

# THE ENFORCEMENT OF MYCOTOXIN LEGISLATION IN EUROPE

## Flep Working Party 'Mycotoxins'

### 1. Background

Mycotoxin contamination of foods has gained much global attention in recent times owing to adverse health and economic effects. Apart from aflatoxin, considerable attention has focused on tricothecenes (DON) and fumonisin. The focus of surveillance programmes has shifted to multiple mycotoxins, particularly in cereal grains. The co-occurrence of mycotoxins such as fumonisin with other fusarium toxins and aflatoxin is being reported by various countries.

The economic impact of mycotoxins on the food and feed industries has been considerable. Losses have been encountered particularly in the peanut industry due to aflatoxin contamination. Affects have been recorded in poultry and swine due to contamination of animal feeds with mycotoxins such as aflatoxin, fumonisin and zearalenone. Exports of agricultural food commodities, particularly pistachio nuts, groundnuts and groundnut products, have been reduced considerably in recent times resulting in huge economic losses to producing countries.

Mycotoxins are produced by fungi which invade crops in the field and which contaminate agricultural commodities during post harvest stages like storage when conditions favour their growth. Among mycotoxins, aflatoxin continues to receive major attention. Newer mycotoxins such as deoxynivalenol (DON), fumonisin and ochratoxin A (OTA) have gained importance.

EU legislation establishing limits and sampling plans for mycotoxins has come into force recently. This concerns aflatoxin (B1 and total) in several products. Legislation for DON and OTA is expected to come into force in the year 2001. Enforcement of these new limits has to be done by the members of FLEP. It is important to develop a transparent, uniform enforcement policy in all Member States of the European Union.

### 2. Working Party and Terms of Reference

In light of the above considerations, the FLEP Forum-meeting decided to create a Working Party 'Mycotoxins' with the following terms of reference:

- to study the enforcement activities for mycotoxins by enforcement bodies,
- to evaluate the measures that are taken by enforcement bodies,
- to make a recommendation for an enforcement policy for present and future limits,
- to prepare a document on these matters to be published on the FLEP-website.

The Working Party decided at its first meeting to have a discussion on these items. Based on this discussion a questionnaire was developed and sent to all contact points of FLEP. In a second meeting of the Working Party, the outcome of the questionnaire was studied. Based on the study, recommendations were formulated in this draft final report. In reading this report, it has to be taken into account, that not all of the responding countries are member countries of the EU.

### **3. Questionnaire**

A questionnaire on ‘mycotoxins’ was distributed through the FLEP contact points during the initial part of this project. This questionnaire was previously presented at a FLEP Forum-meeting in autumn 2000.

The Working Party received answers from 14 countries. These were: United Kingdom, Germany, Spain, Norway, France, Czech Republic, Austria, Belgium, Finland, Greece, Denmark, Sweden, Malta, The Netherlands. Not responded: Ireland, Luxembourg, Portugal, Iceland and Italy.

### **4. General findings concerning monitoring and enforcement**

The responding EU countries do all enforce the EU legislation for mycotoxins (Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for contaminants in foodstuffs replacing Commission Regulation (EC) No 1525/98 of 16 July 1998, amending Regulation No 194/97).

The total number of samples taken for analysis on mycotoxins varied from country to country. The range was 100 – 4000 samples/year. This number includes all controls: at the point of entry, at the premises of importers/producers and at retail level.

#### **4.1 Monitoring**

Most countries perform surveys or are monitoring mycotoxins for which there is no legislation in force. These include:

- ochratoxin A
- patulin
- zearalenone
- HT-2-toxin
- Fumonisin
- Nivalenol
- Deoxynivalenol (DON)
- Moniliformin

The next chapter concerns those mycotoxins for which legislation is in force, specifically aflatoxin B1, B2, G1 and G2 (Regulation No 466/2001).

#### **4.2 Enforcement**

##### **4.2.1 Import controls**

Foods are now more widely distributed than years ago. Consumers are further removed from the source of the foods bought, either by time or distance. Each year about 10 million tonnes of foodstuffs enter into the European Union (EU) through the port of Rotterdam alone. Therefore, it is important to obtain assurance that the products, produced and/or processed far away from the final consumers, are safe and of good quality. Food inspection at ports of entry plays an increasingly important part in food controls.

There are obvious advantages in checking imported foods at the point of entry where effective action can be taken, as opposed to point of sale where authorities will typically only respond to complaints. In the latter, action taken is isolated and can result in non-complying foods elsewhere in the marketplace from the offending supplier, going undetected.

With regard to the control of imported foods from third countries, the situation for most EU countries until 1993 (when the internal borders between Member States were abolished) was that the bulk of imported foods entered the European Community unchecked at the point of entry. However, the foods were subject to point of sale checks and sampled in importers' premises by the Member State health authorities.

This system had the disadvantage of detection often being too late to take effective action against non-complying foods already in the marketplace. It also made coordinated actions against offending food importers difficult. This is not in the interest of either the consumer or the owner of the goods.

