EXHIBIT 56

The European Commission

Health and Consumer Protection

Residues of Veterinary Medicinal Products - Third Countries

Imports of animals and their products from third countries: Provision of guarantees equivalent to EU requirements on residues of veterinary medicines, pesticides and contaminants.

1. Background

Article 168 of the Treaty establishing the European Union (EU) states that a high level of human health protection shall be ensured in the definition and implementation of all EU policies and activities. A comprehensive body of EU legislation has been put in place to achieve this objective. All of this legislation is publicly available and can be accessed via the European Commission's EurLex website: http://eur-lex.europa.eu/en/index.htm

With regard to the safety of food, articles 11 to 13 of Regulation 178/2002/EC (Food Law) require that food and feed imported into the EU *"shall comply with the relevant requirements of food law or conditions recognised at least equivalent thereto or, where an agreement exists between the EU and the exporting country, with requirements contained therein"*.

To top

2. EU legislation on monitoring of residues and contaminants in food of animal origin.

With regard to residues of veterinary medicines, and some pesticides (dual use substances and organophosphates) and contaminants (heavy metals) in food of animal origin, there is specific EU legislation in place. Council Directive 96/23/EC lays out the requirements that must be met in relation to the planning and execution of national residue control plans for live animals and products of animal origin. The principal objective of the legislation is to detect illegal use of substances in animal production and the misuse of authorised veterinary medicinal products and to ensure the implementation of appropriate actions to minimise recurrence of all such residues in food of animal origin.

Under this legislation Member States are required to submit national residue control plans for approval by the European Commission on an annual basis.

With regard to consignments of food of animal origin imported into the European Union from third countries, samples of these consignments are liable to be taken by the Member States Competent Authorities at Border Inspection Posts (point of entry into the EU) and tested for residues. The conditions of such sampling and testing are described in Commission Regulation (EC) No 136/2004.
Consignments of food which contain residues in excess of EU Maximum Residue Limits - MRLs - (for veterinary medicines), Maximum Residue Levels - MRLs - (for pesticides) and Maximum Limits - MLs - (for contaminants e.g. heavy metals, dioxins etc), or contain residues of substances which do not have an EU MRL or ML may not be legally placed on the EU market and will be rejected. If a particular residue problem is identified, the EU or individual Member States may reinforce checks at the point of import (see Article 24 of Directive 97/78/EC). All reasonable efforts are made to avoid trade disruption. However, in certain cases where there is an evident structural problem in complying with requirements, the European Commission has imposed import bans, pending satisfactory resolution of the problem in the affected third country.

To top

3. Residue monitoring: requirements sought from third countries wishing to export food to the EU.

Residue monitoring requirements for third countries wishing to export food of animal origin to the EU are outlined in Articles 29 and 30 of Council Directive 96/23/EC. Article 29 (1) of the Directive states that a third country must submit a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I to Council Directive 96/23/EC. The guarantees must have an effect at least equivalent to those provided for in the Directive for Member States. The guarantees provided by third countries must, (a) meet the requirements of Article 4 and specify the particulars laid down in Article 7 of this Directive, and (b) meet the requirements of Article 11 (2) of Directive 96/22/EC as amended by Directive 2003/74/EC and Directive 2008/97/EC. A consolidated version of both Directives is available.

The key points are:

- Article 4 of Council Directive 96/23/EC specifies *inter alia* that there must be a centrally co-ordinated residue monitoring plan in place;
- Article 7 (indent 1) of Council Directive 96/23/EC requires a description of the legislation governing the authorisation, distribution and use of veterinary medicinal products;
- Article 7 (indent 6) of Council Directive 96/23/EC states that the number of samples taken should be in accordance with the sampling levels and frequencies laid down in Annex IV to that Directive;
- Article 11 (2) of Council Directive 96/22/EC prohibits Member States from importing from third countries, animals (and/or products derived therefrom) to which stilbenes, thyrostats and estradiol have been administered under any circumstances, or animals (and/or products derived therefrom) to which certain steroid hormones and beta-agonists have been administered for growth *promotion purposes*.

This latter point is particularly important - if a third country authorises the use of hormones and beta-agonists for growth promotion, their residues control plan can only be approved if there is a 'split system' in place, which guarantees that animals (products from which are destined for export to the EU) have not been treated at any time during their rearing.

To top

4. The evaluation and approval of residue monitoring plans from third countries:

Third countries may only be approved for exporting certain food commodities to the EU on submission of a residues monitoring plan, covering each of these food commodities, which has been favourably evaluated by the European Commission services. Plans which are favourably evaluated by the European Commission are *de facto* deemed to offer guarantees equivalent to those provided for by Council Directive 96/23/EC for domestic production. The information from the evaluation is the basis for the formal approval of the plans by means of a Commission Decision. The information is published in Commission Decision 2011/163/EU . Third countries listed in this Commission Decision are eligible to export those commodities for which they are listed to the EU, subject to animal and public health conditions.

