FOOD STANDARDS AGENCY
SCOTLAND
Buidheann Inbhe-Bìdhe an Alba

EXECUTIVE NOTE

The Contaminants in Food (Scotland) (Amendment) Regulations 2007
S.S.I. 2007/470

Description

1. The above instrument was made in exercise of the powers conferred by sections 16(1)(a), 17(2) and 48(1) of the Food Safety Act 1990. The instrument is subject to negative resolution procedure.

2. Policy Objective

2.1 This instrument provides for the enforcement in Scotland of Commission Regulation (EC) No. 1126/2007 which revises maximum levels for Fusarium toxins in maize and maize products by amending Commission Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs

2.2 This instrument amends The Contaminants in Food (Scotland) Regulations 2007 (SSI 2007 No. 29), which provides for the necessary legislative framework to enforce the measures laid down in Commission Regulation (EC) No. 188/2006.

3. Legislative Background

3.1 The Contaminants in Food (Scotland) 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.

3.2 Commission Regulation (EC) No. 1126/2007 is expressed in Article 2 thereof to apply retrospectively from 1 July 2007 although it did not enter into force until 30 September 2007.

4. Policy Background

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 In view of the requirement to protect public health by restricting contaminants to levels that are toxicologically acceptable, the European Commission in co-operation with Member States investigates whether limits should be set for additional contaminants. It also reviews the maximum levels for those contaminants currently in the legislation and the foods that are subject to control. As not all of the factors involved in the formation of Fusarium toxins were precisely known in 2005 when they were set, deferred application dates for the maximum levels for Fusarium toxins in maize and maize products were stipulated to allow new data on occurrence and formation to be determined.

4.3 Subsequently, new information has been established, which demonstrates that the maximum levels previously laid down in Commission Regulation (EC) No. 1881/2006 are in some cases lower than appropriate. A reassessment of the maximum levels for Fusarium toxins in maize and maize products has therefore been made and consequently they 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.

5. Consultation

5.1 Three hundred and thirty four stakeholders were consulted on these proposals, including food industry organisations and enforcement bodies. We also included the Scottish Federation of Small Businesses, consumer organisations and other non-government organisations as part of the Food Standards Agency's ongoing Rapidly Developing Policy consultation scheme.

5.2 Other government departments have also been kept fully aware of developments during negotiations and the UK position has been fully supported throughout.

6. Other Administrations

6.1 This instrument applies in relation to Scotland only. Separate but parallel legislation is being enacted for England, Wales and Northern Ireland.

7. Impact

7.1 In order to ensure that enforcement authorities are provided with the correct domestic legislation for the official control of the maximum levels specified in Commission Regulation (EC) No. 1126/2007 in a timely manner i.e. to correspond as close to possible with the application of the EC Regulation, the Food Standards Agency has not carried out a formal consultation on this occasion.

7.2 A Regulatory Impact Assessment has been prepared and is available at the address below.

Food Standards Agency Scotland
19 October 2007

Contact: Fiona Bruce, Food Standards Agency Scotland, St Magnus House, 25 Guild Street, Aberdeen, AB11 6NJ fiona.bruce@foodstandards.gsi.gov.uk

FINAL REGULATORY IMPACT ASSESSMENT

THE CONTAMINANTS IN FOOD (SCOTLAND) (AMENDMENT) REGULATIONS 2007

Maximum limits for Fusarium toxins in maize and maize products

1. TITLE OF PROPOSAL

The Contaminants in Food (Scotland) (Amendment) Regulations 2007

1.1. Provision for the enforcement of Commission Regulation (EC) No. 1126/2007 of 28 September 2007 amending Commission Regulation (EC) No. 1881/2006 as regards Fusarium toxins in maize and maize products.

2. Purpose and intended effect of measure

The Objective

2.1. The purpose of this measure is to provide both industry and enforcement authorities in Scotland with the necessary domestic legal framework to ensure compliance with Commission Regulation 1126/2007, which amends Commission Regulation 1881/2006 and sets maximum levels for Fusarium toxins in food. The Regulation was published in the Official Journal on 29 September 2007 and will apply retrospectively from 1 July 2007 although the maximum levels laid down in the annex to the Regulation will apply from 1 October 2007.

2.2. The specific objective of EC Regulation 1126/2007 is to introduce revised maximum levels for Fusarium toxins in maize and maize-based food products following new data which has become available since the original maximum levels were determined in 2005 and laid down in Regulation 1881/2006. The maximum levels were originally due to apply from 1 July 2007 for deoxynivalenol and zearalenone and from 1 October 2007 for fumonisins. The revised maximum levels will now apply from 1 October 2007 for all three toxins. No other changes are being made with respect to maximum levels for Fusarium toxins in food.

2.3. The purpose of setting maximum levels for Fusarium toxins in food is to provide consumers, including young children and babies with an appropriate 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.

2.4. The Contaminants in Food (Scotland) (Amendment) Regulations 2007 will amend The Contaminants in Food (Scotland) Regulations 2007 and extend to Scotland only. Similar Regulations will apply in England, Wales and Northern Ireland.

The Background

2.5. 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 Scotland under The Contaminants in Food (Scotland) Regulations 2007 [SSI 2007 No. 29]. Similar Regulations apply in England, Wales and Northern Ireland.

2.6. The intention of Commission Regulation 1881/2006 is to provide consumers with an increased measure of protection by setting 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, polycyclic aromatic hydrocarbons (PAHs), nitrate, 3-MCPD, aflatoxins, ochratoxin A, patulin, Fusarium toxins and inorganic tin have already been set under this legislation.

