JUDGMENT OF THE GENERAL COURT (Seventh Chamber)
26 September 2013 (*)
(Approximation of laws – Deliberate release into the environment of genetically modified organisms – Authorisation procedure for placing on the market – Failure by the Commission to submit a draft decision to the Council – Action for failure to act)

In Case T-164/10,

Pioneer Hi-Bred International, Inc., established in Johnston, Iowa (United States), represented by J. Temple Lang, Solicitor, and T. Müller-Ibold, lawyer,

applicant,

v

European Commission, represented by L. Pignataro-Nolin, N. Yerrell and C. Zadra, acting as Agents,

defendant,

APPLICATION for a declaration under Article 265 TFEU that, by failing to submit to the Council a draft of the measures to be taken in accordance with Article 5(4) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23) and by failing to take all other measures that may, depending on the development of the decision-making procedure, be necessary to ensure the adoption of the decision referred to in Article 18 of Directive 2001/18/EC of 12 March 2001 of the European Parliament and the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ 2001 L 106, p. 1), the Commission has failed to fulfil its obligations under Article 18 of Directive 2001/18,

THE GENERAL COURT (Seventh Chamber),

composed of A. Dittrich, President, I. Wiszniewska-Białecka (Rapporteur) and M. Prek, Judges,
Registrar: N. Rosner, Administrator,
having regard to the written procedure and further to the hearing on 20 June 2012,
gives the following

Judgment

Background to the dispute

On 6 July 2001, the applicant, Pioneer Hi-Bred International, Inc., notified the competent Spanish authority of an application for authorisation for the placing on the market of a genetically modified organism called 'insect-resistant genetically modified maize 1507' ('maize 1507') for cultivation, in accordance with 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). The competent authority in Spain registered that notification under reference C/ES/01/01.

Following the repeal of Directive 90/220 by 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), the notification of the application for authorisation for the placing on the market of maize 1507 was modified on 17 December 2002 in order to meet the requirements of Directive 2001/18.

On 1 August 2003, the competent Spanish authority adopted a positive assessment report concerning the notification of the application for authorisation for the placing on the market of maize 1507. In that report the competent Spanish authority concluded, on the basis of Article 14(3)(a) of Directive 2001/18, that there was no scientific evidence indicating that the marketing of maize 1507 constituted a risk to human or animal health or the environment.

In accordance with the second indent of Article 14(2) of Directive 2001/18, the competent Spanish authority sent that report to the Commission of the European Communities, which forwarded it on 20 August 2003 to the competent authorities of the other Member States.

Certain Member States raised objections to the placing on the market of maize 1507, pursuant to Article 15(1) of Directive 2001/18. The competent authorities and the Commission did not reach an agreement within the 105-day period provided for by Article 15, which was extended until 13 May 2004, and the objections of certain Member States were maintained.

On 19 May 2004, the Commission requested the opinion of the competent scientific committee, the European Food Safety Authority (EFSA), in accordance with Article 28(1) of Directive 2001/18. On 19 January 2005, EFSA delivered an opinion concluding that there was no evidence that placing maize 1507 on the market was likely to have adverse effects on human or animal health or on the environment in the context of its proposed use.

On 19 June 2006, the Commission convened a technical meeting between its staff, the Member States, EFSA and the applicant in order to address the concerns of the Member States relating to the applicant's notification. Following that meeting, on 24 July 2006, the Commission asked EFSA to deliver a further scientific opinion on maize 1507. In the second opinion, published on 17 November 2006 in the form of an annex to the first opinion

of 19 January 2005, EFSA confirmed the findings set out in its first opinion.

By letter of 19 January 2007, received at the Commission on 24 January 2007, the applicant called on the Commission to act and, in particular, to submit to the regulatory committee a draft of the measures to be taken, in accordance with Article 5(2) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23). It indicated that that letter constituted a formal request for action for the purposes of Article 232 EC.

