JUDGMENT OF THE COURT (Sixth Chamber)

20 November 2003 *

In Case C-296/01,

Commission of the European Communities, represented by G. zur Hausen, acting as Agent, M. van der Woude and V. Landes, avocats, with an address for service in Luxembourg,

applicant,

v

French Republic, represented by G. de Bergues and R. Loosli-Surrans, acting as Agents, with an address for service in Luxembourg,

defendant,

APPLICATION for a declaration that, by failing to transpose correctly and fully Articles 5(1) to (4), 6(2) and (5), 9(3), 11(1), (2), (3) and (6), 12(3) and (4) and 19(2), (3) and (4) of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms

* Language of the case: French.

(OJ 1990 L 117, p. 15), as amended by Commission Directive 97/35/EC of 18 June 1997 adapting to technical progress for the second time Directive 90/220 (OJ 1997 L 169, p. 72), the French Republic has failed to fulfil its obligations under that directive and Article 249 EC,

THE COURT (Sixth Chamber),

composed of: J.-P. Puissochet, President of the Chamber, R. Schintgen, V. Skouris, N. Colneric (Rapporteur) and J.N. Cunha Rodrigues, Judges,

Advocate General: J. Mischo,
Registrar: R. Grass,

having regard to the report of the Judge-Rapporteur,

after hearing the Opinion of the Advocate General at the sitting on 22 May 2003,

gives the following

Judgment

1 By application lodged at the Court Registry on 25 July 2001, the Commission of the European Communities brought an action under Article 226 EC for a declaration that, by failing to transpose correctly and fully Articles 5(1) to (4), 6(2) and (5), 9(3), 11(1), (2), (3) and (6), 12(3) and (4) and 19(2), (3) and (4) of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ 1990 L 117, p. 15), as amended by Commission Directive 97/35/EC of 18 June 1997 adapting to technical progress for the second time Directive 90/220 (OJ 1997 L 169, p. 72) ('Directive 90/220'), the French Republic has failed to fulfil its obligations under that directive and Article 249 EC.

Legal context

Community legislation

2 According to Article 1(1) of Directive 90/220, the objective of that directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment as regards the deliberate release of genetically modified organisms into the environment and the placing on the market of products containing, or consisting of, genetically modified organisms intended for deliberate release into the environment.

3 Article 2(2) of Directive 90/220 provides that, for the purposes of the directive, 'genetically modified organism (GMO)' means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. Article 2(4) provides that, for the purposes of the directive, 'product' means 'a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market'.

4 Article 5(1) to (4) provides:

'Member States shall adopt the provisions necessary to ensure that:

(1) any person, before undertaking a deliberate release of a GMO or a combination of GMOs for the purpose of research and development, or for any other purpose than for placing on the market, must submit a notification to the competent authority referred to in Article 4(2) of the Member State within whose territory the release is to take place;

(2) the notification shall include:

(a) a technical dossier supplying the information specified in Annex II necessary for evaluating the foreseeable risks, whether immediate or delayed, which the GMO or combination of GMOs may pose to human

health or the environment, together with the methods used and the bibliographic reference to them and covering, in particular:

(i) general information including information on personnel and training,

(ii) information relating to the GMO(s),

(iii) information relating to the conditions of release and the receiving environment,

(iv) information on the interactions between the GMO(s) and the environment,

(v) information on monitoring, control, waste treatment and emergency response plans;

(b) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged;

(3) the competent authority may accept that releases of a combination of GMOs on the same site or of the same GMO on different sites for the same purpose and within a limited period may be notified in a single notification;

(4) the notifier shall include in the notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by him either inside or outside the Community.

The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing'.

5 Article 6(2) and (5) of Directive 90/220 provides:

'2. The competent authority, having considered, where appropriate, any comments by other Member States made in accordance with Article 9, shall respond in writing to the notifier within 90 days of receipt of the notification by either:

(a) indicating that it is satisfied that the notification is in compliance with this Directive and that the release may proceed, or

(b) indicating that the release does not fulfil the conditions of this Directive and the notification is therefore rejected.

...

5. If the competent authority considers that sufficient experience has been obtained of releases of certain GMOs, it may submit to the Commission a request for the application of simplified procedures for releases of such types of GMOs. The Commission shall, in accordance with the procedures laid down in Article 21, establish appropriate criteria and take a decision accordingly on each application. The criteria shall be based on safety to human health and the environment and on the evidence available on such safety.'

6 Article 9(3) of Directive 90/220 states:

'The competent authorities shall inform the other Member States and the Commission of the final decisions taken in compliance with Article 6(2).'

7 Article 11(1), (2), (3) and (6) reads as follows:

'1. Before a GMO or a combination of GMOs are placed on the market as or in a product, the manufacturer or the importer to the Community shall submit a notification to the competent authority of the Member State where such a product is to be placed on the market for the first time. This notification shall contain:

— the information required in Annex II, extended as necessary to take into account the diversity of sites of use of the product, including information on data and results obtained from research and developmental releases concerning the ecosystems which could be affected by the use of the product and an assessment of any risks for human health and the environment related

to the GMOs or a combination of GMOs contained in the product, including information obtained from the research and development stage on the impact of the release on human health and the environment;

— the conditions for the placing on the market of the product, including specific conditions of use and handling and a proposal for labelling and packaging which should comprise at least the requirements laid down in Annex III.

If on the basis of the results of any release notified under Part B of this Directive, or on substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a product do not pose a risk to human health and the environment, he may propose not to comply with one or more of the requirements of Annex III B.

2. The notifier shall include in this notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by the notifier either inside or outside the Community.

3. The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing.

...

6. If new information has become available with regard to the risks of the product to human health or the environment, either before or after the written consent, the notifier shall immediately:

— revise the information and conditions specified in paragraph 1,

— inform the competent authority, and

— take the measures necessary to protect human health and the environment.'

8 Article 12(1) to (4) of Directive 90/220 provides:

'1. On receipt and after acknowledgement of the notification referred to in Article 11, the competent authority shall examine it for compliance with this Directive, giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product.

2. At the latest 90 days after receipt of the notification, the competent authority shall either:

(a) forward the dossier to the Commission with a favourable opinion, or

(b) inform the notifier that the proposed release does not fulfil the conditions of this Directive and that it is therefore rejected.

3. In the case referred to in paragraph 2(a), the dossier forwarded to the Commission shall include a summary of the notification together with a statement of the conditions under which the competent authority proposes to consent to the placing on the market of the product.

The format of this summary shall be established by the Commission in accordance with the procedure laid down in Article 21.

In particular where the competent authority has acceded to the request of the notifier, under the terms of the last subparagraph of Article 11(1), not to comply with some of the requirements of Annex III B, it shall at the same time inform the Commission thereof.

