International Coffee Organization
Organización Internacional del Café
Organização Internacional do Café
Organisation Internationale du Café

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OTA risk management:
Guidelines for green coffee buying

Background

The Executive Director presents his compliments and wishes to inform Members that the European Coffee Federation Bureau has approved the attached document entitled "OTA risk management: Guidelines for green coffee buying". The Guidelines are in addition to a separate Code of Practice for the Prevention of Mould Formation which provides recommendations to all participants in the chain on how to prevent mould formation and OTA contamination (previously circulated as PSCB No. 36/02).

Action

Members are requested to circulate these guidelines to appropriate institutions in their countries.

OTA risk management: Guidelines for green coffee buying

11 January 2005

OTA risk management: Guidelines for green coffee buying

Contents:

1 INTRODUCTION

After long debate the European Union is about to issue its legislation on OTA. See annex 1 for the final draft, soon to be published in the EU Official Journal.

For coffee the key provisions of this legislation are:

- 5 ppb (= parts per billion or µg/kg) maximum limit for roasted coffee
- 10 ppb maximum limit for soluble (instant) coffee
- no maximum limit for green coffee, to be reviewed mid-2006

National limits (or instructions from customs or food safety authorities) are included in annex 2. Finished product limits should be brought into conformity with the EU limits.

In a separate Code of Practice for the Prevention of Mould Formation (available from the website of the European Coffee Federation www.ecf-coffee.org under 'publications') we[2] have provided recommendations to all participants in the chain (growers, trade and industry, transporters, shipping lines and operators of storage facilities) how to prevent mould formation and OTA contamination.

These Guidelines are an addition to this Code of Practice, specifically addressing the question how green coffee buyers should deal with the new EU legislation in their buying operations.

Throughout the Guidelines, the key messages are:

- Buying inferior coffee (i.e. coffee which has been badly harvested, poorly prepared, and stored and transported under inadequate conditions) results in a high risk of serious OTA contamination.
- Traditional quality control criteria, routinely applied by every green coffee buyer, go a very long way in reducing the risk of OTA contamination: if a coffee looks clean, smells clean and cups clean, there is hardly any risk of serious OTA contamination. Chapter 4 contains supporting material to convince food safety authorities of the effectiveness of this methodology.

2 HOW TO USE THESE GUIDELINES

2.1 Towards food safety authorities

The new EU maximum levels for OTA apply only to finished coffee products and not to green coffee. Nevertheless, food inspection authorities will ask: "how are you, green coffee buyer, going to make sure that the green coffee used in the manufacturing of

[2] The European Coffee Co-operation Task Force on OTA represents the entire European coffee sector and several scientific bodies:
AFCASOLE: soluble coffee manufacturing industry of the EU
CECA: European green coffee trade
EUCA: European coffee roasting industry
ECF: umbrella organisation of green coffee trade, soluble manufacturers and roasting industry
EDA: European Decaffeinators Association
ASIC: Association Scientifique Internationale du Café
ISIC: Institute for Scientific Information on Coffee
PEC: Physiological Effects of Coffee research group

roasted or soluble coffee will result in a product meeting the maximum limits." Contacts with several national food safety authorities indicate that they expect green coffee to be included in an HACCP or Quality Assurance system. These Guidelines therefore explain the HACCP principles (chapter 3) and how to apply these to green coffee buying (chapter 4).

2.2 Towards business partners

OTA risk management is chain management from tree to finished product. Key factors include good harvesting, elimination of risky defects, rapid drying and avoiding re-wetting of the coffee through clean and dry storage and transportation. The requirement of good practices throughout the chain is not easy to manage. From retailer back to roaster, trader, exporter and grower is a long and complex series of relationships. The Guidelines obviously can not enter into bilateral commercial relationships. Nevertheless, they may contribute to a better understanding and hopefully help partners to properly determine actions and responsibilities.

3 EU FOOD HYGIENE LEGISLATION: HACCP

The EU has set maximum limits for finished coffee products. This is clear enough, but the next question is: how does this affect the upstream green coffee operations. These are governed by the EU Food Hygiene legislation [3] . This defines the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff (Article 2). One of the measures is that food business operators shall put in place, implement and maintain permanent procedures based on the *Hazard Analysis and Critical Control Points* principles (Article 5). These HACCP principles consist of the following (emphasis added):

a) **identifying any hazards** that must be prevented, eliminated or reduced to acceptable levels;

b) **identifying the critical control points** at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;

c) **establishing critical limits** at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;

d) establishing and implementing effective **monitoring procedures** at critical control points;

e) establishing **corrective actions** when monitoring indicates that a critical control point is not under control;

f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are **working effectively**; and

g) establishing **documents and records** commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

[3] Regulation 852 / 2004 of 29 April 2004 on the Hygiene of Foodstuffs; Official Journal L139 of 30 April 2004. This Regulation is part of a package regulating the hygiene of food and feed and the official controls, parts of which are awaiting final approval by the European Parliament. The Regulation on the Hygiene of Foodstuffs can for all practical purposes be considered as final.

We mention this legislation in some detail because it is helpful to know the legal basis of the requirements of inspection authorities.

It is possible to argue against OTA contamination being part of an HACCP system, but with the EU legislation for OTA in finished coffee in place, it is in practice almost unavoidable that OTA in green coffee is considered by food inspection authorities as a "hazard", to be included in individual companies'[4] HACCP procedures. Even if the full application of HACCP to OTA is not required, it is prudent to follow essentially the same steps, but to use different terms: "Quality Assurance" or "OTA management" instead of HACCP, "quality deficiency" instead of "hazard" and "quality specification" instead of "Critical Control Point". In any case, green coffee buyers of a roasting or soluble coffee manufacturing company are recommended to integrate or link their operations very closely with the companies' HACCP system .

Assuming the incorporation of OTA in an HACCP system, the strictness of the measures that need to be applied to prevent or eliminate the hazard or to reduce it to acceptable levels is dependent on the risk associated with the hazard. To clarify: if "engine failure" is a hazard, the risk associated with this hazard is different in the case of a car engine (leaving the occupants stranded at the side of the road) or of an airplane engine (possibly causing the death of several hundred passengers). Requirements for the inspection and maintenance of airplane engines are therefore stricter and more closely supervised.

4 HACCP/QUALITY ASSURANCE

4.1 Identify the hazard

What is the hazard, i.e. the health risk in relation to OTA intake?
The following will be helpful to keep the proper perspective in discussions with national food safety authorities:

- The Dutch National Institute of Public Health and the Environment (RIVM) concluded "…. that there are no health risks associated with the dietary intake of OTA in the Netherlands."[5]. While the study specifically addressed Dutch consumption, on balance the situation in the other EU countries is not very different.
- The FAO/WHO Joint Expert Committee on Food Additives and Contaminants reported (2001) that "… no cases of acute intoxication in humans have been reported."
- Recommendation of the EU Scientific Committee on Food (September 1998): OTA intake from all sources should remain below 5 nanogram per kilo bodyweight per day

[4] The obligation to implement a HACCP system applies to all 'food business operators'. In this context, food business means "any undertaking …. carrying out any of the activities related to any stage of production, processing and distribution of food" (General Food Law article 3, par. 2). This definition covers coffee traders ('distribution') as well as decaffeinators, roasters and soluble manufacturers ('production', 'processing').

