

ANNEX B

TABLES SUMMARIZING THE HISTORY OF THE INDIVIDUAL APPROVAL PROCEDURES AT ISSUE IN THIS DISPUTE

1. The Panel has prepared a series of tables summarizing relevant aspects of the history of the individual approval procedures at issue in this dispute. The tables were prepared on the basis of information provided by the Parties, and in particular the detailed chronologies of individual approval procedures submitted by the European Communities.

2. Since the Panel's findings tend to focus on specific stages of individual approval procedures, it seemed useful to provide some background information on developments and activities at other procedural stages. Consistent with their limited purpose, the Panel's tables do not reflect any and all activities of member State authorities, EC authorities or applicants of which the Panel has been made aware. It should also be noted that the information provided in the tables is more detailed for those stages and activities which the Panel has focused on for the purposes of its analysis, and less detailed for other stages and activities.

3. In preparing the tables, the Panel has found it useful to distinguish the following procedural stages, which also reflect the main stages of the approval procedures set out in the relevant EC approval legislation for biotech products (Directives 90/220 and 2001/18 as well as Regulation 258/97):

- (a) Consideration of application at member State level ("Member State Level")
 - (i) Initial assessment of application by lead CA. ("Lead Member State Level").
- (b) Consideration of application at Community level ("Community Level")
 - (i) Circulation of lead CA assessment to other member States ("Other Member States").
 - (ii) Consultation of EC scientific committee ("Scientific Committee Process").
 - (iii) Preparation of draft measure to be submitted to the Regulatory Committee ("Commission").
 - (iv) Consideration by the Regulatory Committee of the draft measure submitted by the Commission ("Regulatory Committee Process").
 - (v) Preparation of draft measure to be submitted to the Council ("Commission").
 - (vi) Consideration by the Council of the draft measure submitted by the Commission, including decision by the Council ("Council").
 - (vii) Adoption by Commission of its draft measure in case the Council fails to decide (Directives 90/229 and 2001/18 as well as Regulation 258/97) and application of applicant of decision (Regulation 258/97) ("Commission").

- (viii) Written consent of lead CA to placing on the market (Directives 90/220 and 2001/18) ("Lead Member State").

4. While the Panel's tables are structured according to the above-mentioned procedural stages, it is important to note that each table provides information on only those stages which have been completed or reached in the relevant approval procedure.


5. Due to constraints of space, the Panel's tables contain a number of abbreviations. They are explained below. Furthermore, the Panel has used short titles to refer to the products which are the subject of the relevant approval procedures. These short titles are explained in a list provided at the beginning of these Panel Reports.

Useful Terms	
ACRE	Advisory Committee on Release into the Environment
CA	Competent Authority
CO	Council
COGEM	Commission on Genetic Modification
COM	Community
DK	Denmark
EFSA	European Food Safety Authority
ISC	Inter Service Consultation
MS	Member States
NBC	National Biosafety Committee
RIKILT	Institute of Food Safety
SCP	Scientific Committee on Plants
SCF	Scientific Committee on Food
SNIF	Summary Application Information Format
vCVNV	Provisional Commission for Food Safety (Food Assessment Body for Novel Foods of the Netherlands)

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>			
	<i>Lead Member State Level</i>	<i>Circulation to other Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>	<i>Regulatory Committee Process</i>
EC-62 Falcon oilseed rape	<u>Directive 90/220/EEC</u>				
	<ul style="list-style-type: none"> • 01/04/1996 Applicant submits application. • 14/05/1996–24/07/1996 Exchange of information between the applicant and the lead CA. • 25/10/1996 Statement by the lead CA. 	<ul style="list-style-type: none"> • 25/10/1996 Full application submitted to COM. • 09/12/1996 Application circulated to all MS. • 01/1997- 10/1997 Requests for additional information by lead CA and replies by applicant. Comments/objections by MS. 	<ul style="list-style-type: none"> • 20/02/1998 COM requests SCP opinion. • 14/07/1998 Opinion of the SCP: favourable. 	<ul style="list-style-type: none"> • 04/09/1998 COM launches ISC on draft COM decision to be submitted to REG COM. 	<ul style="list-style-type: none"> • 29/06/1999 COM launches vote in REG COM by written procedure. • 7/99 – 9/99 Additional information provided by the applicant. • 29/10/1999 Meeting of REG COM: vote postponed. • 10/11/1999 Applicant submits update of application, including additional information and commitments. • 09/03/2000 Meeting of REG COM: no vote held due to further requests for information. • 14/03/2000 Fax from the Italian Competent Authority requesting additional information from the applicant. • 20/04/2000 Letter of German CA to applicant about modification of the scope of application. • 11/00 Responses provided by the applicant.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>			
	<i>Lead Member State Level</i>	<i>Circulation to other Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>	<i>Regulatory Committee Process</i>
	<p style="text-align: center;">↓</p> <p><u>Directive 2001/18/EC</u></p> <ul style="list-style-type: none"> • 16/01/2003 Statement of completeness by applicant. Applicant updates SNIF. • 14/10/2003 Request for clarification and further update of SNIF. 				<ul style="list-style-type: none"> • 29/05/2001 Applicant submits letter, claiming that the application is already in line with Directive 2001/18. • 25/07/2001 Lead CA requests for clarification by the applicant on additional documents. • 21/11/2001 Applicant submits documents to support "working group on HT crops". • 02/04/2002 Lead CA requests further modifications and supplementary information, after applicant provided additional information. • 08/05/2002 Reply by the applicant to the request of 02/04/2002 for additional information. • 23/12/2002 Lead CA requests applicant for clarification on submitted documents.

Product	Member State Level	Community Level			
	Lead Member State Level	Circulation to Member States	Scientific Committee Process	Commission	Regulatory Committee Process
EC-63 MS8/RF3 oilseed rape	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 30/09/1996 Applicant submits application to Belgium. • 10 and 17/12/1996 Meetings of the Belgian Biosafety Council. <p>(Positive advice of the Scientific Committees on Transgenic Plants and on Novel feed/food).</p>	<ul style="list-style-type: none"> • 07/01/1997 Submission by lead CA to COM of full application. • 29/01/1997 Application circulated to all MS. • 02/1997 – 12/1997 Statements, comments and objections by MS. Applicant provides additional information. 	<ul style="list-style-type: none"> • 27/01/1998 COM requests for SCP opinion. • 19/05/1998 SCP opinion: favourable. 	<ul style="list-style-type: none"> • 04/09/1998 COM launches ISC on draft COM decision to be submitted to REG COM. 	<ul style="list-style-type: none"> • 30/06/1999 COM launches vote in REG COM by written procedure. • 22/10/1999 COM invites applicant to present additional information following interim approach to REG COM. • 10/11/1999 Applicant submits update in line with revised EC legislation. • 29/10/1999 REG COM meeting: presentation by applicant of update; no vote held. • 14/03/2000 Fax from Italian CA raising questions subsequent to the REG COM meeting. • 13/11/2000 Applicant provides answers to questions raised by Italy on 14/03/2000. • 20/12/2000 COM circulates applicants answers to all CAs. • 05/06/2001 Applicant provides clarifications to lead CA on the scope of the application, and updates to bring dossier in line with provisions of Directive 2001/18/EC.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>			
	<i>Lead Member State Level</i>	<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>	<i>Regulatory Committee Process</i>
	 <p><u>Directive 2001/18/EC</u></p> <ul style="list-style-type: none"> 14/01/2003 Applicant submits updated application. 				<ul style="list-style-type: none"> 19/06/2001 Meeting of CAs. 12/07/2001 Letter of lead CA to applicant acknowledging receipt of further information and soliciting envoy of reference material. 11/09/2001 Applicant submits reference material and information on detection methodology, in response to prior requests by the lead CA on 12/07/2001. 13/11/2001 Meeting of Belgian Biosafety Council. 07/02/2002 Meeting of Belgian Biosafety Council (Scientific Committee "Transgenic Plants"). 28/03/2002 Lead CA communicates that Belgian Biosafety Council requested additional data. 24/09/2001- 07/05/2002 Applicant provides answers to pending questions by the CA.