4. If the competent authority receives additional information pursuant to Article 11(6), it shall immediately inform the Commission and the other Member States.'

9 Article 13(1), (2) and (4) of Directive 90/220 provides:

'1. On receipt of the dossier referred to in Article 12(3), the Commission shall immediately forward it to the competent authorities of all Member States together with any other information it has collected pursuant to this Directive and advise the competent authority responsible for forwarding the document of the distribution date.

2. The competent authority, in the absence of any indication to the contrary from another Member State within 60 days following the distribution date referred to in paragraph 1, shall give its consent in writing to the notification so that the product can be placed on the market and shall inform the other Member States and the Commission thereof.

...

4. Where the Commission has taken a favourable decision, the competent authority that received the original notification shall give consent in writing to the notification so that the product may be placed on the market and shall inform the other Member States and the Commission thereof.'

10 Article 19(2), (3) and (4) of Directive 90/220 states:

'2. The notifier may indicate the information in the notification submitted under this Directive, the disclosure of which might harm his competitive position, that

should therefore be treated as confidential. Verifiable justification must be given in such cases.

3. The competent authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decisions.

4. In no case may the following information when submitted according to Articles 5 or 11 be kept confidential:

— description of the GMO or GMOs, name and address of the notifier, purpose of the release and location of release;

— methods and plans for monitoring of the GMO or GMOs and for emergency response;

— the evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.'

11 As provided by Article 23(1) of Directive 90/220, the Member States were to bring into force the laws, regulations and administrative provisions necessary to comply with the directive before 23 October 1991.

National legislation

12 Law No 92-654 of 13 July 1992 on the control of the use and release of genetically modified organisms and amending Law No 76-663 of 19 July 1976 on plant classified for the protection of the environment (JORF of 16 July 1992, p. 9523) provides in Article 11:

'Any deliberate release or any coordinated programme of such releases shall be subject to prior authorisation.

Authorisations shall be issued by the administrative authority after an examination of the risks for public health or the environment posed by release. Conditions may be attached to an authorisation. An authorisation shall apply only in respect of the operation for which it has been sought.'

13 Article 15 of Law No 92-654 provides:

'The placing on the market must be the subject of prior authorisation.

Authorisations shall be issued by the administrative authority after an examination of the risks for public health or the environment posed by the placing on the market. Conditions may be attached to an authorisation. An authorisation shall apply only in respect of the use envisaged by it.'

14 Article 19 of Law No 92-654 states:

'Any person who has obtained an authorisation referred to in Articles 11 and 15 must inform the authority of any new information liable to alter the assessment of risk for public health or the environment.

Where appropriate, he shall take the measures necessary to protect public health or the environment.'

15 In accordance with the first subparagraph of Article 21(1) of Law No 92-654, an applicant for authorisation to release GMOs or to place a product on the market may indicate to the authority the information supplied in support of his application the disclosure of which might prejudice his interests or which concerns confidential matters protected by legislation. Information recognised by the administrative authority as confidential may not be disclosed to third parties.

16 By virtue of Article 31 of the Law, the detailed rules for implementation of Title III thereof, which encompasses Articles 9 to 32, are to be laid down by décret en Conseil d'État (decree adopted after being submitted to the Council of State).

17 In Decree No 95-1172 of 6 November 1995 adopted to implement Title III of Law No 92-654 so far as concerns medicinal products for human use and products referred to in Article L. 511-1(8), (9) and (10) of the Public Health Code

(JORF of 8 November 1995, p. 16360), as amended by Decree No 99-144 of 4 March 1999 (JORF of 5 March 1999, p. 3294) ('Decree No 95-1172'), Article 2(3) provides:

'The application shall be drawn up by the person responsible for the release. It shall be accompanied by a technical dossier whose content is laid down by order of the minister with responsibility for health adopted following a proposal from the Director-General of the French Health Product Safety Agency. It shall indicate information which, according to the applicant, must remain confidential.

The dossier shall include in particular:

1. all information enabling the impact of the tests on public health and the environment to be assessed;

2. the standard-form dossier intended to be forwarded to the Commission of the European Communities for information;

3. a public information sheet including, to the exclusion of any information which is covered by industrial and commercial confidentiality or protected by legislation or the disclosure of which might prejudice the interests of the person responsible for the release:

(a) the purpose of the release;

(b) a comprehensive description of the genetically modified organism or organisms;

(c) the assessment of the effects and risks for public health and the environment;

(d) the methods and plans for monitoring the operations and for emergency response.'

18 The second and fourth paragraphs of Article 4 of Decree No 95-1172 state:

'The Director-General of the French Health Product Safety Agency shall notify his decision to the applicant within 90 days from the date of registration of the application, subject to the provisions of Article 5 of this decree. Reasons must be stated if authorisation is refused.

...

Subject to the provisions of Article 5 of this decree, authorisation shall be deemed to be refused in the absence of a decision on expiry of the period of 90 days prescribed in the second paragraph of this article.'

19 Article 21 of Decree No 95-1172 provides:

'Any new information of which the applicant is aware and which relates to the risks for public health or the environment posed by the genetically modified organism or organisms, either before or after authorisation has been obtained, must be disclosed without delay by the applicant to the Director-General of the French Health Product Safety Agency who shall forward that information to the Commission of the European Communities. Where appropriate, the applicant shall take without delay the measures necessary to protect public health and the environment.'

20 Decree No 95-1173 of 6 November 1995 adopted to implement Title III of Law No 92-654 so far as concerns veterinary medicinal products (JORF of 8 November 1995, p. 16363) provides in Article 3(2):

'Once the dossier for the application for authorisation is complete, the Director-General of the National Centre for Veterinary and Food-Product Research shall issue to the applicant an acknowledgment of receipt stating its date of registration and shall forward the application to the Research Commission for the Release of Products derived from Biomolecular Engineering for its opinion.'

21 The wording of the second and fourth paragraphs of Article 4 of that decree is analogous to that of the second and fourth paragraphs of Article 4 of Decree No 95-1172, except that the Director-General of the National Centre for Veterinary and Food-Product Research is responsible for notifying the decision to the applicant.

22 The wording of Article 2(3) of Decree No 95-1173 and of Article 3(2) of Decree No 96-317 of 10 April 1996 adopted to implement Title III of Law No 92-654 so far as concerns elements or products of the human body genetically modified after having been removed or collected (JORF of 13 April 1996, p. 5740) is analogous to that of Article 2(3) of Decree No 95-1172, except that the content of the technical dossier is laid down, in the case of Decree No 95-1173, by order of the ministers with responsibility for agriculture and for health adopted following a proposal from the Director-General of the National Centre for Veterinary and Food-Product Research and, in the case of Decree No 96-317, without a proposal from the Director-General of the French Health Product Safety Agency.

