

## **COMMUNITY REGULATION ON AFLATOXINS**

### *Effects on the trade in groundnuts and pistachios*

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***Résumé :** Dans un but d'harmonisation la commission européenne a édicté en juillet 1998 un règlement (CE 1525/98) fixant des limites en aflatoxines pour un certain nombre de denrées alimentaires ainsi qu'une directive (98/53/CE) précisant les modalités d'échantillonnage et d'analyse en laboratoire.*

*La mise en œuvre de cette réglementation depuis le 1<sup>er</sup> janvier 1999 a révélé des dysfonctionnements majeurs dans son application et a montré que les limites retenues pour l'arachide et la pistaches conduisaient à rejeter un très fort pourcentage du flux des importations vers l'Europe de ces deux fruits à coque.*

*Cet article fait une étude critique objective de ce règlement et de la directive qui lui est attachée et propose une série d'amendements visant à corriger et à clarifier certains points de ces textes qui sont aujourd'hui à l'origine de disparités de jugement entre états membres.*

***Mots clés :** Aflatoxines, législation, arachides, pistaches*

***Abstract :** In an effort to harmonise, the European Commission decreed in its regulation (1525/98 EC) of July 1998 the threshold for aflatoxins for a variety of commodities. This regulation was accompanied by a directive specifying sampling methods and defining laboratory testing procedures.*

*Since its enactment as of the 1<sup>st</sup> of January 1999, the regulation has revealed some major shortcomings in the way it was implemented, causing a high percentage of imports to Europe being rejected because of the strict limits imposed particularly with regards to groundnuts and pistachios.*

*This article is an objective criticism of the regulation and the directive and proposes that some amendments aiming to correct and clarify some points of the text which are nowadays at the origin of judgement disparity between European State members are required.*

***Key-words :** Aflatoxins, regulation, groundnuts, pistachios*

## **INTRODUCTION**

The implementation of the new European regulation on aflatoxins (*EC n°1525/98*) as of January 1<sup>st</sup> 1999 has particularly disrupted the international trade in certain dried fruits, especially in groundnuts (*HPS*) and pistachios.

Since the regulation entered into force, the European Union has witnessed a large increase in the number of trade disputes and rejections of imported lots of the above mentioned nuts.

We should recall that in September 1997 Brussels was led to suspend all imports of Iranian pistachio (*decision 97/613EC*) following the discovery of too high levels of aflatoxin contamination in many of the lots (*10 to 400 µg/kg*).

Although the suspension on these imports was lifted at the end of December 1997 (*decision 97/830/EC*), the Iranian pistachio currently remains very closely monitored by the European authorities (*each batch of imports is checked systematically*).

In May 1999, imports of Egyptian groundnuts were also suspended temporarily by Brussels and placed under supervision for the same reason, namely a level of aflatoxin contamination exceeding the requirements of the community regulation.

Recently in February 2002, the Commission of the European Communities imposed an automatic control on the aflatoxin level for groundnuts exported from China (*decision 2002/79/EC*), and also a random check for certain products originating in Turkey (*figs, hazelnuts and pistachios*) (*decision 2002/80/EC*).

These different measures (*automatic control, embargo, rejection of imported lots*) meant a drop in imports from certain origins. This can be seen particularly in the level of pistachios imported from Iran, which is the world's leading exporter and the principal source of supply of the European market. Exports of Iranian pistachios to the European community consequently dropped from 90,000 tonnes before the embargo to 35,000 tonnes today, a situation from which California, the world's second exporter, took advantage to increase its position in the European market.

With regard to the rejection of imported lots, large differences in the judgement of Member States is observed. For pistachios originating from Iran, for example, a rejection level of 70% for France and the Netherlands was observed over the year 1999, against 50% for Germany and only 20% for Italy and Spain.

This situation led operators (*exporters and importers*) to boycott the French and Dutch ports (*Marseilles & Le Havre, and Rotterdam*), while favouring Hamburg and Barcelona.

This disparity of judgement on a same product and on a same origin highlights a major shortcoming in the implementation of the regulation, the main objective of which is to harmonise control in all Member States in order to avoid distortion of competition.

This disparity of judgement can be largely explained by the differences of interpretation of certain points in the regulation and more particularly in directive n° 98/53/EC which supplements the text by defining the conditions of sampling and analysis.