By letter of 16 March 2007, the Commission replied to the applicant's invitation to act. It indicated, first, that it was examining the information contained in the notification, the opinions of EFSA, the objections raised by the Member States and the need for additional measures to monitor the effects on non-target organisms and, second, that it was finalising a draft decision for submission to the Member States in due course.

On 2 May 2007, the applicant brought an action before the General Court (Case T-139/07) seeking a declaration under Article 232 EC that, by failing to submit to the regulatory committee, in accordance with Article 5(2) of Decision 1999/468, a draft of the measures to be taken with regard to its notification relating to the placing on the market of genetically modified maize 1507, the Commission had failed to fulfil its obligations under Article 18(1) of Directive 2001/18.

On 24 July 2008, the Commission requested a new opinion from EFSA. On 29 October 2008, EFSA delivered its opinion which confirmed its previous opinions on the safety of maize 1507.

On 29 January 2009 the Commission informed the Registry of the General Court that, by letter of 21 January 2009, it had called the Member States to a meeting of the regulatory committee on 25 February 2009. The agenda for that meeting provided for a discussion and a vote on the proposal for a decision concerning the applicant's notification. The Commission accordingly submitted the proposal for a decision to the regulatory committee, pursuant to Article 5(2) of Decision 1999/468.

Consequently, by order of 4 September 2009 in Case T-139/07 *Pioneer Hi-Bred International* v *Commission*, not published in the ECR, the General Court ruled that there was no need to adjudicate.

When the draft decision concerning the placing on the market of maize 1507 was put to a vote at the meeting of the regulatory committee of 25 February 2009, there was no qualified majority either in favour of or against the proposal. The summary report of the meeting states that '[a]ccording to Article 5(4) of Council Decision 1999/468/EC … the Commission shall therefore, without delay, submit to the Council a draft of the measures to be taken and shall inform the European Parliament'.

By letter of 15 December 2009, received at the Commission on 29 December 2009, the applicant formally called upon the Commission, within the meaning of Article 265 TFEU, to take all the measures necessary for the adoption of the decision referred to in Article 18 of Directive 2001/18 concerning its notification. The applicant requested the Commission to send to the Council of the European Union, without delay, a proposal relating to the measures to be taken pursuant to Article 5(4) of Decision 1999/468 and to take all the other measures that might, depending on the development of the decision-making procedure, be necessary in order to ensure that the decision referred to in Article 18 of Directive 2001/18 was adopted.

By letter of 21 January 2010, the Commission replied that the outcome of the regulatory committee meeting of 25 February 2009 should be taken into account when considering sending the proposal for a decision to the Council and that the new College of Commissioners would take a decision on this file once it had been entrusted with its new mandate.

Procedure and forms of order sought

By application lodged at the Registry of the General Court on 13 April 2010, the applicant brought the present action.

The parties presented oral argument and answered the questions put to them by the General Court at the hearing on 20 June 2012.

By order of 29 January 2013, the General Court (Seventh Chamber) ordered that the oral procedure be re-opened so that the parties could be requested to answer, in the context of the measures of organisation of procedure, a series of questions. The parties replied within the prescribed periods.

By decision of 14 May 2013, the General Court again closed the oral procedure.

The applicant claims that the Court should:

declare that the Commission, by failing to submit to the Council a proposal relating to the measures to be taken pursuant to Article 5(4) of Decision 1999/468, and by failing to take all other measures that may, depending on the development of the decision-making procedure, be necessary to ensure that the decision referred to in Article 18 of Directive 2001/18 is adopted, has failed to act in accordance with Article 18 of Directive 2001/18;

order the Commission to pay the costs.

The Commission contends that the Court should:

declare the application inadmissible or unfounded;

order the applicant to pay the costs.

Law

Under the third paragraph of Article 265 TFEU, any natural or legal person may complain to the Union judicature that one of the institutions has failed to address to that person any act other than a recommendation or an opinion.