It must be emphasised that an approved residue plan is only one of the prerequisites for export to the EU - relevant EU animal and public health conditions must also be satisfied and guidance on this aspect is given on this website at: http://ec.europa.eu/food/international/trade/index_en.htm

4.1. Timetable for submission of plans and results.

Third countries are required to submit their residue control plans and results of the previous years exercise to the European Commission by the 31 March each year. The contact details are:

The Director,
Food and Veterinary Office,
Health and Consumer Protection Directorate General,
European Commission,
Grange, Dunsany, Co Meath, IRELAND

Tel: 00353 46 9061833
Fax: 00353 46 9061703
E-mail: SANCO-TCRESIDUEPLANS@ec.europa.eu

4.2. The evaluation process

The aim of the evaluation is to assess whether the third country regulatory systems described for the control of residues, authorisation of veterinary medicinal products etc and the plan, offer guarantees which are at least equivalent to those provided for by EU legislation. Sections 5 and 6 of this document explain the features and information which the European Commission services require in order to make such an evaluation. The evaluation exercise recurs annually.

It should be noted that a favourable evaluation is based on the guarantees received on paper. If a subsequent inspection carried out by the FVO, to assess the implementation of residues and veterinary medicines controls, demonstrates that the paper guarantees can not be relied upon, the status of the third country on the list could be revised.

To top

5. Key elements required in a residue control plan

5.1. The initial plan submitted by a third country must include:

- information on the structure of the competent authority (central public body) responsible for drawing up the residues control plan and co-ordinating the activities of all subordinate departments playing a role in execution of the plan. The structure and resources of the subordinate bodies needs to be included;
- a description of the legislative framework covering, for example, rules on the use of veterinary medicines and pesticides (organophosphorus compounds and dual use substances), authorisation (and/or prohibition) procedures etc. In particular information on the authorisation/use/prohibition of hormones and beta-agonists for growth promotion and, if authorised, details of particular EU export programmes ('split systems') such as specific programme requirements, advance approval and certification procedures, record keeping requirements, identification systems to distinguish the animals produced under this programme and their food products derived thereof from animals / food produced under the national or other programmes;
- a list of approved laboratories for residues controls and the accreditation status of these laboratories;
- rules covering the collection of official samples;
- details on measures to be taken in the event of an infringement;

5.2. Subsequent residue control plans

Third countries are not required to send a detailed description of their regulatory systems every year. Only relevant updates or changes to the system need to be communicated to the European Commission. For a third country with a well established regulatory system, details of which were sent with the initial plan, subsequent communication with the European Commission would normally include:

- the (prospective) residue control plan;
- the results and of the previous year's residue control plan, details on its implementation (i.e. numbers of samples taken compared to the number planned) and the measures taken in the event of non-compliant ('positive') results - this gives the European Commission some indication of how the plan has been implemented and allows the competent authority performance to be evaluated.

However, third countries are welcome to submit all background data (e.g. on the structure of the competent authority, authorisation process for veterinary medicines etc) if they so wish on an annual basis.

5.3 Importation of horses into the EU and residue requirements.

Under EU law there are essentially three categories of equidae which are:

- **equidae for slaughter** are defined in Council Directive 90/426/EC as "equidae intended to be transported either directly or after transit through a market or an approved marshalling centre to the slaughterhouse for slaughter".
- **registered equidae** are equidae identified by means of an identification document issued by the breeding authority or any other competent authority of the country where the animal originated, which manages the studbook or register for that breed of animal or, any international association or organisation which manages horses for competition or racing;
- **equidae for breeding and production.** These are all other equidae except those equidae intended for slaughter according to Council Directive 90/426/EC.

5.3.1. Residue import requirements for equidae
The ultimate goal of residue-related import requirements is to protect consumers form harmful substances in food. Food obtained from equidae should be safe whether imported (as meat) or whether it is derived from equidae imported and slaughtered in the EU.

5.3.1.1. Situation in the EU

In the EU, all equidae have to be accompanied by an identification document (passport) during their movements Commission Regulation (EC) No 504/2008. This provision has amongst others been introduced for the protection of consumers against harmful residues in food obtained from equidae treated with pharmacologically active substances.

There is a new Regulation of the European Parliament and of the Council laying down EU procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (Regulation (EC) No 470/2009 pdf). Under this Regulation substances for which a full EU evaluation has been possible are listed in Table 1 in the Annex to Commission Regulation (EU) No 37/2010 pdf . In the EU, equidae may be treated with such substances and, provided that appropriate medicine withdrawal periods are met prior to slaughter, the meat from such animals may enter the food chain. Such treatments must be recorded in a medicines record kept on the farm as required by Article 10 of Council Directive 96/23/EC pdf and Annex I, Part A, III, point 8(b) to Regulation (EC) No 852/2004 pdf .

A full EU evaluation has not been possible for certain substances deemed essential for the treatment of equidae. These are listed in Commission Regulation (EC) No 1950/2006 pdf but as they have not been fully assessed are therefore **excluded** from Table 1 in the Annex to Commission Regulation (EU) No 37/2010 pdf . In the EU treatments of equidae with such substances is possible provided that it is documented in the equine passport and that a default withdrawal period of six months is observed. It should be noted that some medicines commonly used in horses world-wide such as phenylbutazone are neither listed in Commission Regulation (EC) No 1950/2006 pdf or in Table 1 in the Annex to Commission Regulation (EU) No 37/2010 pdf . Any horse in the EU treated with phenylbutazone must be excluded from the food chain and be signed out of the food chain in the equine passport.