The regulation is also heavily criticised today by the countries producing the products which consider it an obstacle to international trade.

A study conducted by the World Bank on the impact of the regulation on exports from 9 African countries estimated a 47% reduction in their exports to Europe of dried fruits (1).

The American groundnut industry estimates that this European regulation will lead to the rejection of 30% of American groundnut exports and that this will result in an additional estimated cost of US\$ 10 per tonne (2).

In this article we propose to undertake an objective critique of the regulation and of the directive attached thereto by concentrating more particularly on the points which lie behind such disparity of judgement within the European Union and to put forward amendments for better application of the two texts.

We shall also examine whether or not the criticisms of this regulation on the part of the exporting countries are founded.

### **REGULATION EC 1525/98**

As we showed in the introduction, European regulation n° 1525/98 of 16 July 1998 (*published in the OJ L 201 of 17/7/98*) set out to harmonise throughout the Member States the limits for aflatoxin B1 and for total aflatoxins (*B1+B2+G1+G2*) in certain foodstuffs (*groundnuts, nuts, dried fruits, cereals and products derived therefrom*) and also for aflatoxins M1 in milk.

In Table n°1 we give the limits laid down in the regulation on groundnuts and pistachios.

Product	Aflatoxin B1	Total Aflatoxins B1+B2+G1+G2
Groundnuts intended for sorting or other physical methods before human consumption or before use as an ingredient in foodstuffs	8 µg/kg	15 µg/kg
Pistachios intended for sorting or other physical methods before human consumption or before use as an ingredient in foodstuffs	5 µg/kg	10 µg/kg
Groundnuts and pistachios and products derived from the processing thereof intended for direct human consumption or as an ingredient in foodstuffs	2 µg/kg	4 µg/kg

**Table 1: Aflatoxin limits for groundnuts and pistachios according to EC regulation EC 1525/98**

Contrary to the large majority of existing regulations in the world, the European Union has decided to limit the content of both aflatoxin B1 and that of the total aflatoxins (*B1+B2+G1+G2*).

In view of the values which have been adopted, the B1 limit is the most restrictive insofar as it generally represents between 70 and 90% of the total aflatoxin. Certain lots of groundnuts or pistachios thus fully pass the total aflatoxins level set by the community, whereas they are rejected for aflatoxin B1.

These limits should be reviewed so that they become compatible; for instance for a total aflatoxin limit of 4µg/kg, a value of 3µg/kg for aflatoxin B1 would be more compatible than the 2µg/kg currently laid down.

The limits laid down also differentiate according to whether a product is intended for direct human consumption and whether, before consumption, it is sorted or submitted to any other physical treatment leading to a reduction in aflatoxin contamination. In this respect groundnuts have enjoyed a wider tolerance in comparison with the other nuts.

The fixing of different limits according to the nature of the product is currently a source of varying interpretation with regard to the classification of the products undergoing the control. This is particularly true for the groundnut and pistachio which, in the large majority of cases, are marketed after being sorted in the raw state and which require roasting (dry or in oil) in order to be consumable.

The ambiguity of the present text in this respect should be corrected and show clearly how to classify groundnuts and pistachios in their raw state (*before roasting*).

It would also be prudent to define more clearly what the legislator means, apart from the sorting process, by “*physical methods*” and to know whether roasting the groundnut can fall within this category as well as its blanching, knowing that these two treatments have a significant effect in reducing aflatoxin contamination.

Concerning the limits laid down by this regulation which is currently amongst the strictest in the world, questions can also be asked as to the basis used by Brussels for setting such low aflatoxin limits and whether the aflatoxin risk to the European consumer has been correctly assessed.

Indeed, today, in order to be in line with the rules of international trade and particularly with measures relating to health and plant health (*SPS agreement*) laid down by the World Trade Organisation (*WTO*), the establishment of any new regulations on food contaminants must be based on the principles of risk analysis as proposed in the paper published in 1995 by the FAO (*Food and Agriculture Organisation of the United Nations*) and the WHO (*World Health Organisation*)(3).

This analysis measures the risk which the contaminant in question represents for the consumer on the basis of objective factors and reliable scientific data from a threefold evaluation :

- Toxicological evaluation
- Epidemiological evaluation
- Exposure evaluation

From the toxicological point of view, on the basis of laboratory experiments conducted on many species of animals it is recognised that aflatoxins feature amongst the most active mutagenic and carcinogenic substances known today.

