

Imports of animals and food of animal origin from non-EU countries:

*Provisions of guarantees
equivalent to EU requirements
on residues of veterinary medicines,
pesticides and contaminants*

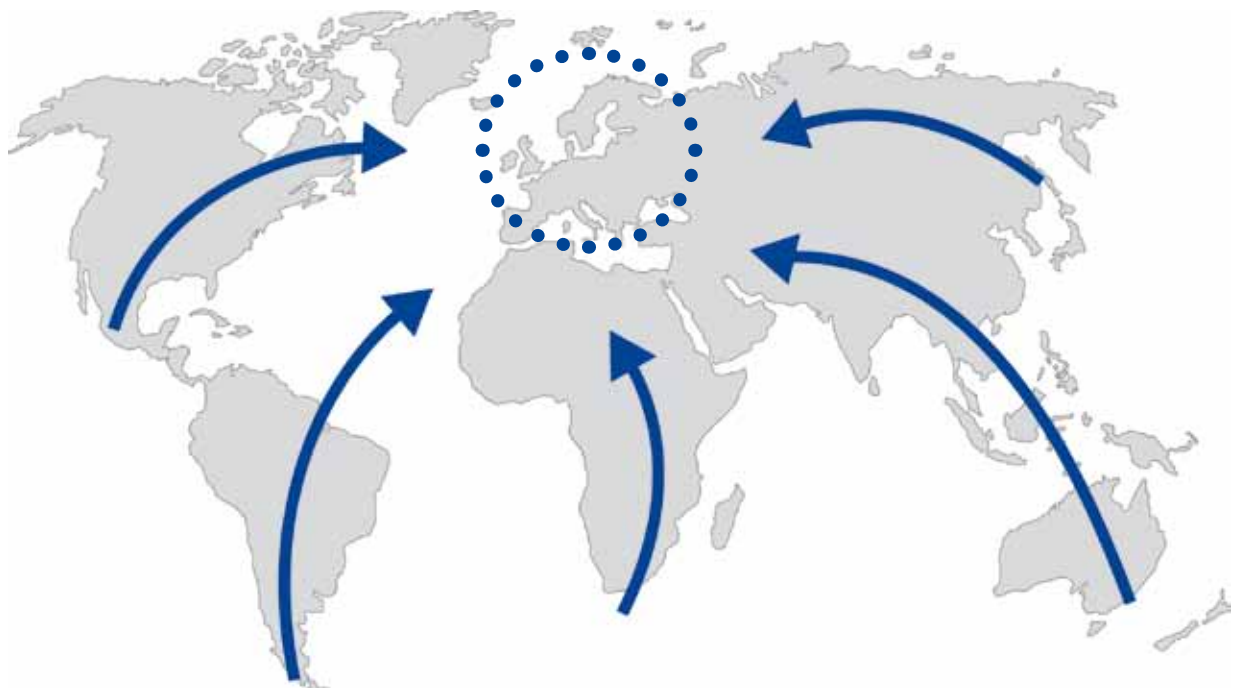


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1. Objective of this brochure

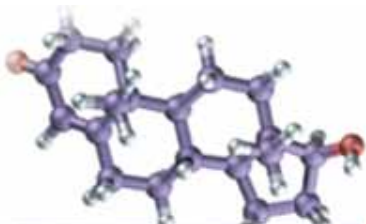
This brochure aims to help non-EU countries interested in exporting food of animal origin to the European Union (EU) to better understand EU legislation and requirements for residues and contaminants.

It gives guidance on how to comply with this legislation e.g. design a residue monitoring plan or report data etc., and describes in detail import requirements for some commodities e.g. horsemeat, honey, casings.

2. Food safety in the EU : protecting consumers

The EU is the world's biggest food importer and one of the biggest food exporters. Our regulations affect trading partners worldwide.

Europeans expect safe food, and safety carries a high political and financial cost.





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



Specific legislation protects consumers from exposure to potentially harmful residues of veterinary medicines, pesticides and environmental contaminants in food of animal origin ([Directive 96/23](#)).

EU countries implement residue monitoring plans for the detection of illegal use of substances in animal production and the misuse of authorised veterinary medicines. They must also take appropriate action to minimise the recurrence of such residues in food. The European Commission approves the submitted residue monitoring plans every year.

