

DIRECTIVES

COUNCIL DIRECTIVE 2009/143/EC

of 26 November 2009

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 ⁽¹⁾,

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 Community ⁽²⁾ 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 in any legal form recognised in the Member State in accordance with their national legislation, provided that they satisfy certain conditions.

(4) It is appropriate that the responsible official bodies verify that the legal persons, to which the execution of the

laboratory testing is delegated, can assure quality. They should for example be impartial, free of conflict of interest and able to ensure reliable results and protection of confidential information.

(5) 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.

(6) The issue of an appropriate diagnostic infrastructure is one of the issues addressed in the ongoing evaluation of the plant health legislation. However, without prejudice to the outcome of the review, it is appropriate in the short term to modify the requirements on the delegation of laboratory testing to existing needs.

(7) The second subparagraph of Article 2(1)(g) of Directive 2000/29/EC should therefore be amended accordingly.

(8) In accordance with point 34 of the Interinstitutional agreement on better law-making ⁽³⁾, Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public,

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 private law, provided that such person, and its members, has no personal interest in the outcome of the measure it takes.

⁽¹⁾ Opinion of 20 October 2009 (not yet published in the Official Journal).

⁽²⁾ OJ L 169, 10.7.2000, p. 1.

⁽³⁾ OJ C 321, 31.12.2003, p. 1.

The responsible official bodies in the Member States shall ensure that the legal person referred to in the second subparagraph is, under its officially approved constitution, charged exclusively with specific public functions, with the exception of laboratory testing which such legal person may perform even where the laboratory testing does not form part of its specific public functions.

Notwithstanding the third 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.

The laboratory testing may only be delegated if the responsible official body ensures throughout the time of the delegation that the legal person to which it delegates laboratory testing can assure impartiality, quality and protection of confidential information, 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 bring into force the laws, regulations and administrative provisions necessary to comply with this

Directive before 1 January 2011. They shall forthwith inform the Commission thereof.

When they are adopted by Member States, those measures shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 26 November 2009.

For the Council

The President

J. BJÖRKLUND
