

Press and Information Division

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Opinion of Advocate General Alber in Case C-236/01

Monsanto Agricoltura SpA and Others v Presidenza del Consiglio dei ministri and Others

THE ADVOCATE GENERAL CONSIDERS THAT NOVEL FOODS MAY BE PLACED ON THE MARKET UNDER A SIMPLIFIED PROCEDURE EVEN WHEN THEY CONTAIN TRACES OF TRANSGENIC PROTEIN, PROVIDED THEY ARE ABSOLUTELY SAFE IN TERMS OF HEALTH

The Member States may, however, adopt protective measures when there are detailed grounds for considering that the use of the food at issue endangers human health or the environment.

In 1997 and 1998 Monsanto Europe S.A. and two other companies placed on the market under the so-called simplified procedure foods, in particular flour, derived from genetically modified maize. The competent United Kingdom food authority had previously certified that the products in question were *substantially equivalent* to traditional foods. The Italian Republic, however, entertained doubts as to the absolute safety of the products and imposed a provisional prohibition on the marketing and use of products derived from the notified maize lines.

Monsanto and Others thereupon challenged the pertinent Italian decree, on the ground that it infringed Community law.

Foods which are produced from genetically modified organisms *but no longer contain them* may, under Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, be placed on the Community market under a simplified procedure without prior authorisation by the Commission. A further condition for the use of the simplified procedure is that the novel food be *substantially equivalent* to comparable traditional food, which can be demonstrated by means of an authorisation from a national food assessment body.

In the present case, genes were inserted into maize which render it resistant to certain herbicides and pests. The genetically modified DNA is destroyed during the processing of the cornmeal, giving rise to a food which is derived from genetically modified organisms but no longer contains them, since no organism capable of growth any longer exists in the flour.

Nevertheless, the cornmeal still contains a very small amount of transgenic protein (a product of the inserted gene), which, however – as far as is known – poses no risk whatsoever to human health.

The Tribunale Amministrativo Regionale del Lazio, before which the dispute over the Italian decree was brought, referred a series of questions to the Court of Justice for a preliminary ruling.

Advocate General Alber has delivered his Opinion in this case today.

The view of the Advocate General is not binding on the Court of Justice. The task of the Advocate General is to propose to the Court, in complete independence, a legal solution to the case concerned.

According to the Advocate General, the first question put by the national court seeks an **interpretation of the concept of substantial equivalence**. Above all, it wishes to know whether substantial equivalence can exist even when foods continue to contain traces of transgenic protein.

An interpretation based on the spirit and purpose of the Community regulation and taking into account the legislative context leads, in the opinion of the Advocate General, to the conclusion that novel foods are to be considered substantially equivalent to traditional foods and may accordingly be placed on the market using a simplified procedure, **even where they continue to contain traces of transgenic protein, provided it has been demonstrated that those substances do not pose any risk to the consumer**.

The Italian court also wishes to know **to what extent the Member States are entitled to take protective measures of their own** where doubts exist as to the substantial equivalence of novel foods with conventional foods.

The Advocate General concludes, in that connection, that the Italian Government was entitled to adopt provisional measures on the basis of Regulation No 259/93, provided that it had **detailed grounds for considering, as a result of new information or a reassessment of existing information, that the use of the food in question endangers human health or the environment**. Those measures may be maintained until the Commission or the Council adopts a decision as regards the validity of the grounds put forward, which has not yet occurred.

The Advocate General points out that the Commission and the Member States agreed, in the light of concerns and criticism, no longer to use the simplified procedure, with effect from January 1998, for products derived from genetically modified organisms. Moreover, the Commission's 2001 proposal for a new regulation no longer provides for a simplified procedure.

Note: *The judges of the Court of Justice will now begin their deliberation on the case. The judgment will be delivered at a later date.*

Unofficial document for media use; not binding on the Court of Justice.

Available in German, English, French, Italian and Spanish.

*For the full text of the Opinion, please consult our internet page
www.curia.eu.int
at approximately 3 pm today.*

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