[5] RIVM Report 388802025/2002 of 12 September 2003: Risk Assessment of Ochratoxin A in the Netherlands, page 17

- Actual intake from all sources is quite below this level (conclusion of the so-called 'SCOOP' study of 2002). Even the highest observed intake of 4,79 nanograms per kg bodyweight per day is still below the SCF recommendation[6].
- The share of coffee in the total intake is comparatively low. According to the 'SCOOP' study, cereals contribute 44-50% to the total intake, wine 10%, coffee 8-9% and beer 6-7%.

In summary and in layman's language: OTA should not be treated as a poison, the risk of any person exceeding the recommended intake maximum is very limited and coffee is a small contributor.

Yes, measures must be taken to reduce the long-term intake of OTA, but these measures must be proportional to the actual risk and to the modest share of coffee.

The natural tendency of food safety authorities is to focus on incoming raw materials. There is some logic to that: what does not enter into the chain will present no problem in the finished product. However, an excessive focus on green coffee is not justified. Firstly, green coffee is not consumed as such. Secondly, the manufacturing process (roasting or soluble coffee manufacturing) reduces any OTA contamination by at least 2/3rd (this is scientifically substantiated; see paragraph 6.1). Thirdly, quality assurance or HACCP procedures applied to green coffee should serve to ensure that the maximum limits on finished products are being met. They are not a goal in themselves.
(See annex 3 for additional information on OTA formation and toxicity).

4.2 Identify the Critical Control Points

For green coffee, the first Critical Control Point (CCP) is the sales sample. This will need to be checked against the critical limits of the next paragraph. Additional control points are receipt of outturn sample and samples from coffee arriving at the factory. In all instances, later samples must be checked to determine that they match the original sample.

4.3 Establish critical limits

For green coffee, this is not so straightforward because there are no green coffee maximum OTA limits. It is therefore not a simple matter of pass/fail but to take the measures to ensure that the final product stays within the established maximum limits.

Upon receipt of samples, check coffee for three criteria: cherries, visual damage, and earthy/mouldy smell. Cherries and damages (broken beans, insect-infested beans) are risk factors for OTA. The skin of the cherry normally protects the coffee bean itself from contamination with spores. This protection is lost if either cherries or skins and husks are not removed from the green coffee or if the skin is broken, of which broken beans or insect-damaged beans are indicative. An earthy/mouldy smell or cup is an indicator for mould damage.

Extensive statistical analysis of green coffee by the European coffee sector has established that such coffees had clearly higher frequencies of OTA contamination. Coffees without an earthy/mouldy smell showed less than 1% risk to contain more than 10 ppb OTA. This is illustrated by the graph below:

[6] SCOOP (Scientific Cooperation) Report of experts participating in Task 3.2.7: Assessment of dietary intake of Ochratoxin A by the population of the EU Member States, January 2002

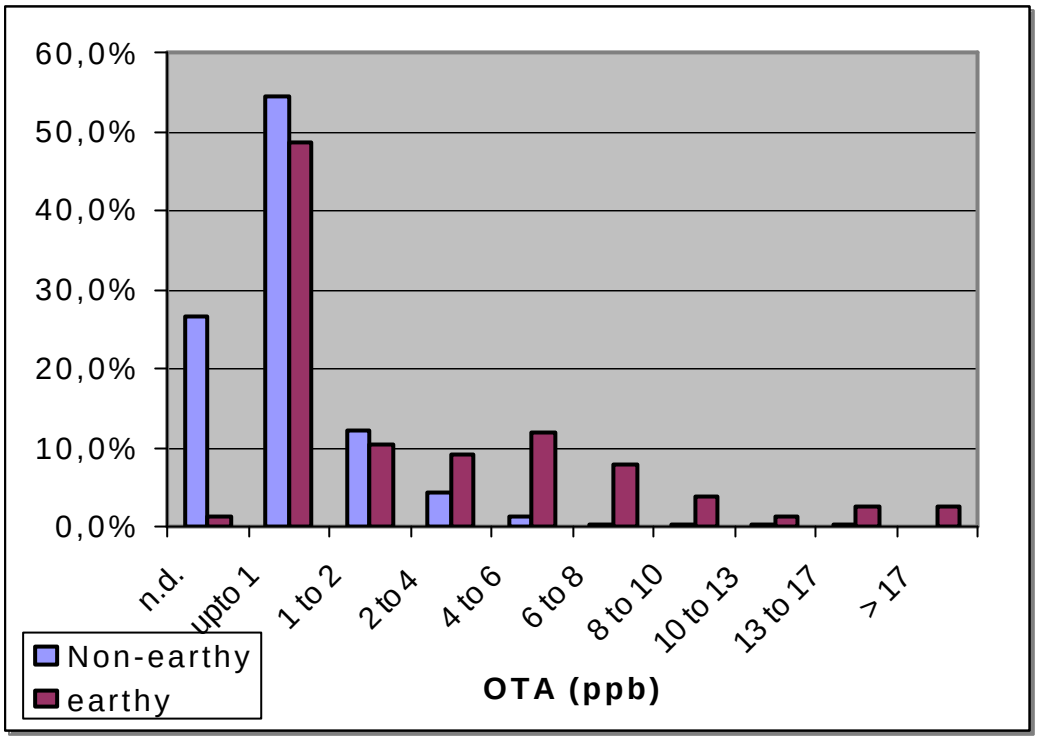


Figure 1 (n.d. = non detectable)

Using smell as an indicator has a major advantage: it is spread much more homogenously in a lot than the actual mould and its OTA and is therefore less dependent on hit-or-miss sampling. Please bear in mind that not every mould is an OTA-forming mould, but an earthy smell or cup should trigger further investigation.

Similarly visually clean coffees without visible damage (rewetted bags / beans, broken beans, insect-infested beans) showed less than 1% risk of containing more than 10 ppb OTA. See the following graph.

