September 2007 Reference:

Dear Sir/Madam

Chemical Contaminants Interested Parties Letter September 2007

Maximum levels of Fusarium toxins in maize and maize based products

I wrote to you in August informing you that the Standing Committee on the Food Chain and Animal Health had adopted the proposal to revise limits for Fusarium toxins in maize and maize products. http://www.food.gov.uk/multimedia/pdfs/chemeuupdate0708 The adopted proposal will be published as a Regulation in the Official Journal (OJ) of the European Union shortly.

I am now writing to inform you that the Regulation will be coming into force on 1 October and we will be making provisions for its enforcement in England by virtue of a Statutory Instrument which is due to come into force on 13 November.

Owing to the recent holiday period and to translation delays within the Commission, there will be a particularly short timescale after publication in which to implement enforcement provisions for the EC measures within our own domestic legislation before the revised limits apply from the beginning of October. We wish to avoid any undue delay in implementing the measures so as to provide Local Authorities and Port Health Authorities with the necessary powers to enforce the Regulation in a timely manner. This will ensure that any difficulties for them or potential confusion for industry will not arise and will also ensure the continued provision of protection of public health.

Therefore, due to these time constraints, we will not be formally consulting on the Regulation having consulted informally and sought your views on this proposal throughout the negotiation stages by way of Food Standard Agency's Rapidly Developing Policy consultation scheme. However we are still interested in receiving any comments you may have at this stage about the enforcement measures provided by the Statutory Instrument. Please send comments to the address below by **Monday 15th October**. The introduction of maximum levels for Fusarium toxins in food and a Regulatory Impact Assessment was previously consulted on formally in 2006.

Summary of the Provisions

The original provisions for Fusarium toxins in food were laid down in Commission Regulation (EC) No. 1881/2006, which came into force on 1 July 2006. However, the limits set for Fusarium toxins in maize and maize products specifically have been reassessed this year in light of new information. Revised limits have therefore now been adopted in this latest EU amending Regulation. This new Regulation will be published shortly and will apply retrospectively from 1 July 2007 on entering into force. However, the new limits for deoxynivalenol, zearalenone and fumonisins in maize and maize products will all apply from 1 October 2007.

Attached are the draft Statutory Instrument, the Commission Directive and the Regulatory Impact Assessment. If you have any further queries relating to this matter, please do hesitate to contact myself or Wendy Matthews, tel 020 7276 8707; e-mail wendy.matthews@foodstandards.gsi.gov.uk.

Yours faithfully

Jonathan Briggs
Chemical Safety and Incident Prevention Team

STATUTORY INSTRUMENTS

2007 No. 0000

FOOD, ENGLAND

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

Made - - - -	*2007*
Laid before Parliament	*2007*
Coming into force - -	*2007*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(a), 17(2) and 48(1) of the Food Safety Act 1990(**a**), and now vested in him(**b**).

In accordance with section 48(4A) of that Act, he has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**c**), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Title, application and commencement

1. These Regulations may be cited as the Contaminants in Food (England) (Amendment) Regulations 2007, apply in relation to England only and come into force on [—] 2007.

Amendment of the Contaminants in Food (England) Regulations 2007

2.—(1) The Contaminants in Food (England) Regulations 2007(**d**) are amended in accordance with paragraph (2).

(2) In regulation 2 (interpretation), for the definition of "the Commission Regulation" substitute the following —

(**a**) 1990 c. 16.

(**b**) Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999 (1999 c. 28). Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act. Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act. Section 17(1) was amended by paragraph 12(a), section 17(2) by paragraph 12(b) and section 48 by paragraph 21, of Schedule 5 to the 1999 Act.

(**c**) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended as at the making of these Regulations by Commission Regulation (EC) No. 575/2006 (OJ No. L100, 8.4.2006, p.3).

(**d**) S.I. 2007/210

“”the Commission Regulation” means Commission Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs(**a**) as amended by Commission Regulation (EC) No. 0000/2007 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards *Fusarium*-toxins in maize and maize products(**b**).”.