EU countries must also sample imported food-stuffs ([Regulation 136/2004](#)).

Food consignments containing residues above EU maximum limits or levels for veterinary medicines, pesticides and contaminants (see section 4.3) or that contain residues of substances without EU limits will be rejected. In the case of a residue problem, the EU or individual EU countries may reinforce point of import checks (Article 24, Directive 97/78/EC).

Reasonable efforts are made to avoid trade disruption. In cases of an evident problem with compliance, the Commission has imposed safeguard measures e.g. import bans or compulsory testing at the point of import until the non-EU country finds a satisfactory resolution.



4. Residue monitoring requirements for non-EU countries wishing to export food of animal origin to the EU

[Directive 96/23](#) outlines the relevant requirements (Articles 29 and 30). Article 29 (1) states that a non-EU country must submit a plan with the guarantees it offers for the monitoring of the residues and substances in Annex I of the [Directive](#). Guarantees must have an effect at least equivalent to those in the Directive and meet the requirements of:

- Article 4 and specify the particulars in Article 7 of the Directive;
- Article 11 (2) of [Directive 96/22](#).

Key requirements:

- a centrally co-ordinated residue monitoring plan must be in place (Article 4, [Directive 96/23](#));
- a description of the legislation governing the authorisation, distribution and use of veterinary medicines (Article 7 (indent 1), [Directive 96/23](#));

- the number of samples taken must comply with the sampling levels and frequencies of Annex IV (Article 7 (indent 6), [Directive 96/23](#));
- EU countries cannot import (Article 11 (2), [Directive 96/22](#)):
 - a. animals (and/or products derived from them) to which stilbenes, thyrostats and estradiol have been administered for any purpose or
 - b. animals (and/or products derived from them) to which certain steroid hormones and beta-agonists have been administered for growth promotion.

Requirement for 'Split system'

If a non-EU country authorises the use of hormones and beta-agonists for growth promotion, their residues monitoring plan can only be approved if a 'split system' is in place guaranteeing that animals (or their products) for export to the EU have not been treated at any time during their rearing.



4.1 Evaluation and approval of residue monitoring plans

The first step in a non-EU country's eligibility to export food of animal origin to the EU is the Commission's approval of a residue monitoring plan for those commodities after evaluating the plan. The list of countries with approved plans is in [Decision 2011/690](#).

An approved residue monitoring plan is one of the pre-requisites for export to the EU. EU animal and public health conditions must also be satisfied. [Guidance on this topic](#)

4.1.1 Deadline for plans and results

Non-EU countries should submit their residue monitoring plans and results of previous years' monitoring to the Commission by **31 March** each year to:

Director

Food and Veterinary Office
DG Health and Consumers
European Commission
Grange, Dunsany, Co Meath IRELAND
Tel: 00353 46 9061833
Fax: 00353 46 9061703
E-mail: SANCO-TCRESIDUEPLANS@ec.europa.eu

4.1.2 Evaluation

The evaluation assesses whether the regulatory systems for the control of residues, authorisation of veterinary medicines etc. and the plan offer guarantees at least equivalent to those in EU legislation. Chapters 4.2, 4.3 and 4.4 of this brochure explain the key elements and requirements for the evaluation. Evaluations are annual.

A favourable evaluation is based on the guarantees received on paper. If a Food and Veterinary Office audit ascertains that these guarantees are not reliable, the status of the non-EU country on the list can be revised.



4.2 Key elements of residue monitoring plans

4.2.1 The initial plan must include:

- Details on the structure of the non-EU country's competent authority i.e. central public body drawing up the residues control plan and co-ordinating the departments involved in its execution, plus their structure and resources;
- A description of the legislative framework on e.g. rules on the use of veterinary medicines, authorisation and/or prohibition procedures etc. In particular, the authorisation/use/prohibition of hormones and beta-agonists for growth promotion and, if authorised, details of particular EU export programmes ('split systems'). These must include the specific programme requirements, advance approval and certification procedures, record-keeping requirements, identification systems for segregation and traceability of the animals produced under this programme and the food products derived from them and from animals/food produced with the aid of hormones and beta-agonists for growth promotion;

- A list of approved laboratories for residue testing and their accreditation status;
- rules on the collection of official samples;
- details on measures to be taken in the event of a non-compliant (positive) result.