By its action, the applicant seeks, primarily, a declaration that the Commission, by failing to submit to the Council a proposal for the measures to be taken pursuant to Article 5(4) of Decision 1999/468, namely the proposal relating to a decision concerning the placing on the market of maize 1507, infringed Article 18 of Directive 2001/18. The applicant claims, in essence, that since the Commission did not submit that proposal to the Council, a decision concerning its application for authorisation for the placing on the market of maize 1507 could not be adopted within the time limits laid down in Article 18(1) of Directive 2001/18.

Admissibility

The Commission contends that the action is inadmissible in the light of Article 265 TFEU, in so far as the act which it failed to adopt would not have produced binding legal effects such as to affect the interests of the applicant by bringing about a significant change in its legal position. The proposal relating to the measures to be taken submitted by the Commission to the Council pursuant to Article 5(4) of Decision 1999/468 is a purely preparatory act, which cannot be the subject of an action for annulment on the basis of Article 263 TFEU nor, by the same token, an action on the basis of Article 265 TFEU.

According to the case-law, an act which is not challengeable by an action for annulment may constitute a 'definition of position' terminating the failure to act if it is the prerequisite for the next step in a procedure which is to culminate in a legal act which itself will be challengeable by an action for annulment (Case T-186/94 *Guérin automobiles* v *Commission* [1995] ECR II-1753, paragraph 25, and order of 26 November 2008 in Case T–393/06 *Makhteshim-Agan Holding and Others* v *Commission*, not published in the ECR, paragraph 52; see also, to that effect, Case 302/87 *Parliament* v *Council* [1988] ECR 5615, paragraph 16).

It must be noted that the General Court, in Case T–212/99 *Intervet International* v *Commission* [2002] ECR II-1445, has already recognised the admissibility of claims alleging failure to act seeking a declaration that the Commission failed to submit draft measures to be taken to the regulatory committee in the context of the application of Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ 1990 L 224, p. 1).

It should be pointed out that, in the present case, certain Member States have raised objections under Article 15(1) of Directive 2001/18 to the applicant's notification concerning the placing on the market of maize 1507. Therefore, the procedure that is to apply is that set out in Article 18 of Directive 2001/18. That article provides that a decision is to be adopted in accordance with the procedure laid down in Article 30(2) of Directive 2001/18, which refers to the regulatory procedure provided for in Article 5 of Decision 1999/468.

In January 2009, the Commission submitted to the regulatory committee a proposal relating to the measures to be taken in accordance with Article 5(2) of Decision 1999/468. When it voted on 25 February 2009, the regulatory committee could not secure a sufficient majority either in favour of or against the draft.

In such a case, Article 5(4) of Decision 1999/468 provides that the Commission is, without delay, to submit to the Council a proposal relating to the measures to be taken and to inform the European Parliament. Article 5(6) of Decision 1999/468 provides that the Council may adopt or reject the proposal by qualified majority and that, where the Council has not taken a decision within three months, that is to say, could not secure a qualified majority either in favour of or against the proposal for implementing measures, the proposed implementing act is to be adopted by the Commission.

It is clear from the procedure laid down in Article 5 of Decision 1999/468 that, should the regulatory committee not deliver an opinion by qualified majority, the adoption of a final decision, whether by the Council or the Commission, is necessarily to be preceded by the submission by the Commission to the Council of a proposal relating to the measures to be taken.

Therefore, in the present case, since the proposal relating to the measures to be taken that must be submitted to the Council constitutes an essential prerequisite for the adoption of the final decision concerning the placing on the market of maize 1507, it must be regarded, in accordance with the case-law cited in paragraph 26 above, as a definition of position terminating the failure to act.

Furthermore, it is necessary to reject the Commission's argument that the proposal relating to the measures to be taken is a purely preparatory act in so far as it does not necessarily lead to the adoption of a final decision and in so far as it is apparent from the factual context of the case that a proposal in favour of the placing on the market of maize 1507 would probably have been blocked at the stage of a vote being taken in the Council.

The Commission cannot, as a basis for refusing to submit its proposal to the Council, claim that, in the next stage of the procedure governed by Article 5 of Decision 1999/468, its proposal might be rejected.

