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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11.8.2009
COM(2009) 424 final

2009/0117 (CNS)

Proposal for a

COUNCIL DIRECTIVE

amending Directive 2000/29/EC as regards the delegation of the tasks of laboratory testing

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

The delegation of laboratory tasks to subsidiary bodies in the context of official controls to be performed by the competent authorities of the Member States in the plant health area (Article 2(1)(g)(ii) of Directive 2000/29/EC¹) has become a recurrent subject of discussion these last years between the Member States and the Commission.

On several occasions, Member States mentioned the difficulties to re-organise their national plant protection services in light of the current provisions of EU plant health legislation which require the bodies to which the laboratory tasks may be delegated to be charged exclusively with specific public functions.

The provisions for delegation were introduced in the Directive in 1991. Since then, the structure and tasks of the plant health authorities of the Member States have evolved. In several Member States the organisations to which the official laboratory analyses could be delegated (universities and research organisations, private laboratories) would frequently not meet the requirements of Article 2(1)(g)(ii) of Directive 2000/29/EC and possible risks of conflict of interests could also show up. However, involvement of such organisations is needed for very specialised analyses for the detection and confirmation of harmful organisms that are not present in the EU and for which expertise is limited. Also, laboratory tests carried out in the framework of Directive 2000/29/EC are highly technical tasks requiring widely different technical facilities and highly specialised and scarce laboratory staff.

In order to adapt the requirements on the delegation of laboratory testing to existing needs, it appears appropriate to modify at short term Article 2(1)(g)(ii) of Directive 2000/29/EC. In a Council working Party which was held on December 2007, a majority of the Chief Plant Health officers (COPHS) supported this approach.

2. CONSULTATION OF STAKEHOLDERS AND IMPACT ASSESSMENT

A light scoping paper illustrating the issue has been produced in April 2008. Because of the limited impact of the proposed changes, no full impact assessment of the proposed changes was deemed necessary.

3. LEGAL ELEMENTS OF THE PROPOSAL

The proposed amendments to Article 2(1)(g)(ii) of Directive 2000/29/EC would include:

¹ Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community, OJ L 169, 10.7.2000, p. 1.

- A provision to allow legal persons carrying out delegated tasks to diversify their activities with other laboratory testing activities than those referred to under that Directive;
- A provision allowing delegation of laboratory testing to legal persons which are not charged exclusively with public functions in the framework of that Directive;
- In both cases, provisions ensuring that the delegated tasks provided for under the Directive remain under the authority and supervision of the responsible official bodies in a Member State and that those responsible official bodies verify that the legal persons in question are impartial and free of conflict of interest as regards the execution of the delegated tasks.

4. BUDGETARY IMPLICATIONS

This proposal for a Council Directive has no financial implications for the Community budget.

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of

amending Directive 2000/29/EC as regards the delegation of the tasks of laboratory testing

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,²

Whereas:

- (1) Under Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community³ the responsible official bodies in the Member States may only delegate the tasks provided for in that Directive, including laboratory testing, to a legal person which under its officially approved constitution is charged exclusively with specific public functions.
- (2) The laboratory tests which have to be carried out in the framework of Directive 2000/29/EC are of a highly technical nature and concern different scientific fields. Such tests require a wide range of different and expensive technical facilities and highly specialised laboratory staff capable of adapting to the rapid development of diagnostic methodology. The number of tests to be carried out has been growing over recent years. As a result, it has grown increasingly difficult to find legal persons fulfilling all the necessary requirements.
- (3) For these reasons it is appropriate to provide that the numerous and diverse laboratory tests required under Directive 2000/29/EC may, in addition to legal persons which are exclusively charged with specific public functions, be delegated to legal persons not fulfilling this requirement, such as universities, research institutes or private laboratories, provided that they satisfy certain conditions.

² OJ C [...], [...], p. [...].

³ OJ L 169, 10.7.2000, p. 1.

- (4) At the same time it is appropriate to allow legal persons carrying out delegated tasks in accordance with Directive 2000/29/EC to use their laboratories for testing activities which do not form part of their specific public functions.
- (5) Article 2(1)(g) of Directive 2000/29/EC should therefore be amended accordingly.

HAS ADOPTED THIS DIRECTIVE:

Article 1

The second subparagraph of Article 2(1)(g) of Directive 2000/29/EC shall be replaced by the following:

'The responsible official bodies in a Member State may, in accordance with national legislation, delegate the tasks provided for in this Directive to be accomplished under their authority and supervision to a legal person, whether governed by public or by private law, provided that such person, and its members, has no personal interest in the outcome of the measure it takes. The responsible official bodies in the Member States shall ensure that such a legal person is, under its officially approved constitution, charged exclusively with specific public functions, with the exception of laboratory testing which such a legal person may perform even where it is not part of its specific public functions.

However, notwithstanding the second sentence of the second subparagraph, the responsible official bodies in a Member State may delegate the laboratory testing provided for in this Directive to a legal person which does not comply with that provision, provided that the responsible official body concerned shall ensure throughout the time of the delegation that the legal person to which it delegates laboratory testing remains impartial and that no conflict of interest exists between the exercise of the tasks delegated to it and its other activities.'

Article 2

Member States shall adopt and publish, by 30 June 2010 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 July 2010.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such a reference is to be made.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

*For the Council
The President*