23 The wording of the second and fourth paragraphs of Article 5 of Decree No 96-317 is analogous to that of the second and fourth paragraphs of Article 4 of Decree No 95-1172, except that notification of the decision to the applicant is a matter for the minister with responsibility for health.

24 Decree No 96-850 of 20 September 1996 on control of deliberate release and of the placing on the market, for civil purposes, of products wholly or partially composed of genetically modified organisms (JORF of 27 September 1996, p. 14273) provides in Article 22:

'I. — Once the application is complete, the minister with responsibility for the environment shall issue to the applicant an acknowledgment of receipt stating its date of registration and shall forward the application to the Research Commission for the Release of Products derived from Biomolecular Engineering for its opinion.

II. — That commission shall submit its opinion to the minister with responsibility for the environment within a period of 60 days from the date on which the application is registered.

III. — Within 90 days from the date on which the application to place a product on the market is registered, the minister with responsibility for the environment shall either:

(a) forward the dossier to the European Commission with a favourable opinion accompanied, where appropriate, by specific conditions relating to the placing on the market of the product, informing the applicant that it has been forwarded; or

(b) inform the applicant by reasoned decision that the application is rejected.

IV. — If the minister with responsibility for the environment considers that additional information, specific studies or consultation are necessary to enable him to determine the application, he may extend the period prescribed in paragraph II above by the corresponding length of time.

He must in that case notify the applicant of the reasons for the extension, and of its duration, which is not taken into account when calculating the period that the minister is allowed for determining the application; where appropriate, the minister shall request the applicant to produce additional information.'

25 Article 25 of Decree No 96-850 states:

'Any new information of which the applicant is aware and which relates to the risks for public health or for the environment posed by the product, either before or after authorisation has been obtained to place it on the market, must be

disclosed without delay by the applicant to the minister with responsibility for the environment who shall forward it to the European Commission.

Where appropriate, the person responsible for placing the product on the market must take without delay the measures necessary to protect public health and the environment.'

26 The annex to Decree No 96-850 states:

'List of products covered by a special marketing authorisation procedure

...

Reagents referred to in Article L. 764-14-1 of the Public Health Code and wholly or partially composed of genetically modified organisms.

...'

27 Law No 79-587 of 11 July 1979 on the requirement to state reasons for administrative measures and on the improvement of relations between administrative authorities and the public (JORF of 4 September 1979, p. 2146), as amended by Law No 86-76 of 17 January 1986 (JORF of 18 January 1986, p. 888), provides in Article 1:

'Natural and legal persons have the right to be informed without delay of the reasons for adverse individual administrative decisions concerning them.

To this end, decisions must be reasoned where:

...

— they refuse an authorisation, except where disclosure of the reasons could be such as to prejudice one of the matters of confidentiality or interests protected by the second to fifth indents of Article 6 of Law No 78-753 of 17 July 1978 establishing various measures to improve relations between administrative authorities and the public.'

28 Article 3 of Law No 79-587, as amended, states:

'The statement of reasons required by this Law must be in writing and set out the considerations of law and of fact on which the decision is based.'

29 Article 5 of Law No 79-587, as amended, is worded as follows:

'An implied decision arising in cases where an express decision would have had to be reasoned is not unlawful merely because reasons are not stated for it. Nevertheless, upon a request by the person concerned, made within the time-limit for bringing proceedings, the reasons for any implied refusal shall be notified to

him within a month of the request. In that case, the time-limit for bringing proceedings against the refusal shall be extended until two months after the day on which the reasons are notified to him.'

30 Article L. 513-3(2) of the Environment Code states:

'The following matters cannot be considered confidential:

1. information supplied in support of an application for release, concerning:

(a) the applicant's name and address,

(b) ...

(c) the purpose of the release and the location where it will be carried out,

(d) the methods and plans for monitoring the operations and for emergency response,

...'

31 Article 1 of Law No 78-753 of 17 July 1978 laying down various measures to improve relations between administrative authorities and the public and various administrative, social and fiscal provisions (JORF of 18 July 1978, p. 2851), as amended by Law No 79-587 ('Law No 78-753'), states that the right of individuals to information is to be specified and guaranteed as regards freedom of access to administrative documents not relating to individuals.

32 Article 6 of Law No 78-753 states:

'The administrative authorities mentioned in Article 2 may refuse to allow consultation of or to provide an administrative document when such consultation or provision would prejudice:

— the confidentiality of the proceedings of the Government and of the responsible authorities attached to the executive;

— the confidentiality of national defence and foreign policy;

— currency and public funds, national security and public safety;

— the conduct of proceedings before the courts or of activities preliminary to such proceedings, subject to authorisation by the competent authority:

— the confidentiality of private life and of personal and medical files;

— commercial and industrial confidentiality;

— investigations by the competent services into fiscal and customs offences;

— or, generally, confidential matters protected by legislation.

For the purpose of applying the foregoing provisions, lists of the administrative documents which may not be supplied to the public because of their character or their subject-matter shall be established by ministerial orders adopted following an opinion from the Commission on Access to Administrative Documents.'

33 Article 24 of Law No 2000-321 of 12 April 2000 on the rights of citizens in their dealings with administrative authorities (JORF of 13 April 2000, p. 5846) provides:

'Except in cases where an application is determined, individual decisions which must be reasoned pursuant to Articles 1 and 2 of Law No 79-587 of 11 July 1979 on the requirement to state reasons for administrative measures and on the improvement of relations between administrative authorities and the public shall not be made until the person concerned has been given the opportunity to submit written observations and where appropriate, on request by him, oral observations. He may be assisted by an adviser or represented by an agent of his choice.

The administrative authority is not required to grant requests for a hearing which are abusive, in particular in their number and their repetitive or systematic nature.

The preceding paragraph shall not be applicable:

1. in an emergency or exceptional circumstances;

2. where requirements of public policy or the conduct of international relations would be liable to be compromised;

3. to decisions for which legislation has established a specific *inter partes* procedure.

The detailed rules for implementation of this article shall be laid down, so far as is necessary, by décret en Conseil d'État (decree adopted after being submitted to the Council of State).'

Pre-litigation procedure

34 The French Government notified measures transposing Directive 92/220 to the Commission between 1992 and 1998.

35 By letter of formal notice of 16 March 1998, the Commission called on the French authorities to send it their observations regarding its complaint that the directive had been transposed incorrectly and incompletely.

36 Since the Commission did not consider the replies provided by the French authorities to be satisfactory, by letter of 5 April 2000 it addressed a reasoned opinion to the French Republic, calling on it to take the measures necessary to comply with the opinion within a period of two months from notification thereof.