In the EU horses which are intended for food production may **not** be treated with substances for which it has not been possible to establish an MRL. Such substances which include chloramphenicol, nitrofurans and nitroimidazoles are listed in Table 2 in the Annex to Commission Regulation (EU) No 37/2010 pdf . If horses have been treated with any of these substances, the animals must be signed out of the food chain and this exclusion has to be documented in the equine passport which accompanies the animal to the slaughterhouse. Furthermore in the EU horses intended for food production may neither be treated with hormonal steroids for growth promotion purposes nor with certain anabolic or gestagenic steroids for therapeutic and/or zootechnical purposes as specified in Council Directive 96/22/EC pdf .

5.3.1.2. Requirements for third countries

Third countries which are exporting meat derived from equidae are obliged to implement a residue control plan which satisfies the requirements of Council Directive 96/23/EC. For equidae caught in the wild, the provisions as laid down for wild land mammals apply. These provisions foresee the submission of an annual residue monitoring plan which is restricted to the analysis of environmental contaminants (e.g. heavy metals). Countries so approved will be listed in the Annex to Commission Decision 2004/432/EC under the column entitled "Equine".

Live equidae exported to the EU for food production (i.e. slaughter) can only be permitted from a third country which has implemented a residue plan giving guarantees equivalent to those required by Council Directive 96/23/EC. Countries so approved will also be listed in the Annex to Commission Decision 2004/432/EC under the column entitled "Equine" with a supplementary footnote "Exports of live equidae for slaughter (food producing animals only)".

If equidae in third countries have been treated with either:

(a) substances listed in Table 2 in the Annex to Commission Regulation (EU) No 37/2010 pdf (e.g. chloramphenicol, nitrofurans or nitroimidazoles etc) *or*;

(b) hormonal steroids for growth promotion purposes *or*;

(c) *certain* anabolic or gestagenic steroids for therapeutic and/or zootechnical purposes as specified in Council Directive 96/22/EC pdf ;

these animals may not be exported for direct slaughter in the EU and meat from these animals is not eligible for export to the EU and should be entirely excluded from the food chain.

Taking into consideration that in most cases horses are not specifically reared as food producing animals and usually end up in the food chain at the end of their productive lives, special attention needs to be given to the requirements of Council Directives 96/23/EC and 96/22/EC which should guarantee that the horses slaughtered are safe for human consumption. Notwithstanding third countries' existing obligations to implement a residue monitoring plan and submit this on an annual basis to the Commission services for approval, third countries are expected to implement the following measures for those

equidae, meat from which is intended to be exported to the EU:

- Equine animals intended for food production should be identified and a system of identity verification should be established.
- In third countries where anabolic steroids are marketed for fattening purposes, there should either be a prohibition on the administration of anabolic steroids for growth promotion purposes to all equidae or there should be a separate system for equidae which may be slaughtered for export of equine meat to the EU. This would require that equidae intended for meat production for the EU would be identified and segregated from those equidae treated with anabolic steroids.
- Treatment records. The purpose of recording treatments of animals with veterinary medicinal products is to ensure that animals are not slaughtered within the withdrawal period of the medicine in question, thus providing guarantees that the EU Maximum Residue Limit (MRL) for the particular pharmacologically active substance is respected. In the EU stock farmers are required to keep medicines records. On that basis it is expected that treatments with veterinary medicinal products should be recorded on a document linked to and accompanying the identified animal when moving from one premise to another or to the slaughterhouse (food chain information).
- At the time of moving the animal to the slaughterhouse, the competent authority of the third country should be able to guarantee that the required withdrawal periods for veterinary medicinal products administered to the animal and recorded in the food chain information have been respected.
- The third-country exporting equine meat should set up a risk based programme for controls on the use of veterinary medicinal products and substances prohibited for use in the EU. The control programme should include regular inspections on holdings, collection centres and at slaughterhouses.

In order for the Commission services to be able to assess the implementation of these measures, third countries intending to export equine meat to the EU **must submit an action plan to the FVO in conjunction with the residue control programme**. Annual updates on these action plans should be submitted along side the residue control plans and results of monitoring.

This action plan should describe how the minimum set of measures referred to above will be implemented and the timelines for so doing. All of these measures should be in place by **31 July 2010**. At that time, only horses with a known medicinal treatment history, and which on the basis of medicinal treatment records can be shown to have satisfied the appropriate veterinary medicine withdrawal periods, should be allowed to be slaughtered for export to the EU. Where appropriate, the implementation of these action plans may be inspected on the spot by the FVO.

In 2010 the EU will reconsider the abovementioned measures and, if appropriate, make the necessary amendments in order to continue ensuring that food safety standards applied in exporting third countries give guarantees equivalent to those foreseen by EU legislation.