In addition, it must be noted that, if the application were to be declared inadmissible on the ground that the proposal for a decision concerning the placing on the market of maize 1507 that the Commission must forward to the Council is a preparatory act, it would be possible for the Commission to block the adoption of the final decision indefinitely. That would adversely affect the applicant, which would be unable to bring any form of action in that regard.

The application must therefore be regarded as admissible.

Substance

According to settled case-law, in order to rule on the merits of the claim for a declaration of failure to act, it is necessary to ascertain whether, at the time when the Commission was called upon to act pursuant to Article 265 TFEU, it was under any obligation to act (Case T-95/96 *Gestevisión Telecinco* v *Commission* [1998] ECR II-3407, paragraph 71, and Case T-423/07 *Ryanair* v *Commission* [2011] ECR II-2397, paragraph 25).

It must be noted that, in the present case, the applicable procedure is that laid down in Article 18 of Directive 2001/18. That article refers to Article 30(2) of Directive 2001/18, which provides that the decision is to be adopted in accordance with the procedure referred to in Article 5 of Decision 1999/468.

It must also be noted that the regulatory committee voted on 25 February 2009 on the draft of the measures to be taken submitted by the Commission and that that vote did not secure a sufficient majority. Pursuant to Article 5(4) of Decision 1999/468, that is the date from which the Commission was required to submit, without delay, to the Council the proposal relating to the measures to be taken. By letter received at the Commission on 29 December 2009, the applicant gave formal notice to the Commission to submit to the Council a proposal relating to the measures to be taken.

It must therefore be ascertained whether, on 29 December 2009, the Commission was obliged to submit to the Council a proposal relating to the measures to be taken concerning the application for the placing on the market of maize 1507.

The Commission recognises that it is under a duty, pursuant to Article 5(4) of Decision 1999/468, to submit a proposal to the Council without delay. However, it claims that the obligation to submit a proposal to the Council 'without delay' must be interpreted according to the context of the measure and the Commission's role in the procedure.

It is true that Article 5(4) of Decision 1999/468 uses the expression 'without delay' but does not precisely determine the period in which the Commission must submit to the Council a proposal relating to the measures to be taken. In using the expression 'without delay', the European Union legislature allowed the Commission a certain freedom of action, whilst requiring it to act swiftly (see, to that effect, Case T-105/96 *Pharos* v *Commission* [1998] ECR II-285, paragraph 65).

However, it must be noted that the procedure for the adoption of a decision regarding the placing on the market of maize 1507 is governed by Article 18 of Directive 2001/18 which provides that, where an objection is maintained, a decision regarding the placing on the market is to be adopted and published within 120 days.

The starting point for the 120-day period is the end of the conciliation period. The second subparagraph of Article 18(1) of Directive 2001/18 provides that, for the purpose of calculating the 120-day period, any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of the scientific committee is not to be taken into account. That provision states that the period during which the Commission is awaiting the opinion of the scientific committee is not to exceed 90 days.

In the present case, the conciliation period ended, after extension, on 13 May 2004. According to the applicant, that date is the starting point for the 120-day period. According to the Commission, the starting point for that period was 17 November 2006, the date of the publication of the second opinion of EFSA, and that period expired on 17 March 2007.

Even if, as claimed by the Commission, the starting point for the 120-day period laid down in Article 18(1) of Directive 2001/18 for the adoption of the decision was 17 November 2006, the fact remains that at the date of receipt of the invitation to act, on 29 December 2009, the Commission had yet to submit the proposal relating to the measures to be taken to the Council.

In the light of the above, it should be found that at the date of receipt of the invitation to act, on 29 December 2009, the 120-day period laid down in Article 18 of Directive 2001/18 for the adoption of a decision concerning the application for the placing on the market of maize 1507 had expired. Since the submission by the Commission of a proposal relating to the measures to be taken is a prerequisite for the adoption of that decision, it must be held that, on the date of the invitation to act, the Commission was under a duty to act.