Product	Member State Level	Community Level			
		Circulation to Member States	Scientific Committee Process	Commission	Regulatory Committee Process
EC-64 RR fodder beet	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> 21/02/1997 Application received by the lead CA. 24/03/1997 – 30/09/1997 Lead CA requests for additional information. Applicant provides the lead CA with additional data. 	<ul style="list-style-type: none"> 07/10/1997 Lead CA forwards the application to COM, together with positive opinion (non- confidential part). 09/10/1997 and 15/10/1997 Non-confidential and confidential part received by COM. 16/10/1997 Non confidential and confidential part sent to MS. 02/12/1997 Technical meeting with CAs where comments/requests for further data were addressed. 10/12/1997 Applicant provides additional information related to the comments raised at the CAs meeting. 	<ul style="list-style-type: none"> 13/03/1998 COM request for SCP opinion. 23/06/1998 Opinion of the SCP: favourable. 	<ul style="list-style-type: none"> 04/09/1998 COM launches ISC on draft decision to be submitted to REG COM. 24/09/1998 – 19/10/1999 Clarifications, additional information and commitments submitted by the applicant. <ul style="list-style-type: none"> On 04/08/1999 the applicant met the Dutch CA. 	<ul style="list-style-type: none"> 29/10/1999 REG COM meeting: presentation by the company of the update; no vote held because of outstanding additional information. 09/03/2000 Meeting of the REG COM: no vote held. 14/03/2000 Fax from the Italian CA raising questions subsequent to SCP opinion. 12/07/2000 Additional data on molecular characterisation (at the request of UK), regarding questions raised from Italy. 04/01/2001 Clarifications by the applicant with regard to undertakings and commitments.
	<p><u>Directive 2001/18</u></p> <ul style="list-style-type: none"> 16/01/2003 Updated application submitted by the applicant. 	<ul style="list-style-type: none"> 12/12/1997 Dutch CA requests additional information. 			

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>				
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>	<i>Regulatory Committee Process</i>	<i>Commission</i>
EC-65 Bt-531 cotton	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> 02/12/1996 Applicant submits application. 30/04/1997 Applicant expresses its intention to submit the dossier also under the Novel Food Regulation. 	<ul style="list-style-type: none"> 17/11/1997 Lead CA submits full application to COM. 15/12/1997 Full application circulated to all CAs. 20/01/1998 – 25/02/1998 Comments and objections by MS. Applicants provides answers to the questions raised. 	<ul style="list-style-type: none"> 06/04/1998 COM request for SCP opinion. 14/07/1998 SCP opinion: favourable. 	<ul style="list-style-type: none"> 04/09/1998 COM launches ISC on draft decision to be submitted to the REG COM. 	<ul style="list-style-type: none"> 26/11/1998 COM launches vote in REG COM by written procedure. 22/02/1999 REG COM vote: absence of qualified majority. Outcomes of the written procedure including written statements from Sweden, Austria and UK. 	<ul style="list-style-type: none"> 07/05/1999 COM launches ISC on draft measure to be submitted to the Council. 25/07/2001 Applicant provides updated molecular characterisation and Safety Assessment. (analysis of flanking regions). 18/02/2002 Applicant provides translations of material sent in July 2001.
	<p><u>Directive 2001/18</u></p> <ul style="list-style-type: none"> 16/01/2003 Applicant submits updated application. 01/08/2003 Lead CA requests for additional information. 					

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>				
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>	<i>Regulatory Committee Process</i>	<i>Commission</i>
<p>EC-66</p> <p>RR-1445</p> <p>cotton</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 30/06/1997 Applicant submits application. 	<ul style="list-style-type: none"> • 19/11/1997 Lead CA submits full application to COM. • 15/12/1997 Circulation of full application to all CAs. • 20/01/1998 - 17/02/1998 Comments, objections and questions raised by MS. Applicant provides additional information. 	<ul style="list-style-type: none"> • 01/04/1998 COM request for SCP opinion. • 30/06/1998 Request by SCP for additional data. • 14/07/1998 SCP opinion: favourable. 	<ul style="list-style-type: none"> • 04/09/1998 COM launches ISC on draft decision. 	<ul style="list-style-type: none"> • 26/11/1998 COM launches vote in REG COM by written procedure. • 30/11/1998 DK requests extension of the deadline for the vote in order to revise additional information submitted by the applicant. • 04/12/1998 COM informs CAs that the deadline for the vote is extended. • 10/12/1998 Belgium requests that the vote be postponed. • 21/12/1998 UK requests that the vote be postponed, in order to meet with the applicant and discuss further information recently submitted. 	<ul style="list-style-type: none"> • 07/05/1999 COM launches ISC on draft Council Decision.
	<p><u>Directive 2001/18</u></p> <ul style="list-style-type: none"> • 16/01/2003 Updated application submitted by the applicant. 					

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>				
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>	<i>Regulatory Committee Process</i>	<i>Commission</i>
					<ul style="list-style-type: none"> • 23/12/1998 COM informs the CAs that the deadline for the vote is extended. • 13/01/1999 Opinion of Commission du Génie Biomoléculaire. • 26/01/1999 COM informs of further extension of the deadline for the vote, at the request of the lead CA. • 22/02/1999 REG COM vote: absence of qualified majority. (Outcomes of the written procedure including statements from Sweden, Austria and UK). 	

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>	
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>
<p>EC-67</p> <p>Transgenic potato</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> 05/08/1996 Lead CA acknowledges receipt of the application submitted by the applicant. ("not complete"). 27/09/1996 Request for completion. 31/01/1997 – 21/11/1997 Further requests by lead CA. Information submitted by the applicant. 07/05/1998 Final complete application and approval by the Swedish Board of Agriculture. 	<ul style="list-style-type: none"> 08/05/1998 Lead CA sends dossier and statement to COM. 11/06/1998 Application statement and positive opinion of lead CA circulated to all CAs. 14/07/1998 Advice by RIKILT (Institute of Food Safety): additional information to be provided by the applicant. 15/07/1998 – 09/09/1998 Comments and objections by MS. Information and clarifications provided by the applicant. 	<ul style="list-style-type: none"> 30/09/1998 COM requests opinion of the SCP. 09/11/1998 SCP meeting. 04/01/1999 Amylogene provides SCP working group with the full application and additional data. 04/02/1999- 19/04/2002 Nine requests for clarifications by the SCP. Answers given by the applicant. - Draft opinion on 12/07/1999 - SCP meeting on 28/01/2000 18/07/2002 Opinion of the SCP. (favourable)
	<p><u>Directive 2001/18/EC</u></p> <ul style="list-style-type: none"> 16/01/2003 Applicant submits updated application. 	<ul style="list-style-type: none"> 14/04/2004 Lead CA forwards dossier and assessment report to COM. 04/05/2004 Circulation of application and statement of lead CA to all CAs 	