Situation regarding 'Registered' equidae

Imports of registered equidae or equidae for breeding and production, under the conditions of Decision 93/197/EEC **and** for which the customs procedures have been completed cannot be slaughtered in the EU for food production before they have received an EU-conforming passport.

Registered equidae temporarily admitted into the EU according to Decision 92/260/EEC cannot be slaughtered for food production in the EU.

The table below summarises the legal position for each type of importation of equidae.

Importing Legislation	Description	Need for a residue plan in the exporting third country	Can these animals be slaughtered in the EU
Council Directive 90/426/EEC	Import for **slaughter**	Yes	Yes - immediate
Commission Decision 93/197/EEC	Import of registered equidae or equidae for	No	Yes, but only on condition that an EU passport has been issued and

	breeding and production		possibly only after a defined period.
Commission Decision 92/260/EEC	Temporary admission	No	No

5.4. Exemption for third countries exporting casings only

Natural casings are membranous cases made of animal intestine which are used to contain sausage or other processed meat. Third countries exporting casings (but no other meat products from that species) to the EU may export these casings without the need for submitting a specific residue control plan for casings to the Commission services. In the latest revision to Commission Decision 2004/432/EC (Commission Decision 2007/115/EC) there is no longer any specific list of third countries authorised to export casings only to the EU i.e. the footnote "approved for import of animal casings", no longer exists.

For completeness, it is reiterated that intestines of bovine animals (cattle) of all ages and the ileum of ovine (sheep) and caprine animals (goats) of all ages are considered a 'specified risk material as regards the transmission of BSE (Bovine Spongiform Encephalopathy). Therefore exports of natural casings derived from cattle, sheep and goats to the EU are only authorised from those third countries where the BSE risk is highly unlikely. These 'low risk' countries are listed under point 15 (b) of Annex XI to Regulation (EC) No 999/2001. Legislation on Regulation (EC) No 999.2001 (TSE - consolidated) pdf

For those third countries which are seeking to export both casings and meat or other animal products, a residue monitoring plan must be in place for the relevant species.

5.5. Residues in honey

Honey is defined in Council Directive 2001/110/EC. In contrast to many food commodities, there are relatively few EU Maximum Residue Limits (MRLs) established for residues of pharmacologically active substances in honey (e.g. tau-fluvalinate and amitraz). In particular antimicrobial/antibiotic drugs are not authorised for the treatment of honey bees in the EU because there are no EU MRLs. However, it is certainly the cas e that antimicrobial drugs are authorised for the treatment of honey bees in many third countries.

This situation may potentially raise some problems with imports of honey into the EU. In the absence of EU MRLs, the presence of any detectable residues in honey imported into the EU would mean that those consignments can not legally be placed on the market in the EU. **Therefore it is important that analytical methods used in third countries' residue control plans are as sensitive and reliable as possible in order to provide assurances that honey exported from third countries to the EU will comply with EU rules.**

EU rules on setting of MRLs for pharmacologically active substances have been updated by Regulation (EC) No 470/2009. This legislation has, for the first time, introduced a mechanism for the extrapolation of MRLs from one species/food commodity to another. In addition the legislation elaborates the principles by which the European Commission can establish so-called "Reference Points for Action" (RPAs) for residues of pharmacologically active substances for which MRLs have not been (nor can not be) established. **It is important to stress that RPAs are NOT MRLs.** RPAs are residue concentrations which are technically feasible to detect by food control laboratories. In the event that the RPA is exceeded, the Member State is obliged to reject the consignment as it can not be legally placed on the EU market (see Article 23 of Regulation (EC) No 470/2009).

If a food control laboratory in an EU Member State unequivocally confirms and quantifies the presence of a substance at a concentration below the RPA (where an RPA has been established) in an imported consignment (i.e. the decision limit CCα as defined in Article 6 of Commission Decision 2002/657/EC has been exceeded), the Member State competent authority is obliged to permit the consignment to be placed on the market, however, it is also obliged to follow certain administrative procedures including, in some circumstances, informing the Commission services.

The RPA concept is not new – it has been described in Commission Decision 2005/34/EC and to date RPAs have been established in honey for substances such as chloramphenicol and nitrofurans. **It is important to stress that in the absence of either MRLs or RPAs for many residues of pharmacologically active substances in honey, the finding**

of any confirmed residue concentration in honey shall result in the rejection of the consignment.

5.6. Structure of the residue control plan

In order to clarify precisely what the European Commission expects third countries to include in their residue control plans, and to facilitate harmonisation of the format in which such plans should be submitted, a number of documents and pro-forma tables are appended which may be used for constructing the plan. These are described in more detail in section 6.

5.6.1. Coverage of the plan - what commodities have to be included:

Only those commodities which are currently being exported to the EU (or which the third country wishes to export to the EU) need to be included in the plan.

