

DRAFT EC REGULATION - AFLATOXIN CONTROL

Submission by Argentina

The following communication was received from Argentina on 13 February 1998.

Proposal by the Commission of the European Communities to Amend Regulation
(EC) 194/97 of 31 January 1997 Setting Maximum Levels for
Certain Contaminants (Aflatoxins) in Foodstuffs

Purpose

The purpose is described in the preamble to the draft Regulation as follows:

Paragraph (1) "Whereas some member States have adopted, or plan to adopt, maximum levels for aflatoxins in certain foodstuffs;"

Paragraph (2) "Whereas, in view of the disparities between member States and the consequent risk of distortion of competition, Community measures are necessary in order to ensure market unity while abiding by the principle of proportionality;"

Paragraph (3) "Whereas rules have to be set concerning the maximum limits which are acceptable in single dried and/or processed agricultural products and in compound foodstuffs in order to ensure human health protection as well as proper functioning of the single market with regard to such products".

Products concerned: Cereals, groundnuts, fresh fruits and milk products.

Annexes

Draft ... "Proposal concerning methods of sampling and methods of analysis of the content of contaminants in certain foodstuffs" with Annex (I) "Methods of sampling for the official control of the levels of aflatoxins in certain foodstuffs" and Annex (II) "Sample preparation and criteria for the methods of analysis for the official control of the levels of aflatoxins in certain foodstuffs".

Entry into force: March 1998

Here below is a description of the technical and legal elements which form the basis for Argentina's objection to this draft.

Introduction

Aflatoxins are toxins produced by the secondary metabolism of certain fungi of the genus *Aspergillus* and are naturally present in most cereal (maize), oilseed (groundnuts) and dried fruit (walnuts, chestnuts, etc.) crops. The distribution of these fungi is universal, and they occur in all habitats in which the mentioned crops are cultivated.

The development of these fungi and the formation of their toxins are influenced by variations in the natural environment, such as temperature and humidity, affecting the different stages of the cultivation process, and of the post-harvest period (storage, transport, etc).

The occurrence of the toxins is diminished considerably by good cultivation and post-harvest practices which, although they cannot ensure complete elimination, help to maintain reasonable acceptance levels.

Five aflatoxins have been identified: B₁, B₂, G₁ and G₂ in cereals, groundnuts, and nuts, and M₁ in milk.

At the cultivation stage, the spread of aflatoxins is favoured by excessive humidity during the formation and ripening of the grain, severe drought, insect infestations or delay in the harvest with the possibility of late rain, etc.

The distribution of aflatoxins, both during cultivation and storage, is entirely random: it is a negative binomial distribution, and not a gaussian one as in most biological phenomena. This means that specific sampling plans must be devised in order to detect and quantify the occurrence of aflatoxins; samples must be taken from goods on the move at given intervals.

Toxicological background

In 1987, the 31st Meeting of the World Health Organization concluded that there was insufficient information to establish a "tolerable level" of intake.

In June 1992, a working group of the International Agency for Research on Cancer (IARC) drew up a report assessing carcinogenic risks to human beings in which it concluded that there was sufficient evidence of carcinogenicity in human beings of mixtures produced naturally from aflatoxins and from aflatoxin B₁ in particular.

In the press report of the 46th Meeting of the World Health Organization, aflatoxins appear among the most potent carcinogenic and mutagenic substances known, particularly in connection with liver cancer (based on experimental evidence).

At the same time, the different reports of the WHO and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) associated the carcinogenicity of aflatoxin B₁ with the hepatitis B virus (HBV) and hence with the levels of vaccination against hepatitis B. And in fact, the population of the EU has one of the highest vaccination levels in the world against hepatitis B.

In the report of the 49th meeting of JECFA, held in June 1997, the Committee considered that the weight of the scientific evidence, which included epidemiological data, laboratory animal studies, and *in vivo* and *in vitro* metabolism studies, supported the conclusion that aflatoxins should be treated as carcinogenic food contaminants, the intake of which should be reduced to levels as low as reasonably achievable.

This report marks a change of position, in the light of the scientific evidence, as regards the regulation of aflatoxins. JECFA's 1989 report recommended that the level of aflatoxin intake should be reduced to irreducible values, i.e. a level at which a significant quantity of the products in question would have to be destroyed. JECFA's current position (June 1997) is that aflatoxin intake should be reduced to as low a level as reasonably achievable.

