
British Retail Consortium (BRC)
Abergavenny Fine Foods Ltd
ADAS Wales
The Association of Public Analysts
Bar & Restaurant Foods Ltd
Biotrace Limited
Clark's Original Pies
Farmer's Union of Wales
Torfaen County Borough Council
Food Safe
Halo Foods Ltd
Iceland Frozen Foods Plc
Welsh Food Alliance
Local Authorities Co-ordinators or Regulatory Services (LACORS) - Welsh Officer
National Farmers Union (Wales)
Rachel's Dairy
School of Environmental Sciences
The Organic Working Group
Shoda Sauces Europe
Tillery Valley Foods Ltd
Tovali Ltd
Welsh Consumer Council
Chartered Institute of Environmental Health in Wales
Welsh Food Microbiological Forum
WDA Food Directorate
Zorba Foods
PRP Training Ltd
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory

Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Member - Welsh Food Advisory Committee
Welsh Local Government Association
Blaenau Gwent CBC
Cardiff County Council
Conwy County Borough Council
Newport CBC
Powys CC
City & County of Swansea
Wrexham County Borough Council
J Sainsbury Plc
NPHS in Wales
Conwy Mussel Company
Flintshire County Council
Member - Welsh Food Advisory Committee
Pembrokeshire County Council
Caerphilly CBC
Merthyr Tydfil Borough Council
Minton, Treharne & Davies Ltd
Cardiff Scientific Services
Rhondda Cynon Taff CBC

Annex III

Consultation of 10 April 2006 on The Draft Contaminants in Food (England) Regulations 2006 – Closing Date 19 May 2006 – Summary of Comments (England)

The Agency circulated a consultation letter seeking views on The Draft Contaminants in Food (England) Regulations 2006. Over 700 letters were sent out to stakeholders (including Consumer Groups, Trade Associations, the Federation of Small Businesses, the Small Business Service, Enforcement Authorities and Other Government Departments) in England.

The Agency received 5 responses to the England consultation.

Similar consultations were carried out in Scotland, Wales and Northern Ireland. The following table summarises the responses for England:

Replies to Formal Consultation

Date	Organisation/Individual	Comments	Agency Response
10/04/06	Combined Edible Nut Trade Association	Returned Feedback Questionnaire. Found package lengthy, requested a forward of key points to assess relevance quickly	<ul style="list-style-type: none"> • Consultation covering letter summarises key points • The Regulations and EC measures cover a wide variety of foodstuffs and as such are relevant to all food business operators
18/04/06	<u>Horticultural Development Council</u>	Returned Feedback Questionnaire. Requested Appendix identifying the crops/commodities affected by the legislation	<ul style="list-style-type: none"> • Interested Parties were made aware of the foodstuffs covered by the new Commission Regulations throughout the negotiations and were also informed that a new SI was being developed. • Industry and Trade Associations have an obligation under general Food Law to ensure that they are aware of the scope of Commission Regulation 466/2001 and its amendments
19/05/06	Association of Port Health Authorities	<ul style="list-style-type: none"> • Supported the setting of maximum limits for Fusarium toxins and dioxins and dioxin-like PCBs and welcomed the consolidation of the sampling and analysis for the official control of 	<ul style="list-style-type: none"> • The Agency acknowledges the costs for sampling and analysis for the contaminants covered in the legislation. However, the EC measures do not specify the number of checks to

		<p>mycotoxins.</p> <ul style="list-style-type: none"> • Commented on the additional burden on resources to ensure compliance. Raised the issue of the high cost of analysis for dioxins and the limited official control laboratory provision • General comment on the remit of the new Regulations in respect to imported foods to be incorporated in to Explanatory Note. 	<p>be made, this is at the discretion of enforcement authorities and food business operators</p> <ul style="list-style-type: none"> • Suggestion in respect to imported food cannot be included for legal reasons. The Agency has drafted Guidance Notes on the scope of The Contaminants in Food (England) Regulation 2006 and will be circulating to enforcement authorities for comment
19/05/06	Food and Drink Federation	<p>Annex 1A</p> <ul style="list-style-type: none"> • Concern that that the RIA does not reflect business costs in relation to introduction of proposed Fusarium mycotoxin in October 2007 for cereal processors sector. • Claims Commission assumption regarding lowering mycotoxin levels when grain is processed, proving incorrect. Leading to food industry paying higher prices for cereals suitable for processing. 	<ul style="list-style-type: none"> • The Agency did contact all the areas of industry likely to be affected by the Regulation in order to obtain estimates of likely costs to business. However, the response was minimal. • There is no evidence to indicate that this is the case across the board.
19/05/06	Defra	<p>Annex 1A</p> <ul style="list-style-type: none"> • Concern with regard to additional cost for specific mycotoxin test with delays in waiting for results. • Impact of regulation may cause costs to be passed back up the food chain to growers affecting their business. • Costs of training and integration of new requirement should be taken into account. 	<ul style="list-style-type: none"> • This issue has been addressed in the final RIA. However, testing is not mandatory. • This issue has been addressed in the final RIA. • This issue has been addressed in the final RIA.

18/05/06	Gafta	<p>Annex 1A</p> <ul style="list-style-type: none"> • UK grain exceeding limits may be sent for animal feed. This may lead to sustainability issues once limits come into force. • Concerns over comparability of testing standards in all Member States. Seeking a level playing field. • Disagrees with RIA in relation that new regulation will not be costly to industry. Testing will cost more to traders and small businesses will be affected. 	<ul style="list-style-type: none"> • The Commission has addressed this and indicated that grain exceeding could be diverted for other uses. • The methods of sampling and analysis are specified in the new Regulation. Although only performance criteria are specified for the analytical method. However, methods of analysis, which comply with the criteria should give comparable results. • This issue has been addressed in the final RIA. However, testing by traders and/or businesses is not mandatory.
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