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PART I/III

COMMISSION STAFF WORKING DOCUMENT

on the implementation of national residue monitoring plans in the Member States in 2011 (Council Directive 96/23/EC)

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The aim of this document is to communicate to the European Parliament and to the Council of the European Union a summary of the Member States' findings and actions taken as a consequence of the non-compliant results found in food of animal origin through the implementation of *Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products* during 2011.

(1) Introduction

Council Directive 96/23/EC[1] on measures to monitor certain substances and residues thereof in live animals and animal products requires Member States to adopt and implement a national residue monitoring plan for specific groups of residues. Member States must assign the task of co-ordinating the implementation of the controls to a central public department or body. This department is responsible for drawing up the national plan, co-ordinating the activities of the central and regional departments responsible for monitoring the various residues, collecting the data and sending the results of the surveys undertaken to the Commission each year.

The Directive lays down specific sampling levels and frequencies, as well as the groups of substances to be monitored for each food commodity. Commission Decision 97/747/EC[2] lays down additional rules for milk, eggs, honey, rabbits and game.

National monitoring plans should be targeted: samples should be taken with the aim of detecting illegal treatment or controlling compliance with the maximum residue limits (MRLs) for veterinary medicinal products set out in Table I in the Annex to Commission Regulation (EU) No 37/2010[3], the maximum levels for pesticides set out in Regulation (EC) No 396/2005[4] or the maximum levels laid down in relevant legislation on contaminants. This means that in the national plan the Member States target the groups of animals/gender/age combinations where the probability of finding residues is the highest. This approach is different from random sampling, where the objective is to gather statistically significant data, for instance to evaluate consumer exposure to a specific substance.

Member States must forward annually to the Commission the national monitoring plans, together with the results of their residue monitoring for the previous year, by 31 March at the latest. The Directive lays down a procedure by which the plans are approved on a yearly basis. This procedure involves the Member States.

(2) Results

As laid down in Article 8 of Directive 96/23/EC, the Commission has to report to the Member States, within the Standing Committee on the Food Chain and Animal Health, the outcome of the checks carried out, in particular on the implementation of

1 OJ L 125, 29.4.1996, p. 10-24.
2 OJ L 303, 6.11.1997, p. 12-15.
3 OJ L 15, 20.1.2010, p. 1.
4 OJ L 70, 16.3.2005, p. 1-16.

the national plans and on the development of the situation in the various regions of the Community. To this end, the Commission has summarised the results of the national residue monitoring plans for the year 2011. Trends within the European Union are also indicated by comparison with previous reports. These aspects were presented to the Member States in the Standing Committee on the Food Chain and Animal Health – section toxicological safety held on 26 November 2012.

Part II/III of this document is a compilation and analysis of data of the results obtained in the Member States in 2011. This compilation and analysis of data is broken down by food commodities (bovines, pigs, sheep and goats, horses, poultry, rabbit, farmed game, wild game, aquaculture, milk, eggs and honey) and groups of substances (hormones, corticosteroids, beta-agonists, prohibited substances, antibacterials, other veterinary medicinal products, "other" substances and contaminants).

At the request of the European Commission, the European Food Safety Authority (EFSA) produces a technical report ("*Report for 2011 on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products*") in the framework of Article 31 of Regulation (EC) No 178/2002[5]. This technical report serves as the basis for the part II/III of this document.

(3) Actions taken as a consequence of non-compliant results

In accordance with Article 8 of Directive 96/23/EC, the Member States were requested, as a follow-up, to provide information on actions taken at regional and national level. The objective is to provide an overview of actions taken as a consequence of non-compliant[6] results for residues of non-authorised substances or when the maximum residue limits (MRLs) established in EU legislation are exceeded.

In order to collect information on actions taken as a consequence of non-compliant results, the Commission sent a questionnaire to the Member States. These actions could be divided into the following three groups: sampling as suspect, modifications of the national plans for 2009 and other actions.

(a) Sampling as suspect

Suspect samples are defined as:

(1) samples taken as a consequence of non-compliant results on samples taken in accordance with the monitoring plan (Article 5 of Directive 96/23/EC);

(2) samples taken as a consequence of possession or presence of prohibited substances at any point during manufacture, storage, distribution or sale throughout the food and feed production chain (Article 11 of Directive 96/23/EC);

(3) samples taken where the veterinarian suspects or has evidence of illegal treatment or non-compliance with the withdrawal period for an

5 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31/1, 1.2.2002, p. 1-24.

6 Non-compliant results correspond to the presence of a prohibited substance or to the presence of an authorised substance above the maximum level allowed in the legislation.

authorised veterinary medicinal product (Article 24 of Directive 96/23/EC).

In summary, this means that the term "suspect sample" applies to a sample taken as a consequence of:

– non-compliant results and/or

– suspicion of an illegal treatment at any stage of the food chain and/or

– suspicion of non-compliance with the withdrawal period for an authorised veterinary medicinal product.

(b) Modifications of the national plan for 2011

The national residue monitoring plan aims at detecting illegal treatment of food-producing animals, controlling compliance with the maximum residue limits for veterinary medicinal products, the maximum residue levels for pesticides and the maximum levels for contaminants. Non-compliant results for a specific substance/group of substances or a specific food commodity should result in intensified controls for this substance/group or food commodity in the plan for the following year.

(c) Other actions taken as a consequence of non-compliant results

Article 16 and Articles 22-28 of Directive 96/23/EC prescribe a series of actions (other than modifications of the residue monitoring plan) to be taken in the case of non-compliant results or infringements:

- To carry out investigations in the farm of origin, such as verification of records and additional sampling
- To hold animals in the farm as a consequence of positive findings
- To slaughter animals in case of confirmation of illegal treatment and to send them to a high risk processing plant
- To intensify the controls in the farms where non-compliant results were found
- To impound carcasses at the slaughterhouse when non-compliant results have been found
- To declare the carcasses or products of animal origin unfit for human consumption.

The changes introduced by some Member States for the 2011 plan together with the responses of the Member States in relation to this type of actions are summarised in **Part III/III** of this document.