From the epidemiological point of view, a clear correlation can be seen between exposure to aflatoxins and occurrence of liver cancer. Nevertheless, it should be noted that the development of this primary cancer has often been observed in persons carrying the hepatitis B virus, leading to the supposition that aflatoxin would only be a joint factor causing cancer in man.

On the above bases, the International Research Cancer Centre (*IRCC*) has classed aflatoxin B1 as a carcinogenic substance for humans without being able to establish an admissible daily dose.

From the point of view of exposure, there should be steps to take into account both the aflatoxin content in foods at risk and the level of ingestion of such foods. Several issues arise in this context such as the problem of availability of reliable data on the level of contamination of products at risk on the one hand and the large differences in exposure levels between countries on the other.

To illustrate the problem of availability of reliable data on aflatoxin contaminants in foodstuffs, it will suffice to refer to the study conducted by the Council for Public Health of France (*CSHPPF*) which shows that the principal aflatoxin vector in this country is wheat (*contributing 86% of the aflatoxins*), and dried fruits such as the groundnut and pistachio only represent 3 to 5% of exposure (4).

To explain how this study arrived at such surprising results, it will suffice to note that the authors of this work took the mean level of aflatoxin contamination, in wheat and wheat products (*flour, bread...*) to be 0.63µg/kg. This is a totally unrealistic figure insofar as all the surveys and analyses carried out on this cereal have always produced negative results, except in the exceptional case of a damaged lot (*non-commercial*).

On the subject of different exposure levels from one country to another, comparison should be made between the Senegalese and the European consumer. The former will be notably more exposed than the latter in view of the importance of groundnuts in the Senegalese diet, of the high level of aflatoxin contaminant and of the high percentage of Senegalese people carrying the hepatitis B virus.

The differences in exposure from one country or continent to another make it difficult to achieve worldwide harmonisation and show that, contrary to what is observed at present, it is in the producing countries that areas at risk (*tropical countries*) are found, and that the lowest limits should be established and not in the importing countries where the risk is appreciably lower.

The Joint FAO/WHO Committee on Food Additives (*JECFA*) has fully demonstrated in a recent study (5) that passing from a statutory aflatoxin limit of 10 to 20µg/kg (*theoretical limits*) would in no way change the risk to the European consumer. This study showed that the risk would go from 0.0039 to 0.0041 cases of cancer per year per 100,000 persons, or an insignificant increase of two cancers per year per billion inhabitants.

On the other hand, a similar study on people living in Asia or Africa where the risk is higher (*high aflatoxin contaminant in foods, population carrying the hepatitis B virus*) shows that the increase would be significant (+ 300 cases of cancer per year per billion inhabitants).

From all these data, it seems that Brussels has voluntarily given priority to protecting the European consumer by preferring the principle of precaution to the detriment of the international trade rules laid down by the World Trade Organisation (*risk analysis*).

## DIRECTIVE 98/53/EC

Regulation 1525/98 was supplemented by directive n° 98/53/EC which defines the laboratory methods for sampling (*annex I*), the preparation and analysis of the samples (*annex II*). The implementation of this directive published like the regulation in the OJ of 17 July 1998 finally came into force on 31 December 2000.

### Annex I – Sampling method

At this point we must rejoice that the European Union has made provision for defining the sampling conditions, as this operation will have a great bearing on the test results. This applies particularly to grain products (*seeds*) in view of the extremely wide heterogeneous distribution of contamination.

To illustrate the above problem in grain products it is necessary to know whether one groundnut or pistachio from 5000 or 10,000 is sufficient for having a significant level of aflatoxins in the lot.

This shows the importance of choosing and defining a sampling protocol when setting up any regulation on aflatoxins, and also means that fixing statutory limits without defining a precise sampling plan is meaningless particularly for grain products.

The fact remains that fixing a sampling plan for aflatoxins is a difficult task which must take into account the cost of the operation (*economic feasibility*) and decide between two possible risks of error :

- 1) *Rejection of “good” lots (risk of producer or exporter)*
- 2) *Acceptance of “poor” lots (risk of importer or consumer)*

There have been many works in this field particularly on groundnut and maize to which one can refer (6) (7).