There was also the problem that a lot of goods entered the Community under a T1 (custom) document and were released, in some cases after two years storage in a warehouse in a harbour, for trans-shipment elsewhere in the community. The consignment would often be broken into smaller parts and released as soon as the owner had found purchasers. This could result in controls by health authorities in different Member States on parts of the same imported consignment. Sometimes, parts of consignments could be sent by the owner/agent, directly to distribution centres.

With respect to the official control of foodstuffs on importation into the Community, a number of Directives have been adopted by the European Community. The main ones are:

- Council Directive on the official control on foodstuffs (89/397/EEC); in this Directive it is stated that inspection should cover all stages of production, manufacture, processing, storage and ...import into the Community. The way (and place where) these import controls should be undertaken is not described.
- Council Directive laying down the principles governing the organization of veterinary checks on products entering the Community from third countries (90/675/EEC). Consignments containing products of animal origin have to be controlled at the external border of the Community (independent of where the consignment is to be released for free circulation in the Community).
- The Council Regulation on checks for conformity with the rules on product safety in the case of products imported from third countries (339/93/EEC). In article 2 of this regulation it is stipulated that when, in the context of checks they carry out in respect of goods declared for free circulation, the customs authorities find products that may cause harm to the European consumer, they shall suspend release of the product or batch of products concerned. They shall immediately notify the national authority responsible for monitoring the market.

As a result of these regulations, from 1993 all consignments of animal products (e.g. meat, fish) from third countries (which means goods exported from non-Member States to Europe) are controlled at the outside border of the EU. All other foodstuffs at that time did enter without controls at these borders (with the exception of the United Kingdom in which country import controls of all foodstuffs were implemented on a routine basis years ago). In 1993 a FLEP Working Party on "Import controls" proposed a system for an imported foods inspection programme for non-animal products. Under these proposed food inspection arrangements, all imported foods from third countries would be subject to a substantially more extensive inspection regime to ensure they complied with EU food standards. The imported foods would be liable to point of entry physical checks (food: all foodstuffs not excluding raw materials, ingredients, and additives, except the animal products for which there are separate provisions). Quoting from the Working Party report:

*"The programme sought to provide a uniform requirement for point of entry monitoring of imported foods to check their compliance with the EC food standards. All imported foods from third countries would be liable to testing, with the frequency of inspection and the checks to be performed determined by the assessed health risks (acute and long term) associated with the food, past reports of non compliance or the past unsatisfactory record of the supplier. The range of checks to be carried out at the time of importation would include product safety, residue concentration and biological impurities.*

*Food deemed to be high risk which is selected for sampling is held under customs control until the results of laboratory analyses are available. Medium risk foods and foods in the surveillance category will normally be released once samples are drawn but provision was sought for holding orders to be issued against suppliers from third countries with a past unsatisfactory history in the European Union.*

*If laboratory results indicated a food with high risk for public health, the food authorities would liaise closely with the other Member States to effect a recall and immediately arrange for the automatic detention of future shipments from the offending supplier. This will necessitate the creation of an external hot line.*

*Foods which fail the EU standard will be destroyed under the supervision of the competent authority, but re-export may be permitted under some circumstances (e.g. no objection from the third country) and, if it is possible, non-complying foods may be treated to bring them into compliance.”*

The situation in 2001 has changed little from the position in 1993. Consignments of nuts and pistachios are transported under customs control (T1-document) through ports to internal destinations within the EU. They are released by customs in great quantities and the content is then transported back to other countries. This gives rise to ‘backdoor-problems’ – for example, in The Netherlands high risk consignments which are released are controlled by the Dutch authorities. Goods may be cleared through other ports with less stringent controls; as a result, now and then consumer packages with products that do not fulfill the EU-legislation can be found in Dutch supermarkets.

Most of the EU-countries sample mycotoxin relevant foodstuffs (as peanuts, nuts, etc.) at the point of entry. However, some do this only when specified by EU-legislation (e.g. pistachios from Iran).

For countries sampling at the point of entry, about half sample before release by customs, the others after the release by customs. This results also in different enforcement policies:

- before release: consignments which do not comply are refused for import to the EU, but where are these rejected consignments to go ??
- After release: some countries give the possibility for blanching the consignment (peanuts) or for feed, oil crushing or re-export under certain conditions. Some countries seize the consignment.

This means there exists in EU-countries different policies on food imports and control measures.

#### **Recommendations:**

- 1. There is still a need for harmonised legislation on imports of non-veterinarian products from third countries (for example the system that is in use for veterinarian products.)**
- 2. A uniform enforcement policy is necessary on non-complying lots.**
- 3. There is a need for a information system on refused consignments.**

Several countries in the EU, when detecting a slight infringement, send a written warning or information on the result to the importer. However, hardly any country has established a maximum limit above which an official report will be issued (or the consignment seized).

EU countries have very different policies for when an official report is issued (which will lead to a penalty). Examples are:

- when the detected level is higher than 4 ppb aflatoxin B1,
- penalties only after repeated rejections, ,
- only if companies do not cooperate,
- never at the point of entry before release by customs (this is a legal problem).

