

**Explanatory Memorandum
The Contaminants in Food (Wales) (Amendment) Regulations 2007**

**This Explanatory Memorandum has been prepared by the Food Standards Agency
Wales and is laid before the National Assembly for Wales.**

1. Description

1.1 This Statutory Instrument provides enforcement measures in Wales for Commission Regulation (EC) No. 1126/2007 which revises maximum levels for Fusarium toxins in maize and maize-based food products.

1.2 This instrument amends The Contaminants in Food (Wales) Regulations 2007 which provide for the necessary legislative framework to enforce the measures laid down in Commission Regulation (EC) No. 1881/2006.

2. Matters of special interest to the Subordinate Legislation Committee

2.1 None.

3. Legislative Background

3.1 Welsh Ministers have the required powers under section 16(1(a) and 17(2) and 48 (1) of the Food Safety Act 1990, and Standing Order 24. The provisions of the Act were transferred from the National Assembly for Wales to Welsh Ministers under the provisions of the Government of Wales Act 2006. The Regulations are subject to the negative resolution procedure.

3.2 The Contaminants in Food (Wales) Regulations 2007 currently provide enforcement authorities and industry with the necessary domestic legal framework to ensure compliance with the provisions and maximum levels for certain contaminants in food laid down in Commission Regulation (EC) No. 1881/2006 of 19 December 2006. Commission Regulation (EC) No. 1126/2007 of 28 September 2007 amends this Regulation by revising maximum levels for Fusarium toxins in maize and maize products. The amending instrument is therefore needed to ensure compliance with those revised maximum levels for Fusarium toxins in maize and maize products. Commission Regulation (EC) No. 1126/2007 is expressed in Article 2 thereof to apply retrospectively from 1 July 2007 although it did not come into force until 30 September 2007.

4. Purpose and intended effect of the legislation

4.1 The intention of Community legislation on food contaminants is to provide consumers with an increased measure of protection by setting EC maximum levels for mycotoxins, including Fusarium toxins and certain undesirable process and environmental contaminants in those foodstuffs that are significant contributors to the total dietary exposure of consumers to those contaminants. The purpose of the legislation is to keep contaminants at levels that are toxicologically acceptable and to exclude grossly contaminated food from entering the food chain, while at the same time seeking to avoid imposing unnecessary burdens on food businesses.

Fusarium toxins have been shown to cause sickness and diarrhoea in humans as well as increased susceptibility to infections, growth retardation and reproductive effects in laboratory animals. Other Fusarium toxins have been shown to cause oestrogenic disruption and kidney and liver damage in laboratory animals if consumed over long periods, as well as carcinogenic effects at higher doses.

4.2 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 levels for contaminants in certain foodstuffs and the consequent risk of distortion of competition, Community measures controlling specific contaminants were introduced under Council Regulation 315/93/EEC to ensure market unity while complying with the principle of proportionality. These provisions and requirements are currently laid down in Commission Regulation (EC) No. 1881/2006 and are enforced in Wales under The Contaminants in Food (Wales) Regulations 2007. Similar Regulations apply in Scotland, Wales and Northern Ireland.

4.3 Maximum levels were established in 2005 for Fusarium toxins in food, including maize and maize products and these are laid down in Commission Regulation 1881/2006. The introduction of maximum levels for Fusarium toxins in food was consulted on formally during 2005/ 2006¹. Details of Fusarium toxins, including their occurrence, toxicity and impact on the food chain can be found in the associated Regulatory Impact Assessment². The Fusarium toxins included in the Commission Regulation are deoxynivalenol, zearalenone and fumonisins (the sum of B1 and B2).

4.4 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 levels for those contaminants currently in the legislation.

4.5 For maize, not all factors involved in the formation of Fusarium toxins, in particular zearalenone and fumonisins B1 and B2, were precisely known in 2005. Thus, a deferred application date for the maximum levels in maize and maize products was determined for deoxynivalenol and zearalenone of 1 July 2007 and for fumonisins B1 and B2 of 1 October 2007, in the event that revised maximum levels based on new information on occurrence and formation were not set before those dates. This time period has enabled food business operators in the cereal chain to perform investigations on the sources of the formation of these mycotoxins and on the identification of the management measures to be taken to prevent their presence as far as reasonably possible.

