

**Explanatory Memorandum to the Contaminants in Food (Wales) Regulations
2010**

This Explanatory Memorandum has been prepared by the Food Standards Agency and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 24.1.

Minister's Declaration

In my view the explanatory memorandum gives a fair and reasonable view of the expected impact of the Contaminants in Food (Wales) Regulations 2010. I am satisfied that the benefits outweigh any costs.

Gwenda Thomas AM
Deputy Minister for Social Services

28 September 2010

Explanatory Memorandum to the Contaminants in Food (Wales) Regulations 2010.

1. Description

This instrument provides for the enforcement in Wales of the provisions of Commission Regulation (EU) No. 165/2010, amending (EC) Regulation No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins (“the Commission Regulation”).

This instrument provides for offences of contravening certain provisions of the Commission Regulation, for defences against prosecution for committing an offence in particular circumstances and specifies the penalties that the Courts may impose upon conviction for an offence.

This instrument will also revoke the Contaminants in Food (Wales) Regulations 2009 (as amended)¹.

2. Matters of special interest to the Constitutional Affairs Committee

None.

3. Legislative Background

Welsh Ministers have the required powers to make these Regulations under sections 16 (1)(a), (e) and (f) , 17 (2), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990, as read with paragraph 1A of Schedule 2 to the European Communities Act 1972. Functions so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the Food Standards Act 1999, and thereafter transferred to the Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006.

This instrument is subject to the negative procedure.

4. Purpose and Intended Effect of the Legislation

European Union (EU) legislation on contaminants in food is made under the contaminants framework Regulation 315/93/EEC (“the framework Regulation). This Regulation lays down the EU procedures for dealing with contaminants in food and it applies general requirements to those contaminants that are not covered by other specific EU legislation. In order to continue reducing the disparities between the existing laws of Member States in regard to maximum limits for contaminants in certain foodstuffs and the consequent risk of distortion of competition, Commission Regulation (EC) No. 1881/2006 was introduced under the framework Regulation to ensure market unity while complying with the principle of proportionality. The

¹ S.I. 2009/1386 (W.142) (as amended)

provisions and requirements of Commission Regulation 1881/2006 (and its predecessor Regulation (EC) No. 466/2001) have applied across the EU since April 2002.

The European Food Safety Authority's (EFSA) Scientific Panel on Contaminants in the Food Chain (Contam Panel) adopted an opinion on 25th June 2007 on the potential increase in risk to consumer health by a possible raising of the existing maximum permitted levels for aflatoxins in almonds, hazelnuts and pistachios and derived products. They concluded that a change in the maximum levels from 4 to 8 or 10 µg/kg in almonds, hazelnuts and pistachios would have minor effects on the estimates of dietary exposure, cancer risk and the calculated margins of exposure (MOEs). Furthermore, the Panel concluded that exposure to aflatoxins from all sources should be as low as reasonably achievable.

On 16th June 2009 the Panel adopted a statement on the effects on public health of an increase of levels for total aflatoxins from 4µg/kg to 10µg/kg for tree nuts other than almonds, hazelnuts and pistachios. Based on the information that was available in 2007, the Panel concluded that public health would not be adversely affected if the levels for total aflatoxins were to be raised from 4µg/kg to 10µg/kg for other tree nuts, including Brazil nuts. Given the current discussions in the Codex Alimentarius on the maximum levels for aflatoxins in Brazil nuts, it was considered appropriate to align the levels for total aflatoxins in almonds, hazelnuts, pistachios with those agreed at Codex Committee on Contaminants in Food in 2008.

In the EFSA opinion on aflatoxins it is observed that oilseeds and derived products are an important contributor to the human aflatoxin exposure. Furthermore, notifications in the Rapid Alert System for Food and Feed (RASFF) indicate high levels of aflatoxins in oilseeds such as sunflower seeds, melon seeds etc. It has therefore also been agreed to set a maximum level for oilseeds other than groundnuts (peanuts), in line with the existing levels for groundnuts (peanuts). However, as aflatoxins are nearly completely removed by the process of producing refined vegetable oils, it appropriate to exclude oilseeds, including groundnuts (peanuts), intended for crushing for refined vegetable.

Commission Regulation (EU) No. 165/2010 of 26 February, amending Regulation (EC) No. 1881/2006 was published in the Official Journal (OJ) of the EU on 27th February 2010² and came into force on 8th March 2010 and applied as from that date. That Regulation aligns EU limits for total aflatoxins in hazelnuts, almonds and pistachios with those agreed at the Codex Committee on Contaminants in Food ("CCCF") in 2008 and the same limit for Brazil nuts, which has now been agreed at CCCF in 2010. .