Before drawing up a sampling plan, the European Commission had to study the database supplied by the Dutch Association of Groundnut Processors on three already existing protocols for the groundnut.

Sampling plan of the Netherlands :	4 samples of 7.5kg (8)
Sampling plan of the UK :	a single sample of 10 kg (9)
Sampling plan of the FAO	a single sample of 20 kg (6)

This study, which covered nearly 900 lots of groundnuts showed that, on the basis of the above three sampling plans and taking a limit of 2 µg/kg of aflatoxin B1, the rejection results given in Table n°2 were arrived at.

Sampling plan	% rejection	Mean contamination of accepted lots
Netherlands	48,5%	0,75 µg/kg
FAO	23,0%	1,15 µg/kg
United Kingdom	22,0%	2,10 µg/kg

**Table n°2 :** Comparison of sampling plans of the Netherlands, United Kingdom and the FAO used on 900 lots of groundnuts

This study shows very clearly the great influence the chosen sampling plan had on results (*lots rejected*). It can be seen that it is the UK plan which presents the best balance between the risk to producer and to consumer with a mean contamination value closest to the 2 µg/kg limit set for this study.

The Dutch plan on the other hand was the least balanced and penalised the producer or exporter the most (*refusal of acceptable lots*).

On the basis of this study the European Commission finally decided on the Netherlands' stance by adopting a sampling plan (*Table no 3*) very close (*3 samples of 10 kg*) to that proposed by the country, once more giving priority to the protection of the consumer at the expense of the producer.

Weight of the lot ( <i>in tonnes</i> )	Weight or number of the sublots	Number of incremental Samples	Laboratory sample weight ( <i>kg</i> )
> 500	100 tonnes	100	30
> 125 et < 500	5 sublots	100	30
> 15 et < 125	25 tonnes	100	30
< 15	-	10-100	3 à 30

**Table 3 :** Sampling plan of groundnut and pistachio lots according to directive 98/53 EC

Although directive 98/53/EC clearly defines the general framework of the sampling plan to be used according to type of product and size of lot to be tested, this text would still require a better definition of the procedures for incremental sampling and making up the samples for the laboratory.

The directive should describe more precisely the following points :

- The points (*places*) in the lot from which the various incremental samples should be taken
- The sampling instruments to be used (*probes*)
- The mixing conditions (*homogenous distribution*) of the aggregate sample
- The conditions and instruments for dividing the aggregate sample into for laboratory samples.

For all these operations, it would be prudent for directive 98/53/EC to draw inspiration from, or refer to, the sampling standards already in force in Europe and internationally for cereals (*ISO 13690*) and oilseeds (*EN ISO 542*).

Finally, the last point to be revised in annex I of the directive deals with the conditions of acceptance or rejection of a lot or a subplot.

The text shows that for groundnuts or pistachios intended for direct human consumption if only one of the sublots exceeds the limits set by the regulation ( $2\mu/\text{kg}$  in *B1* and  $4\mu/\text{kg}$  in *B1+B2+G1+G2*) this is sufficient for the whole lot to be rejected even if the mean result of the three sublots is below the limits.

This provision is certainly the most disputable point in the community text insofar as, on account of the problem of heterogenous distribution of aflatoxin contamination, it is the mean of the largest possible number of analyses which best represents the true level of contamination of a lot and not a single analysis result taken in isolation.

The provision comes down in the end to demanding a zero contamination level which is of course totally impossible to guarantee in products such as the groundnuts and pistachios and which is contrary to the ALARA principle (*As Low As Reasonably Achievable*) laid down by JECFA.

JECFA recommends fixing the statutory limits for a food contaminant at the lowest level that it is technically possible to obtain, without jeopardising the supply of and trade in foodstuffs.

In addition it should be noted that the rule to refuse imports on the basis of a single result outside the limit is rendered all the more restrictive for operators since at present there is no recourse in the text for contesting the result issued by the official laboratory.

## **Annex II – Preparation and analysis of laboratory samples**

### **Treatment of samples received in the laboratory**

According to this annex, each laboratory sample from 1 to 30 kg should be finely ground in its entirety and carefully mixed according to a method which ensures that it is completely homogeneous.

The text, on the other hand, gives no indication as to the conditions for grinding or homogenisation procedures, the laboratory being able to use the grinder of its choice.