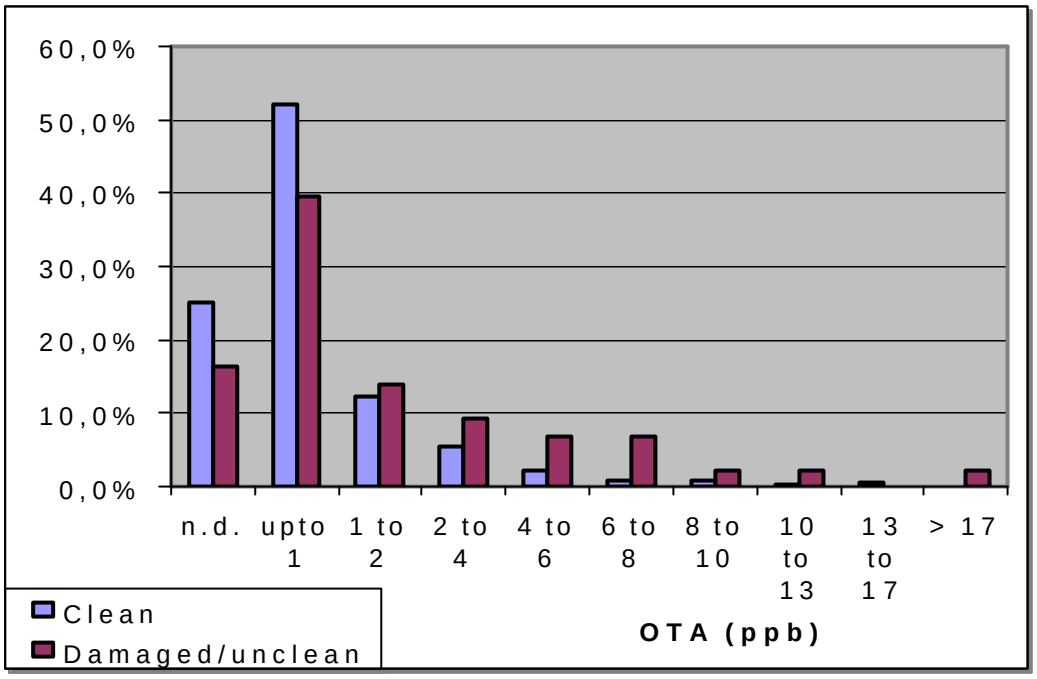


Figure 2

"Visually clean" does not mean zero defects. The recommended criterion for "clean" is: meeting the requirements of NYBOT or LIFFE grading. See annex 4 for the most relevant provisions of the grading standards. If this criterion is not met, it will be more difficult to determine whether coffee is sufficiently clean. This will depend on the type of defect. The green coffee bean is protected from contamination by the skin of the coffee cherry. Conversely this means that the presence of cherries, skins and husks is a risk element. Similarly, the presence of insect infested beans indicates that the protection of the skin has been breached and contamination may have reached the bean. It is not possible to put a figure (X cherries, Y percentage skins / husks, Z insect infested beans) on this. Practical experience on an individual basis, including feedback of finished coffee contamination data, will be necessary to determine what is acceptable and what is not.

The important advantage of these traditional characteristics is that they are much more easily checked and are less dependent on the strongly inhomogeneous distribution of the moulds.

If suspicions are raised on the basis of these criteria, it is advisable not to use the coffee and to have the sample analysed for OTA. There is a CEN method for determination of OTA in roasted coffee [7]. For green coffee there is no legally prescribed method of analysis, but a method for grinding of green coffee samples for OTA analysis is currently in the CEN pipeline. It is recommended to select a laboratory on the basis of the general EU

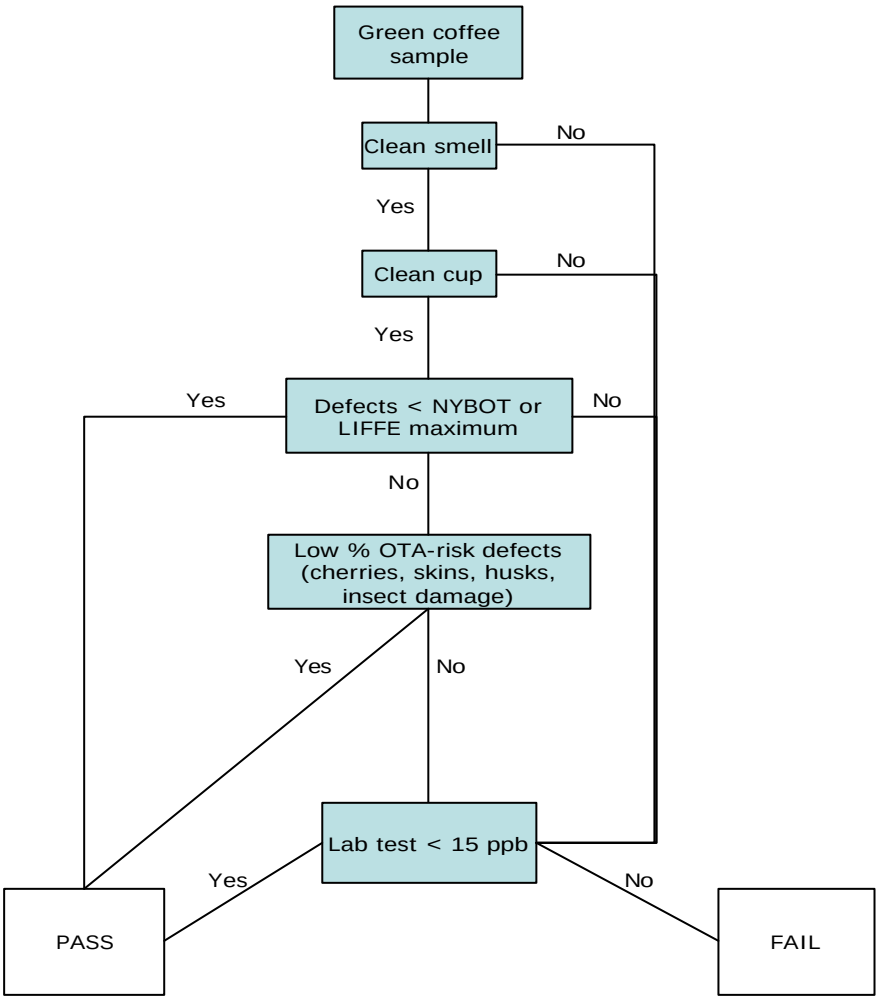
[7] EN 14132:2003: Determination of ochratoxin A in barley and roasted coffee using immunoaffinity column clean up and high performance liquid chromatography (HPLC). This method has been validated for OTA contents in barley in the range from 0,1 µg / kg up to 4,5 µg / kg and for roasted coffee in the range from 0,2 µg / kg up to 5,5 µ / kg.

requirements for OTA laid down in Directive 2002/26[8], defining parameters like repeatability, reproducibility and standard deviation.

Nevertheless, the practical experience with a large number of labs shows substantial variations even with certified and competent labs. For a given green coffee sample with low OTA contamination of 5 ppb, the variation between samplings was about 40% and the variation between labs ranged from 25 - 50%. In practical terms this means that if two different labs sample and analyse the same 5 ppb green coffee, one may report 2 ppb and the other 8. Given the variability, this is within normal range! The OTA Task Force can suggest an experienced lab that has participated in OTA tests before.

The preceding paragraphs were based on an evaluation of a sales or outturn sample. Obviously, even if the sample does not raise any concerns, the incoming coffee must still be checked for conformity with the sample. If there is a discrepancy, and it becomes necessary to sample the actual lot for OTA analysis, it is recommended to take samples throughout the lot to a total of at minimum 5 kilo per 20 tons.

The entire process to check green coffee is summarised in the following decision tree.



[8] Directive 2002/26 of 13 March 2002 laying down the sampling methods and the methods of analysis for the official control of the levels of ochratoxin A in foodstuffs; Official Journal L 75 of 16 March 2002

4.4 Monitoring, corrective action, documentation

These elements of an HACCP system are very company-specific. Some recommendations by way of general guidance:

- Clearly identify the person(s) responsible for entry control of the coffee
- Establish a system to feed the results of finished product spot-checks back into the green coffee buying operation. Suppose, for instance, that roasted coffee contamination gradually increases and comes close to the maximum. This is indicative that the green coffee quality evaluation is not strict enough. Perhaps the cut-off level for risky defects (cherries, skins, husks, insect-infested beans) needs to be set stricter.
- Keep records of "problem origins". See also paragraph 5.2. Perhaps suppliers need to be instructed to prepare their coffee better or to improve their drying. It is important to be able to show to food safety authorities that such corrective systems are in place.