37 On 6 December 2000 the French Government sent the Commission a copy of the order of 18 October 2000 laying down the content of the technical dossier accompanying applications for authorisation for the deliberate release of genetically modified organisms in the course of biomedical research relating to medicinal products for human use or products referred to in Article L. 5121-1(8), (9) and (10) of the Public Health Code (JORF of 11 November 2000, p. 17883; 'the order of 18 October 2000').

Consideration of the application

Article 5(1) and (2) of Directive 90/220

38 Article 5(1) of Directive 90/220 essentially provides that any person, before undertaking a deliberate release of a GMO, must submit a notification to the competent authority. In accordance with Article 5(2), the notification is to include a technical dossier supplying the information specified in that paragraph and in Annex II to the directive, and a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged.

Arguments of the parties

39 The Commission alleges that the French Republic has failed to transpose Article 5(1) and (2) of Directive 90/220 fully. The various sector-based decrees lay down only partially the content of the technical dossier prescribed by that provision. According to the decrees, the remaining information to be supplied is to be specified by order. Apart from the order of 18 October 2000, a copy of which was sent on 6 December 2000, only two ministerial orders have been adopted in this regard, namely the order of 21 September 1994 on the application dossier for deliberate release into the environment for any purpose other than placing on the market and the dossier for the placing on the market of genetically modified seedlings, seeds or plants (JORF of 18 October 1994, p. 14782) and the order of 18 July 1995 laying down the content of dossiers in respect of applications for authorisation for the deliberate release, whether or not for the purpose of placing on the market, of genetically modified organisms intended for human consumption other than plants, seeds, seedlings and animals, or included in the composition of cleaning products for materials and articles intended to come into contact with foodstuffs, products or beverages for human or animal consumption (JORF of 31 August 1995, p. 12889; 'the order of 18 July 1995').

40 Only draft orders exist for plant-protection products, livestock, medicinal products for human use, veterinary medicinal products, products wholly or partially composed of GMOs, animal feed and fertilisers, so that Article 5(2) of Directive 90/220 and Annex II thereto are not fully transposed.

41 The French Government submits that Article 5 of Directive 90/220 is transposed into French law at the level of primary legislation by Article 11 of Law No 92-654 and that, under Article 31 of that Law, the detailed rules for implementation of that provision will be determined by decree. It maintains that, in the health-product field, the detailed rules for implementation of Article 11 of Law No 92-654 have been established by decrees which all provide that applications to release GMOs are to be accompanied by a technical dossier whose content is

laid down by order of the competent minister. It refers to the adoption of the order of 18 October 2000 and to that of the order of 23 December 1999 laying down the content of the technical dossier accompanying applications for authorisation for the deliberate release of genetically modified organisms in the course of experiments relating to veterinary medicinal products (JORF of 23 January 2000, p. 1229; 'the order of 23 December 1999'), made pursuant to Decree No 95-1173, which has not yet been officially produced to the Commission. The drafting of other orders is in progress.

42 In addition, the French Government produces the text of an order of 30 November 2001 laying down the content of the technical dossier accompanying applications for authorisation for the deliberate release of genetically modified organisms in the course of biomedical research relating to elements and products of the human body genetically modified after having been removed or collected (JORF of 15 December 2001, p. 19921: 'the order of 30 November 2001').

Findings of the Court

43 It is settled case-law that the question whether a Member State has failed to fulfil its obligations must be determined by reference to the situation obtaining in the Member State at the end of the period laid down in the reasoned opinion and that the Court cannot take account of any subsequent changes (see, inter alia, Case C-103/00 *Commission* v *Greece* [2002] ECR I-1147, paragraph 23, and Case C-323/01 *Commission* v *Italy* [2002] ECR I-4711, paragraph 8).

44 In the present case, the orders of 18 October 2000 and 30 November 2001 were not adopted until after the period laid down in the reasoned opinion had expired. The French Government itself indicates that the drafting of other orders is still in progress.

45 Consequently, transposition of Article 5(1) and (2) of Directive 90/220 is incomplete and the application must be held to be well founded in this regard.

Article 5(3) of Directive 90/220

46 Article 5(3) of Directive 90/220 lays down that the competent authority may accept that releases of a combination of GMOs on the same site or of the same GMO on different sites for the same purpose and within a limited period may be notified in a single notification.

Arguments of the parties

47 The Commission contends that the rule laid down in Article 5(3) of Directive 90/220 has not been transposed in the decrees relating to plants, seeds and seedlings, to plant-protection products wholly or partially composed of GMOs, and to genetically modified animal organisms.

48 It maintains that Article 11 of Law No 92-654 is not precise enough to constitute, in itself and without implementing provisions, a precise, clear and transparent transposition of Article 5(3) of Directive 90/220. The view cannot reasonably be taken that, by virtue of Article 11 of the Law, the possibility of submitting a single notification for various releases has been provided for under French law, and all the less so in the circumstances set out in Article 5(3) of Directive 90/220, namely in the case of releases on different sites, for the same purpose and within a limited period.

49 The Commission submits that in so far as Article 5(3) of Directive 90/220 provides that the competent authority 'may' accept a single notification, it confers a power not on the Member States but on the competent authorities receiving notifications.

50 The French Government states in response that Article 5(3) of Directive 90/220 confers merely a power, which the Member States are free to use or not. It reserves the possibility of making use of that power by adopting specific provisions or when transposing Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Directive 90/220 (OJ 2001 L 106, p. 1).

51 Furthermore, inasmuch as the first paragraph of Article 11 of Law No 92-654 provides that 'any deliberate release or any coordinated programme of such releases shall be subject to prior authorisation', there is nothing to rule out the possibility of a single notification for various releases.

52 The French Government adds that Law No 92-654 specifically refers to the competent authority since the second paragraph of Article 11 provides that 'authorisations shall be issued by the administrative authority after an examination of the risks for public health or the environment posed by release'.

53 The French Government concludes that the spirit and letter of Article 5(3) of Directive 90/220 are observed and that the transposition of that provision is sufficiently precise, clear and transparent.

Findings of the Court

54 The provisions of directives must be implemented with unquestionable binding force, and with the necessary specificity, precision and clarity, in order to satisfy the requirements of legal certainty. Mere administrative practices, which by their nature are alterable at will by the authorities and are not given appropriate publicity, cannot be regarded as constituting the proper fulfilment of a Member State's obligations flowing from Community law since they maintain, for the persons concerned, a state of uncertainty as regards the extent of their rights and obligations in a field governed by that law (see, to this effect, in particular Case C-80/92 *Commission* v *Belgium* [1994] ECR I-1019, paragraph 20, Case C-151/94 *Commission* v *Luxembourg* [1995] ECR I-3685, paragraph 18, and Case C-415/01 *Commission* v *Belgium* [2003] ECR I-2081, paragraph 21).

