Press and Information Division

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Judgment of the Court in Case C-236/01

Monsanto Italia SpA and Others v *Presidenza del Consiglio dei Ministri*

THE MERE PRESENCE OF RESIDUES OF TRANSGENIC PROTEIN IN NOVEL FOODS DOES NOT PREVENT THEIR BEING PLACED ON THE MARKET UNDER A SIMPLIFIED PROCEDURE PROVIDED THERE IS NO RISK TO HUMAN HEALTH

However, if a Member State has detailed grounds to suspect such a risk, it may temporarily restrict or suspend the trade in and use of the food in question in its territory

The Community regulation relating to novel provides that foods which are produced from genetically modified organisms *but no longer contain them* may be placed on the market within the Community under a "simplified" procedure, which requires merely that a notification be made to the Commission, if they are *substantially equivalent* to comparable traditional foods: proof of which can be given by a national food assessment body.

Monsanto Europe SA and other undertakings active in the development of genetically modified food plants for use in agriculture had obtained authorisations from France and the United Kingdom to market certain genetically modified maize grain (Bt-11 and MON 810). Genetically modified maize is resistant to certain insects and herbicides.

In 1997 and 1998 Monsanto and Others notified the Commission, under the "simplified procedure", of their intention to market products derived from genetically modified maize, such as cornflour.

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1 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ 1997 L 43, p. 1).

The competent UK authority for food assessment had previously concluded that those foods were *substantially equivalent* to conventional foods. The Commission forwarded those notifications to the Member States.

In 2000, an Italian scientific institute noted the presence of residues of transgenic protein (expressed by the inserted gene) in the flour in question but did not consider that they posed any risk to human health.

The Italian Republic – in the light of the differing opinions put forward by Italian scientific bodies – had concerns as regards the safety of the products. It therefore adopted a decree on 4 August 2000 providing for the precautionary suspension of the trade in and use of products derived from those maize lines. Monsanto and Others subsequently challenged the Italian decree, which they considered to be in breach of Community law.

The Administrative Court of Lazio accordingly asked the Court of Justice of the European Communities whether novel foods which contain residues of transgenic protein at certain levels can be considered substantially equivalent to existing foods and may consequently be marketed under the simplified procedure.

The Court of Justice first observes that the Community regulation concerning novel foods has a twofold objective:

– to ensure the functioning of the internal market in novel foods, and

– to protect public health.

The Regulation characterises as "substantially equivalent to existing foods" those foods which present differences in composition but have no effect on public health.

Substantial equivalence is assessed by specialised bodies on the basis of the scientific evidence available, prior to the novel food being placed on the market: it does not require the risk assessment laid down under the normal procedure. On the other hand, **the absence of substantial equivalence does not imply that the food is unsafe but merely that it should be subject to risk assessment.**

The Court considers that in no case should the simplified procedure lead to a relaxation of the safety requirements that must be met by novel foods.

The Court nevertheless points out that certain differences in the composition of novel foods do not prevent their being deemed substantially equivalent: on the contrary, they must be specifically **mentioned on the labelling**.

It is for the Italian national court to decide whether the novel foods are substantially equivalent to existing foods in the light, *inter alia*, of the Court's ruling on the interpretation of Community law.

The Court finds that where use of the simplified procedure is not warranted, **a Member State can** – as a preventive measure – **temporarily restrict or suspend the marketing** of those foods in its territory (under the "safeguard clause" laid down in the Regulation) **without first being required to challenge the lawfulness of the procedure.**

Demonstration of the existence of a risk to health can justify the adoption of such a measure: in that case, the risk must not be purely hypothetical or be founded on mere suppositions which are not yet verified; the State must base its action on detailed grounds and not on reasons of a general nature.

The safeguard clause reflects the precautionary principle and allows protective measures to be taken without having to wait until the reality and seriousness of risks become fully apparent, even if a full risk assessment proves impossible because of the inadequate nature of the scientific data available.

In the framework of close cooperation between the Commission and the Member States, the initial assessment of substantial equivalence by a scientific body of a Member State is subject to verification at Community level. Similarly, the protective measure adopted by the Member State under the safeguard clause is subject to verification at Community level.

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