5 GREEN COFFEE BUYING: ADDITIONAL RECOMMENDATIONS

5.1 Contractual requirements

It is recommended to use the European standard coffee contracts such as the ECC (available from www.ecf-coffee.org) or to incorporate its key requirements. The ECC is linked to the Code of Practice "Enhancement of quality through the prevention of mould formation" to determine whether parties have done the necessary to supply coffee of sound and merchantable quality (ECC article 7). The ECC also specifies that one criterion to determine whether coffee is unsound is an excessive moisture level. Moisture has been shown to be the main risk factor for OTA formation after the first processing stage.

The ECC deliberately does not mention a figure for excessive moisture because this is regulated elsewhere, namely in ICO Resolution 420. This provides for a quality standard for exported green coffee and specifies maximum moisture levels as follows:

- for both Arabica and Robusta, not to have a moisture content below 8% or in excess of 12.5%, measured using the ISO 6673 method (see annex 5).
- Where moisture percentages below 12.5% are currently being achieved, exporting Members shall endeavour to ensure that these are maintained or decreased.
- Exceptions to the 12.5% maximum moisture content shall be permitted for speciality coffees that traditionally have a high moisture content, e.g. Indian Monsooned coffees. Such coffees shall be clearly identified by a specific grade nomenclature.

It is recommended to include the key provisions (no less than 8 and no more than 12,5% moisture, measured using the ISO 6673 method) in bilateral green coffee contracts with suppliers, specifying that the 12,5% maximum must not be exceed at the point of stuffing of the container.

Finally, it is recommended that bilateral contracts with suppliers specify moisture and risk of condensation reduction measures such as lining the container walls, the use of cardboard or another water-adsorbent sheet on top of the bags and / or the positioning of an appropriate drying agent ("dry-bags") in the headspace. The exact measures depend

on the risk, which is in turn dependent on the sailing area: more anti-moisture measures are necessary if the coffee is shipped from a humid climate than from a dry climate.

Traders and roasters may wish to include the provision that coffee containers are stored below deck in their contractual arrangements with shipping lines. Exposure to the sun, even in moderate climates, results in large day / night temperature swings and substantially increases the risk of condensation and hence re-wetting of the coffee.

5.2 Risk management and countries of origin

Because the EU Rapid Alert system has happened to identify relatively high OTA levels in African producing countries, food inspection authorities regularly insist on stricter controls for these origins. However, extensive statistical analysis by the industry has confirmed that, while no origin is "OTA-free", some origins have more frequently problems than others and that these countries are spread around the globe.

It is recommended that – in accordance with HACCP requirements - traders and roasters document the results of the traditional evaluation as well as the results of analyses triggered by the traditional evaluation. Together with (low frequency) random checking of green coffee from different origins for OTA to establish their level of performance, this will over time provide a pattern establishing the sources of higher risk.

This will allow for properly targeted control measures as well as feedback to suppliers to improve their performance.

5.3 Rejection

One element in the HACCP system – and undoubtedly also in the requirements of food inspection authorities – will be the critical limit to separate acceptability from unacceptability (par. 3 under (c)). The relevant critical limit here is the maximum level for OTA in green coffee assured not to cause the finished product to exceed 5 or 10 ppb as appropriate. As stated before (par. 6.1), this is 15 ppb. This is already a prudent critical limit. There is no need to set a lower limit, nor is this helpful since the analytical uncertainty becomes larger the lower the level that needs to be tested.

What if either finished coffee products or green coffee needs to be rejected?

Finished products not complying with the EU maximum limits must be recalled from the market and the national food safety authorities must be notified (Article 19 of the General Food Law, see annex 6).

For **green coffee** the bilateral contract between seller and buyer will need to determine what to do if the green coffee does not meet the contract specifications.

Please note that from 1 January 2006 returning a shipment rejected at the external border of the EU will be subject to Article 21 of the Regulation 882 / 2004 of 29 April 2004 on official controls. The relevant part of this article, which applies to green coffee as well as to imported finished coffee products, reads:

> 1. The competent authority shall allow re-dispatch of consignments only if:
> (a) the destination has been agreed with the feed or food business operator responsible for the consignment; and
> (b) the feed and food business operator has first informed the competent authority of the third country of origin or third country of destination, if different, of the reasons and circumstances preventing the placing on the market of the feed or food concerned within the Community; and

(c) when the third country of destination is not the third country of origin, the competent authority of the third country of destination has notified the competent authority of its preparedness to accept the consignment.

This may lead to quite a bit of discussion in the case of OTA contaminated green coffee. In the absence of an EU maximum limit for OTA in green coffee, can this article be invoked if national green coffee maximum limits are exceeded?

Destruction of a non-acceptable lot should be carried out in line with national requirements to meet environmental standards and must result in total destruction of the lot to the extent of preventing human or animal consumption.

6 GREEN COFFEE BUYING: QUESTIONS

Having established that coffee is a minor contributor to a low-risk contaminant, we can establish an appropriate and practical way to deal with the risk of mould and OTA in green coffee.

6.1 How do the finished product limits translate to green coffee?

A common mistake in contracts as well as in food inspection requirements is to take the limits of 5 and 10 ppb for roasted and soluble coffee and to insist that green coffee meets the same limits. This ignores the fact that processing (roasting, soluble coffee manufacturing or decaffeination) removes a very significant percentage of OTA. Ten different studies on OTA and roasting are now available. Two studies applied conditions fully outside the commercial roasting practice. All other 8 studies have clearly shown substantial reduction of OTA during roasting. For green coffees with relevant OTA contamination the reduction ranged from 69% to 96%.
Studies have shown that the usual decaffeination processes remove about three-quarters of the OTA present before decaffeination. This is plausible, as OTA is quite soluble in the extraction media normally used in decaffeination.

Taking a very conservative reduction of OTA during processing of 2/3rd, a green coffee contamination of 15 ppb will result in a finished product (be it roasted or soluble) that does not exceed the EU maximum limits.

6.2 Will I need to test all incoming green coffee?

Most certainly not! This is expensive (up to € 100 per sample), time consuming (about 5 to 7 working days before results come in), unworkable (where to store the coffee in the meantime), impracticable (because of sampling problems) and – above all – totally unnecessary.

Regarding the sampling, it is important to note that OTA occurrence in green coffee is usually very localised. For a representative measurement it will be necessary to take a total of at least 5 kg of samples per 20 tons from different spots spread over the lot. The total combined sample should be ground (notoriously difficult for green coffee!) and homogenised thoroughly. Only then a smaller sample can go into the actual analysis. Be aware that a test procedure that ignores the sampling and homogenisation issue may give either a false rejection or a false sense of security. Also be aware that test results even by well-performing labs may show a variation of + or – 25% in a given sample.

With these uncertainties, it is not recommended to go to arbitration should sampling and analysis reveal that contractual OTA specifications have been exceeded only marginally.