55 While it is therefore essential that the legal situation resulting from national implementing measures is sufficiently precise and clear to enable the individuals concerned to know the extent of their rights and obligations, it is none the less the case that, according to the very words of the third paragraph of Article 249 EC, Member States may choose the form and methods for implementing directives which best ensure the result to be achieved by the directives, and that provision shows that the transposition of a directive into national law does not necessarily require legislative action in each Member State. The Court has thus repeatedly held that it is not always necessary formally to enact the requirements of a directive in a specific express legal provision, since the general legal context may be sufficient for implementation of a directive, depending on its content. In particular, the existence of general principles of constitutional or administrative law may render superfluous transposition by specific legislative or regulatory measures provided, however, that those principles actually ensure the full application of the directive by the national authorities and that, where the relevant provision of the directive seeks to create rights for individuals, the legal situation arising from those principles is sufficiently precise and clear and that the persons concerned are put in a position to know the full extent of their rights and obligations and, where appropriate, to be able to invoke them before the national courts (see in particular, to this effect, Case 29/84 *Commission* v *Germany* [1985]

ECR 1661, paragraphs 22 and 23, Case C-97/01 *Commission* v *Luxembourg* [2003] ECR I-5797, paragraph 37, and Case C-233/00 *Commission* v *France* [2003] ECR I-6625, paragraph 76).

56 It is in the light of that case-law that the Commission's complaint should be examined.

57 Contrary to the submissions of the French Government, Article 5(3) of Directive 90/220 does not confer merely a power which the Member States are free to use or not, but obliges the Member States to lay down that a single notification may be considered sufficient by the competent authorities in the cases prescribed by that provision.

58 The wording of Article 11 of Law No 92-654 does not specify in a sufficiently precise, clear and transparent manner the circumstances in which a single notification may be accepted for various releases, that is to say in the case of releases of a combination of GMOs on the same site or of the same GMO on different sites for the same purpose and within a limited period.

59 Consequently, Article 5(3) of Directive 90/220 has not been transposed adequately and the application must be held to be well founded in this regard.

Article 5(4) of Directive 90/220

60 Article 5(4) of Directive 90/220 provides that the notification is to include information on data or results from releases of GMOs or combinations of GMOs previously or currently notified and/or carried out by the applicant either inside or outside the Community.

Arguments of the parties

61 The parties agree that each of the decrees implementing Law No 92-654 refers to the applicant's obligation to supply 'all' information enabling the impact of the releases on public health and the environment to be assessed.

62 The Commission contends that the word 'all' used in those decrees does not reproduce with the necessary precision the matters specified in Article 5(4) of Directive 90/220.

63 It accordingly submits that, with the exception of the orders of 18 July 1995 and 18 October 2000, the French legislation does not transpose that provision.

64 The French Government maintains that the rule set out in Article 5(4) of Directive 90/220 also appears in the order of 23 December 1999.

65 It further submits that the use of the word 'all' in the decrees implementing Law No 92-654 is intended to cover all relevant matters, which includes information on data or results from releases of the same GMOs or the same combination of GMOs previously notified.

Findings of the Court

66 As is apparent from paragraphs 54 and 55 of this judgment, a directive's transposition is not complete if it leaves a state of uncertainty as regards the extent of the rights and obligations of individuals in the field governed by the directive. Even if the word 'all' used in the decrees implementing Law No 92-654 is to be interpreted as encompassing the information required by Article 5(4) of Directive 90/220, those decrees do not make that sufficiently clear.

67 Consequently, the application must be held to be well founded in so far as it relates to this provision of Directive 90/220.

Article 6(2) of Directive 90/220

68 Article 6(2) of Directive 90/220 states that the competent authority must respond in writing to the notifier within 90 days of receipt of the notification. It also provides that a positive response must indicate that the notification has been verified to be compliant with that directive and that the release may proceed, while a negative response must mention that the notification does not fulfil the conditions of the directive and that it is therefore rejected.

Arguments of the parties

69 The Commission acknowledges that the sector-based decrees transposing Directive 90/220 require the competent authority to notify its decision within a period of 90 days, stating reasons if authorisation is refused. However, those decrees provide that authorisation is deemed to be refused in the absence of a decision on expiry of that period. In that situation, reasons are clearly not stated for the competent authority's refusal. Even if the reasons for the refusal are disclosed to the notifier subsequently, the 90-day time-limit prescribed by Directive 90/220 cannot be observed.

70 The French Government contends that, having regard to Article 4 of Decree No 95-1172, Article 4 of Decree No 95-1173 and Article 5 of Decree No 96-317, the provisions of Article 6(2) of Directive 90/220 are complied with as regards the time-limit for notifying the decision and the obligation to state reasons for a refusal.

71 The French Government explains that the insertion, in the decrees transposing Directive 90/220, of an obligation to state reasons for refusals was not necessary from a legal point of view inasmuch as, under Article 1 of Law No 79-587 as amended, reasons must, as a matter of principle and unless otherwise provided, be stated for adverse individual administrative decisions.

72 The French Government also points out that it follows from Law No 2000-321 that, under the law generally applicable in France, a failure by the competent administrative authority to respond by the end of a period of two months is to be deemed an implied refusal. Accordingly there is no doubt as to the notifier's position in such a case.

73 It further contends that establishment of a system of implied authorisation would have been contrary to the spirit of Directive 90/220, which sought to wrap the deliberate release of GMOs in guarantees, given in particular the uncertainties that exist as to effects of those organisms on health and the environment. That is why, in its submission, the decrees referred to provide that, if the competent authority has been unable to determine the application for authorisation within the prescribed period, authorisation is deemed to be refused. In light of the requirements related to protection of health and the environment, it is not possible for a state of uncertainty to be maintained with regard to the consequences of a failure on the part of the competent authority to respond within the prescribed period.

Findings of the Court

74 The Commission calls into question the fact that, in the event of an implied refusal of authorisation where no express decision has been made by the competent authority within the 90-day period laid down in Article 6(2) of Directive 90/220, a reasoned written response is not notified to the applicant within that period.

75 However, as the Commission acknowledges, the sector-based decrees transposing Directive 90/220 require the competent authority to notify its decision within a period of 90 days, stating reasons if authorisation is refused. Accordingly, the corresponding obligation contained in Article 6(2) of Directive 90/220 has been transposed into French law.

76 The fact that the sector-based decrees transposing the directive also provide, in the applicant's interest, that if the competent authority fails to comply with that obligation there is an implied refusal capable of being challenged immediately in legal proceedings cannot affect this finding.

77 The application must therefore be dismissed in so far as it relates to Article 6(2) of Directive 90/220.

Articles 6(5), 9(3) and 12(3) and (4) of Directive 90/220

78 Article 6(5) of Directive 90/220 provides for simplified procedures: it allows the competent authority, where it considers that sufficient experience has been obtained of releases of certain GMOs, to submit to the Commission a request for the application of simplified procedures for releases of such types of GMOs.

