

**Discussion Paper:**

**Implementation of Regulation (EC) No 258/97 of the European  
Parliament and of the Council of 27 January 1997 concerning novel  
foods and novel food ingredients**

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(SANCO D4)  
European Commission

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## *Preface*

Article 14 of Regulation (EC) No 258/97 (the Novel Food Regulation) requires that no later than five years from the date of its entry into force, and in light of the experience gained, the Commission forward a report on the implementation of the Novel Food Regulation to the European Parliament and the Council. This Discussion Paper and the responses to the consultation will form the basis of the Report on the Novel Food Regulation. This Discussion Paper has been prepared in order to facilitate the consultation process. It is being circulated to elicit feedback on the implementation of the Novel Food Regulation, including potential improvements that may be made. The responsible Services will then have regard to this feedback in developing the Report and any associated proposal.

The Discussion Paper provides an overview of the Novel Food Regulation and its implementation, and presents some of the major issues that have emerged in relation to this regulation. It also outlines various options for addressing these issues.

These options are not exhaustive, and they do not represent any firm preferences on the part of the Commission or of its Services. Alternative proposals for the issues raised in the discussion paper will be welcomed.

You should also not feel constrained to limit your comments to those aspects of the Novel Food Regulation discussed in this paper. We would appreciate comments on all aspects of the Novel Food Regulation although comments should focus on non-genetically modified novel foods. The reason for limiting discussion to non-GM novel foods is that there are already two legislative proposals before the European Parliament and Council concerning the authorisation and traceability of GM novel foods. This Discussion Paper is therefore concerned principally with novel foods and novel food ingredients that do not consist of, do not contain and are not derived from genetically modified organisms

**We invite you to send us your comments to the Discussion Paper and to any other aspect of the Novel Food regulation related to non-GM novel foods**

**The deadline for comments is: 30 September 2002**

**Written comments should be forwarded to:**

**SANCO-NOVELFOOD@cec.eu.int**



## ***Table of Contents***

<i>Preface</i> .....	
<i>Table of Contents</i> .....	<i>i</i>
<b>1. Outline of the Novel Food Regulation</b> .....	<b>1</b>
<b><i>1.1 What are the objectives of the Novel Food Regulation?</i></b> .....	<b><i>1</i></b>
<b><i>1.2 What is novel food?</i></b> .....	<b><i>1</i></b>
1.2.1 Definition of novel food.....	1
1.2.2 Novel food in practice.....	2
<b><i>1.3 What is <u>not</u> novel food?</i></b> .....	<b><i>2</i></b>
1.3.1 Food consumed before 15 May 1997.....	2
1.3.2 Food not within the novel food categories.....	3
1.3.3 Food additives, flavourings and extraction solvents.....	3
1.3.4 New food formulations – but with familiar ingredients.....	3
<b><i>1.4 What are the procedures for determining whether or not a food is novel?</i></b> .....	<b><i>3</i></b>
1.4.1 Applicant and Member State consideration – is this product a novel food? 3	
1.4.2 Novel Foods Working Group consideration .....	3
1.4.3 If a food is novel .....	4
1.4.4 If a food is not novel .....	4
1.4.5 Arbitration procedure.....	4
<b><i>1.5 What criteria must novel foods satisfy in order to be placed on the market?</i></b> .....	<b><i>4</i></b>
<b><i>1.6 What are the procedures for placing a novel food on the market in the Community?</i></b> .....	<b><i>5</i></b>
1.6.1 Principal Procedure .....	5
1.6.2 Simplified Procedure .....	7
<b><i>1.7 How must a novel food be labelled?</i></b> .....	<b><i>8</i></b>
<b><i>1.8 What information is disclosed or protected under the Novel Food Regulation?</i></b> .....	<b><i>8</i></b>
<b><i>1.9 What are the procedures for removing novel foods from the market in the Community?</i></b> .....	<b><i>9</i></b>
<b>2. Applications under the Novel Food Regulation</b> .....	<b>10</b>
<b>3. Particular issues relating to the Novel Food Regulation, including options for the future</b> .....	<b>14</b>
<b><i>3.1 What is a novel food?</i></b> .....	<b><i>14</i></b>
3.1.1 Whole animals .....	14
3.1.2 Production processes.....	14
3.1.3 Separation of GM foods from the Novel Food Regulation.....	16

<b>3.2 Decisions under the Novel Food Regulation .....</b>	<b>17</b>
<b>3.3 Processes for dealing with applications under the Novel Food Regulation.....</b>	<b>19</b>
3.3.1 The simplified procedure .....	19
3.3.2 The principal procedure .....	20
3.3.3 Transparency and public consultation .....	22
<b>3.4 Labelling of Novel Foods.....</b>	<b>23</b>
<b>Glossary of Terms .....</b>	<b>24</b>
<b>Attachment 1 – Table of Applications under the Novel Food Regulation.....</b>	<b>1</b>
<b>Attachment 2 – Table of Notifications under the Novel Food Regulation.....</b>	<b>9</b>

## **1. Outline of the Novel Food Regulation**

### ***1.1 What are the objectives of the Novel Food Regulation?***

The Novel Food Regulation was enacted on 27 January 1997 and came into force on 15 May 1997. Its principal objectives are:

- to protect the functioning of the internal market within the Community<sup>1</sup>; and
- to protect public health.<sup>2</sup>

Consistent with these objectives, the Novel Food Regulation establishes a Community system for the pre-market approval of novel foods.<sup>3</sup>

This regulation fixes a single cut-off date of 15 May 1997, after which novel foods require approval based on a safety assessment before they can be placed on the market in the Community. For foodstuffs that were on the market in some Member States only before that date, the principle of mutual recognition applies, ensuring the functioning of the internal market. Making novel foods subject to a single safety assessment before they are placed on the market in the Community provides the public with a positive assurance of safety. This contrasts with the previous situation, when pre-market safety assessments were not generally conducted in relation to novel foods. Where appropriate, public health can also be safeguarded by the establishment of conditions of use in relation to novel foods.

### ***1.2 What is novel food?***

#### **1.2.1 Definition of novel food**

The Novel Food Regulation defines novel foods as foods and food ingredients that were not used for human consumption to a significant degree within the Community before 15 May 1997. In addition, these foods and food ingredients must fall into particular categories, namely they must be foods and food ingredients:

- containing or consisting of genetically modified organisms (GMOs) within the meaning of Directive 90/220/EEC; or
- produced from, but not containing, GMOs; or
- with a new or intentionally modified primary molecular structure; or
- consisting of, or isolated from, micro-organisms, fungi or algae; or
- consisting of or isolated from plants, or food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices, and having a history of safe use; or

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<sup>1</sup> Recital 1, Novel Food Regulation.

<sup>2</sup> Recital 2, Novel Food Regulation.

<sup>3</sup> For ease of reference, in this discussion paper the term ‘novel foods’ includes novel food ingredients.

- to which a production process not currently used has been applied, where that process gives rise to significant changes in the composition or structure of the food or food ingredient, which affects its nutritional value, metabolic effect or level of undesirable substances.<sup>4</sup>

These categories will be referred to as the novel food categories in this Discussion Paper.

### 1.2.2 Novel food in practice

By February 2002, Commission Decisions had been made in relation to eight novel foods.

#### *Decisions authorising the placing on the market:*

- yellow fat spreads with added phytosterol esters;
- phospholipids from egg yolk;
- dextran produced by *Leuconostoc mesenteroides*;
- pasteurised fruit-based preparations produced using high pressure pasteurisation;
- trehalose;<sup>5</sup>
- coagulated potato proteins.

#### *Decisions refusing the placing on the market:*

- *Stevia rebaudiana* Bertoni, plants and dried leaves;
- Nangai (Ngali) nuts (*Canarium indicum* L.);

None of these consist of, contain or are derived from GMOs. However, one non-GM product and 11 GM products have been notified, using the simplified procedure under the Novel Food Regulation (Attachment 2).