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>	
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>
<p>EC-68</p> <p>Liberator oilseed rape</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 13/01/1998 Applicant submits application. • 09/02/1998 – 15/06/1998 Requests for further completion and clarification of the dossier. Applicant submits further amendments and corrections. • 17/06/1998 Completeness of the dossier confirmed. 	<ul style="list-style-type: none"> • 26/10/1998 Full application and statement of lead CA submitted to COM. • 14/01/1999 Full application (confidential part) circulated to all CAs. • 15/01/1999 – 28/04/1999 Comments, objections and requests for additional information by MS. Applicant provides replies to questions. 	<ul style="list-style-type: none"> • 18/08/1999 COM requests SCP opinion. • 27/08/1999 – 06/11/2000 Applicant forwards dossier to SCP and provides answers and additional information. • 30/11/2000 Opinion of the SCP. • 05/11/2002 Request for update.
	<p>▼</p> <p><u>Directive 2001/18/EC</u></p> <ul style="list-style-type: none"> • 16/01/2003 Submission of update by the applicant. 		

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>	
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>
EC-69 Bt-11 maize (EC-69)	<u>Directive 90/220/EEC</u> <ul style="list-style-type: none"> • 28/05/1996 Applicant submits application. • 17/06/1996 Lead CA receives application. • 06/1996 – 01/1999 Requests for additional information. Applicant provides additional information. 	<ul style="list-style-type: none"> • 04/04/1999 Lead CA submits application to COM with a favourable opinion. • 07/05/1999 Application sent to all CAs. • 06/1999 – 10/2000 Requests for further information and objections by CAs. Applicant provides additional information. 	<ul style="list-style-type: none"> • 30/11/2000 SCP opinion. (favourable) • 03/05/2002 Applicant updates application by including new sequence data.
	<u>Directive 2001/18/EC</u> <ul style="list-style-type: none"> • 15/01/2003 Applicant updates application. 	<ul style="list-style-type: none"> • 16/06/2003 Applicant submits updated application (including the new SNIF, environmental risk assessment and supplementary information) to the COM, together with the statement of the lead CA and its favourable assessment report. 	

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>	
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>
<p>EC-70</p> <p>RR oilseed rape (EC-70)</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 07/07/1998 Applicant submits application. • 05/08/1998 – 18/11/1999 Requests for additional information and replies provided by the applicant. • 29/02/2000 Advice on application by the scientific committees. • 22/03/2000 Update of status and completeness of dossier. • 03/2000 – 03/2001 Additional information and clarifications submitted by applicant. (We note two dates: <ul style="list-style-type: none"> - on 28/04/2000 applicant submitted additional information - on 17/05/2000 applicant submitted clarifications) • 12/03/2001 Request for detection method. • 10/05/2001 Request for motivation for confidentiality status of the detection method detection method. 	<ul style="list-style-type: none"> • 16/01/2003 COM receives new SNIF. • 24/01/2003 COM circulates dossier to other CAs. • 24, 25/03/2003 Objections raised by MS. • 28/04/2003 Meeting with COM, applicant and all CAs in order to solve the outstanding issues. • 05/08/2003 – 29/09/2003 Applicant provides additional information. Evaluation of the additional information. 	<ul style="list-style-type: none"> • 23/10/2003 COM requests scientific opinion from EFSA Scientific Panel on GMOs. • 11/02/2004 Opinion of the Scientific Panel on GMOs issues: favourable.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>	
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>
	<ul style="list-style-type: none"> • 20/09/2001 Applicant provides lead CA with detection method after the exchange of information on the confidentiality issue. • 13/11/2001 – 29/11/2002 Exchange of information between the lead CA and applicant with regard to the confidentiality status of the primer sequences of the detection method. <ul style="list-style-type: none"> - On 17/01/2002 the lead CA grants confidentiality status on primer sequences and requests reference material. <p><u>Directive 2001/18/EC</u></p> <ul style="list-style-type: none"> • 13/12/2002 Applicant provides a full updated application. 		

<i>Product</i>	<i>Member State Level</i>
<p>EC-71 LL soybeans (EC-71)</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 28/09/1998 Applicant submits application. • 30/10/1998 – 05/09/2001 Lead CA requests for additional information and answers provided by the applicant, including: <ul style="list-style-type: none"> - 31/03/1999: Letter from Biosafety Council requesting further data. - 01/12/2000: Applicant clarifies that the application is maintained in Belgium and provides information on when requested data will be sent. - 05/12/2000: Lead CA confirms the continuation of the evaluation process and requiring additional information. • 05/09/2001 Lead CA requests for clarifications about the status of the double application in Belgium and Portugal and explains that the maintenance of the application in Portugal will entail suspension of the evaluation process in Belgium. • 08/10/2001 Applicant asserts the maintenance of double concurrent applications. <p><u>Directive 2001/18</u></p> <ul style="list-style-type: none"> • 15/01/2003 Update of the application. • 27/01/2003 Withdrawal of the application (Portugal). • 17/03/2003 Preliminary informal answer from the applicant with some of the information requested. • 29/06/2004 Withdrawal of the application.

<i>Product</i>	<i>Member State Level</i>
<p>EC-72</p> <p>LL oilseed rape</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 28/01/1999 Applicant submits application to the UK CA. • 15/02/1999 and 24/03/1999 Lead CA requests for additional information. • 30/06/1999 Lead CA acknowledges receipt ("clock restarted"). • 20/07/1999 Request for additional information. • 11/11/1999 Minutes of 62nd meeting of ACRE. • 02/12/1999 UK Scientific Committee advises the applicant that the dossier requires substantial revision and clarification. • 16/01/2003 Applicant updates application. • 27/01/2003 Lead CA requests completion of up-dated notification. • 26/03/2004 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>
	<p data-bbox="298 375 531 402"><u>Directive 2001/18/EC</u></p> <ul data-bbox="298 435 1318 841" style="list-style-type: none"><li data-bbox="298 435 1318 492">• 13/01/2003 Applicant submits General Surveillance Plan in accordance with Annex VII of Directive 2001/18/EC.<li data-bbox="298 524 743 581">• 16/01/2003 Applicant submits new SNIF to the UK CA.<li data-bbox="298 613 827 670">• 13/06/2003 Applicant provides clarifications on the notification.<li data-bbox="298 703 793 760">• 26/03/2004 Applicant withdraws application C/GB/99/M5/2.<li data-bbox="298 792 905 849">• 30/03/2004 SNIF re-submitted to COM under reference C/GB/04/M5/4.