² OJ L50, 27.02.2010 p. 8-12

5. Consultation

The Food Standards Agency fully consulted 800 stakeholders on these proposals and on the draft Regulations to provide for their enforcement. These ranged from sector specific stakeholders, such as manufacturers of breakfast cereals and cereal-based foods; oils and similar edible fats; and importers of commodities such as treenuts, oil seeds and oil seed oils, rice and apricot kernels. Enforcement bodies, other government departments, consumer organisations, non-government organisations and others with an interest in chemical contaminants in foods were also consulted. The process was carried on consistently during negotiations with the European Commission and other EU Member States on the amendments to Commission Regulation 1881/2006.

Stakeholders, in particular enforcement bodies, were asked to comment with supporting evidence, on the cost of enforcing the new legislation, and on the assumptions that it would take one hour for enforcement authorities and businesses to read and familiarise themselves with the new Regulations and a further hour to disseminate this information to key staff within their respective organisations. They were also asked to comment on any others costs associated with Commission Regulation 1881/2006 and/or the new Regulations and whether they introduced any additional burden.

No responses were received from stakeholders in Wales. The following three responses were received from stakeholders in England; one from the Food and Drink Federation (FDF), one from the East of England Trading Standards Association (EETSA) and one from the Trading Standards Institute (TSI).

The EETSA agreed with the Agency's assessment that one hour was a sensible estimate for enforcement officers to familiarise themselves with the new requirements. EETSA also agreed with the Agency's assessment that there were no new or additional administrative burdens on businesses or enforcement authorities associated with the new Regulations or Commission Regulation 1881/2006.

In relation to the specific questions on familiarisation costs, the TSI supported the Agency's assessment that the proposal did not introduce new or additional costs for enforcement bodies, other than familiarisation costs. The TSI further agreed with the Agency's assessment that one hour for familiarisation by enforcement agencies and a further hour for disseminating the new Regulations to key staff was a reasonable estimate. However, they were unable to comment on familiarisation costs for industry.

The FDF commented that they circulated the consultation documents on the proposed Regulations to members of the FDF's Residues and Contaminants Committee. However, no comments were received from their members, which was an indication that the Committee and its members had monitored the development

and publication of the underlying EU legislation and were already aware of the issues covered by the consultation.

6. Regulatory Impact Assessment

Options:

Option 1 – Do Nothing – Do not provide for the enforcement of the new Commission Regulation in Wales

Doing nothing will not prevent the new Commission Regulation from applying in Wales; it is already legally binding and applicable throughout the EU. However, enforcement authorities would not have the necessary powers to enable them to enforce it. Therefore the obligation to put in place provisions for its enforcement, for offences to be prosecuted and for penalties to be imposed on those found to be in breach of the new Commission Regulation will not be fulfilled. This would lead the UK Government being cited in infringement proceedings by the Commission and these could result in financial penalties being incurred.

Option 2 – Fully implement the necessary requirements and make appropriate domestic Regulations for the execution and enforcement that will support the Commission Regulation and provide for its enforcement.

Option 2 meets the Government's commitment to fulfil its EU obligations and contributes significantly to providing for the means of protecting consumers from ingesting harmful chemical contaminants in food. Commission Regulations are binding in their entirety and directly applicable in Member States from the date they take effect. The UK has a legal obligation to ensure that provisions are in place to provide for their enforcement in full. Failure to do so may result in infringement proceedings against the UK government. This option would also provide enforcement authorities with the necessary powers to enforce the Commission Regulation. Also, local authorities and port health authorities will benefit from the greater clarity provided by the Commission Regulation and from the power of enforcement devolved to them from these proposed Regulations

Costs and Benefits

Option 1

There are no identifiable incremental benefits for this option. This option is the baseline for comparison.

Option 2 Costs to Enforcement Authorities

There will be a small one-off cost to businesses and enforcement authorities for reading and familiarising themselves with the new Regulations. The enforcement of food law is devolved to the enforcement authorities. In some cases this is divided between the Environmental Health Departments of the local, district/borough etc. councils and the Trading Standards Departments of the county councils. In some instances these two departments of the different levels in local government liaise closely and deal with issues in common to make it easier for consumers and businesses.

Each food authority in its area and each port health authority in its district are responsible for enforcing the legislation with respect to food safety and food hygiene. They have responsibility for enforcing the contaminants in food legislation and will, as outlined above, be affected by these proposals. The Agency believes that the incremental costs to enforcement authorities are unlikely to have a significant cost impact and are likely to be minimal, if any. Local authority enforcement bodies have always had responsibility for the enforcement of chemical contaminants legislation. The proposed Regulations for Wales merely provide the means by which this role can be extended to cover the new Commission Regulation.