2.7. Fusarium toxins belong to a group of chemicals called mycotoxins, produced naturally by moulds and are commonly found on cereals. Fusarium toxins have been associated with a wide range of detrimental health effects. Deoxynivalenol has been shown to cause sickness and diarrhoea in humans as well as increased susceptibility to infections, growth retardation and reproductive effects in laboratory animals. Fumonisins have been shown to cause

kidney and liver damage in laboratory animals if consumed over long periods. Zearalenone has been shown to have oestrogenic effects on laboratory animals and carcinogenic effects at higher doses.

2.8. 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/ 2006[1]. Details of Fusarium toxins, including their occurrence, toxicity and impact on the food chain can be found in the associated Regulatory Impact Assessment[2]. The Fusarium toxins included in the Commission Regulation are deoxynivalenol, zearalenone and fumonisins (the sum of B1 and B2).

2.8. 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.

2.9. 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 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 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.

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

2.11. 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.

2.12. 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 industry[3]. 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.

Rationale for Government Intervention

2.13. 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. Enforcing the maximum levels laid down in Commission Regulation 1126/2007 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 levels, which are directly applicable to all Member States.

3. CONSULTATION

Within Government

[1] Consultation on The Contaminants in Food (Scotland) Regulations 2006; http://www.food.gov.uk/consultations/consultscot/2006/contamscot07

[2] http://www.food.gov.uk/multimedia/pdfs/contamscotfinalria2007.pdf

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

3.1. Other government departments including the Scottish Government DG Health & Wellbeing and DG Rural Affairs & Environment were made aware of negotiations relating to the EC Regulation through Commission Working Group and Standing Committee meeting reports and Interested Parties letters. 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

3.2. 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 2006[4].

4. Options

Option 1: Do nothing.

Option 2: *Make provision for the enforcement of Commission Regulation (EC) No. 1126/2007 under The Contaminants in Food (Scotland) (Amendment) Regulations 2007. Corresponding legislation would be introduced separately in England, Wales and Northern Ireland.*

5. COST AND BENEFITS

Sectors and Groups Affected

5.1. The purpose of the Contaminants in Food (Scotland) (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.

Impact on Race Equality

5.2. The Contaminants in Food (Scotland) (Amendment) Regulations 2007 are not considered to have any impact on race equality.

Impact on Sustainability

5.3. The Contaminants in Food (Scotland) (Amendment) Regulations 2007 will not have any specific impact on sustainability. However, these issues are taken into consideration during the negotiations and consultations, and maximum levels are set such that they aim to balance the ability of businesses to provide the items subject to maximum levels with a continued high level of consumer health protection, consumer confidence in the safety of the UK food chain and consumer choice.

5.4. No pertinent comments on the specific costs to industry arising from these Regulations have been received by the Agency.

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

Costs and Benefits

Option 1

5.5. 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 (Scotland) (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. There would be no incremental benefits from following this option.

Option 2

5.6. 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 (Scotland) (Amendment) Regulations 2007 will continue to ensure a high level of consumer health protection.

5.7. 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.

6. the small firms impact test

6.1. Stakeholders including the Scottish Federation for Small Businesses and the Scottish Chamber of Commerce have been consulted throughout the negotiations on the EC measures. No comments on the changes were received from these organisations. The obligation to provide safe food in compliance with food law applies equally to all food business operators regardless of size and is proportionate to the size of the business.

7. 'test run' of business forms

7.1 There are no forms associated with this piece of legislation.

8 Competition assessment

8.1. The Contaminants in Food (Scotland) (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.

9. Enforcement, Sanctions AND MONITORING

Enforcement

9.1 Local Authorities are responsible for enforcing Food Safety Regulations.

Sanctions

9.2. Local Authorities will be responsible for enforcing The Contaminants in Food (Scotland) (Amendment) Regulations 2007. A fine not exceeding level 5 on the standard scale will apply in the case of breaches of the main offences cited in the principal Regulations [The Contaminants in Food (Scotland) Regulations 2007] of placing contaminated food on the market, using contaminated food in the manufacture of other foodstuffs, or chemically detoxifying food containing mycotoxins (regulation 3).

Monitoring

9.3. 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.

10. implementation and delivery plan

10.1. Local Authorities are responsible for enforcing the majority of food safety legislation, including the maximum levels for contaminants in food. The Convention of Scottish Local Authorities (CoSLA) and the Association of Public Analysts are consulted specifically through established Agency liaison mechanisms such as interested parties letters during the development of the EU proposals.

10. POST IMPLEMENTATION REVIEW

10.1. 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.

11 SUMMARY AND RECOMMENDATION

11.1. 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.

11.2. 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.

11.3. 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**	• **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 of Regulation 1126/2007 under The Contaminants in Food (Scotland) (Amendment) Regulations 2007	• **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'.**	• **There are no likely changes in cost to either enforcement bodies or industry from the introduction of enforcement for the new measures.**

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

The Contaminants in Food (Scotland) (Amendment) Regulations 2007 will provide enforcement authorities with the necessary powers to effectively enforce the provisions and maximum levels set in Commission Regulation (EC) No. 1126/2007. The Regulations will amend The Contaminants in Food (Scotland) Regulations 2007 (SSI 2007 No 29).

12. declaration and publication

Declaration

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister _____

Date _____

CONTACT POINT:

Fiona Bruce
Contaminants, Hygiene, Additives & Shellfish Branch
Food Standards Agency Scotland
6th Floor, St Magnus House
25 Guild Street
Aberdeen AB11 6NJ
Tel: 01224 285170 Fax: 01224 285168
E-mail: fiona.bruce@foodstandards.gsi.gov.uk