

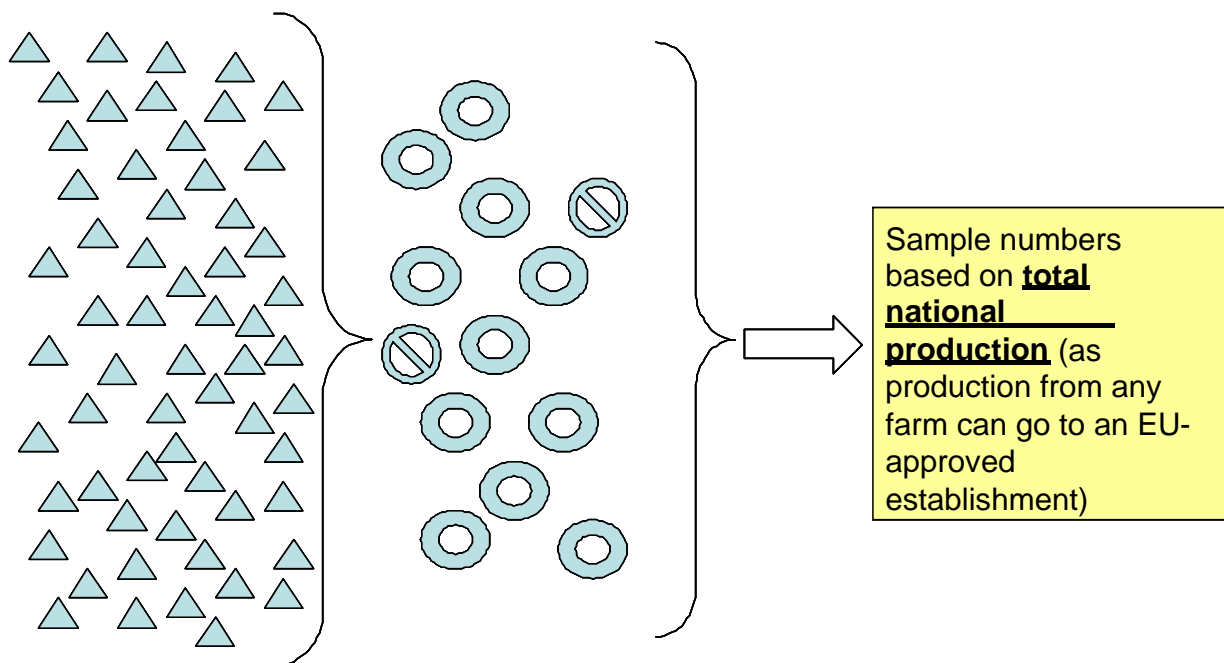
SAMPLING LEVELS AND FREQUENCY¹

The purpose of this document is to define the **minimum number samples which must be taken** in accordance with Council Directive 96/23/EC and Commission Decision 97/747/EC.

EU Member States **must** base the **number of samples** on national production (e.g. number of animals slaughtered or tonnage of certain commodities – eggs, fish, milk, honey etc). However, this is not necessarily the case for third countries. Essentially there are three possible scenarios which will influence the numbers of samples third countries may take in order to comply with the numbers specified in the Directive.

Scenario I:

For those countries where animals and products from **any** farm are eligible to be exported to the EU, and **the majority of export establishments are EU-approved**, the number of samples should be taken **relative to the annual national production figures**. It is expected that the majority of third countries will fall under this scenario which is graphically represented in the figure below.