4.6 Since 2005, new information has been put forward to demonstrate that these maximum levels are not appropriate, particularly in light of observations made

¹ Consultation on The Contaminants in Food (Wales) Regulations 2006; www.food.gov.uk/consultations/consulteng/2006/contameng2006.

² www.food.gov.uk/multimedia/pdfs/riacontamengfusar06.pdf

regarding levels of these toxins found in the 2005 harvest linked to climatic conditions. Therefore, a reassessment was made and the maximum levels for Fusarium toxins in maize and maize products have now been revised to take into account these factors whilst continuing to maintain a high level of public health protection by ensuring that human exposure remains significantly below those levels that are deemed to be safe.

4.7 In order to ensure a methodical and smooth application of these maximum levels, it has also been agreed that they apply to all maize and maize products harvested in one season and therefore the date of application should reflect the beginning of the marketing season of the next harvest year. As the harvest of maize in Europe usually starts in mid September and runs until the end of October, it is deemed appropriate to take 1 October 2007 as the date of application.

4.8 Since 2005, Commission Recommendation 2006/583/EC of 17 August 2006 on the prevention and reduction of Fusarium toxins in cereals and cereal products, including maize and maize products has also been introduced and contains general principles for the prevention and reduction of Fusarium toxin contamination in cereals to be implemented by the development of national codes of practice based on these principles. Accordingly, the Food Standards Agency has produced a code of Practice specifically relevant to UK industry³. Such an approach will ensure that food business operators have the opportunity to apply all possible measures to prevent or reduce Fusarium toxin contamination as far as possible in order to protect public health.

5. Implementation

5.1 It is intended that these Regulations be made on 24 November 2007 to come into force on 19 December 2007. Parallel legislation is being introduced in England and is due to come into force on 25 November. Parallel legislation is also being made in Scotland and Northern Ireland and is due to come into force during December.

6. Consultation

6.1 Around 500 organisations food industry organizations and enforcement bodies have been consulted on this matter as part of the Food Standards Agency's ongoing Rapidly Developing Policy consultation scheme. Other government departments have also been kept fully aware of developments during negotiations and the UK position has been fully supported by The Department for Environment, Food and Rural Affairs throughout.

7. Regulatory Impact Assessment

7.1 A Regulatory Impact Assessment is included in this Explanatory Memorandum.

³ www.food.gov.uk/multimedia/pdfs/mycotoxincop2007.pdf

Regulatory Impact Assessment

8. Options

8.1 Option 1: Do nothing. Commission Regulations are directly applicable in Member States from the date that they take effect and the UK agreed to the measures after consultation during the negotiating stages. The UK has a legal obligation to ensure that provisions are in place providing for their enforcement. The Contaminants in Food (Wales) (Amendment) Regulations 2007 have been developed for this purpose. To do nothing would risk incurring infraction proceedings on the UK from the EC. To follow this option will also hamper enforcement authorities to carry out their duties in protecting public safety.

8.2 Option 2: Put in place the domestic regulations which provide for the execution and enforcement of the Commission Regulation (EC) No. 1126/2007 under The Contaminants in Food (Wales) (Amendment) Regulations 2007. Corresponding legislation would be introduced separately in Scotland, England and Northern Ireland.

9. Sectors and groups affected.

9.1 . The purpose of the Contaminants in Food (Wales) (Amendment) Regulations 2007 is to give effect to EC measures which aim to provide an increased level of food safety for consumers by setting maximum levels for Fusarium toxins in food and to provide a harmonised approach to enforcement. Consequently they apply to enforcement authorities and all businesses involved in the food sector.

10. Benefits

10.1 **Option 1:** There are no identifiable incremental benefits for this Option.

10.2 **Option 2:** This option would provide enforcement authorities with the necessary domestic legislation for the enforcement of Commission Regulation 1126/2007. This option would harmonise standards with other 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 Contaminants in Food (England) (Amendment) Regulations 2007 will continue to ensure a high level of consumer health protection.