<i>Product</i>	<i>Member State Level</i>
<p>EC-73 BXN cotton</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 03/05/1999 Applicant submits application. • 01/07/1999 6th Meeting of the National Biosafety Committee ("NBC") of the lead CA: several questions raised and amendments proposed. • 17/09/1999 Applicant sends fax addressing some of the issues raised. • 25/01/2000 9th Meeting of the Spanish NBC (further examination of the application). • 02/02/2000 Lead CA informs applicant about persisting doubts. <p style="text-align: center;">↓</p>

<i>Product</i>	<i>Member State Level</i>
	<p><u>Directive 2001/18/EC</u></p> <ul style="list-style-type: none">• 16/01/2003 Applicant updates application following Article 35 of Directive 2001/18.• 19/03/2003 Applicant sends SNIF summary.• 18/07/2003 SNIF circulated to COM.• 26/09/2003 Analysis of the notification by the Spanish NCB – 36th Meeting.• 02/10/2003 Lead CA sends fax to applicant requesting additional information related to labelling proposal, molecular characterization and general surveillance plan.• 07/10/2003 Fax of lead CA to the applicant requesting additional information related to substantial equivalence.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>	
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>
<p>EC-74</p> <p>Bt-1507 maize (EC-74)</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 23/11/2000 Applicant submits application. • 12/2000 – 11/2002 Lead CA requests additional information. Applicant provides additional information. <ul style="list-style-type: none"> - On 16/10/2001 the applicant provides first set of answers, indicating that further responses would be delivered in December 2001. - On 21/11/2001 the applicant provides additional information and replies to questions. <p style="text-align: center;">↓</p>	<ul style="list-style-type: none"> • 15/08/2003 Full application and assessment report sent to COM. • 26/08/2003 Application and assessment report circulated to all MS. • 08/2003 – 02/2004 Comments and objections by MS. Applicant provides responses. 	<ul style="list-style-type: none"> • 26/02/2004 COM requests EFSA opinion. • 12/03/2004 Letters from COM to EFSA clarifying some MS objections.
	<p><u>Directive 2001/18/EC</u></p> <ul style="list-style-type: none"> • 21/11/2002 Applicant updates application. • 02/2003 – 03/2003 Lead CA requests additional information. Applicant provides additional information. <ul style="list-style-type: none"> - On 10/02/2003 the lead CA requests further information on compositional data, monitoring plan, confidentiality of detection method. - On 24/03/2003 applicant provides additional information. • 28/05/2003 Applicant provides clarifications with regard to confidentiality status. 		

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>
		<i>Circulation to Member States</i>
<p>EC-75</p> <p>Bt-1507 maize (EC-75)</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> 06/07/2001 Applicant submits application. 09/2001 – 12/2002 Lead CA requests for additional information. Applicant submits additional information. <p style="text-align: center;">↓</p> <p><u>Directive 2001/18/EC</u></p> <ul style="list-style-type: none"> 13/02/2003 Lead CA submits updated SNIF to COM. 02/2003 – 04/2003 Requests for additional information. Applicant provides additional information. 28/05/2003 Applicant submits updated application. 	<ul style="list-style-type: none"> 08/2003 - Lead CA submits full application and assessment report to COM. - Application and assessment report circulated to all MS. 10/2003 – 03/2004 Comments, objections and requests for additional information by MS. Applicant provides additional information. 05/2004 – 06/2004 Comments/objections by MS.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>				
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>	<i>Regulatory Committee Process</i>	<i>Council</i>
EC-76 NK603 maize	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 04/08/2000 Applicant submits application. • 20/12/2000 Applicant clarifies the scope of the application and provides Spanish translation. • 02/01/2001 Lead CA acknowledges receipt. 	<ul style="list-style-type: none"> • 14/01/2003 Lead CA submits full application and assessment report to COM. • 24/01/2003 Application and assessment report circulated to all MS. • 24/02/2003 – 28/08/2003 Comments and objections by MS. Answers and additional information given by the applicant. 	<ul style="list-style-type: none"> • 04/09/2003 COM requests EFSA opinion. • 25/11/2003 EFSA opinion adopted: favourable. 	<ul style="list-style-type: none"> • 08/12/2003 COM launches ISC on draft COM Decision. 	<ul style="list-style-type: none"> • 18/02/2004 Absence of qualified majority in REG COM. 	<ul style="list-style-type: none"> • 26/03/2004 Transmission of the proposal to the Council.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>				
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>	<i>Regulatory Committee Process</i>	<i>Council</i>
	<ul style="list-style-type: none"> • 15/02/2001-19/06/2002 National Biosafety Committee requests additional information. Applicant provides additional information. - 27/02/2001: In the 18th Meeting of the National Biosafety Committee ("NBC"), additional information requested on molecular characterisation, nutritional analysis, environmental impact, etc. - On 05/09/2001 applicant provides additional information. - On 10/10/2001 lead CA forwards request of NBC for further information. - On 21/05/2002 lead CA forwards persisting doubts of NBC over certain information supplied. <ul style="list-style-type: none"> • 29/08/2002 Applicant updates application in line with the requirements of the Directive 2001/18/EC. <p><u>Directive 2001/18/EC</u></p> <ul style="list-style-type: none"> • 20/11/2002 Applicant provides updated SNIF. 					

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>			
		<i>Circulation to Member States</i>	<i>Commission</i>	<i>Regulatory Committee Process</i>	<i>Commission</i>
<p>EC-77</p> <p>Transgenic red-hearted chicory</p> <p>(Notification C/NL/94/25)</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 15/12/1994 Applicant submits full application to lead CA. • 23/01/1995 Advice of Commission on Genetic Modification (COGEM): information insufficient. • 31/03/1995 Statement of Dutch CA with evaluation summary: favourable. 	<ul style="list-style-type: none"> • 31/03/1995 Lead CA forwards full application to COM. • 20/04/1995 Full application forwarded to all CAs. • 30/05/1995-27/07/1995 Comments and objections by MS. Responses to questions and clarifications by the lead CA. 	<ul style="list-style-type: none"> • 25/01/1996 COM launches ISC on draft COM decision. 	<ul style="list-style-type: none"> • 08/03/1996 Consultation of the REG COM by written procedure. • 24/04/1996 Consultation of REG COM: Positive opinion. 	<ul style="list-style-type: none"> • 03/05/1996 Request by written procedure for approval by COM members. • 10/05/1996 Written procedure suspended. • 14/05/1996 Written procedure re-launched subject to specific labelling requirements. • 20/05/1996 Decision 96/424/EC for placing of the product on the market. • 05/08/1996 Written consent by Dutch CA to applicant. • 01/03/2003 Letter of withdrawal. • 24/04/2003 Confirmation letter of withdrawal to applicant.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>		
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>
<p>EC-77</p> <p>Transgenic red-hearted chicory</p> <p>(Notification C/NL/94/25/A)</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> 10/09/1996 Applicant submits the part of the application dealing with food safety aspects to lead CA. 	<ul style="list-style-type: none"> 13/09/1996 Lead CA forwards application to COM. 11/07/1996-08/05/1998 Requests for additional information, comments and objections by MS. Applicant provides answers and additional information. 	<ul style="list-style-type: none"> 02/06/1998 COM requests SCP opinion. 07-09/1998 Questions raised by the SCP and answers provided by the applicant. 19/10/1998 SCP requests for further information. 01/12/1998 Applicant provides further information. 18/12/1998 Opinion of the SCP: favourable. 10/09/1999 Questions by SCP raised in the context of the evaluation according to the 258/97 Regulation. 16/11/1999 Comments by the SCP on the draft opinion of the SCF. 	<ul style="list-style-type: none"> 30/03/1999 Proposal to amend COM Decision 96/424/EC. Request for launching of ISC. (Same GM product had already been authorised for breeding activities at the Community level.) 10/05/1999 ISC launched. 26/05/1999 ISC closed.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>		
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>
			<ul style="list-style-type: none"> • 10/07/2000 – 18/06/2001 SCF requests applicant to submit additional information and clarifications. <ul style="list-style-type: none"> - On 10/07/2000 SCF requests further information about substantial equivalence. - On 14/11/2000 the applicant submits further clarifications. - On 11/06/2001 the applicant requests further clarifications on the antibiotic resistance markers. - On 18/06/2001 SCF requests additional information (already requested on 10/07/2000). • 24/07/2001 Clarifications by COM to applicant about the phasing-out of antibiotic resistance markers. 	