## 1.3 What is not novel food?

### 1.3.1 Food consumed before 15 May 1997

Any food that was used for human consumption to a significant degree within the Community before 15 May 1997 is not a novel food. This is the case even if a food falls into one of the novel food categories.

‘Human consumption to a significant degree within the Community’, in this context, has been interpreted as being demonstrated by a food having been generally available within the Community. For example, if a food was only available in pharmacies within the Community, this would not constitute evidence of use for human consumption to a significant degree. In contrast, if a food was available in general food stores, this would constitute evidence of use for human consumption to a significant degree.

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<sup>4</sup> Article 1(2), Novel Food Regulation.

<sup>5</sup> For further details on these, see Attachment 1.

### **1.3.2 Food not within the novel food categories**

In order to be considered novel, food must fall into one of the novel food categories. This is the situation even if the food was not used for human consumption to a significant degree within the Community before 15 May 1997.

### **1.3.3 Food additives, flavourings and extraction solvents**

Foodstuffs that are authorised pursuant to the relevant provisions covered by Community legislation are excluded from the Novel Food Regulation. These products are food additives, flavourings and extraction solvents falling within the scope of specified Directives.<sup>6</sup> However, as a safeguard, this exclusion is conditional upon the safety levels in the specified Directives corresponding to the safety level of the Novel Food Regulation.<sup>7</sup>

### **1.3.4 New food formulations – but with familiar ingredients**

Most new food products are simply new formulations using familiar ingredients obtained by conventional means and having a history of safe use, and as such do not fall within any of the novel food categories. For example, a new praline filling for a chocolate bar, or a new flavour of yoghurt, will usually be developed by using food ingredients that are commonly used in similar foods in the Community, as well as approved food additives and flavourings. This is the reason the majority of new food products that enter the market in the Community every year are not regarded as novel foods.

## ***1.4 What are the procedures for determining whether or not a food is novel?***

### **1.4.1 Applicant and Member State consideration – is this product a novel food?**

The procedures start with a potential applicant considering whether their product is novel, and gathering evidence to support their case. If the product's novelty is not clear, they may choose to seek advice from Commission officers or Member States. Commission officers generally refer such inquiries to the relevant Member State. It is important to note that in practice, by accepting an application in respect of a food, a Member State is taken to have decided that the food is a novel food. If, however, the relevant Member State is not certain as to whether the product is a novel food, they generally refer the matter to the Novel Foods Working Group.<sup>8</sup>

### **1.4.2 Novel Foods Working Group consideration**

It is sometimes clear that a food falls into one of the novel food categories, but it is not clear whether it was used for human consumption to a significant degree within the Community before 15 May 1997, and so falls within the scope of the Novel Food Regulation. When this occurs, the members of Novel Foods Working Group investigate whether the food was used for human consumption in their countries before 15 May 1997. A person who is marketing or wishes to market such food within the Community and does not consider it to be a novel food should also provide any

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<sup>6</sup> Article 2(1), Novel Food Regulation.

<sup>7</sup> Article 2(2), Novel Food Regulation. It should be noted that as the 'safety level' of the Novel Food Regulation is not static or quantifiable, this condition would appear difficult to apply in practice.

<sup>8</sup> A group comprised of experts from the Member States, and chaired by an officer of the Commission, whose task is to facilitate the co-ordinated implementation of the Novel Food Regulation.

evidence of significant human consumption within the Community before 15 May 1997.

Alternatively, there are cases where although it is clear that a food was not used for human consumption to a significant degree within the Community before 15 May 1997, it is not clear whether it falls into one of the novel food categories. In these circumstances, the Novel Foods Working Group provides a platform for consideration of the matter in consultation with affected parties.

The results of these inquiries will usually enable the Novel Foods Working Group to form a view as to whether a food is novel or not.

#### **1.4.3 If a food is novel**

If the food is viewed as novel, an application to assess the food under the Novel Food Regulation can then be accepted by the relevant Member State. In addition, Member States may then take appropriate action in relation to such food. For instance, if a novel food has not been assessed in accordance with the Novel Food Regulation, this may involve removing the novel food from their markets.

#### **1.4.4 If a food is not novel**

If the food is not viewed as novel, applications to assess the food under the Novel Food Regulation will not be accepted by Member States. The food may be placed on the market in the Community, provided it complies with all other applicable legal requirements at both Community and Member State levels.

#### **1.4.5 Arbitration procedure**

If the Novel Food Working Group cannot form a view, the arbitration procedure set out in the Novel Food Regulation may be followed.<sup>9</sup> In addition, this procedure may be used more generally to determine whether a type of food is novel.<sup>10</sup>

It should be noted that, up until now, the Novel Food Working Group has formed a view as to a food's novelty in relation to all cases it has considered. The arbitration procedure has not been used to determine whether a food is novel.

### ***1.5 What criteria must novel foods satisfy in order to be placed on the market?***

The basic criteria for the authorisation of novel foods is that they must not:

- present a danger for the consumer; or
- mislead the consumer; or
- differ from foods or food ingredients that they are intended to replace to an extent that their normal consumption would be nutritionally disadvantageous for the consumer.<sup>11</sup>

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<sup>9</sup> This involves referring the matter to the Standing Committee for Foodstuffs in accordance with the 'Comitology' procedure set out in Article 13 of the Novel Food Regulation. See Article 1(3), Novel Food Regulation.

<sup>10</sup> Article 1(3), Novel Food Regulation.

## ***1.6 What are the procedures for placing a novel food on the market in the Community?***

There is a harmonised procedure for placing a novel food on the market in the Community. This procedure begins with an initial assessment, and may proceed to a Community decision in certain circumstances.<sup>12</sup> Certain products, however, may benefit from a simplified procedure.

### **1.6.1 Principal Procedure**

#### ***Initial Assessment – submission of request***

For an initial assessment to occur, the person responsible for placing a novel food on the Community market for the first time, submits a request to the Member State where the product is to be first placed on the market, and copies this request to the Commission.<sup>13</sup> This request must contain specific information as outlined in the Novel Food Regulation. This information includes:

- a copy of any studies and any other material available to demonstrate that the food or food ingredient complies with the basic criteria (see above);
- an appropriate proposal for the presentation and labelling of the food or food ingredient;
- a summary of the dossier; and
- for foods or food ingredients containing or consisting of a GMO, within the scope of Article 2(1) and 2(2) of Directive 90/220/EEC, copies of other specified documentation.<sup>14</sup>

#### ***Initial Assessment – the report***

After the Member State accepts a request, they ensure an initial assessment is conducted.<sup>15</sup>

Following notification from the Member State, the Commission forwards to other Member States the summary provided by the applicant and the name of the competent food assessment body that will be conducting the initial assessment.<sup>16</sup>

The competent food assessment body completes the initial assessment report,<sup>17</sup> in accordance with the Commission's published recommendations.<sup>18</sup> The initial assessment report generally makes recommendations in respect of:

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<sup>11</sup> Article 3(1), Novel Food Regulation.

<sup>12</sup> Community decisions are referred to as 'authorisation decisions' in the Novel Food Regulation; see, for instance, Article 7(1).

<sup>13</sup> Article 4(1), Novel Food Regulation.

<sup>14</sup> Article 9(1), Novel Food Regulation.

<sup>15</sup> Article 6(2), Novel Food Regulation.

<sup>16</sup> Article 6(2), Novel Food Regulation.

<sup>17</sup> The Novel Food Regulation requires that the initial assessment report is completed within three months of receipt of a request containing the necessary information. However, this timeframe has not been met in practice.

<sup>18</sup> Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council.

- the conditions of use of the novel food;
- the designation of the novel food;
- the specification for the novel food; and
- specific labelling requirements.

### ***Initial Assessment report – inclusion of decision***

The Novel Food Regulation requires that the initial assessment report must include a decision as to whether the food or food ingredient requires additional assessment.<sup>19</sup> However, this has not always occurred in practice. Rather, initial assessment reports have sometimes not reached a conclusion, or have recommended authorisation of the novel food in question. Reports lacking conclusions have been unhelpful. Those recommending authorisation, whilst not formally ideal, have at least provided some guidance to Member States and the Commission for decision-making purposes, as they imply that no additional assessment is required. Such reports have been forwarded to the other Member States for comments or objections.<sup>20</sup>

If the initial assessment report requires additional assessment of the novel food, or is otherwise unable to reach a positive conclusion in relation to the novel food, then a Community decision in respect of authorisation is required.

