

Case T-257/07 R

French Republic

v

Commission of the European Communities

(Application for interim measures — Health measures —
Regulation (EC) No 999/2001 — Eradication of certain transmissible
spongiform encephalopathies — Regulation (EC) No 727/2007 —
Application for suspension of operation — Prima facie case —
Urgency — Balancing of interests)

Order of the judge hearing the application for interim measures, 28 September
2007 II - 4159

Summary of the Order

1. *Agriculture — Common agricultural policy — Implementation — Measures to protect human health*
(Art. 174 EC)
2. *Applications for interim measures — Suspension of operation — Conditions for granting — Prima facie case*
(Art. 242 EC; Commission Regulation No 999/2001)

3. *Applications for interim measures — Suspension of operation — Conditions for granting — Prima facie case*
(Art. 242 EC; Commission Regulation No 999/2001)
4. *Applications for interim measures — Suspension of operation — Conditions for granting — Urgency — Serious and irreparable damage*
(Art. 242 EC; Commission Regulation No 999/2001)
5. *Applications for interim measures — Suspension of operation — Conditions for granting — Weighing-up of all the interests at stake*
(Art. 242 EC)

1. In accordance with Article 174 EC, the precautionary principle is one of the principles on which is founded the Community policy on the environment, which includes the policy relating to the protection of human health, and the principle also applies where the Community institutions take, in the framework of the common agricultural policy, measures to protect human health.

which has the power of legislative initiative, to bring about an amendment to the rules in the light of the new information. Thus, the Community institutions may adopt less restrictive measures than the existing measures when such measures are capable of containing a risk the perception of which has been changed by new elements.

Under that principle, where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent. On the other hand, when new elements change the perception of a risk or show that that risk can be contained by less restrictive measures than the existing measures, it is for the institutions and in particular the Commission,

The Community legislature is allowed a broad discretion in this area, which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments. In that regard, review by the Community judicature of the substance of the relevant act must be confined to examining whether the exercise of such discretion is vitiated by

a manifest error or a misuse of powers or whether the Community institutions clearly exceeded the bounds of their discretion.

(see paras 60, 61, 66, 67)

2. In order to determine whether the condition for establishing a *prima facie* case is satisfied in a particular case, where in support of the main action an allegation is put forward of infringement by the Commission due to an error in the risk assessment by virtue of the adoption of Regulation No 727/2007 amending Annexes I, III, VII and X to Regulation No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSE), which introduces a relaxation of the health measures applicable to a flock of ovine or caprine animals in which a case of TSE has been detected, it is necessary to carry out a *prima facie* examination of the substance of that plea in law and therefore to ascertain whether the arguments concerning the alleged infringement are so weighty that they cannot be ruled out in proceedings for interim measures.

Since a 'zero risk' cannot actually exist, the precautionary principle can there-

fore apply only in situations in which there is a risk, in particular to human health, which, although it is not founded on mere hypotheses that have not been scientifically confirmed, has not yet been fully demonstrated. Thus, in a situation in which the precautionary principle is applied, which by definition coincides with a situation in which there is scientific uncertainty, a risk assessment cannot be required to provide the Community institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality.

Where it may be considered, at least *prima facie*, that genuine scientific uncertainties persist with regard, on the one hand, to the possibility that TSE responsible agents of animal origin, other than bovine spongiform encephalopathy agents, may be transmissible to humans and, on the other hand, to the reliability of the discriminatory tests, the claim that the advance of scientific knowledge concerning TSE in small ruminants does not alter the perception of the risk represented by those diseases to public health is not without substance. In those circumstances, the claim that the Commission infringed the precautionary principle by committing an

error in the risk management requires an in-depth examination which may be carried out only by the court adjudicating on the merits.

(see paras 59, 65, 79, 85, 86)

3. The scientific risk assessment must enable the competent authority to decide, in relation to risk management, which measures appear to it to be appropriate and necessary to prevent the risk from materialising. It appears, therefore, that the relevance of the risk assessment is crucial to an appraisal of the management of that risk.

In adopting Regulation No 727/2007 amending Annexes I, III, VII and X to Regulation No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSE), the Commission introduced a relaxation of the health measures applicable to the flock of ovine or caprine animals in which a TSE case has been detected by means of an initial rapid test.

It may be considered, at least *prima facie*, that the opinions of the scientific authorities in the area express genuine scientific uncertainties regarding the circumstances in which TSEs other than BSE may be transmissible to humans and that, at the current stage of scientific knowledge, it cannot be ruled out that the consumption of meat and products obtained from animals infected by TSEs other than BSE present a risk to human health. Those opinions also appear to express genuine scientific uncertainties with regard to the reliability of the discriminatory tests aimed at eliminating the possibility of cases of BSE, which means that meat and products obtained from animals carrying undetected BSE strains may be put on the market, which represents a real danger to human health.

In those circumstances, the applicant's claim that those provisions do not make it possible to contain the risk which the TSEs represents for human health and are even likely to aggravate it does not seem, at least *prima facie*, irrelevant. Therefore, the claim that the Commission infringed the precautionary principle by committing an error in the risk management requires an in-depth examination which falls which may be carried

out only by the court adjudicating on the merits.

(see paras 88, 89, 107, 108, 116)

4. The purpose of proceedings for interim relief is to ensure the full effectiveness of the definitive future decision, in order to ensure that there is no lacuna in the legal protection provided by the Community judicature. To attain that objective, the urgency of an application for the adoption of interim measures must therefore be assessed in the light of the extent to which an interlocutory order is necessary in order to avoid serious and irreparable damage to the party seeking the adoption of the interim measure.

Where the authorities of a Member State, which are responsible for the public interest in connection with the protection of public health, request suspension of the operation of provisions of Regulation No 727/2007 amending Annexes I, III, VII and X to Regulation No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSE), introduced a relaxation of the health measures applicable to the flock of ovine or caprine animals in which a TSE case has been detected, owing to the risk to human health resulting from their implementation, it is necessary to take into consideration, when assessing

urgency, the fact that, in the light of the information available to the judge hearing the application for interim measures, the factual and legal arguments presented by that Member State in support of the *fumus boni juris* appear serious and that it is therefore possible that meat or meat products from animals infected by a TSE will be released for human consumption.

Therefore the condition for urgency is satisfied in this case.

(see paras 122, 127, 128, 133)

5. In proceedings for interim measures, it is for the judge hearing the application, when weighing the various interests at stake, to examine whether the annulment of the contested measure by the Court giving judgment in the main action would make it possible to reverse the situation that would have been brought about by its immediate implementation and conversely whether suspension of the operation of that measure would be such as to prevent its being fully effective in the event of the main application being dismissed.

In that regard that, as a rule, there can be no question but that the requirements of the protection of public health must take precedence over economic considerations. It follows that, where a serious risk to human health is invoked by a defendant Community institution, the Judge hearing the application for interim relief, notwithstanding his formal discre-

tion in balancing the interests, will almost inevitably lean in favour of protecting public health.

(see paras 140, 141)