There are a total of 22 Local Authorities (LA's) and 1 Port Health Authority (PHA) in Wales that will be affected by the Regulations. It is expected that one Environmental Health Officer (EHO) from each LA and PHA will read the Regulations and disseminate the information to key staff. We estimate that each EHO will invest one hour reading and familiarising themselves with the Regulations and a further one hour disseminating to key staff in the organisation; meaning a total of two hours for familiarising. Earlier consultation responses have also indicated the Trading Standards Officers (TSO's)³ would need to read and understand these Regulations. We assume that the time taken would be the same as for EHOs.

A wage rate of £20.70⁴ has been applied to EHO which equates to a one-off familiarisation cost £911 for LA's and £41 to the PHA in wales, which gives a total one-off familiarisation cost of £952. Table 1 displays the one-off familiarisation cost for Enforcement Authorities for the UK. While this legislation applies only to Wales, we assume similar incremental familiarisation costs will also be faced by the other administrations.

Table 1 – Familiarisation costs for Enforcement Authorities

Region	Local Authorities
England	£17,716
Wales	£952
Scotland	£1,325
N. Ireland	£1,076
UK	£21,027
Rounded*	£21,000

*Totals may not sum due up to rounding

Costs to Industry

The affected industries themselves will determine the extent and regularity with which they check compliance with the new maximum levels, as they currently do with the existing maximum levels.

³ The Annual Survey of Household Earnings (2009) gives median hourly pay excluding overtime, for 'inspectors of factories, utilities and trading standards'.

⁴ Wage rate obtained from The Annual Survey of Household Earnings (2009) (<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage for 'Environmental health officers' is used (£20.70 including 30% overheads).

Whilst the Regulations are not specifically aimed at any one type of food business, however, they apply to any food business operator involved in placing on the market products covered by the Commission Regulation, i.e. almonds, hazelnuts and pistachios and other commodities. Thus, importers, distributors, wholesalers, supermarkets etc are all responsible and it would be the responsibility of individual businesses to ensure compliance with the Regulations, within the supply chain.

The primary business sectors likely to be affected by these proposals will be those that manufacture breakfast cereals and cereal-based foods; oils and fats; margarine and similar edible fats; importers of commodities such as, treenuts, oil seeds and oil seed oils, rice and apricot kernels. For these sectors, there will be a small one-off cost for reading and familiarising themselves with the new Regulations.

Table 2 – Number of UK Businesses Affected by the Regulations

Summary of firms by size	Micro	< 20	Small	Medium	Large	Total
England	408	63	95	36	28	630
Wales	26	4	6	2	2	40
Scotland	52	8	12	5	4	80
N. Ireland	29	5	7	3	2	45
UK*	515	80	120	45	35	795

*Totals may not sum up due to rounding

Notes:

1. Sizes are defined by number of employees per premises as follows: Micro – less than 10 employees; <20 – 10-20 employees; Small 20-49 employees; Medium – 50-249 employees; Large – more than 250 employees.
2. Distribution of premises by employees' size is available only at UK level, for individual regions of the UK distribution of premises by size is applied by the total number of premises in each region.

We have estimated that such businesses will typically invest one hour reading and familiarising themselves with the new single set of Regulations. In addition, we have estimated that each person uses a further hour for dissemination to key staff within the organisation, meaning a total of two hours.

To calculate the familiarisation cost for businesses a wage rate of £25,19⁵ has been applied to the employee who reads and familiarises themselves with the Regulations. The wage rate is multiplied by the number of businesses affected by the Regulations, which is then multiplied by the reading and dissemination time. This equates to a one-off familiarisation cost to industry in Wales of approximately £2000. Table 3 displays the one-off familiarisation cost to industry broken down by region.

⁵ Wage rate obtained from The Annual Survey of Household Earnings (2009 (<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>)). Median hourly wage of a 'Production Manager' is used (£25,19 including 30% overheads)

Table 3 – Familiarisation costs to industry in the UK

Region	Industry
England	£31,744
Wales	£2,016
Scotland	£4,031
N. Ireland	£2,267
UK	£40,058
Rounded*	£40,000

*Totals may not sum up due to rounding

Impact on other Government bodies

Government departments, such as the Agency may also be affected as and when they carry out any surveys on foods. This impact may involve having to carry out more research on chemical contaminants in food, including work to establish methodologies for determining such contamination and to ensure compliance with the legislation. These are carried out to inform consumers, monitor trends and assess dietary exposure to harmful contaminants in food.