**Recommendation:**

- 4. For aflatoxins a strict enforcement policy is necessary. Lots with excessive levels should not enter the food chain. An exception is when physical treatments are possible to reduce the contamination. Physical treatment must be carried out under supervision of the enforcement bodies.**

Most enforcement bodies in the EU include confidence limits to take account of analytical variability. However, some do not. This may give rise to different enforcement measures. A consignment of peanuts in which a level of 2,1 ppb aflatoxin B1 is analysed by an enforcement body/laboratory may be rejected by one certain European country but entering the EU may be permitted by another EU-country.

When an analytical result is found, the enforcement authority must be sure that the result is higher than the official limit. Methods always have uncertainties. Analysing the same sample (with a true value of 2 ppb aflatoxin B1) twice may give results such as 1,9 and 2,1 ppb.

About half of the responding countries consider in some way the analytical recovery. The Working Party on Mycotoxins is of the opinion that if the recovery is higher than 80% no recalculation of the result is necessary. However, based on new information, it may be advisable to correct for recovery.

**Recommendations:**

- 5. In taken measures the enforcement bodies must take into account the analytical uncertainty in the method.**
- 6. Harmonisation on enforcement measures is urgently needed. The Working Party is of the opinion that a very strict enforcement is needed. This means: If levels detected are higher than official limits (taking into account the analytical uncertainty) and the lots are already imported, in all cases an official report must be prepared. Depending on the level analysed and depending of the goods, physical treatment may be allowed, crushing for oil, feed purposes or (when other destinations are not possible) destruction. Re-export should not be allowed!  
However: if the detected level is 25 times higher than the official limit (for example 50 ppb aflatoxin B1 in a lot intended for direct human consumption) the lot may be seized by the official authorities.**

Almost all EU-enforcement bodies are using the sampling procedures for determining mycotoxins in foodstuffs as described in the Commission Directive 98/53/EC laying down the sampling methods and the methods of analysis for the official control of the levels for certain contaminants in foodstuffs.

Most of the countries perform a kind of risk analysis for decision-making on sampling certain lots from certain countries. Factors that play a role are:

- notifications of Rapid Alert System for Foodstuffs
- experiences with certain importers/producing countries
- quality of the harvest in a certain country.

About half of the enforcement bodies in Europe take into account certificates from third countries, but to a varying degree. Remarks that were made:

- resample in suspicious cases,
- only certificates from accredited labs
- only as information
- bad experiences with certificates
- not much confidence
- the private laboratory's method of analysis may be accredited but the method of sampling is very often not accredited. If the sample was not taken in a proper way, the result of the analysis is questionable.

**Recommendation:**

- 7. Enforcement bodies in Europe must perform an analysis on accretability for certificates from third countries or issued by an accredited lab in Europe.**

**4.2.2 Importer/producer**

All but one country samples consignments of mycotoxin relevant foodstuffs (peanuts, nuts, etc.) in the premises of importers and/or producers.

Measures that are taken if a level of aflatoxin above the permitted limit is detected vary from country to country:

- Destruction when health risk, at lower levels re-export
- re-export
- seizing the lot
- penalty,
- physical treatment
- destination feed or oil.

**4.2.3 Retail**

Almost all European enforcement bodies sample consignments at retail level. One country samples at retail level only after a Rapid Alert Notification when there is the possibility that the foodstuffs are sold in the country.

In principle, because of import controls and controls at the premises of importers and producers, one might conclude that at retail levels all product would comply with legislation. However, as described above there still exists the problem of the ‘back door’.

**Recommendation:**

- 8. At this moment controls at retail level cannot be neglected (with a focuss on distribution centers). A certain number of samples have to be analysed each year.**

In paragraph 4.2 of Directive 98/53 the following is stated: ‘in the case of lots in retail packages, the weight of the incremental sample depends on the weight of the retail packing’. The Working Party on Mycotoxins asked the enforcement bodies how they interpret this sentence (how to sample retail packs of each 100 gram). The answers were very different. This part of the directive has to be clarified.

**Recommendation:**

- 9. Add at paragraph 4.2. the following : ‘, when the packaged sample is higher than 300 gram; if the packaged weight is lower or equals 300 gram, the aggregate sample weight must be 3 kg’.**

**4.2.4 Miscellaneous**

Most countries react adequately on a recall from other Member States for a product that is still available at retail level. These products are removed from the food chain. However, in all cases, in order to confirm an offence has been committed, the enforcement bodies have to sample the suspicious foodstuffs and perform the analysis before legal action is possible.

As a consequence of European legislation all laboratories that analyse foodstuffs have to be accredited. It would improve efficiency if enforcement bodies could take action on results of laboratories of enforcement bodies in other Member States. This makes a rapid reaction on notifications possible.

## 5. References

- 'System for an Imported Foods Inspection Program' – FLEP Bulletin – September 1993
- Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for contaminants in foodstuffs (replacing Commission Regulation (EC) No 1525/98 of 16 July 1998)

Cork, March 2002

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