### ***Initial Assessment – comments and objections on the report***

Within sixty days of the Commission circulating the initial assessment report, a Member State or the Commission may make comments or present a reasoned objection to the marketing, the presentation or the labelling of the novel food.<sup>21</sup> Such objections and comments are not limited to scientific matters, but may encompass broader non-scientific issues. The distinction between objections and comments is important: an objection triggers a Community decision in respect of authorisation, whereas comments do not.

If no Community decision is required, the novel food may be placed on the market in accordance with the applicant's proposal, and the conclusions of the initial assessment report. In these circumstances, the applicant's proposal and the initial assessment report conclusions would constitute the terms of the authorisation for the novel food. However, this potential outcome has not yet occurred during the implementation of the Novel Food Regulation.

### ***Community Decision***

This decision must define the scope of the authorisation, and if appropriate, establish:

- the conditions of use of the novel food;
- the designation of the novel food;
- the specification for the novel food;

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<sup>19</sup> Article 6(3), Novel Food Regulation.

<sup>20</sup> In accordance with Article 6(4), Novel Food Regulation.

<sup>21</sup> Article 6(4), Novel Food Regulation.

- specific labelling requirements.<sup>22</sup>

The Community decision is taken by referring the matter to the Standing Committee for Foodstuffs in accordance with the procedure under the Novel Food Regulation.<sup>23</sup> Usually, the Commission develops the draft decision concerning the authorisation of the novel food in consultation with the Novel Foods Working Group, before submitting it to the Standing Committee for Foodstuffs.

In the case of novel foods containing or consisting of GMOs, additional requirements apply.<sup>24</sup>

## 1.6.2 Simplified Procedure

### *What foods does the simplified procedure apply to?*

The initial assessment/Community decision process does not apply to certain novel foods, namely those that are considered to be substantially equivalent to existing foods or food ingredients as regards composition, nutritional value, metabolism, intended use and level of undesirable substances contained, and that:

- are produced from, but do not contain, GMOs;
- consist of or are isolated from micro-organisms, fungi or algae; or
- are foods or food ingredients that consist of or are isolated from plants, or food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices, and having a history of safe use.<sup>25</sup>

These novel foods simply require notification.<sup>26</sup> That is, the applicant notifies the Commission that it is placing the food or food ingredient on the market, and includes with this notification material establishing substantial equivalence.<sup>27</sup>

### *Establishing substantial equivalence*

There are two possible grounds for substantial equivalence. First, a food can be considered to be substantially equivalent to an existing food on the basis of available and generally recognised scientific evidence. Second, substantial

<sup>22</sup> Article 7(2), Novel Food Regulation.

<sup>23</sup> That is, the ‘Comitology’ procedure set out in Article 13 of the Novel Food Regulation.

<sup>24</sup> The Community decision must respect environmental safety requirements to ensure that all appropriate measures are taken to prevent the adverse effects on human health and the environment that might result from the deliberate release of GMOs (Article 9(2), Novel Food Regulation). These requirements are laid down in Directive 90/220/EEC (This Directive will shortly be replaced by Directive 18/2001/EC) In addition, during evaluation of requests to place on the market food or food ingredients containing or consisting of GMOs, consultations must be held by the Commission or Member States with the bodies established in accordance with Directive 90/220/EEC (Article 9(2), Novel Food Regulation; this Directive will shortly be replaced by Directive 18/2001/EC).

<sup>25</sup> Article 3(4), Novel Food Regulation. History of use alone is insufficient, regardless of the length of use; it is evidence of safe use that is required.

<sup>26</sup> Article 3(4), Novel Food Regulation.

<sup>27</sup> Article 5, Novel Food Regulation.

equivalence can be based on an opinion of a competent food assessment body, that a food is substantially equivalent to an existing food.<sup>28</sup>

In practice, it has been very difficult for applicants to fulfil the criteria of ‘generally recognised’ scientific evidence of substantial equivalence. Accordingly, all foods notified so far have relied upon opinions of competent food assessment bodies with respect to substantial equivalence.

If it is not clear whether a novel food falls within this category, the arbitration procedure under the Novel Food Regulation may be used.<sup>29</sup>

### ***1.7 How must a novel food be labelled?***

In addition to general labelling requirements that apply to food, the Community decision must establish specific labelling requirements for foodstuffs, where this is appropriate. These requirements must ensure that the final consumer is informed of:

- any characteristic or property which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient (such as composition, nutritional value or effects, or intended use of the food), and the method by which the characteristic or property was obtained;
- the presence of material in the novel food or food ingredient which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population, or gives rise to ethical concerns; and
- the presence of an organism genetically modified using the techniques of genetic modification.<sup>30</sup>

Where there is no existing equivalent food or food ingredient, appropriate provisions shall be adopted where necessary to ensure that consumers are adequately informed of the nature of the food or food ingredient.<sup>31</sup>

### ***1.8 What information is disclosed or protected under the Novel Food Regulation?***

A regulation laying down rules for making certain information available to the public and for protecting information submitted under the Novel Food Regulation came into force on 10 October 2001.<sup>32</sup>

The regulation promotes transparency by making available to the public specified information concerning applications made under the Novel Food Regulation, and the initial assessment report.<sup>33</sup>

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<sup>28</sup> Article 3(4), Novel Food Regulation.

<sup>29</sup> Article 3(4), Novel Food Regulation.

<sup>30</sup> Article 8(1), Novel Food Regulation.

<sup>31</sup> Article 8(2), Novel Food Regulation.

<sup>32</sup> Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97 (Information Regulation).

<sup>33</sup> Article 2, Information Regulation.

This regulation also provides for the protection of confidential information submitted by an applicant under the Novel Food Regulation. The only confidential information protected is that which relates to the manufacturing process, whose disclosure might harm the applicant's competitive position.<sup>34</sup> The Commission, Member State authorities and competent food assessment bodies must not divulge such information except if it must be made public to protect human health.<sup>35</sup>

### ***1.9 What are the procedures for removing novel foods from the market in the Community?***

There are general procedures for removing unsafe food from the market in the Community, and these of course apply to novel foods as well as conventional foods.

However, if despite pre-market assessment, safety problems arise in relation to a novel food that has been authorised under the Novel Food Regulation, specific provisions under this regulation may also be utilised.

These provide that the only grounds for restricting or suspending the use of a food or food ingredient that complies with the Novel Food Regulation are that it endangers human health or the environment. If a Member State has such grounds, based on new information or reassessment of existing information, it may temporarily restrict or suspend trade in and use of that food or food ingredient in its territory.<sup>36</sup>

If a Member State restricts or suspends the use of a novel food, the Commission must examine the Member State's grounds as soon as possible and take appropriate measures. The Member State's restriction or suspension may remain in force only until the Commission's measures commence.<sup>37</sup>

These procedures under the Novel Food Regulation have not yet been used.

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<sup>34</sup> Article 1(2), Information Regulation.

<sup>35</sup> Article 1, Information Regulation.

<sup>36</sup> Article 12(1), Novel Food Regulation.

<sup>37</sup> Article 12(2), Novel Food Regulation.

## 2. Applications under the Novel Food Regulation

Progress Of Applications Under The Novel Food Regulation <sup>38</sup>	
Total number of applications accepted by Member States	37
Applications withdrawn	2
Erroneous application (Article 2)	1
Initial assessment report pending	10
SCF opinion requested	5
SCF opinion suspended	2
SCF opinion delivered but no decision (March 2002)	2
Initial assessment report complete – clarification/SCF consultation requested	4
Additional assessment required (Community decision)	2
Authorised	6
Refused	2

Less than half of the applications accepted were for novel foods consisting of, containing or derived from GMOs, but none of these applications have been finalised at this time.