This point is at present an important factor in the divergent results between laboratories as it is on the fineness of the milled product and its homogeneity that the final result will depend.

Today, for example, within the European Union there are two grinding techniques, namely dry grinding and wet grinding (*slurry*).

For dry grinding, different types of grinders are used (*knife, hammer, ball. ..*). The limiting factor for this type of grinding is the fineness of the milled product because of the high fat content of the groundnut and pistachio which enables at best a grain size from 1 to 2 mm to be attained.

Wet grinding which consists of grinding 10 kg of nuts with 15 litres of water using a Warring high-speed mixer-grinder makes it possible to achieve a very fine grain size (*200 to 500 microns*) providing a completely homogenous distribution, with the product being transformed into a paste.

The comparative study of the two grinding techniques conducted by us in our laboratories (*Table n°4*) shows indisputably that the best homogenous distribution of the product is obtained by wet grinding, which leads to better repeatability with regard to determining the aflatoxin levels.

Sample 10 kg	Dry grinding		Wet grinding ( <i>slurry</i> )	
	Results <i>µg/kg</i>	Mean <i>µg/kg</i>	Results <i>µg/kg</i>	Mean <i>µg/kg</i>
Groundnut 1	5,6/8,9/9,2	7,9	9,2/8,8/9,5	9,2
Groundnut 2	17,8/13,5/20,2	17,2	18,5/18,0/18,7	18,4
Pistachio 1	2,0/3,9/1,8	2,6	3,2/3,5/3,2	3,3
Pistachio 2	28,0/39,2/25,6	30,9	30,2/31,0/30,5	30,6

**Table n°4** : Influence of the grinding techniques (dry and wet) on the repeatability of the determination of the aflatoxin levels.

We recommend therefore that the directive be amended to specify exclusively wet grinding (*slurry*) and to describe fully the conditions under which the operation should be carried out (*type of grinder, grinding time...*).

**Method of analysis to be used by the laboratory**

For the determination itself the directive makes no reference to any specific method (standard or approved). The laboratories are free to use whichever method they choose, provided it complies with the performance criteria (*recovery and precision rates*) stated in Table n°5.

Criterion	Concentration range	Recommended Value	Maximum permitted Value
Blanks	All Concentrations	Negligible	/
Recovery Rates of aflatoxins B & G	< 1,0 µg/L 1 – 10 µg/L > 10 µg/L	50 à 120 % 70 à 110 % 80 à 110%	/
Precision <i>RSD<sub>R</sub></i>	All Concentrations	As derived from the Horwitz equation	2 x value derived from the Horwitz equation

**Table n°5 :** Performance criteria for choosing the method of determining of aflatoxin levels

It is regrettable that the directive fails to refer to a specific method of analysis and leaves the choice of method to the laboratory (*TLC, ELISA, HPLC, ...*) since we consider that this will introduce a new element into the level of disparity of the analytical results.

It would be prudent to refer to European standard EN 12955 published by the CEN (*European Committee for Standardisation*) in 1999.

This method uses high performance liquid chromatography (*HPLC*) and spectrofluorescent detection after post-column derivation of the aflatoxin molecule by a halogen (*iodine or bromine*). It is at present the most appropriate technique for the detection and determination of the mycotoxin in many food matrices and the one most used by European laboratories.

It should be noted moreover that the performance criteria currently laid down in the directive (*recovery rate of the aflatoxin – precision of the method*) and with which the method used must comply, do not seem to us sufficient to guarantee results which agree well between the laboratories.

With regard to the recovery rate, steps should be taken to establish whether or not it should be taken into account when calculating the result, in view of its effect on the final judgement (*correction factor 0.5 to 1.2*).

The precision criterion which depends on the Horwitz equation (10) and which is based solely on the concentration (*content*) of the analysis without taking into account the nature of the product being analysed, is not appropriate for determining the aflatoxins in groundnuts and pistachios for which the matrix effect is very significant (*heterogeneous distribution of contamination*).

In view of the great variability in results for the determination of aflatoxins, it seems to us essential to consider the precision of the method of determination when drawing up the analysis report. Each result should be compulsorily accompanied by the uncertainty of measurement as demanded by standard EN/ISO/CEI-17025, which is the reference for the accreditation of the laboratories undertaking the analysis.