5.6.2. Sampling levels and frequencies

Sampling levels and frequencies are laid down in Council Directive 96/23/EC and Commission Decision 97/747/EC. They are based on annual national production figures. Every EU Member State is obliged to observe these sampling levels and the relevant information is included in this file: Sampling levels and frequencies

For third countries, the number of samples to be taken depends on the structure of the relevant industry. For example in the case of those third countries where animals and products from any farm are eligible to be exported to the EU, the proportion of animals sampled should be taken relative to the annual national production figures i.e. in line with the sampling levels and frequencies used by the Member States. Briefly, the sampling requirements are as follows:

Species	Commodity	Frequency
Bovine	Meat	0.4 % of the animals slaughtered the previous year
Bovine / Ovine / Caprine	Milk	One per 15000 tonnes of annual production - minimum 300 samples
Porcine	Meat	0.05 % of the animals slaughtered the previous year
Caprine, ovine	Meat	0.05 % of the animals slaughtered the previous year
Equine	Meat	No frequency or minimum number of samples established
Poultry	Meat	One per 200 tonnes of annual production (deadweight)
	Eggs	One per 1000 tonnes of annual production for human consumption - minimum 200 samples
Rabbit	Meat	10 per 300 tonnes of annual production (deadweight) for the first 3000 tonnes + 1 sample for every 300 tonnes thereafter
Farmed & wild game	Meat	At least 100 samples
Farmed fin fish	Meat	One per 100 tonnes of annual production (deadweight)
Bees	Honey	10 per 300 tonnes of annual production for human consumption for the first 3000 tonnes + 1 sample for every 300 tonnes thereafter

However, for those countries where only a defined population of animals are eligible for export to the EU, and where there is a system in place guaranteeing that only those animals from those farms are eligible for export, it is permissible that the proportion of animals sampled is relative to that defined population rather than the national population. Each sample can be analysed for detecting the presence of one or more substances within a substance group. The use of multi-residue analytical methods is to be encouraged.

5.6.3. Selection of residues to be included in the residue control plan.

Council Directive 96/23/EC, requires that third countries must be able to provide guarantees on the residue status of exported product with respect to all of the specified substance groups listed in Annex I to that Directive. The substance groups are classified in two main categories - Group A and Group B. Group A contains most of the substances which are prohibited from use in food producing animals in the EU and the Group is subdivided into 6 subgroups (A1-A6). Group B contains residues of many pharmacologically active substances which may be authorised for use in food producing animals in the EU (i.e. are listed in Annex I to III to Council Regulation (EEC) No 2377/90). It also comprises organochlorine and organophosphate pesticides and also chemical elements such as lead, cadmium and mercury.

Annex II to Council Directive 96/23/EC lists for each commodity (e.g. bovine animals, milk, eggs etc) which Group A and Group B subgroups must be monitored for in the respective commodities. Although Member States are obliged to follow these rules, there is some flexibility in the case of third countries.

Those substance groups classified in Group A are of greatest concern to the EU as their use is either entirely prohibited or firmly restricted are. Consequently, third countries are advised that, in respect of compounds in Group A1, A2, A3, A4, A5 and A6, these must be monitored for in the relevant commodities. The absence of testing could result in the residue plan not being approved and the third country would therefore be ineligible to export those commodities.

There are several *other* substances banned from use in animal production in the EU which are *not* currently listed in Group A. Examples include malachite green (which has been used for the treatment of fungal disease in fish) and several growth promoting antibiotic substances which have been expressly prohibited for inclusion in animal feedingstuffs in the EU because of identified chemical risks (e.g. olaquindox pdf and carbadox pdf and the nitrofuran, nifursol pdf). Data on all of these substances were examined by an independent scientific committee which provided advice to the European Commission. The assessments for nifursol pdf , carbadox and olaquindox pdf are available here.

In the interests of harmonising the analytical capability of Member State laboratories testing for residues of these substances in food of animal origin, the European Commission services are in the process of establishing minimum required performance limits (MRPLs) for olaquindox and carbadox residues - MRPLs have already been established for residues of several 'banned' substances including the nitrofurans and malachite green - see section 5.5.4. below.

If the use of such substances is authorised in a third country, particular in livestock production destined for the EU market, the country should consider analytical and/or other control strategies which will provide equivalent guarantees to those provided for by current EU legislation. Such strategies should result in the European consumer being protected from exposure to the presence of residues in food of animal origin

exported to the EU - the same objective achieved by the ban on use within the EU.

In respect of the Group B substances, third countries should test for those substances which are likely to be used in their livestock production systems. They should justify their choice of substances tested with a documented risk-based approach. If there are substance-sub-groups listed in Group B which are *not* tested for in their plans, such omissions would have to be justified and supported by appropriate documentary evidence submitted with the plan. Such evidence could consist of one or more of the following:

- a register of authorised medicines (and chemical class) for use in each species of food producing animal;
- historical residue monitoring data justifying any decisions not to include specific substance groups in the monitoring plan etc;
- toxicological data or preferably an assessment of the chemical risk of individual compounds, the use patterns of these compounds in each of the (export) livestock sectors, the likelihood of potentially harmful residues occurring and the relative risk of consumers being exposed to such residues.