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>		
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>
<p>EC-78 GA21 maize (EC-78)</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 29/05/1998 Receipt of application. • 16/06/1998-13/07/1998 Two meetings of the Spanish scientific committee (33rd and 35th). Answers provided by the applicant to questions posed. • 31/07/1998 Request for further data. 	<ul style="list-style-type: none"> • 11/05/1999 Spanish lead CA forwards application to COM. • 06 and 07/1999 Application sent to MS. Comments/objections of MS circulated. • 28/07/1999 Voluntary commitments by the applicant. • 29/07/1999 Technical meeting on pending products. Applicant provides general information. • 08/1999 Comments by MS. Applicant provides answers. 	<ul style="list-style-type: none"> • 29/10/1999 COM sends dossier to SCP for opinion. • 22/02/2000 SCP requests clarification. • 15/03/2000 Applicant provides answers to request for clarification. • 06 and 07/2000 Further requests for additional information and responses provided by the applicant. • 22/09/2000 SCP opinion: favourable. 	<ul style="list-style-type: none"> • 19/01/2001 Applicant submits letter on the change of scope (import and processing only, planting now excluded). • 21/09/2001 Undertakings from applicant accordance with the requirements of Directive 2001/18/EC. • 18/03/2002 Applicant submits updates and commitments to COM.
	<p>↓</p> <p><u>Directive 2001/18/EC</u></p> <ul style="list-style-type: none"> • 15/01/2003 Applicant submits new SNIF and updated risk assessment to lead CA. 	<ul style="list-style-type: none"> • 29/09/1999 11th meeting on technical aspects of product application dossiers pending under part C of Directive 90/220/EEC. • 21/10/1999 Responses to MS objections. <p>↓</p>		
		<ul style="list-style-type: none"> • 15/09/2003 Applicant withdraws application. 		

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>
		<i>Circulation to Member States</i>
<p>EC-85</p> <p>GA21 maize (EC-85)</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 12/12/1997 Applicant submits application. • 23/12/1997 UK CA requests further information. • 01 and 02/1998 Applicant submits further information. • 27/02/1998 Amended dossier requested. • 30/03/1998 Applicant submits amended dossier. • 04 – 12/1998 Requests for further information. Applicant submits additional information. • 16/02/1999 UK CA requests amended dossier. • 03/03/1999 Applicant submits further information. • 16/09/1999 Meeting of ACRE. 	<ul style="list-style-type: none"> • 15/10/1999 Lead CA sends full application to COM. • 01/12/1999 COM circulates application to all CAs. • 12/1999 – 02/2000 Comments and objections by MS. Applicant provides answers and clarifications. • 27/06/2001 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>
		<i>Circulation to Member States</i>
<p>EC-79 RR oilseed rape (EC-79)</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 21/05/1995 Applicant forwards application to the lead CA. • 05/1995 – 10/1996 Requests for additional information. Applicant submits additional information. <ul style="list-style-type: none"> - On 06/02/1996 the Commission du Génie Biomoléculaire requests applicant to submit studies on rats (28 days). • 02/12/1996 Applicant submits update to initial dossier. 	<ul style="list-style-type: none"> • 02/12/1996 Lead CA forwards application to COM. • 30/06/1997 Applicant submits proposal for labelling and appropriate information. • 15/01/2003 Official withdrawal.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>
		<i>Circulation to Member States</i>
<p>EC-80</p> <p>Bt-11 maize (EC-80)</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 29/05/1998 Applicant submits application. • 16/06/1998 Meeting of the Spanish Scientific Comité. • 31/07/1998 Lead CA requests additional information by the applicant. • 03/09/1998 Applicant submits additional information. • 09/1998 and 01/1999 Meetings of the Spanish Scientific Comité. • 26/04/1999 Lead CA forwards positive risk assessment report to COM. 	<ul style="list-style-type: none"> • 30/04/1999 Lead CA forwards application to COM. • 20/05/1999 Applicant notifies withdrawal of application from Spain. • 27/05/1999 COM circulates full application to all CAs. • 28/05/1999 Official withdrawal circulated to all CAs. Review of the application closed.

<i>Product</i>	<i>Member State Level</i>
<p>EC-81 LL soybeans (EC-81)</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 24/09/1999 Applicant submits application. • 07/12/1999 Opinion of the Portuguese Ministry of Agriculture: not favourable. Request for additional information to be submitted by the applicant. • 07/01/2000 Portuguese Ministry of Health requests further information. • 17/01/2000 Request for additional information. • 11/05/2000 Additional request for information. • 28/09/2001 Applicant provides responses. • 18/10/2001 Acknowledgment of additional information and transmission of the additional information to the Portuguese Ministry of Health. <p><u>Directive 2001/18/EC</u></p> <ul style="list-style-type: none"> • 20/11/2001 Portuguese CA requests applicant to bring application into line with the new requirements of Directive 2001/18/EC. • 28/01/2002 Portuguese Ministry of Health requests applicant to provide further clarification. • 27/01/2003 Applicant submits letter of withdrawal.