Two factors make this conceptual change on the part of JECFA particularly significant:

1. The low tolerable levels of intake (those currently being developed for the Codex Alimentarius and those proposed by the EU) do not result in a significant enough difference in terms of risk evaluation to provide a scientific justification for such a reduction.
2. The concept of reasonably achievable levels implies weighing the toxicological aspects against production aspects, and hence the supply of foodstuffs, with a view to achieving a fair balance.

Sampling plans

The sampling plan proposed by the EU contains a lot of new elements that are not backed by an international bibliography and do not take account of the practical aspects of handling an enormous quantity of samples; moreover, the acceptance/rejection criteria are clearly biased in favour of the importer.

According to this sampling plan, if one of the three subsamples shows a value exceeding the set limit, the entire lot must be rejected, even if the average level of the three subsamples is below the set limit. This means that risks are not equal for the exporter and the importer.

From the economic point of view, the draft EU Regulation implies, at the very least, a significant cost increase due to the sampling process alone, not to mention the rejection of large volumes of samples upon loading and unloading, the evaluation of alternative uses of the raw material, possible detoxification, etc.

In 1993, the FAO consulted a number of international experts regarding sampling plans for the analysis of aflatoxins in groundnuts and maize, the results of which were published in FAO Food and Nutrition Paper No. 55.

The paper contains an analysis of the occurrence of aflatoxins in groundnuts and maize traded internationally and of the development and evaluation of sampling plans with a study of characteristic performance curves and theoretical probability models, and provides recommendations for sample taking and preparation.

The technical consultations revealed that the sampling plans must be simple, must provide for relatively large samples and, contrary to the EU proposal, both the exporter and the importer must be subjected to the same risk.

Codex Alimentarius

This subject is currently being discussed in four Committees: the Codex Committee on Food Additives and Contaminants (CCFAC), the Codex Committee on Cereals, Pulses and Legumes (CCCPL), the Codex Committee on Food Hygiene (CCFH) and the Codex Committee on Methods of Analysis and Samples (CCMAS). It comes within the domain of the first two Committees in particular, and

is the subject of agenda item 12 of the next meeting of the CCFAC to be held during the first half of March of this year.

The work of these Committees began a few years ago, and efforts to set acceptance/rejection levels encountered problems due essentially to diverging views between exporting and importing countries. A large number of countries participate in the meetings, and pin their hopes on the possibility of adopting recommendations that will be respected by all members. They consider these Committees to be the appropriate forum for scientific discussions concerning food standards in international trade.

Conclusions

- The maximum limits proposed by the EU are without scientific justification in terms of risk to the consumer, and consequently, may be considered as representing a para-tariff barrier to international trade. As such, they would be violating the principles of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (Article 2.2, 2.3 and 2.4; Article 3.2 and 3.3; Article 5.1, 5.2, 5.3, 5.4 and 5.5; and Article 6.1).

Indeed, although the proposal is ostensibly based on scientific arguments, its true justification lies in the need for the EU to harmonize the legislations of its different member States, particularly with the incorporation of the Scandinavian countries whose regulations are stricter than those of the southern States - a fact which is perfectly understandable, since regions with a cold climate do not offer the natural conditions for the proliferation of aflatoxins. This justification can be inferred from the preambular part of the proposal (paragraphs 1, 2 and 3).

At the same time, due consideration should be given to the studies of the IARC, the results of the 46th Meeting of the World Health Organization, and the 49th Report of the JECFA which takes account of the epidemiological studies of risk allocation concerning aflatoxins, to the fact that the CCFAC has found that there is insufficient up-to-date information to set maximum limits for total aflatoxin and B₁ levels, and that on the basis of the latest studies, JECFA has altered its 1989 position and now mentions "reasonable values" instead of "*irreducible* values", as well as to the sampling plans proposed by FAO/WHO studies and workshops and the infeasibility of implementing the EU proposal.

Aflatoxins appear to present a lesser risk for human beings than for the animals on which the laboratory experiments were conducted, since they do not metabolize them in the same way. The experiments prove that aflatoxins present a greater risk in populations where hepatitis B is endemic, and that for populations in regions such as Europe, where hepatitis B is rare, to reduce the maximum level of aflatoxins in foodstuffs from 20 to 10 ppb would yield an increase in the risk of liver cancer in two cases per 1,000 million inhabitants (Report of the 49th Meeting of the FAO/WHO JECFA, Rome, June 1997).

- The sampling plan mentioned in the EU draft has no scientific justification and is biased in favour of one of the parties (exporting country-importing country); hence it is inconsistent with the spirit and letter of the Agreement on Technical Barriers to Trade.