Those third countries electing to implement in their national provisions measures fully equivalent to Council Directive 96/23/EC in full (as all EU Member States are obliged to do) would not be obliged to provide information on (2) and (3) above. Third countries following the residue monitoring approach advocated by the Codex Alimentarius /download/standards/11252/CXG_071e.pdf pdf would have to justify (on the basis of risk) the absence of monitoring of any Group B substances which are listed in Council Directive 96/23/EC.

Table 2 pdf lists the substance groups that should be monitored for each animal species or product. Substances or groups of substances which are of particular concern for the EU and for which monitoring is therefore expected, are detailed and highlighted by means of the letter "E" (essential) in the corresponding cell. The same is done for substances which are frequently detected in the different commodities and therefore should be included in the programme. Other substances or groups of substances to be tested in the different commodities are highlighted by means of the letters "HD" (highly desirable). Decisions to *omit* HD substances/substance groups from the plan should be justified and supported by appropriate documentary evidence. The list of individual substances in this table is not exhaustive. If on the basis of a risk assessment, third countries wish to test for additional substances, they are encouraged to so.

5.6.4. Maximum Residue Limits and 'action levels' in food of animal origin.

Regulation (EC) No 470/2009 pdf of the European Parliament and of the Council lays down Maximum Residue Limits (MRLs) for residues of pharmacologically active substances in food of animal origin. A complete list of pharmacologically active substances and their MRLs is available in the Annex to Commission Regulation (EU) No 37/2010 pdf . EU Maximum Residue Levels have been established for a wide range of pesticides by Regulation (EC) No 396/2005. These are laid down in various Commission Regulations and may be accessed via the Commission's on-line database of pesticides accessible here. Maximum Levels for certain environmental contaminants are laid down in Commission Regulation (EC) 1881/2006.

In the case of coccidiostats and histomonostats, some of these are 'dual-use' substances i.e. have been authorised either as veterinary medicinal products and/or as feed additives. A Community Register of Feed Additives has been established and the coccidiostats and histomonostats so authorised include decoquinate, robenidine, halofuginone, diclazuril and the ionophores monensin, salinomycin, maduramycin, semduramycin, lasalocid, narasin and narasin combined with nicarbazin.

When an MRL for the substance concerned has already been established for that substance when used in a veterinary medicinal product, that MRL shall also apply to residues originating from the use of the same substance as a feed additive. Consequently the MRLs established for decoquinate, halofuginone, lasalocid and monensin as veterinary medicinal products under Regulation (EC) No 470/2009 pdf and listed in the Annex to Commission Regulation (EU) No 37/2010 pdf apply if those substances are used as feed additives in the species for which the MRL has already been set.

For those coccidiostats and histomonostats which are not authorised for use as veterinary medicinal products, but only as feed additives, MRLs have been established for individual formulations of each of these feed additives. For example, in the case of monensin, Coxidin (a formulation of monensin sodium authorised as a feed additive for chicken and turkeys), MRLs have been set in chicken and turkey tissues by Commission Regulation (EC) No 156/2008 pdf .

It has also been recognised that unavoidable cross contamination of animal feedingstuffs can occur with these additives

(i.e. trace quantities can end up in feed intended for other species) and give rise to residues in food derived from those animals. Commission Regulation (EC) No 124/2009 pdf lays down maximum levels for the presence of coccidiostats or histomonostats in food derived from these so-called 'non-target' species which have resulted from the unavoidable carry-over of these substances into animal feedingstuffs.

For several substances which have been expressly prohibited from use in food producing animals in the EU (e.g. chloramphenicol, nitrofurans), or not authorised (e.g. malachite green), the concept of the minimum required performance limit (MRPL) has been established in Commission Decision 2002/657/EC.

MRPLs are defined as *"minimum content of an analyte in a sample, which at least has to be detected and confirmed"* and are the reference point for action in relation to the evaluation of consignments of food (Commission Decision 2005/34/EC pdf). To date MRPLs have been established for the following substances:

Substance and/or metabolite	Matrices	MRPL	Reference
Chloramphenicol	Meat, Eggs, Milk, Urine, Honey Aquaculture products	0,3 µg/kg	Commission Decision 2003/181/EC
Medroxyprogesterone acetate	Pig kidney fat	1 µg/kg	
Nitrofuran metabolites*: - furazolidone - furaltadone - nitrofurantoin - nitrofurazone	Poultry meat for all Aquaculture products	1 µg/kg	
Sum of malachite green and leucomalachite green	Meat of aquaculture products	2 µg/kg	Commission Decision 2004/25/EC pdf

With regard to each of these EU limits/levels, Member States are required to ensure that they have validated laboratory analytical methods in place which are capable of meeting these thresholds.

In the context of providing guarantees on the residue status of commodities exported to the EU, third countries should also be able to demonstrate that the analytical methods used in their national residue control plans are validated and can meet these levels/limits.

To top

6. General instructions and pro formas for submission plans and results.

The following instructions and pro forma tables provide for all of the necessary information which the European Commission needs in order to evaluate whether the third country residue control plan can offer guarantees equivalent to those provided for by EU legislation.