<i>Product</i>	<i>Member State Level</i>
<p>EC-82</p> <p>MON810 x GA21 maize</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 04/08/1999 Applicant submits application to lead CA. • 31/08/1999 Applicant submits new SNIF and translated documents. • 11/11/1999 7th session of Spanish National Commission on Biosafety. • 30/11/1999 Lead CA requests further information. • 08/2001 Applicant submits additional information. • 17/01/2002 Applicant provides translated documents. • 04/04/2002 Meeting of the Spanish National Commission on Biosafety. • 17/01/2003 Applicant submits updates to the lead CA. (Lead CA did not receive updates.) • 15/09/2003 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>				
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>	<i>Regulatory Committee Process</i>	<i>Commission</i>
EC-83 MON809 maize	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> 18/12/1995 Applicant submits full application to lead CA concerning the two events (MON 801 and MON809). 06/02/1996 National scientific committee (CGB) delivers an opinion and requests additional information as well as separate applications for the two events. 06/03/1996 New application concerning MON809 and further data provided. 04/04/1996 Opinion of the National scientific committee (CGB). 	<ul style="list-style-type: none"> 06/08/1996 Lead CA forwards application to COM. 29/08/1996 COM forwards full application to all CAs. 25/09/1996-14/07/1997 Comments, requests for further clarifications and objections my MS. 	<ul style="list-style-type: none"> 27/01/1998 COM submits application to SCP for opinion. 11/03/1998 Meeting of the GMO working group of the SCP. 03-04/1998 Applicant provides responses to SCP's questions. 19/05/1998 SCP opinion: favourable 	<ul style="list-style-type: none"> 12/06/1998 COM launches ISC on draft COM decision to be submitted to REG COM. 09/07/1998 ISC concluded. 	<ul style="list-style-type: none"> 04/09/1998 COM launches consultation of REG COM. 23/10/1998 Consultation of REG COM ends with no opinion. 	<ul style="list-style-type: none"> 22/04/1999 COM launches vote in REG COM by written procedure. 29/04/1999 Written procedure suspended because of Bt resistance management program. 08/06/1999 Additional questions sent to SCP: consultation done in the context of the safeguard measures invoked by Austria about MON810 maize (because laboratory results showed harm to butterflies treated with pollen from Bt maize) 24/09/1999 SCP opinion: favourable. 04/10/2002 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>				
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>	<i>Regulatory Committee Process</i>	<i>Commission</i>
<p>EC-84</p> <p>Transgenic tomato</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 15/11/1996 Lead CA receives dossier from the applicant. • 12/1996, 01 and 02/1997 Three meetings of the Spanish Commission on Biosafety. • 19/02/1997 Lead CA requests additional information. • 02, 03 and 04/1997 Exchange of information among Spanish Ministry of Health, Spanish Ministry of Environment and lead CA. • 24/04/1997 Meeting of the Spanish Commission on Biosafety. • 23/10/1997 Fax from the applicant to the Spanish Ministry of Health: submission on genetically modified tomatoes to be assessed under the Novel Food Regulation. 	<ul style="list-style-type: none"> • 17/11/1997 Lead CA forwards dossier to COM together with a favourable opinion. • 15/12/1997 Lead CA circulates full dossier to all MS. • 01/1998 Requests for further information by MS. • 27/01/1998 Meeting held by the COM on technical aspects of Part C dossiers. Request for further info. • 04/02/1998 Applicant provides CA with additional data. • 02 and 03/1998 Comments and some objections by MS. Applicant provides additional information. 	<ul style="list-style-type: none"> • 23/06/1998 SCP opinion: favourable. 	<ul style="list-style-type: none"> • 05/10/1998 Outcomes of ISC. 	<ul style="list-style-type: none"> • 26/11/1998 COM launches consultation of the REG COM by written procedure. • 18/12/1998 Consultation of the REG COM concluded: No opinion. 	<ul style="list-style-type: none"> • 16/02/1999 COM sends proposal for CO decision to Cabinet Bjeregaard for approval. • 09/03/1999 COM sends proposal for CO decision to Legal Service for approval. • 20/08/1999 COM launches written procedure on draft CO decision. • 23/09/1999 SCF opinion: favourable. • 24/11/1999 Consultation of other DGs on draft Commission Decision under the Standing Committee on Foodstuffs. • 04/02/2002 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>		
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>
<p>EC-86</p> <p>T25 x</p> <p>MON810</p> <p>maize</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 26/06/1998 Applicant submits full application to lead CA. • 10/08/1998 Advice of COGEM: - No risks for human health or the environment. - Need for further testing. • 08 and 09/1998 Requests for additional information. Applicant provides additional information. • 01/12/1998 RIKILT (advisory body for feed aspects) states that there are no reasons to conclude that the GMO is unsafe. • 21/01/1999 Lead CA sends draft evaluation summary to the applicant. • 22/04/1999 Applicant's response to draft evaluation summary. 	<ul style="list-style-type: none"> • 26/04/1999 Dutch CA sends evaluation summary and application to COM. • 17/05/1999 COM circulates full application to all CAs. • 06 and 07/1999 Requests for further information, comments and objections by MS. Applicant provides additional information. • 01/09/1999 Applicant proposes for alternatives with respect to the scope of the dossier. 	<ul style="list-style-type: none"> • 21/09/1999 COM requests SCP opinion. • 26/10/1999 Comments by SCP and draft opinion. • 17/11/1999 SCP requests further information by the applicant. • 01 and 02/2000 Applicant submits additional information. • 06/06/2000 SCP opinion: favourable. 	<ul style="list-style-type: none"> • 18/12/2002 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>
<p>EC-87 High-oleic soybeans</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 19/06/1998 Applicant submits full application to lead CA. • 07/1998 – 09/1998 Lead CA requests additional information. Applicant provides additional information. • 28/09/1998 Advice of COGEM: - Information submitted is sufficient - No risk to human life or the environment. • 12/10/1998 Addendum to COGEM advice: - Alteration of fatty acid composition will not result in risks in food or feed safety. - Food and feed safety due to the change of protein composition can not be guaranteed based on the information supplied. - Based on the information, no toxicological effects are foreseen in case of incidental consumption. COGEM states that this basically confirms their earlier assessment. • 07/12/1998 RIKILT requests additional information. • 01/07/1999 Applicant provides additional information. • 27/10/1999 Request for additional information to applicant, concerning feed safety aspects. • 12/12/2002 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>	<i>Member State Level (continues)</i>
<p>EC-88 RR sugar beet</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 22/12/1998 Applicant sends application to lead CA. • 23/02/1999 Lead CA requests additional information. • 11/03/1999 Applicant provides additional information. • 14/04/1999 Lead CA requests additional information. • 14/04/1999 Applicant provides additional information. • 26/04/1999 Biosafety Advisory Council Meeting. • 02/06/1999 Biosafety Advisory Council raises remaining questions on agricultural practices, molecular characterisation, toxicology, allergenicity, and food/feed equivalence. • 07/06/1999 Lead CA requests additional information. • 14/07/1999 Applicant provides additional information. 	<ul style="list-style-type: none"> • 08/12/1999 Applicant provides additional information. • 18/01/2000 Applicant provides additional information on horizontal gene transfer. • 02/02/2000 Lead CA requests additional information. • 02 and 03/2000 Applicant provides additional information. • 04/04/2000 Meeting with the applicant (regarding identity preservation, GAP, post market monitoring, traceability, public information, line-specific detection methods and primers). • 26/07/2000 Applicant submits additional information. • 16/11/2000 CA requests additional information on further characterisation of a protein and detection protocols. • 04/01/2001 Lead CA requests additional information on labelling and traceability. • 13/06/2001 Lead CA requests applicant to adapt the application with one of the expert's comments.

<i>Product</i>	<i>Member State Level</i>	<i>Member State Level (continues)</i>
	<ul style="list-style-type: none"> • 01/10/1999 Lead CA requests additional information (allergenicity, molecular characterisation, gene transfer in digestive tracts). 	<p><u>Directive 2001/18/EC</u></p> <ul style="list-style-type: none"> • 16/01/2003 Applicant updates application. • 25/02/2003 Lead CA requests additional information. • 16/04/2004 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>		
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>
<p>EC-91 GA21 maize (food)</p>	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none"> • 24/07/1998 Applicant submits application to Dutch CA. • 11/08/1998 COM forwards the application to MS. • 15/09/1998 Lead CA requests applicant to complete the dossier. • 09/1998 – 02/1999 Applicant submits additional information. • 24/02/1999 Advisory Committee on the Safety of Novel Foods and Foods Ingredients requests additional information. • 25/03/1999 Applicant submits additional information. • 18/06/1999 Advisory Committee on the Safety of Novel Foods requests additional data. • 26/10/1999 Applicant submits requested data. • 21/12/1999 Initial assessment by Gezondheidsraad. 	<ul style="list-style-type: none"> • 21/01/2000 Lead CA sends initial assessment to COM. • 18/02/2000 COM circulates initial assessment to MS. • 03 – 05/2000 Requests for additional information, comments and objections by MS. Applicant provides additional information. 	<ul style="list-style-type: none"> • 18/05/2000 COM requests SCF opinion. • 18/07/2000 Applicant provides additional labelling proposal. • 08/2000 Applicant submits additional information. • 24/04/2001 SCF requests further information by applicant. • 17/05/2001 Applicant responds to the request for additional information. • 12-13/12/2001 Discussion on draft opinion postponed to February meeting of SCP due to lack of time. • 27/02/2002 Opinion of the SCF. 	<ul style="list-style-type: none"> • 23/04/2002 Applicant changes scope of application. • 05/06/2002 Meeting with applicant. Applicant agrees to provide additional information. • 18/09/2002 Meeting with applicant on validation method.