▲ Farm

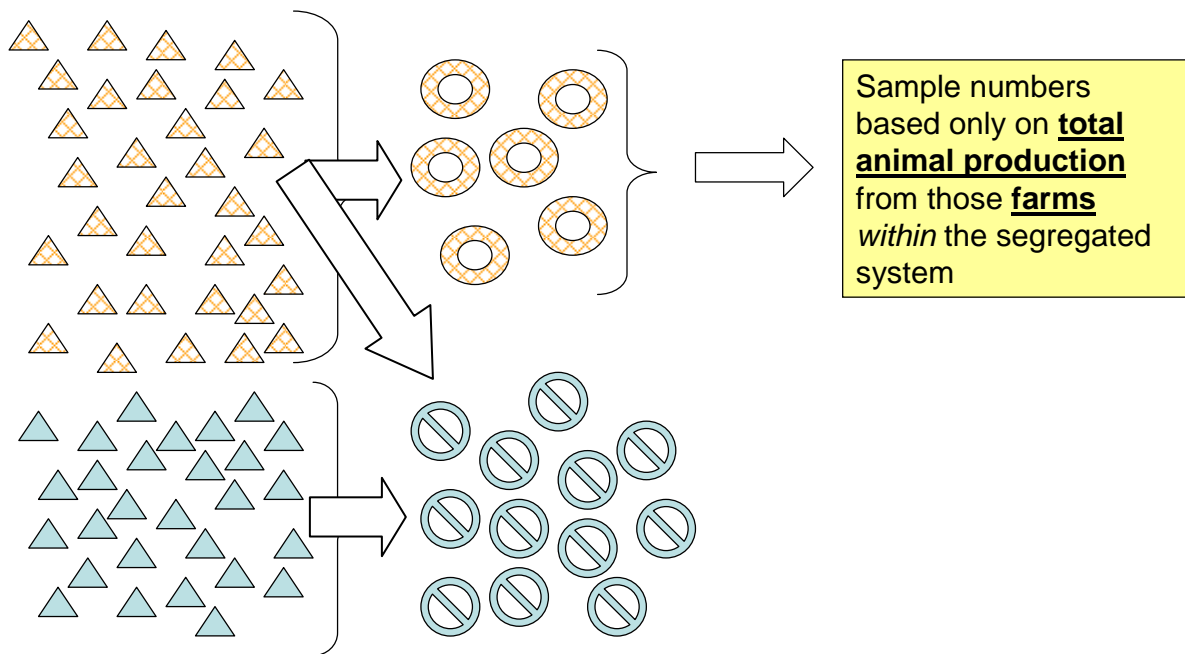
○ EU-approved establishment

⊘ Non-EU-approved establishment

¹ Description of the groups of substances in the Annex to Directive 96/23/EC (also annexed to this document).

Scenario II:

For those countries where only a **defined population of animals or production sites are eligible for export to the EU**, and where there is a **segregated system in place** guaranteeing that *only those animals/products from those farms are eligible for export to the EU*, it is permissible that the number of samples taken is relative to that defined population. This is graphically represented in the figure below.



- ▲ Farm ▲ EU-farm within segregated system
- ⊘ Non-EU-approved establishment (may receive material from both EU-farms and non-EU farms)
- ⊗ EU-approved establishment within segregated system (can **only** accept product from EU-farms within the segregated system)

Scenario III: (only in exceptional circumstances)

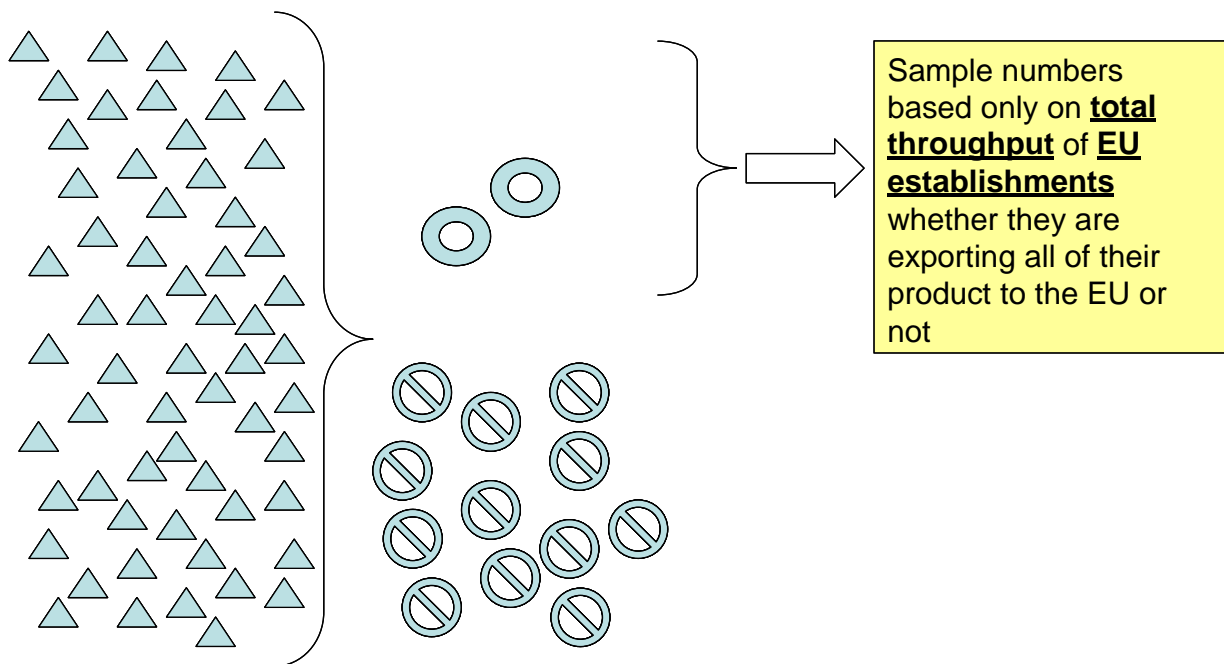
When a third country has a **very limited number of establishments approved for export** to the EU and elsewhere and where animals/products from **any** farm are eligible to supply these establishments, it would be appropriate to calculate the numbers of samples based on the **total production capacity of these establishments**, rather than just the total exported to the EU (as theoretically all of these establishments' throughput could be sent to the EU). **However there are a number of caveats to this assumption.**