Since 98% of green coffee arrives with very low levels of OTA (2 ppb or less), testing of all green coffee is unnecessary and disproportionate. The application of traditional quality criteria described in chapter 4 is a practical, workable and risk-related alternative.

6.3 Should I ask a "maximum OTA" certificate from my supplier?

Asking for a certificate guaranteeing a certain maximum level of OTA in green coffee is a superficially attractive method to allocate responsibility in the commercial chain. However, we recommend against it. If the supplier is an exporter in a coffee producing country, the best such a certificate can achieve (assuming that sampling and analysis have been done properly) is to provide a snap-shot picture. Remember that OTA formation may occur throughout the chain. After testing the coffee may have become wet again, be it at the exporters premises (stuffing of the container in the rain) or during later storage or transport. Essentially the same applies to testing after arrival in Europe, although the chain is shorter and the risk of a mishap after testing smaller. However, the basic problems with testing (par. 6.2) remain the same.

A more positive and fundamental way to steer clear of OTA-related problems is to buy coffee which has been properly harvested, prepared, dried, stored and transported.

7 CLOSING REMARK

These Guidelines are not engraved in stone. In the practical implementation of the EU legislation, some of the 'blank spots' will be filled in, food safety and inspection authorities will develop their implementation policies and companies will gain practical experience how to manage their operations. This is therefore a living document, and the OTA Task Force very much welcomes your input to improve it. Please address your comments to ecf@coffee-associations.org.

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Amsterdam, 11 January 2005
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Annex 1: EU OTA legislation

Draft

COMMISSION REGULATION (EC) No …/..

of […]

amending Regulation (EC) No 466/2001 as regards ochratoxin A

[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 466/2001[2] sets maximum levels for certain contaminants in foodstuffs.

(2) According to Regulation (EC) No 466/2001, the Commission shall review the provisions as regards ochratoxin A (OTA) in dried vine fruit and with a view to including a maximum level for OTA in green and roasted coffee and coffee products, wine, beer, grape juice, cocoa and cocoa products and spices taking into account the investigations undertaken and the prevention measures applied to reduce the presence of OTA in these products.

(3) The Scientific Committee on Food (SCF) concluded in its opinion on OTA, expressed on 17 September 1998, that OTA is a mycotoxin which possesses carcinogenic, nephrotoxic, teratogenic, immunotoxic and possibly neurotoxic properties. The Committee mentioned also that further studies are ongoing to elucidate the mechanisms involved in OTA carcinogenicity. It is anticipated that the European research project on the mechanisms of OTA induced carcinogenicity will be finished by the end of 2004. Once the comprehensive research results are available, the European Food Safety Authority (EFSA) will be requested by the Commission to update the scientific opinion from SCF in the light of these new research results.

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1 OJ L 37, 13.2.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

2 OJ L 77, 16.3.2001, p. 1. Regulation as last amended by Regulation (EC) 684/2004 (OJ L 106, 15.4.2004, p. 6).

(4) An assessment of the dietary intake of OTA by the population of the Community has been performed in the framework of Council Directive 1993/5/EEC of 25 February 1993 on assistance to the Commission and co-operation by the Member States in the scientific examination of questions relating to food[3] (SCOOP). The main contributor to the OTA exposure is cereal and cereal products. Wine, coffee and beer were identified as significant contributors to the human OTA exposure. Dried vine fruit and grape juice contributed to a significant extent to the OTA-exposure for specific groups of vulnerable groups of consumers such as children.

(5) A maximum level for OTA has been established for cereal and cereal products and dried vine fruit by Regulation (EC) 466/2001. The level of OTA in beer is indirectly controlled as the OTA in beer originates from the presence of OTA in malt, for which a maximum level has been established. The setting of a maximum level for OTA in beer is therefore not immediately necessary to protect public health, but should be considered in the frame of the foreseen review.

(6) Given the significant contribution of wine and roasted coffee together with soluble coffee to the OTA human exposure and the significant contribution of grape juice to the OTA exposure of children, it is appropriate to set already at this stage for these foodstuffs maximum levels to protect public health by preventing the distribution of unacceptably highly contaminated foodstuffs.

(7) OTA has also been observed in dried fruit other than dried vine fruit, cocoa and cocoa products, spices and licorice. The appropriateness of setting a maximum level for OTA in these foodstuffs, including green coffee, as well a review of the existing maximum levels will be considered after the availability of the EFSA assessment of the research results on OTA toxicology.

(8) Regulation (EC) No 466/2001 should therefore be amended accordingly.

(9) 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:

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[3] OJ L 52, 4.3.1993, p. 18.

Article 1

Regulation (EC) No 466/2001 is amended as follows:

(1) In Article 4 (2) point (b), "and 2.2.2." is replaced by ", 2.2.2., 2.2.3, 2.2.4 and 2.2.5"

(2) In Article 5, paragraph 2a is replaced by the following:

"2a. The Commission shall, based on an up to date risk assessment on ochratoxin A (OTA) performed by the EFSA and taking into account the prevention measures applied to reduce the OTA content, review the provisions under the heading 2.2. of section 2 of Annex I by 30 June 2006 at the latest. This review will concern in particular the maximum level for OTA in dried vine fruit and grape juice and the consideration of setting a maximum level for OTA in green coffee, dried fruit other than dried vine fruit, beer, cocoa and cocoa products, liqueur wines, meat and meat products, spices and licorice.

For this purpose, Member States and interested parties shall communicate each year to the Commission the results of the investigations undertaken and the progress with regard to the application of prevention measures to avoid contamination by OTA. The Commission will make these results available to the member States."

(3) Annex I is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 1 April 2005.

This Regulation shall not apply to products which were placed on the market before 1 April 2005 in conformity with the provisions applicable. The burden of proving when the products were placed on the market shall be borne by the food business operator.

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

Done at Brussels, […]

For the Commission
[…]
Member of the Commission

ANNEX

In Section 2 Mycotoxins of Annex I, the point 2.2. Ochratoxin A is replaced by the following:

Products	Ochratoxin A: maximum levels (µg/kg or ppb)	Sampling method	Reference analysis method
2.2. OCHRATOXIN A			
2.2.1 Cereals (including rice and buckwheat) and derived cereal products			
2.2.1.1. Raw cereal grains (including raw rice and buckwheat)	5.0	Commission Directive 2002/26/EC (*)	Directive 2002/26/EC
2.2.1.2.All products derived from cereals (including processed cereal products and cereal grains intended for direct human consumption)	3.0	Directive 2002/26/EC	Directive 2002/26/EC
2.2.2 Dried vine fruit (currants, raisins and sultanas)	10.0	Directive 2002/26/EC	Directive 2002/26/EC
2.2.3. - Roasted coffee beans and ground roasted coffee with the exception of soluble coffee - Soluble coffee (instant coffee)	5.0 10.0	Directive 2002/26/EC	Directive 2002/26/EC
2.2.4. - Wine (red, white and rosé) (**)and other wine and/or grape must based beverages (***)	2.0(****)	Directive 2002/26/EC	Directive 2002/26/EC
2.2.5. - Grape juice, grape juice ingredients in other beverages, including grape nectar and concentrated grape juice as reconstituted (*****)	2.0(****)	Directive 2002/26/EC	Directive 2002/26/EC
-Grape must and concentrated grape must as reconstituted, intended for direct human consumption (*****)	2.0(****)	Directive 2002/26/EC	Directive 2002/26/EC
2.2.6. Baby foods and processed cereal-based foods for infants and young children(******)	0.50	Directive 2002/26/EC	Directive 2002/26/EC
2.2.7. Dietary foods for special medical purposes (*******) intended specifically for infants	0.50	Directive 2002/26/EC	Directive 2002/26/EC
2.2.8. Green coffee, dried fruit other than dried vine fruit, beer, cocoa and cocoa products, liqueur wines, meat products, spices and licorice.	---		

(*) OJ L 75, 16.3.2002, p. 38. Directive as last amended by Directive 2004//EC (OJ L […], […]2004, p. […]).