Product	Member State Level	Community Level					
		Circulation to Member States	Scientific Committee Process	Regulatory Committee Process	Commission	Council	Commission
<p>EC-92</p> <p>Bt-11 sweet maize (food)</p>	<p><u>Regulation (EC) N° 258/97</u></p> <ul style="list-style-type: none"> • 11/02/1999 Applicant submits application. • 09/03/1999 COM forwards the summary of the application to MS. • 04/1999 – 05/2000 Requests for additional information. Applicant provides additional information. • 12/05/2000 Lead CA forwards the initial assessment report to COM. 	<ul style="list-style-type: none"> • 15/06/2000 COM forwards the initial assessment report to MS for comments/objections. • 06/2000 – 11/2000 Comments and objections by MS. Applicant provides additional information and answers to comments/objections. 	<ul style="list-style-type: none"> • 13/12/2000 COM requests SCF opinion. • 13/12/2000 Italy requests additional information. • 15/04/2001 SCF requests further data. • 10/05/2001 Italy reiterates objections raised in July 2000. • 12/11/2001 SCF reminds applicant of request for additional information. • 27/02/2002 Applicant submits data. • 17/04/2002 SCF opinion: favourable. 	<ul style="list-style-type: none"> • 08/11/2003 Draft Commission Decision on the agenda of the Standing Committee. (No formal opinion delivered by MS). • 08/12/2003 Vote held in REG COM. (No qualified majority was reached). 	<ul style="list-style-type: none"> • 28/01/2004 Formal COM decision to refer the matter to the Council. 	<ul style="list-style-type: none"> • 26/04/2004 Vote held in Council. (No qualified majority reached) 	<ul style="list-style-type: none"> • 19/05/2004 COM adopts decision.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>					
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Regulatory Committee Process</i>	<i>Commission</i>	<i>Council</i>	<i>Commission</i>
			<ul style="list-style-type: none"> • 04/2002 – 10/2003 Requests for additional material on validation method. Applicant submits additional material. - On 05/06/2002, applicant agrees to provide detection measures, traceability, reference material and identification - On 22/01/2003 applicant provides material for detection method validation - On 07/07/2003 applicant submits a new method. 				

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>
		<i>Circulation to Member States</i>
<p>EC-93</p> <p>LL soybeans (food)</p>	<p><u>Regulation (EC) N° 258/97</u></p> <ul style="list-style-type: none"> 30/11/1998 Applicant submits application. 	<ul style="list-style-type: none"> 02/02/1999 Application sent to COM. 08/02/1999 Belgian CA sends e-mail, confirming that it will assess the dossier. 02/03/1999 COM note to the Permanent Representations of the MS-summary of the file. 28/04/1999 Letter from Louis Pasteur Scientific Institute for Public Health requesting additional information. 26/05/1999 COM informs MS that the initial assessment will not be completed on time. 06/1999 – 07/2004 Requests for additional information. <ul style="list-style-type: none"> On 07/06/1999 Greece requests additional information On 21/07/1999 Italy sends its comments On 01/12/2000 applicant sends letter to Ministère Dr W Moens (BE) concerning additional information on the application and notification On 18/07/2001 applicant providing additional information on the application to the Ministère Fédéral des Affaires Sociales, de la santé Publique et de l'Environnement. 06/07/2004 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>
		<i>Circulation to Member States</i>
<p>EC-94 MON810 x GA21 maize (food)</p>	<p><u>Regulation (EC) N° 258/97</u></p> <ul style="list-style-type: none"> • 29/02/2000 Applicant submits application. • 29/03/2000 Note of the European Commission to the Permanent representations of the Member States – summary of the file. 	<ul style="list-style-type: none"> • 29/02/2000 Copy of application sent to COM. • 04-05/2000 UK, Greece and Denmark request applicant to provide full dossier. • 06/2000 Comments from Austria, UK and Italy. • 17/07/2000 Gezondheidsraad requests applicant to provide additional information. • 15/02/2002 Applicant provides additional information. • 02/07/2002 Gezondheidsraad requests applicant to provide additional information.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>
		<i>Circulation to Member States</i>
<p>EC-95</p> <p>Bt-1507 maize (food)</p>	<p><u>Regulation (EC) N° 258/97</u></p> <ul style="list-style-type: none"> • 15/02/2001 Applicant submits application. • 03/2001 – 05/2003 Requests for full dossier and additional information. Applicant provides technical dossier and additional information. - On 28/06/2001 Gezondheidsraad sends letter to applicant, requesting for additional information. - In February 2002 applicants responds to the request of 28/06/2001. - On 25/03/2003 Gezondheidsraad sends letter to applicant, requesting for further examination. - On 16/05/2003 the applicant responds to the request of 25/03/2003. - On 11/06/2003 Gezondheidsraad requests further clarification with regard to the reply of 16/05/03. - Following the request of 11/06/2003, the applicant provides additional information to Gezondheidsraad. • 03/2003 – 07/2003 Requests for additional information. Applicant provides additional information. • 04/11/2003 Initial assessment report by CA. 	<ul style="list-style-type: none"> • 18/11/2003 Initial assessment sent to COM. • 10/12/2003 COM forwards initial assessment report to MS for comments/objections. • 02/2004 Comments by MS.
	<p><u>Regulation (EC) N°1829/2003</u></p> <ul style="list-style-type: none"> • 17/03/2004 COM note to MS: transfer of application to Regulation (EC) N° 1829/2003. 	