That conclusion is not called into question by the Commission's arguments seeking to show that the fact that it did not submit a proposal during the period of approximately 12 months between the date of the meeting of the regulatory committee on 25 February 2009 and the date of expiry of the two-month period following the invitation to act on 1 March 2010 is manifestly reasonable and justified.

First, the Commission states that it indicated in its letter of 21 January 2010 in reply to the invitation to act that it had to take into account the outcome of the meeting of the regulatory committee of 25 February 2009. In its defence, it states that it had to take into account the fact that the regulatory committee could not secure a qualified majority either in favour of or against the draft decision and that a significant number of Member States had abstained or voted against that draft.

The Commission claims that, in accordance with Case C-151/98 P *Pharos* v *Commission* [1999] ECR I-8157, it must have sufficient time to consider the various courses of action open to it. The period which followed 25 February 2009 was necessary in order to consider the possible courses of action in the light of the complexity of the problem and the need to ensure that its proposal was not rejected by the Council by simple majority.

However, it must be held that the approach followed in *Pharos* v *Commission*, cited in paragraph 50 above, is not applicable in the present case. On the one hand, it must be noted that the legislation applicable in that case is different to that which applies in the present case. In particular, as the applicant points out, unlike Directive 2001/18, the legislation at issue in that case did not lay down a period within which the decision was to be adopted. In addition, in that judgment (paragraphs 20 and 25), the Court of Justice recognised that the length of time indicated by the expression 'without delay' presupposed a certain degree of rapidity.

On the other hand, in that judgment, the Court of Justice accepted that, where it was confronted with a matter which is highly sensitive and complex, the Commission had the right to request a new scientific opinion (*Pharos* v *Commission*, cited in paragraph 50 above, paragraph 26). The Court of Justice stated that, in the circumstances of that case, the Commission could seek a scientific opinion in order to prevent its proposal from being rejected by the Council by simple majority (*Pharos* v *Commission*, cited in paragraph 50 above, paragraph 27).

In the present case, the Commission did not request a new scientific opinion from EFSA during the period between the vote of the regulatory committee on 25 February 2009 and the date of the receipt of the invitation to act on 29 December 2009. On the expiry of the period of two months following receipt of the invitation to act on 1 March 2010, the Commission had not raised any issue of scientific uncertainty that had been reported to it concerning the placing on the market of maize 1507. It merely stated that the period since 25 February 2009 was necessary in order to examine the various possible courses of action, but without explaining what the various available options were.

As regards the Commission's argument that the aim was to prevent the proposal relating to the measures to be taken from being rejected by the Council by simple majority, it must be noted that, under the second subparagraph of Article 5(6) of Decision 1999/468, the Council may oppose the Commission proposal by qualified majority. If there is no qualified majority at the time of the Council vote, the third subparagraph of Article 5(6) of Decision 1999/468 will apply. That provision states that if 'the Council has neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures, the proposed implementing act shall be adopted by the Commission'. Therefore, should there be no qualified majority in the Council due to the opposition of certain Member States, as was the case with the vote of the regulatory

committee, and where the Council is acting by simple majority, Decision 1999/468 expressly provides that the decision is to be adopted by the Commission. Thus, contrary to what the Commission appears to submit, a Council vote by simple majority does not preclude the adoption of a final decision. It follows that the Commission cannot plead such circumstances in order indefinitely to delay its obligation to submit the proposal to the Council 'without delay'.

Secondly, the Commission indicated, in its letter of 21 January 2010 in reply to the invitation to act, that the College of Commissioners would take a decision on the matter once it had been entrusted with its new mandate. In its defence, it states that, until the new Commission took up its duties on 10 February 2010, the Council could not be seized of that individual procedure without running the risk of prejudging future political discussions on the general issue of the cultivation of genetically modified organisms ('GMOs'). The Commission adds that in March 2010 it announced a new initiative on GMOs for the summer of 2010 and that it adopted measures on the adoption of a new framework for the cultivation of GMOs on 13 July 2010. Having regard to the circumstances of the present case, the fact that it did not submit a proposal to the Council during the 12-month period between 25 February 2009 and 1 March 2010 is reasonable and justified.