79 Article 9(3) of the directive lays down that the competent authorities are to inform the other Member States and the Commission of the final decisions taken in compliance with Article 6(2) thereof.

80 Article 12(3) of the directive provides that, if the competent authority forwards the notification dossier to the Commission with a favourable opinion, that dossier is to include a summary of the notification together with a statement of the conditions under which the competent authority proposes to consent to the placing on the market of the product. Article 12(4) states that if the competent authority receives, pursuant to Article 11(6), new information with regard to the risks posed by the product, it is to inform the Commission and the other Member States immediately.

Arguments of the parties

— Article 6(5) of Directive 90/220

81 According to the Commission, the option offered by Article 6(5) of Directive 90/220 can be available to the competent authority only if that provision is transposed into national law. However, it is not transposed in Decree No 94-46 of 5 January 1994 laying down conditions for the deliberate release of genetically modified organisms intended for human consumption other than plants, seeds, seedlings and animals, or included in the composition of cleaning products for materials and articles intended to come into contact with foodstuffs, products or beverages for human or animal consumption (JORF of 19 January 1994, p. 982). In addition, the Commission alleges that Decree No 93-1177 of 18 October 1993 adopted to implement Title III of Law No 92-654 so far as concerns plants, seeds and seedlings (JORF of 20 October 1993, p. 14593), Decree No 94-359 of 5 May 1994 on the control of plant-protection products (JORF of 7 May 1994, p. 6683) and Decree No 95-487 of 28 April 1995 adopted to implement Title III of Law No 92-654 so far as concerns genetically modified animal organisms (JORF of 30 April 1995, p. 6766), which lay down arrangements for a simplified dossier, do not provide for such a dossier to be submitted to the Commission.

82 The fact that the practice of the competent authorities has, according to the French Government, been in compliance with Directive 90/220 does not justify the failure to transpose it fully.

83 The Commission also submits that Article 6(5) of the directive does not seek to govern relations between the Member States and the Community, but to define the detailed rules of a procedure partly centralised at Community level, in which the national administrative bodies are directly empowered to communicate with the Commission. It is necessary for national law to set out for those authorities the legal framework in which they operate.

84 The French Government contends that Article 6(5) of Directive 90/220 provides for a possibility and does not lay down an obligation. That possibility is subject to a condition and to an analysis, namely that the competent authority considers that sufficient experience has been obtained of releases.

85 With regard to Decree No 94-46, the French Government submits that no dossier has yet been submitted and that no experience has therefore been obtained. Once accumulated experience justifies a decision that a simplified procedure is necessary, the French Republic will be able to submit such a request to the Commission, without any need for that to be stated in the legislation. So far as concerns Decrees No 93-1177, No 94-359 and No 95-487, the French Government maintains that it has complied fully with the provisions of Directive 90/220 which organise the relations of the Member States amongst themselves and with the Commission. Those provisions do not have to be integrated into national law.

86 In any event, the Commission has not shown that sufficient experience has been acquired for a simplified procedure to be set up in individual fields.

— Article 9(3) of Directive 90/220

87 Contrary to the Commission, the French Government takes the view that Article 9(3) of Directive 90/220 does not have to be the subject of measures transposing it since it organises relations of the authorities of the Member States amongst themselves and with the Commission.

— Article 12(3) and (4) of Directive 90/220

88 The Commission contends that Article 12(3) of Directive 90/220 has not been fully transposed on the ground that only two orders, adopted on the basis of Decrees No 93-1177 and No 94-46, refer to a summary of the dossier in respect of applications for authorisation to place a product on the market. Nor does any of the legislation intended to transpose the directive into French law mention the obligation on the competent authority to draw up, for the Commission's attention, a statement of the conditions under which that authority proposes to consent to the placing on the market of the product.

89 The Commission adds that Article 12(4) of Directive 90/220 has been transposed only in Decrees No 94-359, No 95-1172 and No 96-850. Nor has that provision been transposed in respect of the sectors not covered by transposition measures.

90 The Commission further submits that Article 12(3) and (4) of Directive 90/220 prescribes the detail of a procedure under which national administrative bodies are empowered to communicate with the Commission. It is therefore necessary for national law to set out for those authorities the legal framework in which they operate.

91 The French Republic contends that the provisions of Directive 90/220 prescribing the communication of information to the other Member States and the Commission do not have to be the subject of measures transposing them. Furthermore, the summary of the notification forms in any event part of the content of the dossier defined by orders which have not yet been adopted but in respect of which the position will be re-examined by the French authorities in the context of the transposition of Directive 2001/18.

Findings of the Court

92 It is apparent from the Court's case-law that a provision which concerns only the relations between the Member States and the Commission does not, in principle, have to be transposed. However, given that the Member States are obliged to ensure that Community law is fully complied with, it is open to the Commission to demonstrate that compliance with a provision of a directive governing those relations requires the adoption of specific transposing measures in national law (see, to this effect, Case C-72/02 *Commission* v *Portugal* [2003] ECR I-6597, paragraphs 19 and 20).

93 Where the Member State has chosen not to specify expressly the legal framework within which the national authorities are led to conduct such relations, it is responsible for any breach of the relevant obligations resulting from Community law.

94 In the present case, Articles 6(5), 9(3) and 12(3) and (4) of Directive 90/220 all concern solely the relations between a Member State and the Commission or the other Member States.

95 Article 6(5) of Directive 90/220 allows the competent authority in clear terms to submit to the Commission a request for the application of simplified procedures where it considers that sufficient experience has been obtained of releases of certain GMOs. That provision is unconditional and sufficiently precise to be applied by the competent authorities.

96 As to the Commission's argument that the provision seeks to define the detailed rules of a procedure in which the national administrative bodies are directly

empowered to communicate with the Commission and that it is therefore necessary for national law to set out for those authorities the legal framework in which they operate, the fact remains that the Commission has not asserted that the French competent authorities are prevented from making use of the option provided for in Article 6(5) of Directive 90/220.

97 Nor has the Commission demonstrated that compliance with that provision requires the adoption of specific transposing measures in national law. Furthermore, the French Government stated, without being contradicted, that no dossier had yet been submitted and that no experience could therefore have been obtained for the purpose of deciding whether a simplified procedure is necessary.

98 Articles 9(3) and 12(3) and (4) of Directive 90/220 lay down unambiguous obligations to inform, imposed on the competent authority in each Member State, so that that authority is required to apply them.

99 The Commission has not put forward arguments seeking to demonstrate a practice on the part of the French authorities contrary to those obligations.

100 Consequently, the Commission's application should be dismissed in so far as it relates to Articles 6(5), 9(3) and 12(3) and (4) of Directive 90/220.