Signed by authority of the Secretary of State for Health

Dawn Primarolo
Minister of State
Department of Health

Date 2007

(**a**) OJ No. L364, 20.12.2006, p.5.
(**b**) OJ No. L

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations, which apply in relation to England only, amend the Contaminants in Food (England) Regulations 2007 (S.I. 2006/210) ("the 2007 Regulations"). They make provision for the execution and enforcement of Commission Regulation (EC) No. [—]/2007 amending Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards *Fusarium* toxins in maize and maize products (OJ No. L——).

2. The Regulations amend the definition of the "the Commission Regulation" in the 2007 Regulations so as to include the amendments effected by Commission Regulation (EC) No. [—] (*regulation 2*).

3. A full regulatory assessment has not been produced for this instrument as no impact on the private or voluntary sectors is foreseen.

DRAFT FINAL REGULATORY IMPACT ASSESSMENT

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

Maximum limits for Fusarium toxins in certain foodstuffs

1. TITLE OF PROPOSAL

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

1.1. Provision for the enforcement of Commission Regulation (EC) No. XXX/2007 of XX September 2007 amending Commission Regulation (EC) No. 1881/2006 as regards Fusarium toxins in certain foodstuffs.

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 England with the necessary domestic legal framework to ensure compliance with Commission Regulation XXX/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 xx 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 XXX/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. 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 are observed primarily as contaminants of maize-based products and 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, as well as carcinogenic effects at higher doses.

2.4. The Contaminants in Food (England) (Amendment) Regulations 2007 will amend The Contaminants in Food (England) Regulations 2007 and extend to England only. Similar Regulations will apply in Wales, Scotland 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 England under The Contaminants in Food (England) Regulations 2007 [SI 2007 No. 210]. Similar Regulations apply in Scotland, 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. Maximum levels were established in 2005 for Fusarium toxins in food, including maize and maize products and these are currently 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

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

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

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 the health based guidance value.

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 XXX/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

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3.1. Other government departments including the Department for Environment, Food and Rural Affairs (Defra), the Department of Health, the Department of Trade

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

and Industry, the Foreign & Commonwealth Office and the Cabinet Office were made aware of negotiations relating to the 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

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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. XXX/2007 under The Contaminants in Food (England) (Amendment) Regulations 2007. Corresponding legislation would be introduced separately in Scotland, Wales and Northern Ireland.

5. COST AND BENEFITS

Sectors and Groups Affected

5.1. The purpose of the Contaminants in Food (England) (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 (England) (Amendment) Regulations 2007 are not considered to have any impact on race equality.

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

Impact on Sustainability

5.3. The Contaminants in Food (England) (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. The potential impact on the public sector is discussed below.

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 (England) (Amendment) Regulations 2007 have been developed for this purpose. To do nothing will incur 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 XXX/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.

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 Small Business Service, the Federation of Small Businesses and the British 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. COMPETITION ASSESSMENT

7.1. The Contaminants in Food (England) (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 XXX/2007 have been identified during the negotiations on the Commission measures, there are no anticipated effects on competition.

8. ENFORCEMENT, SANCTIONS AND MONITORING

Enforcement

8.1 Local Authorities and Port Health Authorities are responsible for enforcing Food Safety Regulations.

Sanctions

8.2. Local Authorities and Port Health Authorities will be responsible for enforcing The Contaminants in Food (England) (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 (England) 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).

9. IMPLEMENTATION AND DELIVERY PLAN

9.1. 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 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 (XXX/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 XXX/2007 under The Contaminants in Food (England) (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 (England) (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. XXX/2007. The Regulations will amend The Contaminants in Food (England) Regulations 2007 (SI 2007 No 210).

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:

Jonathan Briggs
Chemical Safety & Incident Prevention Team
Food Standards Agency
Room 707C, Aviation House
125 Kingsway, London. WC2B 6NH

Tel: 020 7276 8716
Fax: 020 7276 8717
E-mail: jonathan.briggs@foodstandards.gsi.gov.uk

SANCO/1989/2007 Rev. 2 (POOL/E3/2007/1989/1989R2-EN.doc)

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2007) final

Draft

COMMISSION REGULATION

of

amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards *Fusarium*-toxins in maize and maize products

(Memorandum from Mr M. KYPRIANOU)

Draft

COMMISSION REGULATION

of

amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards *Fusarium*-toxins in maize and maize products

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[1], and in particular Article 2 (3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs[2] sets maximum levels for Fusarium-toxins in certain foodstuffs.