(**) Wines, including sparkling wines but excluding liqueur wines and wines with an alcoholic strength of not less than 15 % vol., as defined in Council Regulation (EC) No 1493/1999 *(OJ L 179, 14.7.1999, p. 1)* and fruit wines.

(***) Aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails as defined in Council Regulation (EEC) No 1601/91 *(OJ L 149, 14/06/1991, p. 1)*. The maximum level for OTA applicable to these beverages is function of the proportion of wine and/or grape must present in the finished product.

(****) Maximum level applies to products produced from the 2005 harvest onwards.

(*****) Fruit juices, including fruit juices from concentrates, concentrated fruit juice and fruit nectar as defined in Annex 1 and 2 of Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (*OJ L 10, 12.1.2002, p. 58)* and derived from grapes.

(******) Baby foods and processed cereal-based foods for infants and young children as defined in Article 1 of Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (OJ L 49, 28.2.1996, p. 17) as last amended by Directive 2003/13/EC (OJ L 41, 14..02.2003, p. 33).

The maximum level for baby foods and processed cereal-based foods for infants and young children refer to the dry matter. The dry matter is determined in accordance with the provisions of Commission Directive 2002/26/EC.

(*******) Dietary foods for special medical purposes as defined in Article 1(2) of Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29)

The maximum level for dietary foods for special medical purposes intended specifically for infants refer
- in the case of milk and milk products, to the products ready for use (marketed as such or reconstituted as instructed by the manufacturer).
– in the case of products other than milk and milk products, to the dry matter. The dry matter is determined in accordance with the provisions of Commission Directive 2002/26/EC.

Annex 2: National maximum limits for OTA

	Green	Roasted	Instant
Czech Republic	10	10	10
Finland	5	5	5
Germany	-	3	6
Greece	20	-	-
Hungary	15	10	10
Italy	8	4	4
Netherlands	-	10	10
Portugal	8	4	4
Spain	8	4	4
Switzerland	5	5	5

Note: the status of these limits differ. Some of them are embodied in law or in implementing legislation, others are customs instructions or guidelines for food safety inspectors.

Annex 3: OTA formation and toxicity

Some moulds produce toxins that can be harmful for human health. Collectively these are known as mycotoxins. One of them is Ochratoxin A (OTA) which is nephrotoxic and possibly carcinogenic to humans. It is predominantly produced by two fungal species, Aspergillus ochraceus and Penicillium verrucosum. OTA is found in many foodstuffs, predominantly in cereals and on grapes but also in coffee beans. These moulds will only grow on foodstuffs that have been subjected to high levels of moisture. In coffee this leads to a contamination of the green coffee bean producing unacceptable flavours, and making such samples rejected for roasting.

It is important to stress that OTA formation is a three-step process: spores present in the foodstuff may – given the right conditions of temperature and humidity – develop the mould that produces the OTA. The presence of spores may be reduced (for instance: reject berries fallen on the soil, which is usually a major source of spores) but can not be entirely eliminated because spores can float in the air. Therefore it is important to prevent the conditions under which the spores can develop the mould, essentially by keeping coffee dry throughout all stages of processing, storage and transport.

Extensive sampling of green coffee from all origins has shown that OTA contamination may be more frequent in some areas, but that no producing country is entirely free from contamination. Similarly it has been shown that, while the initial contamination may occur at farm level, the actual OTA formation may happen throughout the entire chain, at every stage of transportation and storage.
The most sensitive toxic effect of OTA is its renal toxicity. This is known from the damage which OTA causes in the kidneys of pigs. At higher doses it was found to cause liver and kidney cancer in rodents. Whether or not OTA is a genotoxic carcinogen is still unclear. The currently available studies show conflicting results in this respect and the experts in the field still have deviating views on it. OTA is also frequently linked to a kidney disease mainly occurring in the Balkan countries, the so called Balkan Endemic Nephropathy (BEN). However, a clear link to this type of kidney disease is not established and other factors are likely to be involved. At doses in animals, which are considered widely beyond the levels of human consumption, OTA can cause neurotoxic, immunotoxic and teratogenic effects. The International Agency on Research on Cancer (IARC) classified OTA as a “possible human carcinogen”.

Annex 4: Summary NYBOT and LIFFE grading standards

EXCERPT FROM NYBOT COFFEE "C" RULES, APPENDIX II:
PROCEDURES FOR GRADING COFFEE AND ISSUANCE OF CERTIFICATES OF GRADE

……...

(f) Minimum Standards.

The minimum standards for delivery under the Coffee "C" Futures Contract are as follows:

(1) The coffee is sound in the cup;

(2) The coffee is of good roasting quality;

(3) The coffee is of such bean size that (i) fifty percent (50%) of the coffee sampled screens fifteen (15) or larger, and (ii) no more than five percent (5%) of the coffee sampled screens below fourteen (14);

(4) The coffee is greenish and free of foreign odors; and

(5) The coffee contains no more than fifteen (15) full imperfections below the basis, except that in the case of Colombian coffee the maximum number of full imperfections below the basis shall be ten (10).

(g) Schedule of Imperfections.

(1) The following constitute one (1) full imperfection:
one (1) full black;
one (1) full sour;
one (1) pod or cherry;
five (5) shells;
five (5) broken or cut beans;
two (2) to five (5) partly black or partly sour beans, depending upon the extent to which each bean is discolored or spoiled;
five (5) floaters;
three (3) sticks smaller than one-half (1/2) inch;
one (1) stick ranging in size from one-half (1/2) inch to one (1) inch;
three (3) stones passing through a screen size below twelve (12);
one (1) stone passing through a screen size no smaller than twelve (12);
two (2) to three (3) hulls or husks, depending upon size; and
two (2) to three (3) parchments, depending upon size.

(2) The following constitute two (2) full imperfections:
one (1) stick ranging in size from one (1) inch to two (2) inches; and
one (1) stone passing through a screen size no smaller than sixteen (16).

(3) The following constitute three (3) full imperfections:
one (1) stick larger than two (2) inches; and
one (1) stone passing through a screen size over twenty (20).

(4) Any additional non-coffee item shall be one (1) full imperfection.

(h) Schedule of Bases.

For purposes of these procedures, the bases of various growths of coffee are as follows:

(1) Coffee of Guatemala, Salvador, Mexico, Costa Rica, Nicaragua, Honduras, Kenya, Tanzania, Uganda, Papua New Guinea, Peru, Venezuela, Dominican Republic, Burundi, Ecuador, India, Rwanda and Panama—eight (8) full imperfections; and

(2) Coffee of Colombia—thirteen (13) full imperfections.