Article 11(1) of Directive 90/220

101 Article 11(1) of Directive 90/220 specifies the content of the notification which the manufacturer of a product or its importer into the Community must submit to the competent authority of the Member State where the product is to be placed on the market for the first time.

Arguments of the parties

102 The Commission submits that the various sector-based decrees transposing the directive lay down the content of the technical dossier in relation to only the assessment of the impact of the releases on health and the environment, the standard-form dossier intended to be forwarded to it for information and the public information sheet. According to those decrees, the remaining elements of the technical dossier are to be specified by order. However, only three ministerial orders have been adopted to this end, which do not transpose the requirements resulting from the second indent of the first subparagraph of Article 11(1) of Directive 90/220 and do not even require communication of the minimum information referred to in Annex III to the directive. Nor has that annex been the subject of any transposing measure at all, according to the information available to the Commission.

103 The French Government contends that Article 15 of Law No 92-654, which makes the placing on the market of products wholly or partially composed of GMOs subject to prior authorisation, transposed the obligations laid down in Article 11(1) of Directive 90/220 and in Annexes II and III thereto. Article 17 of that Law indicates in respect of the categories of products which are subject to specific authorisation procedures before being placed on the market that a single authorisation is issued under those specific procedures and the procedure established by the Law, in accordance with detailed rules laid down by secondary legislation.

104 The parties are in agreement that Article 11 of Directive 90/220 does not apply — and therefore does not have to be transposed — in respect of medicinal products for human or veterinary use which are composed of GMOs and subject to a Community marketing authorisation.

Findings of the Court

105 The only general provision pleaded by the French Government, namely Article 15 of Law No 92-654, merely provides that prior authorisation is needed, issued after an examination of the risks. This provision does not mention the information prescribed in Article 11(1) of Directive 90/220. That gap has evidently not been filled by the transposing decrees, given that the French Government has not contested the Commission's finding that those decrees establish the content of the technical dossier only partially.

106 Consequently, the application must be held to be well founded in so far as it relates to Article 11(1) of Directive 90/220.

Article 11(2) and (3) of Directive 90/220

107 Article 11(2) of Directive 90/220 states that the applicant is to include in his prior notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by him either inside or outside the Community. Article 11(3) of the directive provides that he may also refer to data or results from notifications previously

submitted by other notifiers, provided that the latter have given their agreement in writing.

Arguments of the parties

108 The Commission submits that the French Republic has not reproduced the content of Article 11(2) and (3) of Directive 90/220 in any legislation, with the exception of the orders of 18 July 1995 and 18 October 2000.

109 The French Government states that implementation of those provisions falls within the domain of the orders envisaged by Decrees No 95-1172 and No 96-850. The situation will be re-examined by the French authorities in the context of transposition of Directive 2001/18.

Findings of the Court

110 Suffice it to state that, as already pointed out in paragraph 43 of this judgment, the question whether a Member State has failed to fulfil its obligations must be determined by reference to the situation obtaining in the Member State at the end of the period laid down in the reasoned opinion.

111 In admitting that Article 11(2) and (3) of Directive 90/220 will be implemented by orders to be adopted, the French Government acknowledges that it has not transposed those provisions fully within the time-limit.

112 Consequently, the application must be held to be well founded in so far as it relates to Article 11(2) and (3) of Directive 90/220.

Article 11(6) of Directive 90/220

113 Article 11(6) of Directive 90/220 states that, should new information have become available with regard to the risks of the product to human health or the environment, either before or after the written consent of the competent authority, the notifier is immediately to revise ('revoir' in the French version of the provision) the information and conditions specified in Article 11(1), inform that authority, and take the measures necessary to protect human health and the environment.

Arguments of the parties

114 According to the Commission, the first of those three obligations laid down in Article 11(6) of Directive 90/220 is not reproduced in any of the sector-based decrees transposing the directive. It further contends that the three obligations are complementary and separate from each other and that they must therefore be transposed separately. In its submission, the argument that the competent administrative authority may impose additional constraints or require additional assessments should new information become available cannot be accepted. The obligation to revise the applicable information and conditions is imposed by that provision on the 'notifier' and must be transposed as such.

115 The French Government contends that Article 19 of Law No 92-654 transposes Article 11(6) of Directive 90/220 correctly since it provides that any person 'must inform the authority of any new information' and take 'the measures necessary' to protect public health or the environment.

116 The French Government also pleads, with regard to medicinal products for human use, Article 21 of Decree No 95-1172 which states that any new information of which the applicant is aware, 'either before or after authorisation has been obtained, must be disclosed' and that, 'where appropriate, the applicant shall take without delay the measures necessary to protect public health and the environment'. It adds that a similar provision is contained in Article 25 of Decree No 96-850.

Findings of the Court

117 Under Article 19 of Law No 92-654, any person who has received an authorisation to release GMOs or to place on the market a product wholly or partially composed of GMOs 'must inform the authority of any new information liable to alter the assessment of risk for public health or the environment' and take 'the measures necessary' to protect public health or the environment. That provision explicitly transposes the second and third indents of Article 11(6) of Directive 90/220. The obligation stated in the first indent, namely the obligation to revise ('revoir') the information and conditions specified in Article 11(1), follows logically from the obligation to inform the authority of any 'new information'. Accordingly, Article 19 of Law No 92-654 fully transposes Article 11(6) of the directive.

118 Consequently, the Commission's application should be dismissed in so far as it relates to Article 11(6) of Directive 90/220.

Article 13(2) and (4) of Directive 90/220

119 In the grounds of its application, the Commission pleads a failure to implement Article 13(2) and (4) of Directive 90/220.

120 However, that article is not referred to in the form of order sought by it.

121 It follows from Article 38(1) of the Rules of Procedure and settled case-law that the form of order sought must be worded in unambiguous terms so that the Court does not risk either giving judgment *ultra petita* or failing to give judgment on a head of claim (see, in particular, Joined Cases 46/59 and 47/59 *Meroni* v *High Authority* [1962] ECR 411, at p. 419).

122 Consequently, the application is inadmissible in this regard.

Article 19(2) and (3) of Directive 90/220

123 Article 19(2) of Directive 90/220 states that the notifier may indicate the information in the notification submitted under the directive the disclosure of which might harm his competitive position and which should be treated as confidential. Verifiable justification must be given in such cases.

124 Article 19(3) of the directive provides that the competent authority is to decide, after consultation with the notifier, which information will be kept confidential and inform him of its decision.

Arguments of the parties

125 The Commission states that Article 19(2) of Directive 90/220 is partially transposed by Article 21(1) of Law No 92-654. Under the latter article, an applicant for authorisation to release GMOs or to place a product on the market may indicate to the authority the information supplied in support of his application the disclosure of which might prejudice his interests or which concerns confidential matters protected by legislation.

126 However, in the Commission's submission, that Law fails to require the notifier to give verifiable justification. All the sector-based decrees apart from one do not oblige the notifier to give such justification.