(2) Maximum levels should be set at a strict level which is reasonably achievable by following good agricultural and manufacturing practices and taking into account the risk related to the consumption of the food.

(3) Climatic conditions during the growth, in particular at flowering, have a major influence on the Fusarium toxin content. However, good agricultural practices, whereby the risk factors are reduced to a minimum, can prevent to a certain degree the contamination by *Fusarium* fungi. Commission Recommendation 2006/583/EC of 17 August 2006 on the prevention and reduction of Fusarium toxins in cereals and cereal products[3], including maize and maize products contains general principles for the prevention and reduction of Fusarium toxin contamination (zearalenone, fumonisins and trichothecenes) in cereals to be implemented by the development of national codes of practice based on these principles.

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1 OJ L 37, 13.2.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

2 OJ L 364, 20.12.2006, p. 5.

3 OJ L 234, 29.8.2006, p. 35.

(4) Maximum levels were established in 2005 for Fusarium toxins in cereals and cereal products, including maize and maize products. For maize, not all factors involved in the formation of Fusarium toxins, in particular zearalenone and fumonisins B_1 and B_2, were precisely known. Therefore, the maximum levels in maize and maize products were foreseen to apply only from 1 July 2007 for deoxynivalenol ad zearalenone and from 1 October 2007 for fumonisins B_1 and B_2, in case no changed maximum levels based on new information on occurrence and formation are set before that time. 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.

(5) Taking into account new information since 2005, it appears necessary to amend the maximum levels in maize and maize products as well as the date of application of these levels.

(6) Recent information has been provided demonstrating that for the harvest 2005 and 2006 higher levels have been observed in maize than for the harvest 2003 and 2004 of mainly zearalenone and fumonisins and to a lesser extent deoxynivalenol, linked to the weather conditions. The foreseen levels for zearalenone and fumonisins are therefore under certain weather conditions not achievable for maize, even when applying prevention measures to the extent possible. Therefore the maximum levels need to be amended in order to avoid a disruption of the market whilst maintaining a high level of public health protection by ensuring that human exposure will remain significantly below the health based guidance value.

(7) In order to ensure a correct and smooth application of these maximum levels, it is also appropriate that they apply to all maize and maize products harvested in a 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 starts usually mid September and runs until end of October, it is appropriate to take 1 October 2007 as date of application.

(8) In the light of the foregoing this Regulation should apply from 1 July 2007.

(9) In addition, a number of minor technical changes should also be made.

(10) It is appropriate to provide that the maximum level does not apply to the unprocessed maize intended to be processed by wet milling (starch production). Indeed, scientific data have shown that regardless the levels of Fusarium-toxins present in unprocessed maize, Fusarium-toxins were not detected or only at very low levels in starch produced from maize. Nevertheless, in order to protect public and animal health, food business operators in the wet milling sector should intensively monitor the by-products from the wet milling process destined for animal feeding to check compliance with the guidance values referred in Commission Recommendation 2006/576/EC of 17 August 2006 on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding[4].

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[4] OJ L 229, 23.8.2006, p. 7.

(11) The dry milling process results in milling fractions with different particle size from the same batch of unprocessed maize. Scientific data show that the milling fractions with smaller particle size contain a higher level of Fusarium toxins than the milling fractions with a larger particle size. Maize milling fractions are classified according to the particle size in different headings in the Combined Nomenclature based upon a rate of passage through a sieve with an aperture of 500 microns. Different maximum levels for milling fractions smaller and larger than 500 microns should be set to reflect the contamination level of the different fractions.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1881/2006 is amended as follows:

1. Article 11, point (b) is replaced by the following:

"(b) 1 October 2007 as regards the maximum levels for deoxynivalenol and zearalenone laid down in points 2.4.3, 2.4.8, 2.4.9, 2.5.2, 2.5.4, 2.5.6, 2.5.8, 2.5.9 and 2.5.10 of the Annex;"

2. The Annex, Section 2 is amended as follows:

(a) The entries for Deoxynivalenol (2.4), Zearalenone (2.5), and Fumonisins (2.6) are replaced by the entries in the Annex to this Regulation.