In that regard, it must be pointed out that between 25 February 2009, the date of the vote of the regulatory committee, and 1 November 2009, the date on which the Commission entered into a transitional arrangement to deal with current matters, several months passed during which the Commission could have sent the proposal relating to the measures to be taken to the Council. Furthermore, the new College of Commissioners was appointed on 10 February 2010. The two-month period following the invitation to act expired on 1 March 2010, which left time for the new College of Commissioners to submit to the Council a draft decision on the application for the placing on the market of maize 1507.

Furthermore, the Commission cannot argue that such an individual procedure risked prejudging future political discussions on the general issue of GMO cultivation. The fact that the Commission, in its new composition, announced a new legislative initiative on GMOs in March 2010 is irrelevant, since that new legislation has, in any event, no bearing on the applicant's notification. Finally, that argument is contradicted by the fact that on 2 March 2010 the Commission adopted Decision 2010/135/EU concerning the placing on the market, in accordance with Directive 2001/18, of a potato product (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch (OJ 2010 L 53, p. 11).

It is apparent from the above that the Commission has not put forward any valid justification for having failed to submit to the Council the proposal for a decision on the placing on the market of maize 1507 upon the expiry of the two-month period following the receipt of the invitation to act, that is to say, 1 March 2010. It must therefore be held that the Commission failed to fulfil its obligation to submit, without delay, that proposal to the Council in accordance with Article 5(4) of Decision 1999/468.

It is necessary to ascertain whether the events that took place after that date are capable of releasing the Commission from its obligation to act.

After 1 March 2010, the Commission requested a new opinion from EFSA on 14 June 2010, inviting it to examine the scientific content of the opinion of an institute carrying out independent impact assessments in the field of biotechnology. In 2010, that institute brought to the Commission's attention new scientific concerns regarding the application for authorisation for the placing on the market of maize 1507.

EFSA delivered its opinion on 19 October 2011, which was replaced by its opinion of 24 February 2012 updating the environmental risk assessment and the risk management recommendations regarding maize 1507 for cultivation.

At the hearing on 20 June 2012, the Commission stated that it had sent a letter to the applicant on 18 June 2012. In that letter, the Commission informed the applicant that, following a new opinion of EFSA of 19 October 2011, certain changes had to be made to its notification. The Commission requested the applicant to modify its monitoring plan and to propose risk mitigation measures for Lepidoptera non-target insects in line with EFSA's recommendations.

By letters of 17 July and 8 October 2012, the applicant informed the Commission that it was examining the questions raised in the letter of 18 June 2012 concerning the monitoring plan.

On 20 June and 13 September 2012, the Commission sent two new requests for opinions to EFSA.

EFSA issued an opinion on 18 October 2012, published on 25 October 2012, updating the risk assessment conclusions and the risk management recommendations regarding maize 1507. EFSA issued another opinion on 18 October 2012, published on 6 November 2012, supplementing the conclusions of the environmental risk assessment and the risk management recommendations regarding maize 1507 for cultivation.

By letter of 11 February 2013, the Commission informed the applicant that EFSA had issued two new opinions and reiterated its requests for modifications to the monitoring plan and the adoption of mitigation measures in order to take into account EFSA's 2011 and 2012 opinions.

By letter of 18 February 2013, the applicant stated that it had examined the current monitoring plan and took the view that that plan remained effective as regards allowing the procedure for adopting a decision concerning maize 1507 to continue and that modifications were not necessary. The applicant indicated that the monitoring plan notified with its application for placing on the market was in line with the recommendations set out in EFSA's latest opinion, that that plan did not require to be modified and that the mitigation measures were already included in the notification.

In that regard, it must be noted that, according to Article 13(6) of Directive 2001/18, '[i]f new information has become available with regard to the risks of the GMO to human health or the environment, before the written consent is granted, the notifier shall immediately take the measures necessary to protect human health and the environment, and inform the competent authority thereof. In addition, the notifier shall revise the information and conditions specified in the notification.'

