COMMISSION DECISION

of 23 February 1998

laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products

(Text with EEA relevance)

(98/179/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC [1], and in particular the second subparagraph of Article 15(1) thereof,

Whereas the procedures set up by the competent authorities of the Member States responsible for sampling and treatment of samples until they reach the laboratory responsible for analysis have a direct and immediate bearing on the presence of illegal substances in samples and the possibilities for detecting the residues of certain substances; whereas such procedures are therefore an important stage in the residue monitoring plan;

Whereas in order to improve the effectiveness of the monitoring plans implemented each year by the Member States for the detection of certain substances and residues thereof in live animals and animal products, and in order to ensure the comparability of the results obtained, detailed rules for sampling should be laid down and harmonised;

Whereas samples must be taken in accordance with Annexes III and IV to the abovementioned Directive; whereas, in this respect, the targeting criteria for sampling must also be specified;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

The detailed rules for official sampling, including the targeting criteria, are set out in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 23 February 1998.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 125, 23. 5. 1996, p. 10.

ANNEX

Rules for official sampling procedures and official sample treatment

1. **Responsibilities**

1.1. *Inspector*

Official inspectors shall be designated by the competent authority for taking, registering, preparing and organising the transport of the official control samples under appropriate condition.

1.2. *Approved laboratories*

The analysis of the samples shall be carried out exclusively by the laboratories approved for official residue control by the competent authority.

Participation in an internationally recognised external quality control assessment and accreditation scheme is required for authorised laboratories. The accreditations must be obtained before 1 January 2002.

These laboratories must prove their competence by regularly and successfully participating in adequate proficiency testing schemes recognised or organised by the national or community reference laboratories.

2. **Sampling**

2.1. *Fundamental aspects*

Whenever official samples are taken, sampling must be unforeseen, unexpected and effected at no fixed time and on no particular day of the week — the Member States must take all the precautions necessary to ensure that the element of surprise in the checks is constantly maintained.

Sampling shall be carried out in variable intervals spread over the whole year at the establishments mentioned in paragraph 1 of Annex III of Council Directive 96/23/EC [1]. In this context it has to be considered that a number of substances is administered only in particular seasons.

Without prejudice of the regulations of the residue control plan, other available information shall be taken into consideration when choosing the samples, e.g. the use of presently unknown substances, diseases suddenly appearing in particular regions, indications of fraudulent activities etc.

2.2. *Sampling strategy*

The residue control plan is aimed at:

(a) detecting all illegal treatment, as defined in Article 2(b) of Directive 96/23/EC;

(b) controlling the compliance with the MRLs for residues of veterinary drugs fixed in Annex I and III of Council Regulation (EEC) No 2377/90 [2] and the maximum levels of pesticides fixed in in Annex II of Council Directive 86/363/EEC [3] or national regulations on environmental contaminants;

(c) surveying and revealing the reasons for residue in food of animal origin;

2.3. *Collection of the samples*

2.3.1. Definitions

2.3.1.1. Targeted sample

Targeted sample is a sample which is taken in accordance with the sampling strategy as defined in 2.2 above.

[1] OJ L 125, 23. 5. 1996, p. 10.
[2] OJ L 224, 18. 8. 1990, p. 1.
[3] OJ L 221, 7. 8. 1989, p. 43.

2.3.1.2. Suspect sample

Suspect sample is a sample which is taken:

— as a consequence of positive results of sample taken in accordance with the requirements of Article 5 of Directive 96/23/EC,

— as a consequence of Article 11,

— as the requirements of Article 24.

2.3.1.3. Random sample

A random sample is a sample which is taken under statistical consideration to provide representative data.

2.3.2. On farm targeted sampling

2.3.2.1. Criteria for the selection of targeted sample

Farms for on farm sampling can be chosen using local knowledge or any other relevant information such as type of fattening system, breed and sex of animal. The inspector then makes an assessment of all the stock on the farm to select those animals to be sampled. In making this assessment the following criteria should be applied *inter alia:*

— indication of use of pharmacological active substances,

— secondary sexual characteristics,

— behavioural changes,

— the same level of development in a group of animals of different breed/categories,

— animals with good conformation and little fat.

2.3.2.2. Type of targeted sample to be collected

For the detection of pharmacological active substances the corresponding suitable samples are taken according to the provisions in the residue control plan.

2.3.3. Targeted sampling at primary processing establishments

2.3.3.1. Criteria for the selection

In making their assessment on the animal carcases and/or the animal products to be sampled the inspector should apply the following criteria *inter alia:*

— sex, age, species, and farming system,

— information about the producer,

— indication of use of pharmacological active substances,

— common practice with regards to the administration of particular pharmacological active substances in the respective farm production system.

When taking the samples, efforts should be made to avoid multiple sampling from one producer.

2.3.3.2. Type of samples collected

For the detection of pharmacological active substances the corresponding suitable samples are taken according to the provisions in the residue control plan.

2.4. *Sample quantity*

The minimum sample quantities must be defined in the national residue control plan. It must be sufficient to enable the approved laboratories to carry out the analytical procedures necessary to complete the screening and the confirmatory analyses.

2.5. *Division into sub-samples*

Unless technically impossible or not required by national legislation, each sample must be divided into at least two equivalent sub-samples each allowing the complete analytical procedure. The subdivision can take place at the sampling location or in the laboratory.

2.6. *Samples containers*

Samples must be collected in suitable containers to maintain sample integrity and traceability. In particular, containers must prevent substitution, cross-contamination and degradation. The containers must be officially sealed.

2.7. *Sampling report*

A report shall be produced after each sampling procedure.

The inspector collects at least the following data in the sampling report:

— address of the competent authorities,

— name of the inspector or identification code,

— official code number of the sample,

— sampling date,

— name and address of the owner or the person having charge of the animals or the animal products,

— name and address of the animal's farm of origin (when sampling on farm),

— registration number of the establishment-slaughterhouse number,

— animal or product identification,

— animal species,

— sample matrix,

— medication within the last four weeks before sampling (when sampling on farm),

— substance or substance groups for examination,

— particular remarks.

Copies of the report are to be foreseen depending on the sampling procedure. The sampling report and its copies shall be signed at least by the inspector: in case of on-farm sampling, the farmer or his deputy may be invited to sign the original sampling report.

The original of the sampling report remains at the competent authority, which has to guarantee that unauthorised persons cannot access this original report.

If necessary, the farmer or the owner of the establishment may be informed of the sampling undertaken.

2.8. *Laboratory report*

The laboratory report established by the competent authorities contains at least the following information:

— address of the competent authorities,

— name of inspector of identification code,

— official code number of the sample,

— sampling date,

— animal species,

— sample matrix,

— substances or substance groups for examination,

— particular remarks.

This report is handed over to the routine laboratory together with the samples.

2.9. *Transport and storage*

Residue control plans shall specify the suitable storage and transport conditions for each analyte/matrix combination to ensure analyte stability and sample integrity. Specific attention must be paid to transport boxes, temperature and delivery times to the responsible laboratory.

In case of any non-compliance with the requirements of the control plan the laboratory shall inform the competent authority without delay.