All of the elements and information which the European EU expects from a third country submitting a residues control plan are summarised in Table 1 (Updated 20-03-2008) which is laid out as a form for completion by the Competent Authority. The table is divided into four main sections - the competent authority, the residue control plan, the laboratory network and the authorisation and control of veterinary medicines. In each of these sections more detailed information is required.

Table 2 (Updated 11/10/2006) summarises all of the substances or groups of substances that should be monitored for each animal species or product.

The sampling levels and frequencies are described for each commodity in: Sampling levels and frequencies .

The Plan Template (Updated 06/10/2009) can be used to enter the production data for each commodity. The minimum numbers of samples required under EU rules are automatically updated. Details of the analytes, materials to be tested, screening and confirmatory analytical methods etc can be entered. An An example of a completed specimen plan for aquaculture products (finfish and shrimp) is included for information for aquaculture products (finfish) is included for information. The list of substances used by all of the Member States Substances is included for reference. This indicates the Group (relative to Annex I to Council Directive 96/23/EC) and the Chemical Abstracts Service (CAS) number for the compounds.

Finally the Tables of results (Updated 22/02/2007) for each commodity have been prepared in order to facilitate the uniform presentation of results of residue monitoring for all third countries. A distinct table can be filled in for each commodity.

Links included in the document

Provision of guarantees equivalent to EU requirements on residues of veterinary medicines, pesticides and contaminants.
http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm
Background
http://ec.europa.eu/food/food/chemicalsafety/residues/#1
EU legislation on monitoring of residues and contaminants in food of animal origin.
http://ec.europa.eu/food/food/chemicalsafety/residues/#2
Residue monitoring: requirements sought from third countries wishing to export food to the EU
http://ec.europa.eu/food/food/chemicalsafety/residues/#3
The evaluation and approval of residue monitoring plans from third countries:
http://ec.europa.eu/food/food/chemicalsafety/residues/#4
Timetable for submission of plans and results
http://ec.europa.eu/food/food/chemicalsafety/residues/#4.1
The evaluation process
http://ec.europa.eu/food/food/chemicalsafety/residues/#4.2
Key elements required in a residue control plan:
http://ec.europa.eu/food/food/chemicalsafety/residues/#5
The initial plan submitted by a third country must include
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.1
Subsequent residue control plans
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.2
Importation of horses into the EU and residue requirements
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.3
Residue import requirements for equidae
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.3.1
Situation in the EU
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.3.1.1
Requirements for third countries
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.3.1.2
Exemption for third countries exporting casings only
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.4
Residues in honey
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.5
Structure of the residue control plan:
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.6

Coverage of the plan - what commodities have to be included
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.6.1
Sampling levels and frequencies
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.6.2
Selection of residues to be included in the residue control plan
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.6.3
Maximum Residue Limits and 'action levels' in food of animal origin
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.6.4
General instructions and pro formas for submission plans and results
http://ec.europa.eu/food/food/chemicalsafety/residues/#6
http://ec.europa.eu/food/food/chemicalsafety/residues/
http://eur-lex.europa.eu/en/index.htm
http://eur-lex.europa.eu/en/index.htm
Regulation 178/2002/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R0178:EN:NOT
To top
http://ec.europa.eu/food/food/chemicalsafety/residues/#top
http://ec.europa.eu/food/food/chemicalsafety/residues/
Council Directive 96/23/EC
http://ec.europa.eu/food/food/chemicalsafety/residues/council_directive_96_23ec.pdf
Commission Regulation (EC) No 136/2004
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0136:EN:NOT
To top
http://ec.europa.eu/food/food/chemicalsafety/residues/#top
http://ec.europa.eu/food/food/chemicalsafety/residues/
Directive 96/22/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996L0022:EN:NOT
Directive 2003/74/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003L0074:EN:NOT
Directive 2008/97/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0097:EN:NOT
consolidated version
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:01996L0022-20081218:EN:NOT
To top
http://ec.europa.eu/food/food/chemicalsafety/residues/#top
http://ec.europa.eu/food/food/chemicalsafety/residues/
Commission Decision 2011/163/EU
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:070:0040:0046:EN:PDF
http://ec.europa.eu/food/international/trade/index_en.htm
http://ec.europa.eu/food/international/trade/index_en.htm
http://ec.europa.eu/food/food/chemicalsafety/residues/
SANCO-TCRESIDUEPLANS@ec.europa.eu
http://ec.europa.eu/food/food/chemicalsafety/residues/mailto:SANCO-TCRESIDUEPLANS@ec.europa.eu
http://ec.europa.eu/food/food/chemicalsafety/residues/
To top
http://ec.europa.eu/food/food/chemicalsafety/residues/#top
http://ec.europa.eu/food/food/chemicalsafety/residues/
http://ec.europa.eu/food/food/chemicalsafety/residues/
http://ec.europa.eu/food/food/chemicalsafety/residues/
http://ec.europa.eu/food/food/chemicalsafety/residues/
Council Directive 90/426/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:01990L0426-20080903:EN:NOT
http://ec.europa.eu/food/food/chemicalsafety/residues/
http://ec.europa.eu/food/food/chemicalsafety/residues/
Commission Regulation (EC) No 504/2008
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R0504:EN:NOT
Regulation (EC) No 470/2009
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0011:0022:EN:PDF
Commission Regulation (EU) No 37/2010
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF
Council Directive 96/23/EC
http://ec.europa.eu/food/food/chemicalsafety/residues/council_directive_96_23ec.pdf
Regulation (EC) No 852/2004
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:226:0003:0021:EN:PDF
Commission Regulation (EC) No 1950/2006
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:367:0033:0045:EN:PDF
Commission Regulation (EU) No 37/2010
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF

Commission Regulation (EC) No 1950/2006
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:367:0033:0045:EN:PDF
Commission Regulation (EU) No 37/2010
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF
Commission Regulation (EU) No 37/2010
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF
Council Directive 96/22/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1996L0022:20081218:EN:PDF
http://ec.europa.eu/food/food/chemicalsafety/residues/
Commission Regulation (EU) No 37/2010
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF
Council Directive 96/22/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1996L0022:20081218:EN:PDF
Decision 93/197/EEC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:01993D0197-20070101:EN:NOT
Decision 92/260/EEC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:01992D0260-20070101:EN:NOT
http://ec.europa.eu/food/food/chemicalsafety/residues/
Legislation on Regulation (EC) No 999.2001 (TSE - consolidated)
http://ec.europa.eu/food/food/chemicalsafety/residues/reg_999_2001_tse_consolidated_en.pdf
http://ec.europa.eu/food/food/chemicalsafety/residues/
Council Directive 2001/110/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:010:0047:0052:EN:PDF
Regulation (EC) No 470/2009
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0011:0022:EN:PDF
Commission Decision 2002/657/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:221:0008:0036:EN:PDF
http://ec.europa.eu/food/food/chemicalsafety/residues/
http://ec.europa.eu/food/food/chemicalsafety/residues/
http://ec.europa.eu/food/food/chemicalsafety/residues/
Commission Decision 97/747/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997D0747:EN:NOT
Sampling levels and frequencies
http://ec.europa.eu/food/food/chemicalsafety/residues/sampling_levels_frequencies_ime.doc
http://ec.europa.eu/food/food/chemicalsafety/residues/
olaquindox
http://eurlex.europa.eu/pri/en/oj/dat/1998/l_347/l_34719981223en00310032.pdf
carbadox
http://eurlex.europa.eu/pri/en/oj/dat/1998/l_347/l_34719981223en00310032.pdf
nifursol
http://eurlex.europa.eu/pri/en/oj/dat/2002/l_265/l_26520021003en00010002.pdf
nifursol
http://ec.europa.eu/food/fs/sc/scan/out119_en.pdf
carbadox and olaquindox
http://ec.europa.eu/food/fs/sc/scan/out13_en.pdf
/download/standards/11252/CXG_071e.pdf
http://www.codexalimentarius.net/download/standards/11252/CXG_071e.pdf
Table 2
http://ec.europa.eu/food/food/chemicalsafety/residues/table2_101106.pdf
http://ec.europa.eu/food/food/chemicalsafety/residues/
Regulation (EC) No 470/2009
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0011:0022:EN:PDF
Commission Regulation (EU) No 37/2010
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF
Regulation (EC) No 396/2005
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:02005R0396-20080410:EN:NOT
here
http://ec.europa.eu/food/plant/protection/pesticides/database_pesticide_en.htm
Commission Regulation (EC) 1881/2006
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1881:EN:NOT
Community Register of Feed Additives
http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm
Regulation (EC) No 470/2009
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0011:0022:EN:PDF
Commission Regulation (EU) No 37/2010
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF
Commission Regulation (EC) No 156/2008
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:048:0014:0015:EN:PDF

Commission Regulation (EC) No 124/2009
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:040:0007:0011:EN:PDF
Commission Decision 2002/657/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002D0657:EN:NOT
Commission Decision 2005/34/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005D0034:EN:NOT
Commission Decision 2003/181/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003D0181:EN:NOT
2004/25/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0025:EN:NOT
To top
http://ec.europa.eu/food/food/chemicalsafety/residues/#top
http://ec.europa.eu/food/food/chemicalsafety/residues/
Table 1 (Updated 20-03-2008)
http://ec.europa.eu/food/food/chemicalsafety/residues/table1.doc
Table 2
http://ec.europa.eu/food/food/chemicalsafety/residues/table2_101106.pdf
Sampling levels and frequencies
http://ec.europa.eu/food/food/chemicalsafety/residues/sampling_levels_frequencies_ime.pdf
Plan Template
http://ec.europa.eu/food/food/chemicalsafety/residues/plantemplate.xls
An example of a completed specimen plan for aquaculture products (finfish and shrimp) is included for information
http://ec.europa.eu/food/food/chemicalsafety/residues/plan_template_specimen_en.pdf
Substances
http://ec.europa.eu/food/food/chemicalsafety/residues/substances_ime.doc
Tables of results (Updated 22/02/2007)
http://ec.europa.eu/food/food/chemicalsafety/residues/resultstemplate.xls