In the present case, the applicant refused to modify its notification. In such a case, none of the provisions of

Directive 2001/18 enables the Commission to require the applicant to modify its notification or to block the procedure for adopting the decision.

It should be pointed out that it was held, at paragraph 58 above, that the Commission was guilty of a failure to act on 1 March 2010. It is only subsequently, in its letter of 18 June 2012, that the Commission relied on the information contained in EFSA's opinion of October 2011 as a justification for not having submitted the draft decision concerning the placing on the market of maize 1507 to the Council.

It must be observed that GMOs constitute a constantly evolving area of research and there is no doubt that new scientific information is likely to become available in the future. However, the Commission cannot, in a dilatory manner, repeatedly request opinions from EFSA pending the arrival of new scientific data and thereby justify its failure to submit the proposal to the Council. That is all the more the case, since Article 20(2) of Directive 2001/18 provides that if new information has become available with regard to the risks of GMOs to human health or the environment, the notifier must immediately revise the information and conditions specified in the notification.

Furthermore, it must be noted that, on 1 March 2011, Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ 2011 L 55, p. 13), which repealed Decision 1999/468, entered into force.

It is true that it is apparent from settled case-law that, unlike substantive rules of Community law, which must be interpreted as not applying, in principle, to situations existing before their entry into force, procedural rules are of immediate application (see Joined Cases T-27/03, T-46/03, T-58/03, T-79/03, T-80/03, T-97/03 and T-98/03 *SP and Others* v *Commission* [2007] ECR II-4331, paragraph 116 and the case-law cited).

However, it must be pointed out that, by virtue of Article 14 of Regulation No 182/2011, which lays down transitional provisions, that regulation does not affect pending procedures in which a committee has already delivered its opinion in accordance with Decision 1999/468.

That is so in the present case. Since the regulatory committee voted on 25 February 2009, the procedure provided for in Article 5 of Decision 1999/468 must be considered as being pending within the meaning of Article 14 of Regulation No 182/2011.

That interpretation is shared by the Commission and the applicant which both stated at the hearing that the present case involves a pending procedure within the meaning of Article 14 of Regulation No 182/2011, which is covered by Decision 1999/468.

At the hearing, however, the Commission argued that EFSA's new opinion of October 2011 entailed modifications to the applicant's notification which led to substantial modifications of the proposal for a decision. The Commission submitted that, as a result of those modifications, the proposal for a decision would differ from that on which the regulatory committee had voted on 25 February 2009. It stated that that amended proposal could no longer be submitted to the Council, but had to be resubmitted to the regulatory committee and that, therefore, the applicable procedure was that laid down by Regulation No 182/2011.

However, that is not the case here, the applicant having stated, in its letter of 18 February 2013, that modifications to its notification were not necessary and that it would not make such modifications.

In those circumstances, it must be held that none of the arguments put forward by the Commission justify it not having submitted the proposal for a decision to the Council.

It follows from all of the above that on 1 March 2010, that is to say, two months after 29 December 2009, being the date on which it received the invitation to act, the Commission must be considered as having failed to act, since it had not submitted to the Council the proposal for a decision concerning the placing on the market of maize 1507 in accordance with Article 5(4) of Decision 1999/468.

Accordingly, the application must be held to be well founded.

Costs

Under Article 87(2) of the Rules of Procedure of the Court, 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 been unsuccessful, it must be ordered to pay the costs, in accordance with the form of order sought by the applicant.

On those grounds,

THE GENERAL COURT (Seventh Chamber)

hereby:

Declares that the European Commission has failed to fulfil its obligations under Article 18 of 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 Council Directive 90/220/EEC by failing to submit to the Council a proposal relating to the measures to be taken pursuant to Article 5(4) of Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission;

Orders the Commission to pay the costs.

Dittrich Wiszniewska-Białecka Prek

Delivered in open court in Luxembourg on 26 September 2013.

[Signatures]

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* Language of the case: English.