4.2.2 Subsequent residue monitoring plans

When submitting their annual residue monitoring plans, non-EU countries are not required to send a detailed description of their regulatory systems every year. Only relevant updates or changes to the system should be communicated to the Commission such as:

- the residue monitoring plan for the current year;
- results of the previous year's plan, details of its implementation i.e. numbers of samples taken compared to the number planned and the measures taken for non-compliant ('positive') results. This is evidence of how the plan was implemented and an indicator of the competent authorities' performance.

Non-EU countries can submit annually all background data required for the initial plan (see 4.2.1) if they wish.

4.3 Structure of the residue monitoring plan

There are templates for constructing the plan and producing supporting information in section 4.4. They outline the information the Commission expects to see in residue monitoring plans, and facilitate presentation of data in a common format.

4.3.1 Commodities to be included in the plan

The plan should include only the commodities currently exported or intended for export to the EU. Plans should be submitted for any new commodities which the non-EU country wishes to export.

4.3.2 Sampling levels and frequencies

Sampling levels and frequencies are laid down in [Directive 96/23](#) and [Decision 97/747](#). They are based on annual national production figures. Every EU country must observe the levels summarised in the following table.

For non-EU countries, the number of samples to be taken depends on the production eligible for export. For example, if countries where animals and products from any farm are eligible for export 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 applied in EU countries.

For non-EU countries where only a certain population of animals is eligible for export with a system guaranteeing that only those animals from those farms are eligible for export, the number of sampled animals can be a proportion of that defined population rather than the national population.

Each sample can be analysed for one or more substances within a substance group.

Importantly samples need to be taken across the various production stages of a certain species or where specified at certain production stages. For example: fish samples to be analyzed for Group B substances should be taken preferably at farm level, on fish ready to be placed on the market for consumption. See details for various species in [Directive 96/23](#) and [Decision 97/747](#).

Summary of sampling requirements by commodity/species

([Directive 96/23](#) and [Decision 97/747](#))

<i>Species</i>	<i>Commodity</i>	<i>Frequency</i>
<i>Bovine</i>	<i>Meat</i>	<i>0.4 % of the animals slaughtered the previous year</i>
<i>Bovine/ Ovine/Caprine</i>	<i>Milk</i>	<i>One per 15.000 tonnes of annual production - minimum 300 samples</i>
<i>Porcine</i>	<i>Meat</i>	<i>0.05% of the animals slaughtered the previous year</i>
<i>Caprine, Ovine</i>	<i>Meat</i>	<i>0.05 % of the animals slaughtered the previous year older than 3 months</i>
<i>Equine</i>	<i>Meat</i>	<i>No frequency or minimum number of samples established</i>
<i>Poultry</i>	<i>Meat</i>	<i>One per 200 tonnes of annual production (deadweight)</i>
	<i>Eggs</i>	<i>One per 1.000 tonnes of annual production for human consumption - minimum 200 samples</i>
<i>Rabbit</i>	<i>Meat</i>	<i>10 per 300 tonnes of annual production (deadweight) for the first 3.000 tonnes + 1 sample for every 300 tonnes thereafter</i>
<i>Farmed & wild game</i>	<i>Meat</i>	<i>At least 100 samples</i>
<i>Farmed fin fish</i>	<i>Meat</i>	<i>One per 100 tonnes of annual production (deadweight)</i>
<i>Bees</i>	<i>Honey</i>	<i>10 per 300 tonnes of annual production for human consumption for the first 3.000 tonnes + 1 sample for every 300 tonnes thereafter</i>

4.3.3 Selection of residues for the residue monitoring plan

[Directive 96/23](#) requires that non-EU countries provide guarantees on the residue status of exported products for all substance groups in its Annex I. Substance groups are divided in **Group A and B**.

Group A contains most of the banned substances in food- producing animals in the EU. It is divided 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. Table 1 of Annex to [Regulation 37/2010](#).

Group B also includes organochlorine and organophosphate pesticides and contaminants like heavy metals e.g. lead, cadmium, mercury. It is divided into 3 subgroups (B1, B2 and B3) with more subdivisions of these subgroups.