In line with the recently published guidelines from the Codex Alimentarius on the design and implementation of national regulatory food safety assurance programmes associated with the use of veterinary drugs in food producing animals (CAC/GL 71-2009)

http://www.codexalimentarius.net/download/standards/11252/CXG_071e.pdf

it is expected that **all** countries establish residue control systems **not solely for the purposes of export to the EU** but also for the protection of their own citizens.

As the majority of the EU's trading partners are proactive in this area, it is expected that the adoption of scenario III to calculate sample numbers is likely to be rare and the scenario is only included for the sake of completeness.



▲ Farm

○ EU-approved establishment

⊘ Non-EU-approved establishment

Number of animals sampled versus number of samples.

European Community rules specify the numbers of animals to be sampled. **It is NOT permissible to take multiple samples from the same animal.**

For third countries, regardless of the basis upon which the number of animals to be sampled are calculated (i.e. Scenarios I, II or, in very exceptional cases III), it may happen that the same sample is analysed for more than one substance group. For example, 10 samples analysed for substance groups A1, A3 and A5, should still be only counted as 10 samples in the plan and in the results (even though the number of *tests* performed has been much greater).

The following text summarises sampling frequencies requirements as laid down in Council Directive 96/23/EC, and Commission Decision 97/747/EC.

1. BOVINE, PORCINE, OVINE, CAPRINE AND EQUINE ANIMALS

1.1. Bovine animals

The minimum number of animals to be controlled each year for all kinds of residues and substances must at least equal 0,4 % of bovine animals slaughtered the previous year, with the following breakdown:

Group A: 0,25 % divided as follows:

- one half of the samples are to be taken from live animals on the holding; (by derogation, 25 % of samples analysed for the research of Group A 5 substances can be taken from appropriate material (feedingstuffs, drinking water, etc.))
- one half of the samples are to be taken at the slaughterhouse.
- Each sub-group in Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.
- The balance must be allocated according to the experience and background information of the country.

Group B: 0,15 % divided as follows:

30 % of the samples must be checked for Group B 1 substances.

30 % of the samples must be checked for Group B 2 substances.

10 % of the samples must be checked for Group B 3 substances.

The balance must be allocated according to the situation of the country.

1.2. Porcine animals

The minimum number of animals to be checked each year for all kinds of residues and substances must at least equal 0,05 % of the pigs slaughtered the previous year, with the following breakdown:

Group A: 0,02 %

In those countries which carry out their sampling of animals at the slaughterhouse, in addition analysis of drinking water, feedingstuffs, faeces, or all other appropriate parameters must be undertaken at farm level. In that case, the minimum number of farms to be visited annually must represent at least one farm per 100 000 pigs slaughtered the previous year.

Each sub-group in Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance will be allocated according to the experience and background information of the country.

Group B: 0,03 %

The same breakdown per sub-group as for bovine animals has to be respected.

The balance will be allocated according to the situation of the country.

1.3. Sheep and goats

The minimum number of animals to be checked for all kind of residues and substances must at least equal 0,05 % of sheep and goats over three months of age slaughtered the previous year, with the following breakdown:

Group A: 0,01 %

Each sub-group of Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance will be allocated according to the experience and background information of the country.

Group B: 0,04 %

The same breakdown per sub-group as for bovine animals has to be respected.

The balance will be allocated according to the experience of the country.

1.4. Equine animals

The number of samples is to be determined by each country in relation to the problems identified.

2. BROILER CHICKENS, SPENT HENS, TURKEYS, OTHER POULTRY

A sample consists of one or more animals depending on the requirements of the analytical methods.