From the commencement of the Novel Food Regulation until the date of this discussion paper, the average time taken from acceptance of an application to a final decision has been just over two years. Since 1999, the situation has improved somewhat, with the average time being reduced to approximately eighteen months.

In particular, after objections were made, Member States and the Commission introduced expert consultations together with the applicant. In cases where the foodstuff in question was not likely to have an effect on public health and the objections or questions raised by Member States did not require further scientific advice, the Scientific Committee on Food was not consulted. Using this approach, duplication of the “scientific risk assessment” was avoided and the authorisation of novel foods could be accelerated.

The following two tables present a comparison of time periods of the different phases of the authorization procedure.

The first table shows that the time between the initial assessment and a final Community Decision has been reduced significantly (products (10) fruit preparations pasteurised by high pressure treatment; (24) dextran; and (28) potato proteins and hydrolysates thereof). If the initial assessment can be done in a short time it will be possible to reach a Community Decision – even in the case of objections – within one year (see (28)).

The long delays in dealing with applications also reflect difficulties in the initial implementation of the Novel Food Regulation. Member States and their competent

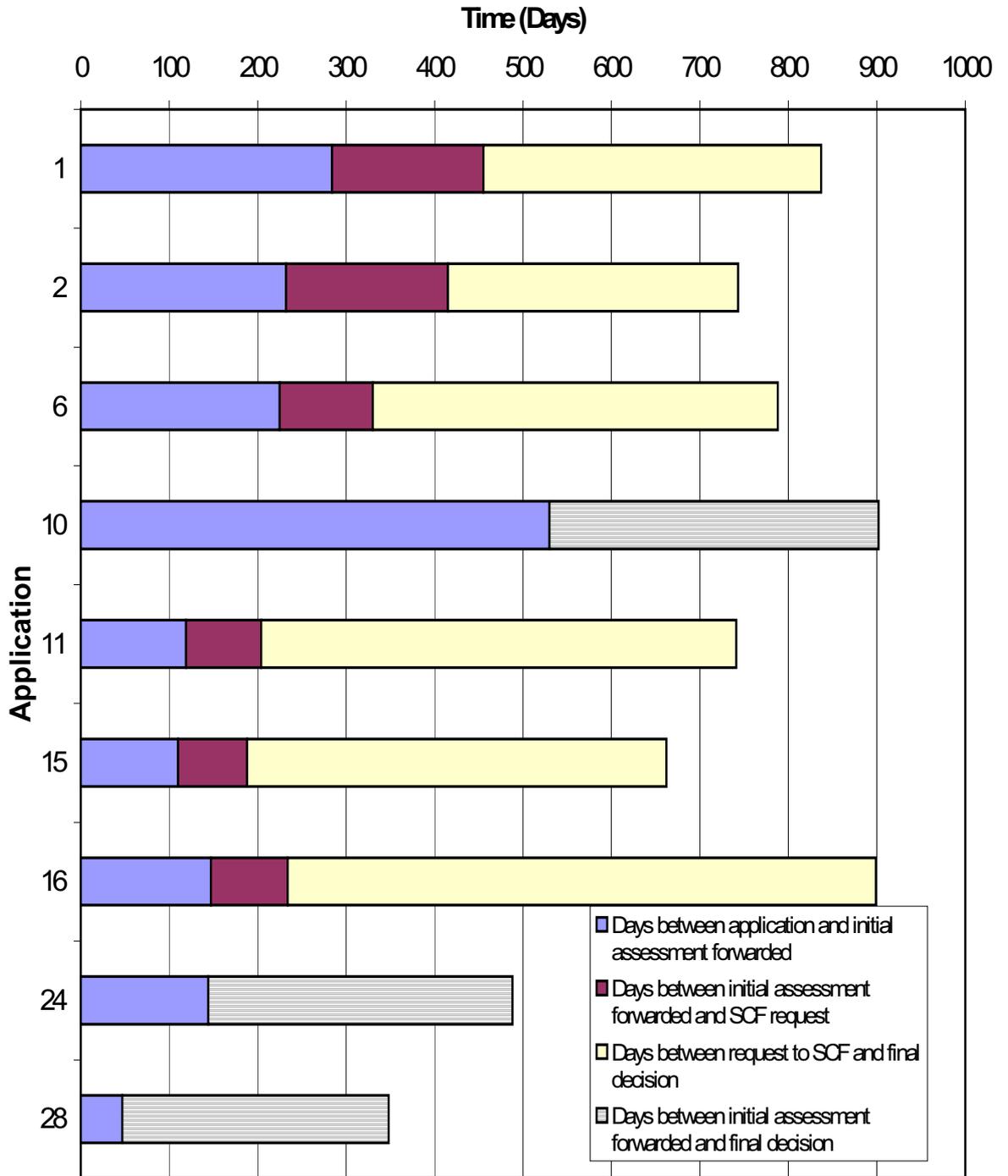
<sup>38</sup> Correct as of March 2002. See Attachment 1 for a more detailed table concerning applications under the Novel Food Regulation.

food assessment bodies had to establish their co-operation. It was often difficult to obtain the necessary data from the applicants. Until March 2002 a Community Decision was required for all applications, not only when an additional assessment had to be carried out, but because objections were raised for all other applications.

The second table shows all pending applications for novel foods and novel food ingredients that are **non-GMO** (as of 1 March 2002).

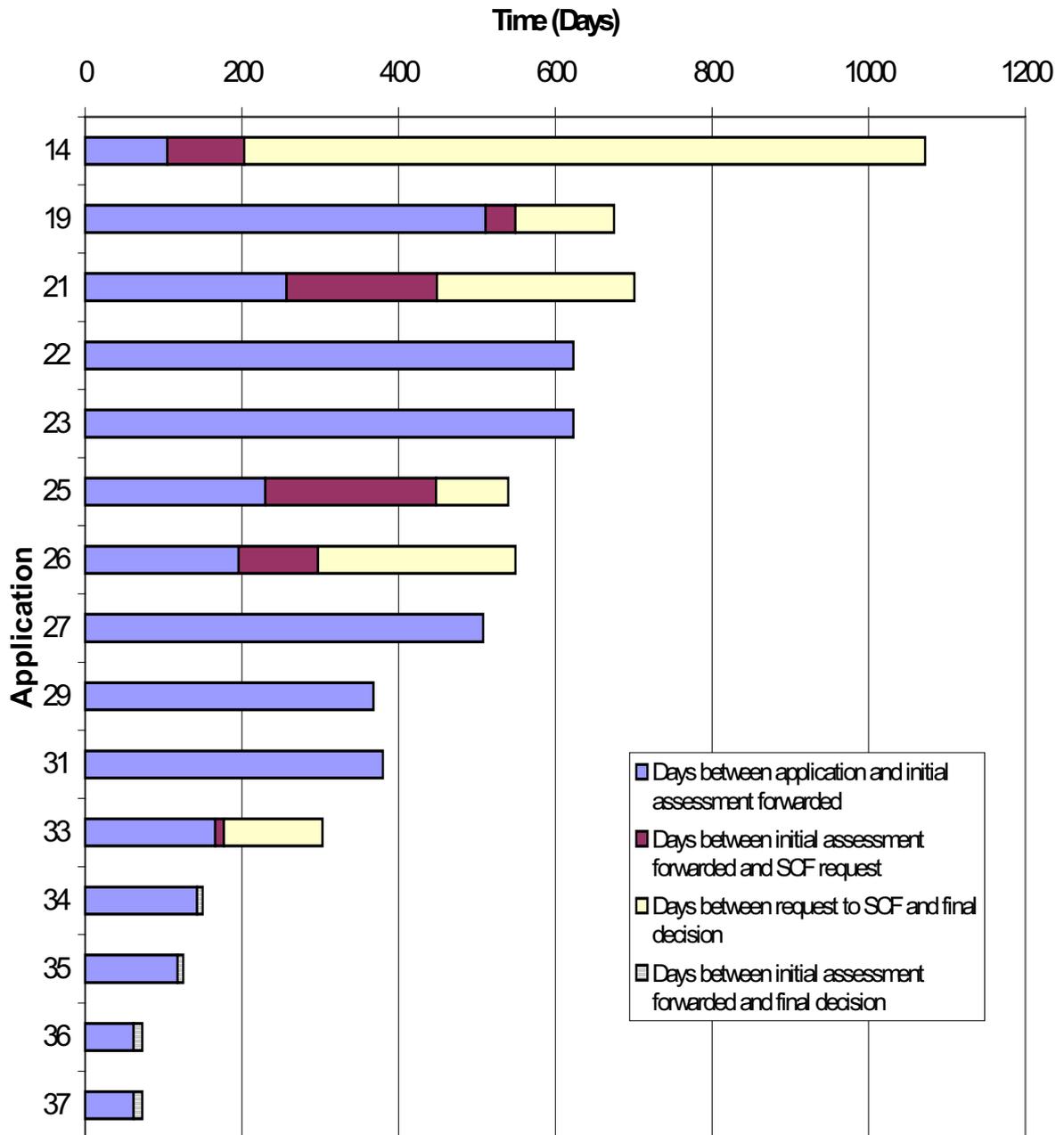
**N.B.: The names and product descriptions for the novel foods and novel food ingredients are given in Attachment 1 under the same number.**