Group A and B subgroups which must be tested for in the commodities/animal species are listed in Annex II to [Directive 96/23](#). EU countries must follow these rules strictly, but non-EU countries can be given some flexibility.

Substances in Group A are of greatest concern to the EU as they are either banned or restricted. Non-EU countries must monitor compounds in Group A1 - A6 in the relevant commodities. If testing for the relevant substances is not in the residue monitoring plan, it may not be approved and the country would not be eligible to export these commodities to the EU.

There are several other substances banned in animal production in the EU not currently listed in Group A e.g. malachite green (for treatment of fungal disease in fish) and several growth promoting antibiotic substances banned from animal feeding stuffs in the EU because of known chemical risks e.g. [olaquinox](#), [carbadox](#), the nitrofurans, [nifursol](#). Independent scientific committees advising the Commission have given an opinion on [nifursol](#), [carbadox and olaquinox](#).

If such substances are authorised in a non-EU country, particularly in livestock production for the EU market, it should consider analytical and/or other control strategies to offer equivalent guarantees to those of EU legislation, which bans their use.

For **Group B**, non-EU countries should test for the substances likely to be used or misused in their livestock production systems. They should justify their choice of tested substances with a documented risk-based approach. If there are substance-subgroups in Group B not included in the residue monitoring plan, the absence of testing would have to be justified and supported with documentary evidence accompanying the plan which could include:

- a register of all authorised therapeutic medicines and their class e.g. antibiotics, anthelmintics, etc. for use in each species of food-producing animals;
- historical residue monitoring data justifying decisions not to include specific Group B substances or substance groups in the monitoring plan etc;
- toxicological data or preferably, an assessment of the chemical risk of individual substances, the use patterns of these substances in each (export) livestock sector, the likelihood of potentially harmful residues occurring and the relative risk of consumer exposure.

Non-EU countries implementing their national rules fully equivalent to those in [Directive 96/23](#) are not obliged to give information on the 2nd and 3rd point above.

Those following the residue monitoring approach endorsed by the Codex Alimentarius [/download/standards/11252/CXG_071e.pdf](#) must justify the absence of monitoring of any Group B substances on the basis of risk.

[Table 2](#) lists the substance groups to be monitored in each animal species or product. Substances/substance groups of particular concern for the EU for which monitoring is expected, are highlighted with the letter “E” (Essential). The same applies to substances frequently detected in various commodities, and should be included in the programme. Other substances/substance groups to be tested are highlighted with letters “HD” (Highly Desirable). Decisions not to test for HD substances/substance groups in the plan should be justified and supported by documentary evidence. The list of individual substances in this table is not exhaustive.

Non-EU countries are encouraged to test for additional substances on the basis of a risk assessment.

4.3.4 Maximum Residue Limits, Maximum Residue Levels and Maximum Limits in food of animal origin

.....
[Regulation 470/2009](#) lays down the procedure for setting Maximum Residue Limits (MRLs) for residues of *pharmacologically active substances* in food of animal origin. See complete list of substances and their MRLs in the Annex to [Regulation 37/2010](#).

[Regulation 396/2005](#) establishes EU MRLs for pesticides. These are laid down in various Regulations accessible [here](#). [Regulation 1881/2006](#) lays down maximum levels (MLs) for certain *environmental contaminants* e.g. heavy metals. Some other substances classified as ‘feed additives’ in the EU (*coccidiostats and histomonostats*) may also leave residues in food derived from animals reared on feed containing them. See [Community Register of Feed Additives](#).

Authorised coccidiostats and histomonostats include:

- decoquinate;
- robenidine;
- halofuginone;
- diclazuril.
- monensin;
- salinomycin;
- maduramycin;
- semduramycin;
- lasalocid;
- narasin and
- narasin combined with nicarbazin.

Some of these are authorised either as veterinary medicines and/or as feed additives (‘dual-use’ substances). The MRL for the substance as a veterinary medicine also applies to its residues as a feed additive. Therefore, the MRLs for decoquinate, halofuginone, lasalocid and monensin as veterinary medicines under [Regulation 470/2009](#) and listed in the Annex to [Regulation 37/2010](#) apply, if they are used as feed additives in the species to which the MRL applies.