For each category of poultry considered (broiler chickens, spent hens, turkeys, and other poultry), the minimum number of samples to be taken each year must at least equal one per 200 tonnes of annual production (deadweight), with a minimum of 100 samples for each group of substances if the annual production of the category of birds considered is over 5 000 tonnes.

The following breakdown must be respected:

Group A: 50 % of the total samples,

The equivalent of one fifth of these samples must be taken at farm level. Each sub-group of Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance will be allocated according to the experience and background information of the country.

Group B: 50 % of the total samples,
30 % must be checked for Group B 1 substances,
30 % must be checked for Group B 2 substances,
10 % must be checked for Group B 3 substances.

The balance will be allocated according to the situation of the country.

3. AQUACULTURE PRODUCTS

3.1. Finfish farming products

A sample is one or more fish, according to the size of the fish in question and of the requirements of the analytical method.

The countries must respect the minimum sampling levels and frequencies given below, depending on the production of farmed fish (expressed in tonnes).

The minimum number of samples to be collected each year must be at least 1 per 100 tonnes of annual production. The compounds sought and the samples selected for analysis should be selected according to the likely use of these substances.

The following breakdown must be respected:

Group A: one third of the total samples.

All the samples must be taken at farm level, on fish at all stages of farming², including fish which is ready to be placed on the market for

Group B: two thirds of the total samples.

The sampling should be carried out:

- (a) preferably at the farm, on fish ready to be placed on the market for consumption;
- (b) either at the processing plant, or at wholesale level, on fresh fish, on condition that tracing-back to the farm of origin, in the event of positive results, can be done.

In all cases, samples taken at farm level should be taken from a minimum of 10 % of registered sites of production.

3.2. Other aquaculture products

When the countries have reason to believe that veterinary medicine or chemicals are being applied to the other aquaculture products, or when environmental contamination is suspected, then these species must be included in the sampling plan in proportion to their production as additional samples to those taken for finfish farming products.

² For sea-farming, in which sampling conditions may be especially difficult, samples may be taken from feed in place of samples from fish.

4. MILK

4.1. Bovine milk

A. Sampling requirements

- Each official sample must be taken by the official competent authorities in such way that it is always possible to trace it back to the farm of origin of the milk.

- The samples, according to the choice of the countries, can be taken:

(a) either at farm level from the collection tank,

(b) or at the level of the dairy industry before the bulk tanker has discharged.

- Derogation from the above principle of traceability to the farm of origin can be accepted for the substances or residues designated in groups B3(a), (b) and (c) in the Annex of this document.

- Samples must be taken only from raw milk.

The sample size will depend on the analytical methods used.

B. Sampling level and frequency

The annual number of samples is 1 per 15000 tonnes of the annual production of milk, with a minimum of 300 samples.

The following breakdown must be respected:

(a) 70 % of the samples must be examined for the presence of residues of veterinary drugs. In this case, each sample has to be tested for at least four different compounds from at least three groups among groups A 6, B 1, B 2 (a) and B 2 (e).

(b) 15 % of the samples must be tested for the presence of residues designated in group B 3 of Annex of this document.

(c) The balance (15 %) must be allocated according to the situation of the country.

4.2. Milk from other species (ovine, caprine, equine)

The number of samples for these species must be determined by each country according to the level of production and the problems identified. The milk from these species must be included in the sampling plan as additional samples to those taken for bovine milk.

5. EGGS

5.1. Hen eggs

A. Sampling requirements

- Each official sample must be taken by official competent authorities in such way that it is always possible to trace it back to the farm of origin of the eggs.

- The samples, according to the choice of the countries, can be taken:

- (a) either at farm level;
- (b) or at the level of the packing centre.

The sample size is at least 12 eggs or more, according to the analytical methods used.

B. Sampling level and frequency

The number of samples to be taken each year must be at least equal to 1 per 1 000 tonnes of the annual production of consumption eggs, with a minimum of 200 samples. The breakdown of samples may be decided by each country according to the structure of its industry, particularly as regards levels of integration within it.

At least 30 % of samples must be collected from packing centres which represent the most significant proportion of eggs supplied for human consumption.

The following breakdown must be respected:

- 70 % of the samples must be tested for at least one compound from each following groups:
 - A 6, B 1 and B 2 (b) mentioned in Annex.
- 30 % of the samples must be allocated according to the situation in the individual Member State, but must include some analyses for substances in Group B 3 (a) of Annex.

5.2. Eggs from other species of poultry

The number of samples for these species is to be determined by each country according to the level of production and the problems identified. The eggs from these species must be included in the sampling plan as additional samples to those taken for hen eggs.