10.3 As maximum levels are already in place for Fusarium toxins in food including maize and maize-based products, there are no anticipated changes in the costs to enforcement authorities to check compliance with the maximum levels as part of their official control responsibilities. Similarly, Food business operators already have responsibility for monitoring potential contamination of their products to ensure compliance with the current maximum levels laid down in Commission Regulation (EC) 1881/2006 in order to satisfy compliance with the “due diligence” requirement under section 21 of the Food Safety Act 1990. During consultation throughout the negotiations, the Agency has not received any indication from industry that consumer products will not be able to comply with the proposed revised maximum levels. In such case, any testing for compliance carried out by industry would be minimal.

11. Costs

11.1 **Option 1.** Possible financial costs to industry arising from lack of consumer confidence in the safety of the UK food supply.

11.2 **Option 2.** There are no likely changes in cost to either enforcement bodies or industry from the introduction of enforcement for the new measures.

12. Competition Assessment

12.1 The Contaminants in Food (Wales) (Amendment) Regulations 2007 apply to all businesses involved in the food industry and enforcement authorities. A competition filter has been completed. Given that no changes in costs to businesses from the enforcement of the revised maximum levels set under Commission Regulation 1126/2007 have been identified during the negotiations on the Commission measures, there are no anticipated effects on competition.

13. Consultation

Within Government

13.1 Other government departments including the Department for Environment, Food and Rural Affairs (Defra), the Department of Health, the Department of Trade and Industry, the Foreign & Commonwealth Office and the Cabinet Office were made aware of negotiations relating to the EC Regulation through Commission Working Group and Standing Committee meeting reports and Interested Parties letters. The ongoing negotiations and UK position have been supported by Defra throughout. No comments have been received from any other departments. Previous consultation within government has been carried out in 2005/2006 when the introduction of maximum levels for Fusarium toxins in food was under discussion.

Public consultation

13.2 UK stakeholders have been kept fully aware of developments relating to maximum levels for Fusarium toxins in food on a rolling basis by Interested Parties letters and have been given the opportunity to put forward their views, comments and data to help inform negotiations. Consultation has occurred from any early stage in negotiations on the introduction of maximum levels for Fusarium toxins in food as well as more recently with regard to revision of maximum levels for maize and maize-based products. In particular, information and updates have been provided as part of the Food Standard Agency's Rapidly Developing Policy consultation scheme, the format of which has been welcomed by stakeholders. Seven consultation updates have been issued since September 2006⁴.

14. Implementation and review

14.1 Local Authorities and Port Health Authorities are responsible for enforcing the majority of food safety legislation, including the maximum levels for contaminants in food. The Local Authorities Co-ordinators of Regulatory Services (LACORS), the Association of Port Health Authorities (APHA) and the Association of Public Analysts are consulted specifically

⁴ www.food.gov.uk/foodindustry/regulation/europeleg/euupdates

through established Agency liaison mechanisms such as interested parties letters during the development of the EU proposals.

14.2 The Agency continually consults 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.

10.2. As stated earlier, the European Commission investigates whether maximum levels should be set for additional contaminants and also reviews the maximum levels 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.

15. Summary

15.1 European Community measures setting maximum levels for certain contaminants in foodstuffs have applied since 2002. The aim of the legislation 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.

15.2 The aim of the new Commission Regulation 1126/2007 is to introduce revised maximum levels for Fusarium toxins in maize and maize-based products based on more robust scientific information that has been provided since the initial maximum levels were agreed on in 2005. Maximum levels for Fusarium toxins in a range of foodstuffs have applied since 1 July 2006.

15.3 Commission Regulations have general application and the direct force of law in all Member States. The UK has a legal obligation to ensure that provisions are in place for their enforcement.

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	<ul style="list-style-type: none"> • Fulfils the UK's legal 	<ul style="list-style-type: none"> • There are no likely

<p>for the enforcement of Regulation 1126/2007 under The Contaminants in Food (Wales) (Amendment) Regulations 2007</p>	<p>obligations to make provision for the enforcement of EC Regulations</p> <ul style="list-style-type: none"> • 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'. 	<p>changes in cost to either enforcement bodies or industry from the introduction of enforcement for the new measures.</p>
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