The European proposal would have extremely serious consequences for sampling of cereal and groundnut shipments in that it would increase the number of samples as much as six-fold, thus constituting a true technical barrier to trade. At the same time, the maximum limits for aflatoxin content in the European proposal are very close to the minimum levels detectable through normal methods of analysis without considering the natural margin of error of such methods.

Here, once again, the draft lacks technical foundation and its implementation is unrealistic in that:

- It calls for a disproportionate increase in the number of samples to be taken for the detection of aflatoxins;
- the methods used have a very high margin of error, which means that the lower the maximum tolerated level, the less significant the difference between analytical values;
- it implies a very high cost which would not only affect exporters, but would be reflected in the price paid by consumers.

The damage to our country would be considerable in view of the impact that the implementation of such a measure would produce (see attached table). Although soya beans and soya and sunflower meal are the chief exports to the EU in terms of volume, both maize and groundnuts as well as their by-products represent a considerable share of export revenue.

In the specific case of flint maize, the product reacts very well to extrusion and is used principally for the production of cornflakes. Between April and December 1997, the volume of flint maize exported to the EU totalled about 400,000 tonnes, exceeding the average of 200,000 to 300,000 tonnes exported during previous periods. According to market estimates, there should be a considerable increase in view of the growing interest of European consumers, and the figure could reach 800,000 tonnes per year.

Finally, it should be borne in mind that this matter is currently being studied and discussed in the appropriate international scientific fora (FAO/WHO Codex Alimentarius) and the future agenda provides for continued discussions on the subject. It would be inappropriate to anticipate the conclusions of those discussions, and it is important that they be respected.

VALUE OF ARGENTINE EXPORTS OF CEREALS, GROUNDNUTS AND
BY-PRODUCTS THEREOF TO THE EUROPEAN UNION

(Thousands of dollars)

	1997*	1996	1995	1994
Maize	73,049	99,606	76,813	65,070
Other cereals	94,281	9,250	5,303	14,995
Groundnuts	32,838	119,518	76,041	62,512
Bran	1,730	1,599	1,622	1,270
Groundnut by-products	7,692	9,649	3,989	3,997
Miscellaneous by-products	2,356	12,456	12,966	12,413
TOTAL	188,897 (?)	252,078	176,734	160,257

*Period January-July.

Source: Secretariat of Agriculture, Livestock and Fisheries.

ARGENTINE EXPORTS OF CEREALS, GROUNDNUTS AND BY-PRODUCTS TO THE EUROPEAN UNION

(In thousands of tonnes)

PRODUCTS	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997(*)
Wheat	40.1	0.0	0.0	0.0	9.0	1.7	1.5	1.5	10.0	4.0	47.2	97.6
Maize	900.7	573.4	858.2	301.8	516.3	582.6	682.0	720.2	471.0	671.0	621.8	850.0
Sorghum	0.0	0.0	100.3	0.0	0.0	0.0	0.0	0.0	0.0	9.0	1.5	25.2
Groundnuts	95.9	94.0	85.6	57.8	71.5	52.4	9.7	0.0	38.0	54.0	139.8	102.5
Millet	28.9	42.8	61.3	22.8	39.6	40.8	29.9	28.9	38.0	21.0	31.8	29.6
Barley	0.0	0.0	25.4	0.0	10.0	0.0	17.3	24.1	0.0	0.0	0.0	22.0
Wheat by-products	418.6	75.7	124.6	92.4	63.6	14.2	0.0	50.8	20.5	28.0	13.6	0.0
Groundnut by-products	23.6	32.5	48.2	21.0	39.1	33.1	95.7	33.4	28.0	39.0	52.1	4.2
Cotton by-products	25.7	46.2	117.6	118.9	98.2	161.2	73.2	72.9	121.2	148.0	140.1	57.6
Maize by-products	0.0	0.0	117.7	110.2	112.4	115.9	291.1	106.1	130.8	122.0	76.7	95.3
Sorghum by-products	0.0	0.0	4.7	2.5	3.2	6.5	5.8	8.0	7.0	8.0	8.6	15.5
TOTAL:	1,533.5	864.6	1,543.6	727.4	962.9	1,008.4	1,206.2	1,045.9	864.5	1,104.0	1,233.2	1,299.5

Period January-November 1997

Rice-groundnuts: January-October 1997

Source: Department of Agri-Food Markets - Secretariat of Agriculture, Livestock and Fisheries.