JUDGMENT OF 9. 9. 2003 — CASE C-236/01

JUDGMENT OF THE COURT

9 September 2003 *

Monsanto Agricoltura Italia SpA and Others

V

Presidenza del Consiglio dei Ministri and Others,

Keywords

1. Approximation of laws — Novel foods and novel food ingredients — Placing on the market — Simplified procedure — Substantial equivalence to existing foods — Concept — Use of that procedure notwithstanding the presence of residues of transgenic protein in novel foods — Whether permissible — Limits — Potential risks to human health — (Regulation No 258/97 of the European Parliament and of the Council, Art. 3(4), first subpara.)

2. Approximation of laws — Novel foods and novel food ingredients — Placing on the market — Simplified procedure — Procedure not covered by consent, even tacit, by the Commission — Member States ' right of recourse to the safeguard clause where use of that procedure is not warranted — Need for a preliminary challenge to such consent — Not required — (Regulation No 258/97 of the European Parliament and of the Council, Art. 5 and Art. 12(1))

3. Approximation of laws — Novel foods and novel food ingredients — Placing on the market — Member States ' right of recourse to the safeguard clause regardless of the procedure followed for placing on the market and its validity — (Regulation No 258/97 of the European Parliament and of the Council, Art. 3(4), second subpara. and Arts 5, 12 and 13)

4. Approximation of laws — Novel foods and novel food ingredients — Placing on the market — Use of the safeguard clause — Justification — Potential risks to human health — Burden of proof — (Regulation No 258/97 of the European Parliament and of the Council, Arts 3(1) and 12)

5. Approximation of laws — Novel foods and novel food ingredients — Placing on the market — Simplified procedure — Condition of substantial equivalence

— Detailed rules sufficient to ensure a high level of protection for human health and the environment — Compliance with the precautionary principle and the principle of proportionality — Validity — (Arts 152(1) EC and 174(2) EC; Regulation No 258/97 of the European Parliament and of the Council, Art. 3(4), first subpara., and Art. 5)

Summary

1. The first subparagraph of Article 3(4) of Regulation No 258/97 concerning novel foods and novel food ingredients must be interpreted as meaning that the mere presence in novel foods of residues of transgenic protein at certain levels does not preclude those foods from being considered substantially equivalent to existing foods and, consequently, use of the simplified procedure for placing those foods on the market. However, that is not the case where the existence of a risk of potentially dangerous effects on human health can be identified on the basis of the scientific knowledge available at the time of the initial assessment.

The concept of substantial equivalence does not preclude novel foods which display differences in composition that have no effect on public health from being considered substantially equivalent to existing foods. The concept does not in itself involve a safety assessment, but rather constitutes an approach for comparing the novel food with its conventional counterpart in order to determine whether it should be subject to such an assessment as regards, in particular, its unique composition and properties. The absence of substantial equivalence does not necessarily imply that the food in question is unsafe, but simply that it should be subject to that assessment.

The concept concerned, moreover, is applied by specialised scientific bodies charged with assessing the risks inherent in novel foods and it must, more precisely, be understood as a specific method concerning novel foods, relating to the identification of hazards which comprises the first stage in scientific risk assessment, namely the identification of the biological, chemical and physical agents liable to give rise to adverse health effects which may be present in a given food or group of foods and which call for scientific assessment in order better to understand them.

see paras 74, 77-79, 84, operative part 1

2. The absence of a reaction by the Commission when the simplified procedure is used for the purpose of placing novel foods on the market in accordance with Article 5 of Regulation No 258/97 concerning novel foods and novel food ingredients cannot be characterised as tacit consent on its part to the marketing of novel foods, since its role in such a procedure is limited to receiving, forwarding and publishing notifications of the placing on the market of those novel foods.

If the use of the simplified procedure is not warranted because of the absence of substantial equivalence between novel foods and existing foods, a Member State may have recourse to the safeguard clause provided in Article 12(1) of Regulation No 258/97 in so far as the conditions for its use are met and it is not first required to challenge the lawfulness of any, even tacit, consent by the Commission.

see para. 100

3. The validity of the use of the simplified procedure for the placing on the market of novel foods in accordance with Article 5 of Regulation No 258/97 concerning novel foods and novel food ingredients does not, in principle, affect the power of the Member States to take safeguard measures which fall within Article 12 of the Regulation. The applicability of the safeguard clause is not defined by the type of procedure which was followed prior to the placing on the market of the novel foods or, in principle, by the validity of the procedure which was followed.

The validity of recourse to the safeguard clause by a Member State on the ground that there is no substantial equivalence in the composition of a novel food cannot be affected by the sole fact that that Member State had recourse to the safeguard clause without the Community procedure specifically designed to verify the advance determination of substantial equivalence, envisaged in the second subparagraph of Article 3(4) and Article 13 of the Regulation, having first been applied, since that ground can be verified at Community level in accordance with Articles 12(2) and 13 of the Regulation.

see paras 102-104, 114, operative part 2

4. Protective measures adopted under the safeguard clause laid down in Article 12 of Regulation No 258/97 concerning novel foods and novel food ingredients may not properly be based on a purely hypothetical approach to risk, founded on mere suppositions which are not yet scientifically verified. Such measures can be adopted only if they are based on a risk assessment which is as complete as possible in the particular circumstances of an individual case, which indicate that those measures are necessary in order to ensure that novel foods do not present a danger for the consumer, in accordance with the first indent of Article 3(1) of the Regulation.

As regards the burden of proof, the reasons put forward by the Member State concerned, such as result from a risk assessment, cannot be of a general nature. None the less, in the light of the limited nature of the initial safety analysis of novel foods under the simplified procedure and of the essentially temporary nature of measures based on the safeguard clause, the Member State satisfies the burden of proof on it if it relies on evidence which indicates the existence of a specific risk which those novel foods could involve.

Given that the safeguard clause must be understood as giving specific expression to the precautionary principle, the conditions for the application of that clause must be interpreted having due regard to this principle. Therefore, such protective measures may be taken even if it proves impossible to carry out as full a risk assessment as possible in the particular circumstances of a given case because of the inadequate nature of the available scientific data and presuppose that the risk assessment available to the national authorities provides specific evidence which, without precluding scientific uncertainty, makes it possible reasonably to conclude on the basis of the most reliable scientific evidence available and the most recent results of international research that the implementation of those measures is necessary in order to avoid novel foods which pose potential risks to human health being offered on the market.

see paras 106-110, 112-114, operative part 2

5. Consideration of Article 5 of Regulation No 258/97 concerning novel foods and novel food ingredients, which lays down a simplified procedure for placing novel foods on the market, does not, in particular as regards the condition for substantial equivalence within the meaning of the first subparagraph of Article 3(4) of the Regulation, disclose factors such as to affect its validity as regards whether it is coupled with detailed rules sufficient to ensure a high level of protection of human health and the environment within the meaning of Articles 152(1) EC and 174(2) EC, respectively, and to guarantee compliance with the precautionary principle and the principle of proportionality. First, if such dangers for human health or the environment are identifiable, the simplified procedure may not be used, since a more comprehensive risk assessment is then required, which must be carried out under the normal procedure; secondly, the recognition in advance of substantial equivalence may subsequently be reassessed by means of various procedures at both national and Community level.

see paras 128-129, 138-139, operative part 3