6. RABBIT MEAT AND THE MEAT-OF WILD GAME AND FARMED GAME

6.1. Rabbit meat

A. Sampling requirements

One sample consists of one or more animals from the same producer, according to the requirements of the analytical methods.

- Each official sample must be taken by official competent authorities in such way that it is always possible to trace it back to the farm of origin of the rabbits.

- The samples, according to the structure of the rabbit production in each country, can be taken:

- (a) either at farm level,
- (b) or at the level of the registered slaughterhouses

Some additional samples of drinking water and feedingstuffs may be taken at farm level, for the control of illegal substances.

B. Sampling level and frequency

The number of samples to be taken each year must be equal to 10 per 300 tonnes of the annual production (dead weight) for the first 3 000 tonnes of production, and 1 sample for each additional 300 tonnes.

The following breakdown must be respected:

- Group A: 30 % of the total number of samples,
 - 70% must be checked for Group A 6 substances,
 - 30% must be checked for substances of other sub-groups of Group A.
 - Group B: 70 % of the total number of samples
 - 30% must be checked for Group B 1 substances
 - 30% must be checked for Group B 2 substances
 - 10% must be checked for Group B3 substances
- The balance must be allocated according to the situation of the country.

6.2. Farmed game**A. Sampling requirements**

The sample size will depend on the analytical method used.

The samples must be taken at the processing unit level. It must be possible to trace the animals or their meat back to the farm of origin.

Without prejudice to the provisions of Directive 96/23/EC, some additional samples of drinking water and feedingstuffs may be taken at farm level, for the control of illegal substances.

B. Sampling level and frequency

The number of samples to be taken each year must at least be equal to 100 samples.

The following breakdown must be respected:

- Group A: 20 % of the total number of samples,
 - The majority of the samples must be analysed for compounds of group A 5 and group A 6.
- Group B: 70 % of the total number of samples.
 - The breakdown must be:
 - 30 % must be checked for Group B 1 substances,
 - 30 % must be checked for Group B 2 (a) and (b) substances,
 - 10 % must be checked for Group B 2 (c) and (e) substances,
 - 30 % must be checked for Group B 3 substances.

The balance (10 %) will be allocated according to the experience of the countries.

The countries shall provide to the Commission the figures corresponding to their national production of farmed game meat destined for human consumption.

6.3. Wild game

A Sampling requirements

The sample size will depend on the analytical method used.

The samples must be taken at the processing unit level or at the hunting place.

It must be possible to trace the animals back to the region where they were hunted.

B. Sampling level and frequency

The number of samples to be taken each year must at least be equal to 100 samples.

These samples must be taken to analyse residues of chemical elements.

The countries will provide to the Commission the figures corresponding to their annual national production of wild game destined for human consumption.

7. HONEY

A. Sampling requirements

The sample size will depend on the analytical method used.

The samples can be taken at any point in the production chain, provided that it is possible to trace the honey back to the original producer.

B. Sampling level and frequency

The number of samples to be taken each year must at least equal to 10 per 300 tonnes of the annual production for the first 3 000 tonnes of production and one sample for each additional 300 tonnes.

The following breakdown must be respected:

- Group B 1 and Group B 2 (c): 50 % of the total number of samples,
- Group B 3 (a),(b) and (c): 40 % of the total number of samples.

The balance (10 %) must be allocated according to the experience of the countries. In particular, consideration could be given to mycotoxins.

ANNEX

GROUP A

SUBSTANCES HAVING ANABOLIC EFFECT AND UNAUTHORISED SUBSTANCES

- (1) Stilbenes, stilbene derivatives, and their salts and esters
- (2) Antithyroid agents
- (3) Steroids
- (4) Resorcylic acid lactones including zeranol
- (5) Beta-agonists
- (6) Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990

GROUP B

VETERINARY DRUGS ⁽¹⁾ AND CONTAMINANTS

- (1) Antibacterial substances, including sulphonamides, quinolones
- (2) Other veterinary drugs
 - (a) Anthelmintics
 - (b) Anticoccidials, including nitroimidazoles
 - (c) Carbamates and pyrethroids
 - (d) Sedatives
 - (e) Non-steroidal anti-inflammatory drugs (NSAIDs)
 - (f) Other pharmacologically active substances
- (3) Other substances and environmental contaminants
 - (a) Organochlorine compounds including PcBs
 - (b) Organophosphorus compounds
 - (d) Chemical elements
 - (d) Mycotoxins
 - (e) Dyes
 - (f) Others

⁽¹⁾ Including unlicensed substances which could be used for veterinary purposes.