'Non GMO' Novel Food Applications Final as at 1 March 2002



# 'Non GMO' Novel Food Applications Pending as at 1 March 2002

\* All final stages are 'pending'



### **3. Particular issues relating to the Novel Food Regulation, including options for the future**

Before moving on to discuss these issues, it is important to recall the principal objectives of the Novel Food Regulation. This regulation is designed to facilitate the functioning of the internal market within the Community, and to protect public health, through the establishment of a Community system for the pre-market approval of novel foods. Ultimately, it is against these objectives that options for development of the Novel Food Regulation need to be assessed.

#### **3.1 *What is a novel food?***

During implementation of the Novel Food Regulation, certain aspects of the definition of novel food have given rise to difficulties in interpretation and application.

##### **3.1.1 Whole animals**

One aspect has been the novel food category of ‘foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe use’.<sup>39</sup>

The wording of this category is different for plants and for animals. Whilst foods and food ingredients consisting of or isolated from plants are explicitly covered, there was in one case an interpretation that only food ingredients isolated from animals are included. Therefore, it could be argued that foods or food ingredients consisting of whole animals, are not included in the category.

In practice, this discrepancy may lead to food ingredients that consist of whole animals falling outside of the scope of the definition of novel foods. The case referred to above involved whole scorpions in spirits, which could not be regarded as novel foods under this category as they were whole animals, not a food ingredient isolated from animals. There does not appear to be any policy reason for excluding whole animals from this novel food category. This exclusion does not appear to have been intended.

This novel food category could be reworded in order to make it clear that it covers foods or food ingredients consisting of animals, as well as those isolated from animals. This would be broadly consistent with the treatment of plants, fungi and algae.

##### **3.1.2 Production processes**

There have also been issues concerning the ‘production process’ novel food category. This category covers ‘foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances’.<sup>40</sup>

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<sup>39</sup> Article 1(2)(e), Novel Food Regulation.

<sup>40</sup> Article 1(2)(f), Novel Food Regulation.

It is important to note that this category applies to foods and food ingredients significantly changed by a new production process, not to new production processes in themselves.

The main implementation issue that has arisen in relation to this category has been confusion about what constitutes a 'significant change' to the composition or structure of foods, given that production processes usually involve some change of this nature. It may also be said that this category was developed with a particular focus on GM food. Accordingly, it appears timely to consider what this category should cover.

There appear to be three main options available.

***Option 1 – remove category from Novel Food Regulation***

This category could be removed from the Novel Food Regulation. This would mean that some foods that previously would have been considered novel foods no longer will be. Could this be cause for concern? It could be argued that it may be, if a new production process applied to a familiar food results in the food having different properties, which have implications for public health or the functioning of the internal market. For instance, if it affects the food's toxicity or allergenicity. However, general food regulations may be sufficient to address such potential problems. If this is the case, it may be argued that additional regulation under the Novel Food Regulation is superfluous.

***Option 2 – category remains, other efforts are made to reduce confusion***

This category could remain unchanged, and efforts made to reduce confusion about what constitutes a 'significant change' to the composition or structure of a food. Such efforts may involve the development of guidelines to assist interpretation, and the provision of expert advice to potential applicants in this regard. This option would directly address the problem of uncertainty about the meaning of 'significant change' that has emerged during the implementation of the Novel Food Regulation. However, such measures can only reduce such uncertainty, not eliminate it altogether.

***Option 3 – assess novel production processes and novel foods***

The existing principle that novel food, not novel production processes, should be assessed could be revised, so that novel production processes as well as novel foods are assessed under the Novel Food Regulation. This would require this category to be expanded to cover novel production processes regardless of whether these result in significant changes to the final food. This removes the need to determine what constitutes a 'significant change' to a food. However, another difficult question – how to determine what constitutes a novel production process – appears likely to replace it. Perhaps more importantly, it is not clear what would be gained by subjecting all novel production processes to pre-market approval. If novel production processes do not have implications for the functioning of the internal Community market, or for public health, regulation of them may be argued to be unnecessary. In addition, such regulation may deter further development of production processes that may be beneficial, for instance, in the promotion of public health.

### 3.1.3 Separation of GM foods from the Novel Food Regulation

There are two legislative proposals currently before the European Parliament and Council for the establishment of a separate regime to deal with the authorisation and traceability of novel foods and novel food ingredients that consist of, contain or are derived from genetically modified organisms.<sup>41</sup> With the changes consequential to the passage of this legislation, the remaining categories of novel food will consist of foods and food ingredients:

- with a new or intentionally modified primary molecular structure; or
- consisting of, or isolated from, micro-organisms, fungi or algae; or
- consisting of or isolated from plants, or food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices, and having a history of safe use; or
- to which a production process not currently used has been applied, where that process gives rise to significant changes in the composition or structure of the food or food ingredient, which affects its nutritional value, metabolic effect or level of undesirable substances.

It may be useful to consider whether these remaining categories, with or without some amendments to address discrete issues that have arisen during implementation, are the best means by which to achieve the Novel Food Regulation's objectives of protecting public health and the functioning of the internal Community market. More generally, will these continue to be the most useful and appropriate ways of defining and thinking about novel foods?

There appear to be two main options in this regard.

#### *Option 1 – Minor amendments to novel food categories*

The novel food categories may remain as they are, with some minor amendments to address particular issues that arose during implementation of the Regulation. It may be argued that the novel food categories have worked reasonably well, and will only require some occasional changes to address unforeseen issues. As such, there is no pressing need to engage in a more general revision of the definition of novel food, and any such revision would mean further upheaval, uncertainty and implementation difficulties. Also, making such a basic change to the Novel Food Regulation may create transitional problems as foods that were regarded as not novel under the category-based definition could now be regarded as novel. The more specific approach of having novel food categories provides more certainty in determining what is a novel food in each individual case. However, the main problem with this type of specific approach is that it may also result in certain

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<sup>41</sup> Proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed, 25/07/2001; COM(2001)425 final; and Proposal for a Regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, 25/07/2001; COM(2001)182 final.

foods that many agree should be within the scope of the Novel Food Regulation, ‘falling between the cracks’ of such novel food categories and hence not being subject to such regulation.

***Option 2 – A broad definition instead of the novel food categories***

A more broadly conceived definition could replace the existing novel food categories. It could be argued that a more broadly conceived definition would make it unnecessary to continuously amend the definition to deal with new borderline cases that do not fit the novel food categories. Such a definition could also be more specifically designed to fit non-GM novel food. This more general approach can probably be used to capture a broader range of foods, including those that have fallen outside of the current category-based definition, despite general views that they ought to be treated as novel foods.