(b) The text of footnote 20 is replaced by "Maximum level shall apply from 1 October 2007."

(c) The footnote 21 is deleted.

Article 2

This Regulation shall enter into force on the day following that of its publication in the Official Journal of the European Union.

It shall apply from 1 July 2007.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

"2.4	**Deoxynivalenol**[17]	
2.4.1	Unprocessed cereals[18,19] other than durum wheat, oats and maize	1250
2.4.2	Unprocessed durum wheat and oats[18,19]	1750
2.4.3	Unprocessed maize[18], with the exception of unprocessed maize intended to be processed by wet milling*	1750[20]
2.4.4	Cereals intended for direct human consumption, cereal flour, bran and germ as end product marketed for direct human consumption, with the exception of foodstuffs listed in 2.4.7, 2.4.8 and 2.4.9	750
2.4.5	Pasta (dry)[22]	750
2.4.6	Bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals	500
2.4.7	Processed cereal-based foods and baby foods for infants and young children[3,7]	200
2.4.8	Milling fractions of maize with particle size > 500 micron falling within CN code 1103 13 or 1103 20 40 and other maize milling products with particle size > 500 micron not used for direct human consumption falling within CN code 1904 1010	750[20]
2.4.9	Milling fractions of maize with particle size ≤ 500 micron falling within CN code 1102 20 and other maize milling products with particle size ≤ 500 micron not used for direct human consumption falling within CN code 1904 1010	1250[20]
2.5	**Zearalenone**[17]	
2.5.1	Unprocessed cereals[18,19] other than maize	100
2.5.2	Unprocessed maize[18] with the exception of unprocessed maize intended to be processed by wet milling*	350[20]
2.5.3	Cereals intended for direct human consumption, cereal flour, bran and germ as end product marketed for direct human consumption, with the exception of foodstuffs listed in 2.5.6, 2.5.7, 2.5.8, 2.5.9 and 2.5.10	75
2.5.4	Refined maize oil	400[20]
2.5.5	Bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals, excluding maize snacks and maize based breakfast cereals	50
2.5.6	Maize intended for direct human consumption, Maize-based snacks and maize based breakfast cereals	100[20]
2.5.7	Processed cereal-based foods (excluding processed maize-based foods) and baby foods for infants and young children[3,7]	20
2.5.8	Processed maize-based foods for infants and young children[3,7]	20[20]

2.5.9	Milling fractions of maize with particle size > 500 micron falling within CN code 1103 13 or 1103 20 40 and other maize milling products with particle size > 500 micron not used for direct human consumption falling within CN code 1904 1010	200[20]
2.5.10	Milling fractions of maize with particle size ≤ 500 micron falling within CN code 1102 20 and other maize milling products with particle size ≤ 500 micron not used for direct human consumption falling within CN code 1904 1010	300[20]
2.6	**Fumonisins**	Sum of B_1 and B_2
2.6.1	Unprocessed maize[18], with the exception of unprocessed maize intended to be processed by wet milling*	4000[23]
2.6.2	Maize intended for direct human consumption, maize based foods for direct human consumption, with the exception of foodstuffs listed in 2.6.3 and 2.6.4	1000[23]
2.6.3	Maize based breakfast cereals and maize-based snacks	800[23]
2.6.4	Processed maize-based foods and baby foods for infants and young children[3,7]	200[23]
2.6.5	Milling fractions of maize with particle size > 500 micron falling within CN code 1103 13 or 1103 20 40 and other maize milling products with particle size > 500 micron not used for direct human consumption falling within CN code 1904 1010	1400[23]
2.6.6	Milling fractions of maize with particle size ≤ 500 micron falling within CN code 1102 20 and other maize milling products with particle size ≤ 500 micron not used for direct human consumption falling within CN code 1904 1010	2000[23]

* The exemption applies only for maize for which it is evident e.g. through labelling, destination, that it is intended for use in a wet milling process only (starch production)."