…….

EXCERPT FROM LIFFE ROBUSTA FUTURES CONTRACT

…….

5. Grades Tenderable

5.01 Subject to these Contract terms, coffee of CTML standard grade shall be tenderable at basis or at the discount shown below:

Type 1: up to 150 defects per 500 g at basis;
Type 2: from 151 to 250 defects per 500 g at a discount of US$15 per tonne;
Type 3: from 251 to 350 defects per 500 g at a discount of US$30 per tonne; or
Type 4: from 351 to 450 defects per 500 g at a discount of US$45 per tonne.

5.02 Defects shall be counted as follows:

(a) in respect of a lot graded prior to 1 February 2000:

Defect	Number of Defects
1 black bean, or pod or cherry	1
2 half blacks, sour beans, parchments or large husks	1
1 large stone (1 cm diameter)	5
1 medium stone (about 5 mm diameter)	2
2 small stones or pieces of earth	1
1 large stick (3 cm length)	5
1 medium stick (2 cm length)	2
2 small sticks (1 cm length)	1
5 broken beans, shells withered, green or unripe beans, bleached beans, small pieces husk	1
1 mouldy bean	50
Insect damaged beans:	
2 beans half eaten away	1
5 beans slightly eaten away	1
Extraneous matter, per item	1 or more at graders' discretion

(b) in respect of a lot graded with effect from 1 February 2000:

Defect	Number of Defects
1 black bean, or pod, or cherry	1
2 half blacks, sour beans, parchment or large husks	1
1 large stone (1 cm diameter)	5
1 medium stone (about 5 mm diameter)	2
2 small stones or pieces of earth	1
1 large stick (3 cm length)	5
1 medium stick (2 cm length)	2
2 small sticks (1 cm length)	1
5 broken beans, shells withered, green or unripe beans, bleached beans, small pieces husk	1
1 partially mouldy bean (i.e. less than 50% mould)	1/2
1 fully mouldy bean (i.e. 50% mould or more)	1
Insect damaged beans:	
2 beans half eaten away	1
5 beans slightly eaten away	1
Extraneous matter, per item	1 or more at graders' discretion

5.03 Coffee containing more than 25 per cent passing through screen 14 round and less than 10 per cent passing through screen 12 round shall be tenderable at a discount of US$60 per tonne.

6. Untenderable Coffee

6.01 Coffee is not tenderable if:

(a) it has more than 450 defects per 500 g;

(b) it is unsound, i.e. for any reason other than those already listed, as determined by the graders;

(c) it contains more than 10 per cent passing through screen 12 round; or

(d) in respect of a lot graded with effect from 1 February 2000, it has more than 5 fully mouldy or 10 partially mouldy beans or any combination thereof such that the total exceeds the equivalent of 5 fully mouldy beans per 500 g.

…….

Annex 5: ISO standards

INTERNATIONAL STANDARD ISO 6673-1983 (E)

Green coffee — Determination of loss in mass at 105 °C

1 Scope and field of application

This International Standard specifies a method for the determination of the loss in mass at 105 °C of green coffee.

It is applicable to decaffeinated and non-decaffeinated green coffee as defined in ISO 3509.

This method of determining the loss in mass can be considered, by convention, as a method for determining the water content and can be used as such by agreement between the interested parties, but it gives results which are lower, by about 1,0 %, than those obtained with the methods described in ISO 1447 and ISO 1446 (this latter method serves only as a reference method for calibrating methods of determining the water content).

2 References

ISO 1446, *Green coffee — Determination of moisture content (Basic reference method).*

ISO 1447, *Green coffee — Determination of moisture content (Routine method).*

ISO 3509, *Coffee and its products — Vocabulary.*

ISO 4072, *Green coffee in bags — Sampling.*

3 Definition

loss in mass at 105 °C: Principally water and small quantities of volatile matter which are vaporized under the conditions specified in this International Standard, and expressed as a percentage by mass.

4 Principle

Heating a test portion at 105 °C for 16 h at atmospheric pressure.

5 Apparatus

Usual laboratory apparatus, and in particular

5.1 Oven, electrically heated, fitted with a system of forcec ventilation and capable of being controlled at 105 ± 1 °C.

5.2 Dish, made of aluminium, glass or stainless steel with a close-fitting lid. The diameter should be approximately 90 mn and the height 20 to 30 mm.

5.3 Analytical balance.

5.4 Desiccator, containing an efficient desiccant, for exam ple anhydrous calcium sulphate or silica gel.

6 Sampling

See ISO 4072.

It is important to proceed as rapidly as possible when sample are exposed to the atmosphere, in order to prevent any pick u or loss of moisture.

7 Procedure

7.1 Preparation of the dish

Dry the dish (5.2) and its lid for 1 h in the oven (5.1) controlle at 105 ± 1 °C.

Remove the dish and its lid from the oven and allow to cool t room temperature in the desiccator (5.4).

Weigh the dish and its lid to the nearest 0,1 mg.

7.2 Test portion

Place a test portion of approximately 10 g into the prepare dish (see 7.1) and spread the beans uniformly over the botto of the dish.

Cover the dish with its lid and weigh to the nearest 0,1 mg.

NOTE — If performing a series of tests, prepare dishes as described in 7.1 and place the covered and weighed dishes in the desiccator in order to avoid any pick up or loss of moisture.

7.3 Determination

Place the dish containing the test portion, with the lid removed but alongside or beneath the dish, in the oven (5.1), controlled at 105 ± 1 °C, and dry for 16 ± 0,5 h.

Fit the lid on the dish and place it in the desiccator (5.4). Allow to cool to room temperature and then weigh to the nearest 0,1 mg.

7.4 Number of determinations

Carry out two determinations on the same test sample.

8 Expression of results

The loss in mass at 105 °C, expressed as a percentage by mass, is equal to

$$\frac{(m_1 - m_2) \times 100}{m_1 - m_0}$$

where

m_0 is the mass, in grams, of the dish and lid (see 7.1);

m_1 is the mass, in grams, of the dish, test portion and lid before drying (see 7.2);

m_2 is the mass, in grams, of the dish, test portion and lid after drying (see 7.3).

Take as the result the arithmetic mean of the two determinations (see 7.4).

9 Precision

An inter-laboratory test, carried out at the international level, in which 14 laboratories, each performing two determinations, participated, gave the statistical information (evaluated in accordance with ISO 5725[1]) summarized in the table.

10 Test report

The test report shall show the method used and the result obtained. It shall also mention any operating details not specified in this International Standard, or regarded as optional, as well as any circumstances that may have influenced the result.

The test report shall include all the information required for complete identification of the sample.