There are numerous ways in which such a broad definition could be formulated. For instance, one broad category could replace the remaining four novel food categories, covering foods and food ingredients consisting of or isolated from animals, plants, micro-organisms, fungi or algae, not used for human consumption to a significant degree within the Community before 15 May 1997. It would of course be important to ensure that any such category did not capture new food products that are simply re-formulations, using ingredients that have a history of safe use within the Community. It would also need to be considered whether new varieties of animals or plants produced by traditional breeding or propagation methods, should be included in this category. Given that there are approximately 2000 – 3000 new varieties of plants included in the EU’s common catalogue each year, however, the inclusion of such new varieties does not appear to be feasible.

### ***3.2 Decisions under the Novel Food Regulation***

Decisions under the Novel Food Regulation are currently addressed to the applicant. That is, if a novel food is authorised, then only the applicant is able to place the novel food in question on the market in the Community. If another party wishes to market the same novel food, they must take the appropriate steps in accordance with the Novel Food Regulation.

Practically speaking, decisions need to be addressed to someone (eg. a Member State, an applicant) and this is of particular relevance for foods that are the results of an innovative process by a firm. Alternatively, regulations with general application, rather than decisions, could be issued in response to applications concerning natural products already on the market in other parts of the world.

***Option 1 – decisions addressed to individuals***

This current approach of making decisions addressed to individuals has the advantage of providing the regulator with more certain and comprehensive information about the novel foods that are legally on the market. It also allows enforceable conditions to be attached to the granting of an individual decision. For instance, in relation to phytosterol esters, post-market surveillance requirements were imposed on the holder of the authorization as part of the decision.

However, it also has certain disadvantages. As the decision only applies to the applicant, it is arguable that any conditions attached to the decision, such as labelling requirements, only apply to the applicant. Other parties involved in the supply of the product may not be bound by these conditions. It may also be inefficient and time-consuming. Situations may arise where multiple applications for a novel food that has already been authorised may need to be processed under the regulation. Although notification is likely to be all that is required, this still takes time and resources on the part of applicants, Member States and the Commission.

Individual decisions may also have the effect of granting the first applicant a privileged position in relation to a product, at least until other applications can be processed under the regulation. Some may argue that this is not unfair, as the first applicant was simply quicker off the mark, and nothing prevents other applications for the same or similar products. Indeed, if a person wishes to market a product that complies with the specifications of a novel food that is already authorised, notification is likely to be all that is required. However, it could also be argued that creating a situation that results in such a privileged position, even in the short term, is inadvisable unless there are very good reasons for this.

#### ***Option 2 – regulations with general application***

The alternative approach, of making regulations with general application in response to applications under the Novel Food Regulation, has the advantage of binding all relevant parties to follow applicable requirements in relation to novel food. It also means that multiple applications for products would not need to be made and processed, and that effective monopolies would not arise due to the nature of the Novel Food Regulation procedures.

#### ***3.2.(a) Who may be an applicant?***

There is an additional issue that is related to this question, and that is the qualifications for being an applicant under the Novel Food Regulation. Currently, only a person responsible for placing a novel food on the Community market may make an application under the Novel Food Regulation. In practice, other people such as manufacturers of processing equipment have wanted to make applications, but have been unable to do so. It makes sense that only food suppliers can be applicants if decisions are addressed to applicants and clearly bind only applicants, as this ensures that the conditions of those decisions apply to this key link in the food supply chain. However, if regulations are made in response to applications under the Novel Food Regulation, the justification for this exclusion appears weakened, as such regulations may bind food suppliers as well as other parties such as manufacturers of food processing equipment. Accordingly, it may be appropriate to amend the Novel Food Regulation to permit other interested parties to be applicants.

### ***3.3 Processes for dealing with applications under the Novel Food Regulation***

#### **3.3.1 The simplified procedure**

Certain foods, namely foods falling into one of three novel food categories, and that are considered substantially equivalent to existing foods or food ingredients, are subject to a simplified procedure based on notification under the Novel Food Regulation. In order to take advantage of this procedure, an applicant is required to provide certain material establishing substantial equivalence. In practice, this has generally been the opinion of a competent food authority with respect to substantial equivalence.

The concept of ‘substantial equivalence’ has played a central role in the GMO debate. Many divergent views exist on the meaning and use of this concept. However, there is now general agreement that although substantial equivalence is a key step in a safety assessment, it is not a safety assessment in itself.

In light of this, it appears preferable to review the simplified procedure. There is a range of possibilities. The following are simply three of the main options available.

#### ***Option 1 – other criteria for a simplified procedure***

One option would be to look for other criteria for a simplified procedure under the Novel Food Regulation. For example, history of safe use as foods in third countries, or satisfactory safety evaluation by approved third countries. This type of criteria requires acknowledgement that safety may be established through third country evidence or processes. Its application would be likely to save the Community both time and resources it would otherwise expend on safety evaluation. However, it is likely that many will be of the view that a more positive assurance of public health can be achieved through a Community assessment that does not rely upon third countries. Alternatively, foods from new varieties of plants or animals developed through the application of traditional breeding or propagation methods could qualify for use of a simplified procedure. However, as noted above, the large number of new varieties developed may affect the feasibility of this (see option 2, section 3.1.3).

Further consideration of whether there are any genuine safety issues associated with such foods would be required to properly assess this criterion.

#### ***Option 2 – different categories of novel foods, with different requirements and procedures***

A second option would be for novel foods to be subject to different levels of requirements and procedures under the Novel Food Regulation, according to categorisation and the associated risks and benefits. For instance, novel foods may be divided into three main groups:

- innovative products with claimed consumer benefits (e.g. phytosterol esters in yellow fat spreads);

- innovative products without claimed consumer benefits (e.g. high pressure pasteurised products); and,
- exotic traditional foods (e.g. ngali nuts).

These categories of foods may then be subject to different levels of requirements and procedures under the Novel Food Regulation. For example, different criteria and evidence requirements could apply to exotic traditional foods, to innovative products that have no such history of long term consumption in third countries. This may be analogous to an approach taken in relation to complementary and conventional medicines, whereby both go through pre-market approval processes, but they are subject to different requirements as to the type and quantity of data they must provide.

***Option 3 – All novel foods use principal procedure***

A third option would be to abandon the simplified procedure altogether, and require that all novel foods go through the principal procedure for authorisation. This single approach would have the advantage of reducing uncertainty and disputes concerning qualification for a simplified procedure. It may also dispel any lingering doubts concerning the safety of novel foods. However, it would be a more resource intensive approach, and would be likely to slow the release of some novel foods onto the Community market. In addition, it may be unreasonably restrictive.

### **3.3.2 The principal procedure**

In addition to considering the simplified procedure, it is important to consider whether the principal procedure should continue in its present form, or whether aspects of it should be altered.

As outlined above, the current Novel Food Regulation sets out a procedure for placing a food on the market in the Community involving an initial assessment by a Member State, followed by a Community decision. Although the Novel Food Regulation provides for the process to end after initial assessment if the report does not determine that additional assessment of the food is required, and no objections are made by another Member State or the Commission, in practice objections have always been made and so the process has invariably progressed to a Community decision.

It is also important to note that the establishment of the European Food Safety Authority constitutes a significant change to the landscape in which food assessment procedures within the Community are established and operate.

***With whom should applications be lodged?***

At present, applications are lodged with Member States. This provides an applicant with a single authority to deal with during this initial phase. Through the implementation of the Novel Food Regulation, Member States have gained experience in dealing with such applications.

An alternative would be for applications to be lodged with the European Food Safety Authority. This type of centralised lodgement system would appear to be simpler, in that applicants would still deal with a single authority and would not have to go through the sometimes artificial process of selecting

which Member State is to be the first market for a food in the Community. It may also be said to be more conducive to the consistent treatment of applications, in that one body rather than different Member States would receive applications.

***The initial assessment report – decision not to permit marketing of food***

At present, under the Novel Food Regulation it is not clear whether an initial assessment report may include a decision that the food should not be marketed within the Community.

It may be said that it is appropriate that initial assessment reports cannot include such decisions, as such significant decisions should be taken by Member States, rather than by a competent food assessment body.