For coccidiostats and histomonostats authorised only as feed additives, MRLs are established for individual formulations of each feed additive. For example, [Regulation 156/2008](#) sets MRLs for monensin in chicken and turkey tissues for Coxidin - a formulation of monensin sodium authorised as feed additive for chicken and turkeys.

Cross-contamination of animal feeding stuffs can occur, i.e. trace quantities can end up in feed for other species, residues may be found in food from those animals. [Regulation 124/2009](#) lays down MLs for coccidiostats or histomonostats in food from such ‘non-target’ species.

4.3.5 Minimum required performance levels and 'Action Levels' in food of animal origin

Minimum required performance limit (MRPL) applies to several substances prohibited or not authorised in food-producing animals in the EU e.g. chloramphenicol, nitrofurans or e.g. malachite green ([Decision 2002/657](#)).

MRPLs are 'the minimum content of an analyte in a sample, which at least has to be detected and confirmed'. They are the reference point for action ('Action levels') when evaluating food consignments ([Decision 2005/34/EC](#)).

Summary of MRPLs for certain substances in the EU

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



4.4 General instructions and templates for residue monitoring plans and results

The following documents summarise the information the Commission needs to evaluate if the non-EU country residue monitoring plan offers guarantees equivalent to those of EU legislation:

1. [Table 1](#) (Updated 20/03/2008) - to be completed by the competent authority. It has 4 main sections - competent authority; residue monitoring plan; laboratory network and authorisation and control of veterinary medicines - each requiring details.
2. [Table 2](#) (Updated 11/10/2006) - summarizes the substances or groups of substances to be monitored for each animal species or product.
3. [Sampling levels and frequencies for](#) each commodity. This document outlines the sampling requirements described in [Directive 96/23](#) and [Decision 97/747](#).

4. [Plan Template](#) (Updated 06/10/2009) The minimum numbers of samples under EU rules are automatically updated, when the production data are entered. Details of the analytes, materials to be tested, screening and confirmatory analytical methods etc. can be entered.
5. [An example of a completed specimen plan for aquaculture products \(finfish and shrimp\)](#) is included for information.
6. The list of substances used by all EU countries: [Substances](#) is included for reference. It shows the Group (relative to Annex I to Directive 96/23) and the Chemical Abstracts Service (CAS) number for the compounds.
7. [Tables of results](#) (Updated 22/02/2007) for each commodity allow the uniform presentation of results for all non-EU countries. A separate sheet can be filled in for each commodity.

It is important that the analytical methods used detect the residues in question at the same level/limits as applied in the EU (see 4.3.4. and 4.3.5.), and that they are validated and fit for purpose.



5. Special rules for certain commodities

5.1 Horses: import into the EU and residue requirements

Food obtained from equidae must be safe when imported as meat or derived from equidae, imported and slaughtered in the EU.

There are 3 categories of equidae under EU law:

- **for slaughter** - 'equidae intended to be transported either directly or after transit through a market or an approved marshalling centre to the slaughterhouse for slaughter' (Directive 90/426);
- **registered equidae** - identified with a document by the breeding or other competent authority of the country of the animal's origin, which manages the studbook or register for that breed or international organisation managing horses for competition or racing;
- **for breeding and production** - all other equidae except those intended for slaughter.

5.1.1 Situation in the EU

EU requirements:

5.1.2 Passport for equidae and medicines records

All EU equidae must be accompanied by a passport during their movements ([Regulation 504/2008](#)). The passport has a section where treatments with certain veterinary medicines must be recorded (see 5.1.2). All medicinal treatments must also be recorded in a medicines record kept on the farm (required by Article 10, Directive 96/23 and Annex I, Part A, III, point 8(b) to [Regulation 852/2004](#)).

5.1.3 Veterinary medicines which can and cannot be used

In the EU, pharmacologically active substances used for treating equidae are grouped as:

Substances with an EU MRL for equidae

Substances with an established MRL in line with [Regulation 470/2009](#) and listed in Table 1 of the Annex to [Regulation 37/2010](#) can be used for treatment of horses. The meat from such animals may enter the food chain if the indicated medicine withdrawal periods are met before slaughter.