Uncertainty of measurement should be taken into account in the final judgement so as not to unjustly penalise the operators (*acceptability or refusal of the consignment*).

To fix the uncertainty values, precision values can be used which have been obtained from interlaboratory tests (*ring tests*) organised as part of the standardisation of analytical methods for aflatoxins.

The proficiency tests, organised by BIPEA (*Bureau Interprofessionnel d'Etudes Analytiques*) in France and by FAPAS (*Food Analysis Performance Assessment Scheme*) in Great Britain can also be useful in establishing the uncertainty values in the analytical method.

It should nevertheless be noted that today no reliable data on whole groundnuts or pistachios has been obtained, as all the available results come from organised ring tests on milled or paste products.

It would therefore be prudent for the European Union to organise quickly an interlaboratory test on 10 kg samples of groundnuts and pistachios prepared in accordance with the directive in order to have the precision data available (*repeatability and reproducibility*) for this type of matrix (grains).

While awaiting these data, in Table n°6 we show the accepted tolerances for the determination of aflatoxin as part of the Ring test organised by BIPEA together with those from the precision criterion laid down by directive 98/53/EC (*twice the value derived from the Horwitz equation*).

Aflatoxin content	Uncertainties of measurement based on the tolerances of the BIPEA ring test	Uncertainties of measurement Calculated on the basis of 2 x the value derived from Horwitz
2 µg/kg	+/- 3,2 µg/kg	+/- 1,8 µg/kg
4 µg/kg	+/- 5,3 µg/kg	+/- 3,6 µg/kg
5 µg/kg	+/- 6,2 µg/kg	+/- 4,5 µg/kg
8 µg/kg	+/- 8,6 µg/kg	+/- 7,2 µg/kg
10 µg/kg	+/- 10,0 µg/kg	+/- 9,0 µg/kg
15 µg/kg	+/- 13,3 µg/kg	+/- 13,5 µg/kg

**Table n°6** : Assessment of the uncertainties in the determination of aflatoxin based on the BIPEA ring test and on the precision criteria laid down in directive 98/53/EC.

## CONCLUSIONS

The work conducted within the framework of the European Union for the harmonisation of the regulations on aflatoxin contamination in certain foodstuffs has clearly shown that the methods of sampling and laboratory analysis and the limits chosen cannot be dissociated, particularly for grain products with their large heterogeneous distribution of contamination.

The implementation of this community regulation since January 1<sup>st</sup> 1999 has nevertheless revealed notable shortcomings in its application between Member States and has greatly disrupted the international trade in certain foodstuffs, particularly that of groundnuts and pistachios.

The problems which have been encountered are due to strict statutory limits with regard to the rigorous sampling plan fixed by the European Union (*3 x 10kg*), as well as to a certain lack of precision in the texts, which has led to a different interpretation according to Member States.

It seems desirable therefore for Brussels to revise the limits, which are currently very difficult to attain technically, on products such as groundnuts and pistachio without excluding a large part of the world production which is opposed to the ALARA principle defined by JECFA.

Harmonisation based on the Codex Alimentarius (*laboratory sample : 1 x 20 kg – Limit : 15 µg/kg in aggregate aflatoxins*) would be a realistic solution insofar as these increased limits, as shown by the Joint FAO/OMS Committee of JECFA, would have no marked effect on the risk to health for the European consumer whose exposure to aflatoxins is very low.

Concerning directive 98/53/EC which has been in force since January 1<sup>st</sup> 2001, certain points in the text should be specified and clarified (*sampling plan, grinding conditions, uncertainty of measurement, interpretation and judgement..*). These different elements are today the main cause of the disparities of judgement between Member States (*20 to 70% of rejections of the Iranian pistachio between countries of the European Union*).

Without revising the statutory limits and amending the directive on sampling and analysis, we shall lay ourselves open to seeing disparities of judgement develop between Member States (*distortion of competition*) and an increased number of trade disputes between operators.

Furthermore, the European regulation runs the risk of being considered by exporting countries as an obstacle (*barrier*) to international trade and becoming the object of an appeal to the WTO authorities.

It should also be noted that the regulation risks ruining the significant efforts made of late by producing countries to improve and control the quality of their produce as we have been able to see for the pistachio in Iran (11) and in Senegal for the groundnut (*HACCP measure, traceability of the products, laboratories for analysis...*).

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