127 With regard to Article 19(3) of Directive 90/220, neither Law No 92-654 nor the sector-based decrees transposing the directive, with the exception of Decree No 94-359 relating to plant-protection products, impose obligations requiring the notifier to be consulted and to be informed once a decision has been taken.

128 The French Government argues that it follows from Law No 92-654 and various provisions of secondary legislation that an applicant indicates in his application to release GMOs or place a product on the market the information which is to remain confidential. Having regard to those provisions, it is for the applicant to indicate to the competent authority the information which he does not wish to be disclosed and, by implication, to make known the reasons why they are to be

'recognised as confidential' by the competent administrative authority. Under French administrative law, it is generally for the person pleading confidentiality to prove the need for it.

129 The French Government submits that French administrative law is sufficient to transpose Article 19(3) of Directive 90/220 precisely, since it provides that administrative decisions, including refusals, must be reasoned (Article 1 of Law No 79-587 as amended) and that individual administrative decisions are adopted following an *inter partes* procedure in the course of which the person concerned is given the opportunity to submit his observations (Article 24 of Law No 2000-321). In addition, under generally applicable law administrative authorities must give notification of decisions adopted.

Findings of the Court

130 According to settled case-law recalled in paragraphs 54 and 55 of this judgment, the provisions of directives must be implemented with unquestionable binding force, and with the necessary specificity, precision and clarity, in order to satisfy the requirements of legal certainty.

131 However, no provision of French law expressly provides that a notifier must give verifiable justification if he requests that certain information be treated as confidential.

132 The argument according to which specific procedural obligations owed by the holder of the right in question result by implication from administrative law must be rejected.

133 So far as concerns the obligation laid down in Article 19(3) of Directive 90/220 to consult the notifier before a decision is taken, it is clear that Article 24 of Law No 2000-321, put forward by the French Republic as transposing the directive appropriately in this regard, is, according to its very wording, inapplicable where an application is determined. That is the case here. The argument derived from the general requirement for an *inter partes* procedure cannot therefore be upheld.

134 As to the obligation laid down in Article 19(3) of Directive 90/220 to inform the notifier of the decision taken by the competent authority, it is to be recalled that the French Government has submitted in relation to Article 6(2) of the directive that, under the law generally applicable in France, a failure by the competent administrative authority to respond by the end of a period of two months is to be deemed an implied refusal. Accordingly, it cannot be asserted that notification of the decision referred to in Article 19(3) of Directive 90/220 is a general requirement of French administrative law.

135 Consequently, the application must be held to be well founded in so far as it relates to Article 19(2) and (3) of Directive 90/220.

Article 19(4) of Directive 90/220

136 Article 19(4) of Directive 90/220 provides that certain information, when submitted in accordance with Articles 5 and 11, cannot in any case be kept confidential, in particular the name and address of the notifier, the location of the release and the emergency response plans.

Arguments of the parties

137 According to the Commission, all the sector-based decrees implementing Law No 92-654 include a standard-form provision requiring applicants for authorisation to release GMOs to annex to the application dossier a public information sheet. The list of data to be included on that sheet contains no reference to the location of the release or the name and address of the notifier. Inasmuch as the French authorities intended to implement the requirements arising from Article 19(4) of Directive 90/220 by means of a public information sheet, it is a mandatory requirement that the information sheet contain all the items referred to in that article as not allowed to be kept confidential.

138 The French Government submits that Article 19(4) of Directive 90/220 is transposed by Article L. 513-3(2) of the Environment Code, which is directly applicable, as, moreover, is that Community provision. French law has distinguished between cases where non-confidential information is produced in connection with applications for deliberate release for the purpose of research and cases relating to applications to place a product on the market. Annex II to the directive provides that certain information required in notifications under Article 5 of the directive for releases for the purposes of research is not required in notifications under Article 11 thereof for placing a product on the market. The Commission is thus wrong in looking for the provisions transposing Article 19(4) of the directive in the sector-based decrees.

139 The French Government also maintains that the absence from the information sheet prescribed by the standard-form provision under Law No 92-654 of certain information which is not listed as confidential by Directive 90/220, namely the location of the release and the name and address of the notifier, does not affect in the slightest its non-confidential nature. That information is, on request, to be communicated to the public as of right, pursuant to Articles 1 and 6 of Law No 78-753.

140 The French Government adds, so far as concerns biomedical research, that it considered it inappropriate to give excessive publicity to the name and address of the research location, with a view to protecting those operations.

Findings of the Court

141 Article 19(4) of Directive 90/220 prevents certain information from being kept confidential. Such an obligation is not equivalent to an obligation to publish. It is accordingly sufficient, in order for it to be transposed, that the public may where relevant have access to all the information referred to by that provision.

142 That is the case under French law. Article L. 513-3(2) of the Environment Code provides that that information cannot be considered confidential.

143 Consequently, the Commission's application should be dismissed in so far as it relates to Article 19(4) of Directive 90/220.

Transposition of the directive with regard to GMO-based reagents

144 The Commission complains that the French Republic has failed to transpose Directive 90/220 so far as concerns GMO-based reagents.

145 Given that this complaint as such does not appear in the form of order sought by the Commission, the application is admissible in this regard only in so far as it relates to the provisions of Directive 90/220 which are referred to in the form of order sought.

146 The French Republic concedes that it has not yet adopted measures transposing the directive in the field of GMO-based reagents, but plans to adopt them in the context of transposition of Directive 2001/18.

147 It follows from the foregoing that the Commission's complaint relating to failure to transpose Directive 90/220 in this field must be held to be well founded so far as concerns the lack of transposition of Articles 5(1) to (4), 6(2), 11(1), (2) and (3) and 19(2) and (3) of the directive and dismissed as to the remainder.

148 Having regard to all the above considerations, it must be held that, by failing to transpose Articles 5(1) to (4), 11(1), (2) and (3) and 19(2) and (3) of Directive 90/220, the French Republic has failed to fulfil its obligations under that directive.

Costs

149 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has applied for costs and the French Republic has been largely unsuccessful, the latter must be ordered to pay the costs.

On those grounds,

THE COURT (Sixth Chamber)

hereby:

1. **Declares that, by failing to transpose Articles 5(1) to (4), 11(1), (2) and (3) and 19(2) and (3) of Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, as amended by Commission Directive 97/35/EC of 18 June 1997 adapting to technical progress for the second time Directive 90/220, the French Republic has failed to fulfil its obligations under that directive;**

2. **Dismisses the remainder of the application;**

3. **Orders the French Republic to pay the costs.**

Puissochet Schintgen Skouris

Colneric Cunha Rodrigues

Delivered in open court in Luxembourg on 20 November 2003.

R. Grass V. Skouris

Registrar President