Substances without an EU MRL for equidae but essential for their treatment

Certain substances not in Table 1 of the Annex to [Regulation 37/2010](#) are considered essential when treating equidae ([Regulation 1950/2006](#)).

Treated animals can enter the food chain if the treatment is documented in the equine passport and a default withdrawal period of 6 months is observed before slaughter.

Substances for which no MRL can be set for equidae in the EU

Horses for food production may **not** be treated with substances for which it is impossible to establish an MRL i.e. chloramphenicol, nitrofurans and nitroimidazoles (Table 2 of Annex to [Regulation 37/2010](#)).

Horses must be signed out of the food chain if they have been treated with any of them. The passport accompanying the animal to the slaughterhouse must record this.

Substances without an EU MRL for equidae which are not nor deemed essential medicines

Some medicines commonly used for horses world-wide e.g. phenylbutazone, are not listed in [Reg. 1950/2006](#) or in Table 1 of the Annex to Regulation 37/2010. Any horse in the EU treated with phenylbutazone must be excluded from the food chain and signed out of the food chain in the passport.

Steroid hormones

Horses for food production in the EU can neither be treated with hormonal steroids for growth promotion, nor with certain anabolic or gestagenic steroids for therapeutic and/or zootechnical purposes ([Directive 96/22](#)). Such treatments are illegal and the animals cannot enter the food chain.



5.1.4 Requirements for non-EU countries

Exporting meat from equidae

Non-EU countries exporting meat from equidae must implement a residue monitoring plan satisfying the requirements of [Directive 96/23](#) (chapter 4). The provisions for wild game apply to equidae caught in the wild and immediately sent for slaughter. They foresee the submission of an annual residue monitoring plan restricted to the analysis of environmental contaminants e.g. heavy metals.

Approved countries are listed in the Annex to [Decision 2011/163/EU](#) under 'Equine'.

Exporting live equidae for food production

Live equidae for food production i.e. slaughter, can only be imported from a non-EU country that has implemented a residue monitoring plan with guarantees equivalent to those in [Directive 96/23](#). These countries are listed in the Annex to [Decision 2011/163](#) under 'Equine' with the footnote: 'Exports of live equidae for slaughter (food producing animals only)'.

If equidae in non-EU countries have been treated with either:

- a. substances in Table 2 of the Annex to [Regulation 37/2010](#) e.g. chloramphenicol, nitrofurans or nitroimidazoles etc. or
- b. hormonal steroids for growth promotion or
- c. certain anabolic or gestagenic steroids for therapeutic and/or zootechnical purposes as in Directive 96/22;

they cannot be imported for direct slaughter in the EU and their meat is not eligible for export to the EU.

Horses are not usually reared specifically for food production. They end up in the food chain at the end of their productive lives. Hence, the requirements of [Directives 96/23](#) and [96/22](#) need to be followed guarantee that slaughtered horses are safe for human consumption.

Besides implementing and submitting an annual residue monitoring plan to the Commission for approval, non-EU countries must implement:

- **Identification** of equine animals for food production and establishment of a system for identity verification.
- **'Split system'** In non-EU countries where anabolic steroids are marketed for fattening, the administering anabolic steroids for growth promotion to all equidae should either be banned or have a separate ('split system') for equidae that may be slaughtered for export of equine meat to the EU. This requires that equidae for meat production for the EU are identified and segregated from those treated with anabolic steroids.

- **Treatment records** to ensure animals are not slaughtered within the withdrawal period of the respective medicine, guaranteeing compliance with the EU MRL for the substance. (EU stock farmers must keep medicines records). Treatments with veterinary medicines must be recorded in a document accompanying the identified animal when moving from one premise to another or to the slaughterhouse (food chain information).
- **Withdrawal period.** When moving the animal to the slaughterhouse, the non-EU country competent authority should guarantee compliance with the required withdrawal periods for veterinary medicines administered to the animal and recorded in the food chain information.
- **Control programme.** The non-EU country exporting equine meat must have a risk-based programme for controls of the *use of veterinary medicines* and substances banned in the EU including regular inspections of holdings, collection centres and slaughterhouses.

Non-EU countries intending to export equine meat to the EU *must submit an action plan to the FVO together with the residue monitoring plan.* Annual updates of the plans should be sent with the residue monitoring plans and monitoring results.