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>			
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Regulatory Committee Process</i>	<i>Council</i>
EC-96 NK603 maize (food)	<p><u>Regulation (EC) N° 258/97</u></p> <ul style="list-style-type: none"> • 24/04/2001 Applicant submits application. • 06/2001 – 03/2002 MS request full dossier and additional information. Applicant provides full dossier and additional information. <ul style="list-style-type: none"> - On 26/06/2001 lead CA requests copies of references. - On 20/07/2001 the applicant provides copies of references in notification. - On 13/12/2001 Gezondheidsraad requests applicant to provide further information. - On 23/01/2002 Italy requests additional information. - On 28/03/2002 applicant provides requested information. • 13/08/2002 Health Council Committee finishes its assessment report. • 05/11/2002 Lead CA forwards initial assessment report to COM. 	<ul style="list-style-type: none"> • 06/01/2003 COM forwards initial assessment report to MS for comments/objections. • 02/2003 – 07/2003 Comments/objections by MS. Applicant provides answers. <ul style="list-style-type: none"> - 26/02/2003: SBB: evaluation 	<ul style="list-style-type: none"> • 18/09/2003 COM requests EFSA opinion. • 25/11/2003 EFSA opinion: favourable. 	<ul style="list-style-type: none"> • 30/04/2004 Draft COM decision presented to REG COM. 	<ul style="list-style-type: none"> • 13/07/2004 Transmission to CO pending.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>		
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>
<p>EC-97</p> <p>Transgenic red-hearted chicory (food)</p>	<p><u>Regulation (EC) N° 258/97</u></p> <ul style="list-style-type: none"> • 08/04/1998 Applicant submits application. • 23/04/1998 Initial assessment by lead CA. 	<ul style="list-style-type: none"> • 13/05/1998 COM forwards request, summary and initial assessment to MS. • 15/09/1998 Confirmation of the initial assessment report. • 27/10/1998 COM circulates initial assessment to MS. 	<ul style="list-style-type: none"> • 29/04/1999 COM requests opinion from the SCF. • 09/1999 – 07/2001 Questions from the SCF to the applicant. Applicant provides responses. <ul style="list-style-type: none"> - On 10/07/2000 the SCF poses additional questions to the applicant. - On 21/07/2000 the applicant responds. - On 31/07/2000 the SCF requests additional information. - On 14/11/2000 the applicant responds. - On 18/06/2001 the SCF requests additional information. - On 23/01/2001 the applicant provides additional information. - On 24/04/2001 the SCF requests additional information. • 24/09/2001 Letter from applicant to SCF suspending the dossiers for market application 	<ul style="list-style-type: none"> • 27/05/2003 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>		
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>
<p>EC-98</p> <p>Transgenic green-hearted chicory (food)</p>	<p><u>Regulation (EC) N° 258/97</u></p> <ul style="list-style-type: none"> • 14/03/1996 Applicant submits application. • 23/04/1998 Lead CA provides its initial assessment. 	<ul style="list-style-type: none"> • 13/05/1998 COM forwards request, summary and initial assessment to MS . • 15/09/1998 Confirmation of the initial assessment report. • 27/10/1998 COM circulates initial assessment report. • 12/1998-03/1999 Comments and objections by MS. 	<ul style="list-style-type: none"> • 29/04/1999 COM requests SCF opinion. • 05/1999-07/2001 Questions and additional requests to the applicant by SCF. Applicant provides responses. <ul style="list-style-type: none"> - On 10/07/2000 the SCF poses additional questions to the applicant. - On 21/07/2000 the applicant responds. - On 31/07/2000 the SCF requests additional information. - On 14/11/2000 the applicant responds. - On 18/06/2001 the SCF requests additional information. - On 24/07/2001 the SCF poses further questions to the applicant. • 24/09/2001 Applicant suspends consideration of the dossier for market application. 	<ul style="list-style-type: none"> • 27/05/2003 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>	
		<i>Circulation to Member States</i>	<i>Commission</i>
<p>EC-99</p> <p>High-oleic soybeans (food)</p>	<p><u>Regulation (EC) N° 258/97</u></p> <ul style="list-style-type: none"> • 24/07/1998 Applicant submits application. 	<ul style="list-style-type: none"> • 11/08/1998 Summary of application forwarded to MS. • 10/1998-09/1999 Netherlands, Germany and Greece request additional information and make comments. Applicant provides responses. (We note the following dates: <ul style="list-style-type: none"> - On 16/10/1998 the applicant provides relevant references. - On 11/03/1999 the Health Council poses questions to the applicant. - On 28/05/1999 the applicant provides additional information. - On 06/09/1999 the Health Council sends further comments to the applicant.) 	<ul style="list-style-type: none"> • 12/12/2002 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>		
		<i>Circulation to Member States</i>	<i>Scientific Committee Process</i>	<i>Commission</i>
<p>EC-100</p> <p>Transgenic tomato (food)</p>	<p><u>Regulation (EC) N° 258/97</u></p> <ul style="list-style-type: none"> 02/03/1998 Applicant submits application. 	<ul style="list-style-type: none"> 22/04/1998 Summary of application forwarded to MS. 04/06/1998 Lead CA sends initial assessment to COM. 22/06/1998 COM circulates initial assessment to MS. 06/1998-10/1998 Comments and objections by MS. 22/10/1998 COM forwards comments/objections to MS. 11/1998 Further comments by MS. Applicant provides responses. 22/12/1998 Italy renews its objections. 	<ul style="list-style-type: none"> 23/12/1998 COM requests SCF opinion. 01-02/1998 Comments, objections by France and Austria. 04/10/1999 SCF opinion: favourable. 07/09/2000 SCF opinion: favourable. 	<ul style="list-style-type: none"> 24/09/2001 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>	
		<i>Circulation to Member States</i>	<i>Commission</i>
<p>EC-101</p> <p>T25 x MON810</p> <p>maize (food)</p>	<p><u>Regulation (EC) N° 258/97</u></p> <ul style="list-style-type: none"> • 20/04/2000 Applicant submits application. 	<ul style="list-style-type: none"> • 03/05/2000 Summary of application forwarded to MS. • 05/2000-11/2001 MS request additional information. Applicant provides responses. (We note the following dates: <ul style="list-style-type: none"> - On 17/07/2000 the Health Council of the Netherlands requests additional information. - On 22/11/2000 the applicant provides additional information. - On 23/04/2001 the Health Council of the Netherlands requests additional information. - On 21/11/2001 applicant provides additional information and clarifies the state of play.) 	<ul style="list-style-type: none"> • 12/12/2002 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>	<i>Community Level</i>	
		<i>Circulation to Member States</i>	<i>Commission</i>
<p>EC-102</p> <p>RR sugar beet (food)</p>	<p><u>Regulation (EC) N° 258/97</u></p> <ul style="list-style-type: none"> • 03/11/1999 Applicant submits application. • 24/03/2000 The Health Council of the Netherlands requests applicant to submit additional information. • 18/04/2000 Response by the applicant. • 10/05/2000 The Health Council of the Netherlands requests applicant to submit further information. 	<ul style="list-style-type: none"> • 29/05/2000 COM forwards application to MS. • 06-07/2000 MS request full dossier. • 12/2000 Applicant provides responses. • 19/01/2001 Denmark acknowledges receipt of the application and comments on it. • 16/05/2001 Netherlands requests additional information. 	<ul style="list-style-type: none"> • 16/04/2004 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>
<p>EC-110</p> <p>Transgenic green-hearted chicory</p>	<p><u>Regulation (EC) N° 258/97</u></p> <ul style="list-style-type: none"> • 11/03/1996 Applicant submits full application to lead CA. • 24/05/1996 Applicant submits the English version of SNIF. • 13/06/1996 Advice of Commission on Genetic Modification (COGEM) concluding that based on the information no environmental risks are foreseen. • 08/07/1996 Draft evaluation summary is sent to the applicant. • 02/01/1997 Applicant requests that the dossier not be forwarded to COM until the dispute around the food safety of dossier C/NL/94/25A is settled. • 23/04/1998 Advice vCVNV (Provisional Commission for Food safety) concerning event GM2-28. • 25/03/1999 RIKILT considers the dossier incomplete and requests additional information. • 21/05/1999 Applicant provides additional information. • 15/04/2003 Applicant withdraws application.

<i>Product</i>	<i>Member State Level</i>
EC-156 T14 maize	<p><u>Directive 90/220/EEC</u></p> <ul style="list-style-type: none">• 10/06/1996 Applicant submits full application to lead CA.• 06/1996 – 02/1997 Commission du Génie Biomoléculaire requests additional information.• 22/07/1997 Applicant submits updated application and additional information.• 23/10/1997 Commission du Génie Biomoléculaire requests modification of the application.• 29/11/1997 Commission du Génie Biomoléculaire issues opinion.• 28/01/1998 Applicant submits new information and a modified application following request from the Commission du Génie Biomoléculaire.• 15/07/1998 Applicant withdraws application.