However, another option would be to permit the initial assessment report to include a decision that a food should not be marketed within the Community as it is not safe for consumption. This would appear to be simpler and more straightforward than requiring such decisions to be taken by Member States. In any case, where the initial assessment concludes that a food is not safe for consumption, Member States would not permit the food to be marketed, so requiring a decision to this effect from Member States seems unnecessary.

***The consideration of issues not directly related to risk or food safety***

An important question concerns who will consider non-scientific matters such as labelling or presentation prior to the Community decision stage of the process. During implementation, it has been apparent that as initial assessment reports are focused on providing scientific advice, and there is no other method under the regulation by which other matters can be dealt with, Member States have had little choice but to use the Community decision procedure to deal with such other issues. This has been one of the main reasons why the procedure has always continued from initial assessment to a Community decision.

There appear to be three main options for addressing this question.

***Option 1 – Status quo***

The situation may remain unchanged, so that a competent assessment body provides initial assessment reports that concentrates on the food safety aspects, and Member States do not receive any comparable report in relation to other matters. This means that the Member States participate in the adoption of Community decisions without the assistance of formal advice on these other matters from a central and independent body. This is also likely to ensure that the situation whereby this procedure always proceeds to a Community decision continues, and accordingly it takes a long time to reach decisions in respect of applications under the Novel Food Regulation.

***Option 2 – EFSA initial assessment report with advice only on risk***

In this option, the EFSA produces initial assessment reports that provide scientific advice only in respect of the safety of the food. This option is

generally similar to the first, except that the initial assessment is carried at Community level.

***Option 3 – EFSA initial assessment report with scientific and other advice***

Third, the EFSA could be asked to produce an initial assessment report containing scientific advice in respect of food safety, and advice on other matters such as the labelling of products. This option is similar to the one proposed by the Commission in respect of GM food and GM feed under COM(2001) 425.

**3.3.3 Transparency and public consultation**

Although the present procedure under the Novel Food Regulation provides for making information available to the public concerning applications and the initial assessment report, it does not provide any opportunity for public consultation in respect of applications. Currently, some consultation may occur through the actions of individual Member States, but this is limited and piecemeal.

In line with general Community aims of improving transparency and responsiveness, consultation processes are being reviewed. This has resulted in, for example, the inclusion of consultation processes in the new proposal for GM food and feed. These processes consist of making a summary of the applicant's dossier available to the public and the EFSA opinion available to the public for comment.

***Option 1 – one stage of comment***

A similar process could be incorporated into the Novel Food Regulation, whereby the summary of the applicant's dossier and the initial assessment report is made available to the public. The public may then provide comments on the initial assessment within a limited time.

***Option 2 – two stages of comment***

Alternatively, the public may provide comments at two stages: first, after the summary of the applicant's dossier is made available, and second, after the initial assessment report is released.

Both options would provide members of the public with an opportunity to contribute, as well as enhancing the openness of processes under the Novel Food Regulation, which may assist in increasing public knowledge and confidence in such processes.

In relation to the two options, it is important to note that whilst comments would be taken into account, no obligation to respond to individual comments or to follow any particular comments is envisaged. Such a process would nonetheless require more resources to assess public comments, and to provide details of relevant comments for the decision-making process. An expanded consultation process may also create expectations in some stakeholders as to their influence on the eventual outcome, and care would need to be taken to manage these expectations.

### **3.4 Labelling of Novel Foods**

As outlined above<sup>42</sup>, Community decisions may include additional specific labelling requirements, where this is appropriate. These requirements are designed to ensure that the final consumer is informed about aspects of the food which make it different to similar existing foodstuffs.

One of these requirements<sup>43</sup> directly relates to informing the consumer of the presence of GMOs. Once the Novel Food Regulation applies only to non-GMO foodstuffs, this requirement would appear to become superfluous. The other requirements do not directly relate to GMOs, although they may have been formulated upon the assumption that novel foods would be likely to contain GMOs.

#### ***Option 1 – Status quo***

One option would be to leave the requirements as they stand, apart from removing the one that directly relates to the presence of GMOs, once GMO labelling is dealt with by another regulation. This has the advantage of maintaining the consistency of the Novel Food Regulation. However, the very specific nature of the requirements may have the disadvantage of limiting the types of matters a consumer must be informed of.

#### ***Option 2 – Simplified general requirement***

Another option would be to substitute a more general requirement for the current requirements. The general requirement could simply be that appropriate provisions be adopted where necessary in order to ensure that the final consumer is informed of significant characteristics about the novel food, in particular, where such characteristics have implications for consumers' health or safety. This would allow for considerable flexibility in consumer information about individual novel foods.

Special attention has to be given to the policies and legal requirements of the different labelling provisions for foods for particular nutritional uses, for nutritional labelling and for claims.

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<sup>42</sup> See section 1.7.

<sup>43</sup> Article 8(1)(d), Novel Food Regulation.

## Glossary of Terms

EFSA	European Food Safety Authority
GMOs	Genetically modified organisms
Information Regulation	Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97.
Novel food	Novel food or novel food ingredient, as defined in the Novel Food Regulation
Novel food categories	The categories of novel food set out in Article 1(2)(a) – (f) of the Novel Food Regulation
Novel Food Regulation	Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients
Novel Foods Working Group	A group comprising experts from the Member States, and chaired by an officer of the Commission, whose role is to facilitate the coordinated implementation of the Novel Food Regulation.

### Attachment 1 – Table of Applications under the Novel Food Regulation

#### Applications under Regulation (EC) N° 258/97 of the European Parliament and of the Council

	Applicant	Food or Food Ingredient	Initial Assessment Carried out by	Application Date	
1	Katholieke Universiteit Leuven Laboratory of Plant Physiology B – 3001 Heverlee	<i>Stevia rebaudiana</i> (plant and dried leaves)	Hoge Gezondheidsraad RAC – Esplanadegebouw 7e verdieping Pachecolaan 19 bus 5 B – 1010 Brussel	7 November 1997	Commission Decision refusing the placing on the market of <i>Stevia rebaudiana</i> <b>2000/196/EC</b>
2	Belovo scri Zone industrielle, 1 B – 6600 Bastogne	Phospholipides from egg yolk	Hoge Gezondheidsraad RAC – Esplanadegebouw 7e verdieping Pachecolaan 19 bus 5 B - 1010 Brussel	9 February 1998	Commission authorising phospholipides (85% and 100%) to placed on the market in the Community <b>2000/195/EC</b>
3	ZENECA Jealott's Hill Research Station Jealott's Hill Bracknell UK – Berkshire RG42 6ET	Genetically Modified Processing Tomatoes	UK Advisory Committee on Novel Foods and Processes	3 March 1998	Withdrawn
4	Bejo-Zaden P.O.Box 50 NL – 1749 Warmenhuizen	Transgenic <i>Radicchio rosso</i> with male sterility	The Provisional Committee for the safety evaluation of novel foods (VcVnv) (NL)	8 April 1998	<b>SCF opinion suspended</b>
5	Bejo-Zaden P.O.Box 50 NL – 1749 Warmenhuizen	Transgenic Green hearted Chicoree with male sterility	The Provisional Committee for the safety evaluation of novel foods (VcVnv) (NL)	8 April 1998	<b>SCF opinion suspended</b>
6	Unilever	Yellow fat spreads with added	The Provisional Committee	28 May 1998	Commission Decision of 24