The action plan should describe how they implement the minimum measures above and the timeline. All measures should be in place from **31 July 2010**. From then on, only horses with a known medicinal treatment history, and whose medicinal treatment records show they satisfy the veterinary medicine withdrawal periods, will be allowed to be slaughtered for export to the EU. The FVO may inspect the implementation of the action plans on the spot.

The EU monitors the implementation of the above measures and may make amendments depending on the content of the action plans and the results of FVO audits of equine meat production in non-EU countries.

'Registered' or breeding equidae

Imports of registered equidae or equidae for breeding and production under [Decision 93/197 that have cleared customs cannot be slaughtered in the EU for food production before receiving an EU-conforming passport.](#)

Registered equidae temporarily admitted into the EU as per [Decision 92/260 cannot be slaughtered for food production](#) in the EU.

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

Summary of legal basis for importing horses into the EU

<i>Importing Legislation</i>	<i>Description</i>	<i>Need for a residue monitoring plan in the exporting non-EU country</i>	<i>Can these animals be slaughtered in the EU?</i>
<i>Directive 90/426/EEC</i>	<i>Import for slaughter</i>	<i>Yes</i>	<i>Yes – immediate</i>
<i>Commission Decision 93/197/EEC</i>	<i>Import of registered equidae or equidae for breeding and production</i>	<i>No</i>	<i>Yes, but only on condition that an EU passport has been issued and possibly only after a defined period.</i>
<i>Commission Decision 92/260/EEC</i>	<i>Temporary admission</i>	<i>No</i>	<i>No</i>



5.2 Casings: Exemption for non-EU countries exporting casings only

Natural casings are membranous cases made of animal intestine used to contain sausage or other processed meat. Non-EU countries exporting casings (and *no other meat products from that species*) to the EU may do so *without* submitting a specific residue control plan for casings.

Rules for ruminant casings

Intestines of cattle and the ileum of ovine and caprine animals of all ages are specified risk material for the transmission of Bovine Spongiform Encephalopathy. Exports of natural casings from cattle, sheep and goats to the EU are only authorised from non-EU countries with a highly unlikely BSE risk. They are listed under point 15 (b) of Annex XI to [Regulation 999/2001](#).

For non-EU countries seeking to export casings **and** meat or other animal products, a residue monitoring plan must be in place for the relevant species.



5.3 Residues in honey

Honey is defined in [Directive 2001/110](#) .

There are relatively few EU Maximum Residue Limits (MRLs) for pharmacologically active substances in honey e.g. tau-fluvalinate and amitraz. Antimicrobial drugs are not authorised for the treatment of honey bees in the EU, as there are no EU MRL established for honey. Such drugs are authorised though in many non-EU countries, and this potentially raises problems with honey imports. Without EU MRLs, the presence of detectable residues in imported honey make the marketing of consignments illegal in the EU. *Analytical methods used in non-EU countries' residue monitoring plans must be sensitive and reliable in assuring that their honey exports to the EU comply with EU rules.*

[Regulation 470/2009](#) updates EU rules on MRLs for pharmacologically active substances. It introduces a mechanism for the extrapolation of MRLs from one species/food commodity to another. It also elaborates the principles for establishing the 'Reference Points for Action'.

(RPAs) for residues of pharmacologically active substances for which MRLs are not or cannot be established.

[RPAs are NOT MRLs \(i.e. not regulatory limits\)](#). RPAs are residue concentrations which are technically feasible to be detected by food control laboratories. If the RPA is exceeded, the EU country rejects the consignment as it cannot legally market it (see Article 23 of Reg. 470/2009).

If a food control laboratory in an EU country unequivocally quantifies a substance at a concentration below the RPA in an imported consignment (above the decision limit CCa as in Article 6, Decision 2002/657), its competent authority must allow marketing. It must also follow certain administrative procedures including informing the Commission.

The RPA concept is described in Decision 2005/34 and to date RPAs are established in honey for substances e.g. chloramphenicol and nitrofurans.

In the *absence of MRLs or RPAs for many residues of pharmacologically active substances in honey, finding any confirmed residue concentration in honey results in the rejection* of the consignment.