Consultation questions:

- (1). It is our assumption that there is a familiarisation cost for enforcement authorities associated with the proposed Regulations. We invite enforcement authorities to comment on our estimated of as one hour for familiarisation and a further hour for reading the new Regulations. If you disagree with this assessment, please provide evidence to support your views.
- (2). It is our assumption that there is a familiarisation cost for industry associated with the proposed Regulations. We invite businesses to comment on our estimated of one hour for familiarisation and a further hour for reading the new Regulations. If you disagree with this assessment, please provide evidence to support your views.
- (3). Is our assumption that there are no new or additional administrative burdens associated with the proposed Regulations. Is this an accurate assessment for both enforcement authorities and businesses? If you disagree, please provide evidence to support you views.

Comments received from stakeholders on these proposals are outlined below.

Whilst the Agency believes that OGDS are unlikely to be affected by these proposals, we would welcome comments if you feel that the proposals affect any research programmes in the area of chemical contaminants. Please provide evidence to support your views

No comments were received from OGDS on these proposals..

Benefits

Option 1 – Do Nothing

There are no identifiable incremental benefits for this option.

Option 2

This option would provide enforcement authorities with the necessary domestic legislation for the enforcement and execution of the Commission Regulation in Wales, which is binding in its entirety and directly applicable to all EU Member States.

Option 2 would also consolidate the important role that the UK plays in negotiating and agreeing standards for contaminants in food within the EU.

This option would also harmonise standards across the Member States and prevent any barrier to trade occurring as a result of there being different regulations in different Member States.

This could encourage additional trade and introduce greater market competition with benefits for the wider UK economy. It is also anticipated that businesses will benefit financially as a consequence of maximum levels for aflatoxins in almonds, hazelnuts and pistachios being relaxed. This would reduce food wastage as fewer commodities are rejected and removed from the supply chain, reducing the marginal costs of Food Business Operators (FBOs). In a competitive market this would be reflected through lower consumer prices and an increase in consumer benefit. However, these benefits are unquantifiable as it depends on the size and type of business including the volume of and profit from production.

Competition Assessment

We fully considered the questions posed in the Office of Fair Trading competition assessment test (http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft876.pdf) and have concluded that the proposed Regulations that implement the enforcement provisions of the Commission Regulation are unlikely to hinder the number or range of businesses or the ability of operators to compete. As such, the proposals are unlikely to significantly affect competition. The proposals do not contain a strong competition element or any significant new or additional burden. This is not expected to result in any reduction or change in businesses operating in this area, nor in their competitiveness or incentive to compete.

There is no current requirement for industry to carry out sampling and analysis within Commission Regulation 1881/2006, as amended. However, it may wish to do so (and may already be doing so) when carrying out its existing programme of checks for contamination in excess of legal limits to gain the protection of ‘due diligence’ defence under section 21 of the Food Safety Act 1990. This is applicable to all food businesses operating in the import, production, processing, storage, distribution and sale of food and in this respect is not likely to have a disproportionate effect on any business or group of businesses.

Small Firms Impact Test

Stakeholders, including the Enterprise Directorate in BIS, the Federation of Small Businesses and small businesses themselves, including those that are members of trade associations, have been consulted throughout the 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 we very much welcome representation from them and their representative organisations. Any potential additional costs arising from checking compliance with the maximum levels will be proportionate to small businesses. It is the responsibility of individual business operators to show how they satisfy compliance with the food law, which may include having systems in place to try and ensure their supplier is providing them with products that are compliant. For example, this may require that businesses specify requirements to be met by their supplier, prior to receiving the product to ensure that their products are not contaminated, above the permitted limits and would therefore not impact disproportionately on SMEs.

Post Implementation Review

The Agency will aim to review the Regulations in 2011. Local Authorities and Port Health Authorities are responsible for enforcing much of the food safety legislation, including the maximum levels for contaminants in food. Local Government Regulation (formerly LACORS), the Association of Port Health Authorities and the Association of Public Analysts are consulted specifically through established liaison mechanisms and provide feedback to the Agency about the effectiveness of these instruments. Businesses operators act similarly through their representative bodies and directly in response to consultation mechanisms.

Central and local authorities in Wales routinely monitor foodstuffs on sale to the public to ensure compliance with the Regulations. The results of this work carried out by the Agency are published and are openly available on the agency's website at:

<http://www.food.gov.uk/science/research/researchinfo/contaminantsresearch/>

The Commission investigates whether limits should be set for additional contaminants and also reviews the maximum limits for those contaminants currently in the legislation and the foods that are subject to control. Scientific data has shown that reduction of total dietary exposure to aflatoxins could be achieved by reducing the number of highly contaminated foods reaching the market through effective enforcement and reducing exposure from food sources other than almonds, hazelnuts and pistachios.

The Agency will also work with enforcement authorities where problems or suspected infringements of the Regulations arise. The effectiveness of the Regulations will be also be monitored via feedback from stakeholders as part of the ongoing policy process..

SF /GT/ 110/10