Table

Results expressed as percentages by mass

Sample	A	B	C	D	E
Number of laboratories retained after eliminating outliers	13	13	13	13	13
Mean	8,50	9,11	9,14	11,10	11,40
Standard deviation of repeatability (s_r)	0,09	0,04	0,06	0,09	0,12
Coefficient of variation of repeatability	1,1 %	0,4 %	0,7 %	0,8 %	1,1 %
Repeatability ($2,83 \times s_r$)	0,25	0,11	0,17	0,25	0,34
Standard deviation of reproducibility (s_R)	0,21	0,42	0,33	0,19	0,22
Coefficient of variation of reproducibility	2,5 %	4,6 %	3,6 %	1,7 %	1,9 %
Reproducibility ($2,83 \times s_R$)	0,59	1,19	0,93	0,54	0,62

1) ISO 5725, *Precision of test methods — Determination of repeatability and reproducibility by inter-laboratory tests.*

The method of sampling referred to in ISO 6673 is ISO 4072:

Green coffee in bags — Sampling

1 Scope and field of application

1.1 This International Standard specifies a method of sampling a consignment of green coffee, shipped in ten bags or more, for the purpose of examination to determine whether the consignment complies with a contract specification.

1.2 The method may also be used for the preparation of a sample intended

a) to serve as a basis for an offer for sale;

b) for examination to verify that the coffee to be offered for sale satisfies the producer's sales specification;

c) for examination to determine one or more of the characteristics of the coffee for technical, commercial, administrative and arbitration purposes;

d) for quality control or quality inspection;

e) for retention as a reference sample for use if required in litigation.

1.3 This International Standard applies to green coffee in bags, as defined in ISO 3509.

2 References

ISO 3509, *Coffee and its products — Vocabulary.*

ISO 6666, *Coffee triers.*[1)]

3 Definitions

For the purpose of this International Standard, the following definitions apply.

3.1 consignment : The quantity of green coffee in bags dispatched or received at one time and covered by a particular contract or shipping document. It may be composed of one or more lots.

3.2 lot : A part of a consignment or a consignment, presumed to be of uniform characteristics, consisting of not more than 1 000 bags of the same type, with the same marks and mass, containing green coffee assumed to have common properties of reasonably uniform character and to which a given scheme of examination can be applied.

3.3 damaged bags : Bags which are torn, stained, soiled or otherwise detectably contaminated, indicating possible damage to the coffee contained in them.

3.4 sample : A part of a lot, from which the properties of the lot are to be estimated by examination.

3.5 increment; primary sample : The quantity of 30 ± 6 g of green coffee beans taken from a single bag of a specific lot.

3.6 bulk sample; lot sample : The quantity of not less than 1 500 g of green coffee beans obtained by combining all the increments (3.5) taken from bags of a specific lot.

3.7 blended bulk sample; blended lot sample : The quantity of green coffee beans obtained by combining and blending all the increments (3.5) taken from bags of a specific lot.

3.8 laboratory sample; final sample : The quantity of not less than 300 g of green coffee beans removed from the blended bulk sample (3.7) of a specific lot.

4 Administrative arrangements

4.1 Sampling personnel

Sampling shall be carried out by experienced samplers or samplers qualified by training, or shall be carried out by specialized sampling organizations.

4.2 Sampling

Sampling shall be carried out on each lot in a place designed to protect the samples, the sampling apparatus and the containers and packages intended to receive the samples, from adventitious contamination, rain, etc. Special care shall be taken to ensure that the sampling apparatus is clean, dry and free from foreign odours.

1) At present at the stage of draft.

The sampler shall note any evidence of damaged bags or potential contamination.

4.3 Sampling report

After preparation of the samples, a sampling report shall be prepared (see clause 11).

5 Identification and general inspection of the lot prior to sampling

Before any samples are taken, positively identify the lot.

6 Principle of the method of sampling

The method specified follows an established scheme of an arbitrary nature, based on experience.

7 Apparatus

7.1 Coffee trier : a special device for removing coffee through the bag wall without opening the bag, as specified in ISO 6666.

8 Sample containers and packages

The containers and packages mentioned in 4.2, together with their closure systems, shall be clean and dry and shall be made from materials which will not affect the odour, flavour or composition of the samples.

They shall be sufficiently robust to withstand hazards during transport by the chosen method and shall have the ability to preserve the samples unchanged for the appropriate period.

9 Procedure

9.1 Taking increments

9.1.1 Unless there is a stipulation to the contrary in the contract, the number of bags selected from a lot for the purpose of taking increments of 30 ± 6 g (see 3.5) shall be not less than 10 if there are 10 to 100 bags in the lot, and shall be not less than 10 % of the total if there are more than 100 bags in the lot.

9.1.2 The increments shall be taken at random from individual bags from different locations on the pile, using the coffee trier (7.1). Each bag should be preferably be sampled at three different points.

NOTES

1 Damaged bags should be separated from the remainder of the lot. They may be sampled separately and increments kept separate (see 9.2.1).

2 In order to obtain a bulk sample of 1 500 g (see 3.6), it may be necessary to take more than three increments from each bag.

9.2 Preparation of samples

9.2.1 Bulk sample

Examine the increments as they are taken. If they are evidently homogeneous, combine them in a container. Label the bulk sample obtained (see clause 10).

If there is a noticeable lack of uniformity among any of the increments, keep them separate and report this condition in the sampling report (see clause 11).

Samples taken from damaged bags shall not be included in the bulk sample (see note 1 to 9.1.2).

9.2.2 Blended bulk sample

Remove the bulk sample (9.2.1) from its container and thoroughly mix it.

9.2.3 Laboratory samples

Prepare each laboratory sample by removing a quantity of not less than 300 g from the blended bulk sample (9.2.2). Pack and label each laboratory sample obtained (see clause 10).

10 Packing and marking of samples

10.1 Precautions to be taken when packing samples

Samples intended for the determination of moisture content, or for any other test liable to be influenced by an alteration of the moisture content, shall be packed in moisture-proof containers fitted with airtight closures. The containers, in this case, shall be completely filled with green coffee and the closures shall be sealed to prevent loss or alteration of the contents.

NOTE — For the examination of quality characteristics that are not liable to be influenced by an alteration of the moisture content, separate samples should be taken and placed in appropriate containers which allow access of air.

10.2 Marking

The samples shall be identified by recording the following information on the container or package, or on a label affixed to the container or package, unless otherwise specified :

1) Date of sampling

2) Name of sampler and his employer

3) Shipping document or contract No.

4) Ship (or other transport vehicle)

5) Location of coffee

6) Identifying marks and numbers (including the origin of the coffee)

7) Number of bags in the lot

8) Mass of the sample

11 Sampling report

The sampling report shall give all information relevant to the method of sampling and shall refer to the presence of damaged bags, the type(s) of damage and approximate number of damaged bags in the lot.

Any other pertinent observation concerning the condition of the lot shall also be included.

The report shall refer to the conditions in the location of the lot, especially with regard to any potentially contaminating material in the vicinity.

12 Precautions during storage and transport of samples

12.1 Laboratory samples shall be dispatched to the place of examination as soon as possible after preparation and only in exceptional circumstances more than 48 h after preparation, non-business days excluded.

A copy of the sampling report (see clause 11) shall be sent with them.

12.2 After taking the laboratory samples, the rest of the blended bulk sample from each lot shall be retained in a container labelled in accordance with 10.2, for further use if necessary (inspection, etc.), until final acceptance of the consignment by the purchaser.

Annex 6: Article 19 General Food Law

Article 19

Responsibilities for food business operators

1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.