	Research and Engineering Division Unilever U.K. Central Resources Ltd. Unilever House Blackfriars UK – London EC4P 4BQ	phytosterol-esters	for the safety evaluation of novel foods (VcVnv) (NL)		July 2000 on authorising the placing on the market of ‘yellow fat spread with added phytosterol esters’ as a novel food or novel food ingredient <b>2000/500/EC</b> OJ L200/59
7	E.I. DuPont Nemours & Co. Agricultural Enterprise Optimum Quality Grains L.L.C. Registration and Regulatory Affairs Europe Ebertstr. 4 D – 07743 Jena	High Oleic Soybean Sublines derived from transformation event 260-05	The Provisional Committee for the safety evaluation of novel foods (VcVnv) (NL)	25 July 1998	<b>Initial assessment report pending</b>
8	Biomim Pharma GmbH Provinenstr. 15 D – 86153 Augsburg	Vit-Enzym		23 June 1998	<b>Withdrawn</b>
9	Monsanto Services International S.A. Ave. de Tervuren 270 – 272 B – 1150 Bruxelles	Roundup Ready Maize line GA21	The Provisional Committee for the safety evaluation of novel foods (VcVnv)	24 July 1998	<b>SCF opinion requested</b>
10	Groupe Danone 7, rue de Téhéran F – 75381 Paris cedex 08	Fruit preparations pasteurised using a high pressure treatment process	1) Conseil supérieur d’hygiène publique de France 2) Commission de technologie alimentaire	3 December 1998	Commission Decision <b>(2001/424/EC)</b> of 23 May 2001 authorising the placing on the market of pasteurised fruit-based preparations using high pressure pasteurisation under Regulation (EC) N° 258/97 of

11	M Yvan Jobert La Meillade n° 65 F – 34150 Montpeyrroux	Noix de nangailles	Conseil supérieur d'hygiène publique de France	9 December 1998	the European Parliament and of the Council OJ L151 of 7 June 2001, p.42 Commission Decision (2001/17/EC) of 19 December 2000 on refusing the placing on the market of “Nangai nuts ( <i>Canarium indicum</i> L.)” as a novel food or novel food ingredient OJ L4 of 9 January 2001, p.4
12	Mr. M. Van den Bulcke Plant Genetic Systems N.V. Jozef Plateaustraart 22 B – 9000 Gent	Liberty Link Soybean by AgrEvo Directive 90/220/EEC N°: <b>C/BE/98/01</b>	Bioveiligheidsraad (B)	2 February 1999	<b>Initial assessment report pending.</b>
13	Dr. P. Ahl Goy Novartis Seeds AG Basel CH – 4002 Basel	Bt11 sweet maize	Gezondheidsraad (NL)	11 February 1999	<b>SCF opinion requested</b>
14	Mr. Martin Livermore Du Pont Cereals Innovation Centre Bloch B, The Mill Site 40 Station Road UK – Cambridge CB1 2UJ	Soluble and insoluble fractions of cereal brans, for use as fat replacers and sources of fibre	Advisory Committee for Novel Foods and Processes (UK)	25 March 1999	<b>SCF opinion requested</b>
15	Dr. Gilles Morelle Puracor n.v. Industrielaan 25	Bacterial dextran	Hoge Gezondheidsraad (B)	9 April 1999	Commission Decision of 30 January 2001 authorising Dextran as a novel food

	B – 1702 Grote Bijlaan				ingredient to bakery products <b>2001/122/EC</b> OJ L44 of 15 February 2001, p.46
16	Dr. N. Baldwin Cultor Food Science Applications Laboratory: Units 3 – 4 72 – 86 Garlands Road UK – Redhill, Surrey RH1 6YS	Salatrim	Advisory Committee for Novel Foods and Processes (UK)	28 June 1999	<b>SCF opinion requested</b>
17	Dr. T.G.A. Clemence Regulatory Affairs for Maize Monsanto Services International S.A. Avenue de Tervuren 270-272 B – 1150	MaisGard®/RoundupReady®	Gezondheidsraad (NL)	16 March 2000	<b>Initial assessment report pending</b>
18	Dr. Firoz Amijee Regulatory Science Manager Pioneer Overseas Corporation Avenue Tedesco, 7 B – 1160 Brussels	Conventionally derived crosses between genetically modified maize lines T25 and MON810 (T25 X MON810)	Gezondheidsraad (NL)	20 April 2000	<b>Initial assessment report pending</b>
19	Mia Declerq Baker & McKenzie Louzalaan 149 B- 1050 Brussel On behalf of Morinda Inc.	Tahitian Noni Juice	Hoge Gezondheidsraad (B)	25 April 2000	<b>Additional assessment required Consultation of the SCF</b>
20	Yann Fichet Regulatory Affairs, Europe-	Foods and food ingredients derived from Roundup	Gezondheidsraad (NL)		<b>Initial assessment report pending</b>

	<p>Africa Monsanto Europe S.A. 270 – 272 Avenue Tervuren B – 1150 Brussels and; Paul Tenning Regulatory Affairs Novartis Seeds AB Box 302 S – 261 23 Landskrona</p>	<p>Ready® Sugar Beet</p>			
21	<p>Riitta Korpela Valio Ltd. Withdrawn on 17 March 2001 <b>Since 12 April 2001</b> For Pouttu: Pijjo Aronen Product Development Manager Pouttu Ltd. Vanh talvitie 11 C FIN – 00580 Helsinki</p>	<p>Plantsterol enriched Frankfurters, sausage, cold cuts (continued on behalf of Pouttu), <i>yougurth, fresh cheese and hard cheese</i> (withdrawn on 17 March 2001 by VALIO)</p>	<p>Uuselinjarvikelautakunta Kauppa- ja teollisuusministeriö (FIN)</p>	<p>30 March 2000</p>	<p><b>SCF opinion requested</b></p>
22	<p>Ms Diane Loiselle Associate Director Regulatory Affairs Abbot International Division Abbot Laboratories 200 Abbot Park Road USA – Illinois 60064-6188</p>	<p>MCT/Sardine Oil Structured Lipid</p>	<p>Gezondheidsraad (NL)</p>		<p><b>Initial assessment report pending</b></p>
23	<p>Ms Diane Loiselle Associate Director Regulatory</p>	<p>Fungal Oil SUN-TGA40S (Manufactured by Suntory)</p>	<p>Gezondheidsraad (NL)</p>		<p><b>Initial assessment report pending</b></p>

	Affairs Abbot International Division Abbot Laboratories 200 Abbot Park Road USA – Illinois 60064-6188	Limited, Tokyo, Japan)			
24	Dr. Albert Bär Bioresco Ltd. Bundesstr. 29 CH – 4045 Basel On behalf of Hayashibara Co. Ltd.	Trehalose	Food Standards Agency (UK)	25 May 2000	Commission Decision authorising the placing on the market of trehalose as a novel food or novel food ingredient <b>2001/721/EC</b>
25	Mr. Philippe Lanners Head of DRA/S&D Novartis Consumer Health Rue De Wandstraat 211-213 B – 1020 Brussel	REDUCOL™	Hoge Gezondheidsraad (B)	7 September 2000	<b>Additional assessment required SCF opinion requested</b>
26	Sampsa Haasilta Director Oy Karl Frazer Fazerintie 6 FIN – 01230 VANTAA P.O.Box 4 FIN – 00941 HELSINKI	Plant sterol enriched bakery products, grain based snack products and gum arabic pastills	Novel Food Board (FIN)	29 August 2000	<b>SCF opinion requested</b>
27	Phil Nicholls Oil Sales & Product Development John K Kings & Sons Limited The Silo	Echium Oil	ACNFP (UK)	9 October 2000	<b>Initial assessment report pending</b>

	Skellingthorpe Road UK – Lincoln LN6 0EL					
28	Dr. Jan H. Lichtenbelt AVEBE R&D Products AVEBE-weg 1 NL – 9607 PT Foxhol	Coagulated potato protein and hydrolysates thereof	Gezondheidsraad (NL)	3 January 2001	<b>Initial assessment report objections</b>	
29	Dr. Firoz Amijee Pioneer Overseas Corporation Avenue Tedesco 7 B – 1160 Brussels	Food products of genetically modified <i>B.t.</i> CRY1F Maize line 1507	Gezondheidsraad (NL)	26 February 2001	<b>Initial assessment report pending</b>	
30	Dr. Albert Bär Bioresco Ltd. Bundesstr. 29 CH – 4045 Basel On behalf of Wacker Chemie	Gamma-Cyclodextrin	Istituto Superiore di Sanità (IT)	10 April 2001	<b>Initial assessment report</b> Forwarded to Member States 4 October 2001 Clarification with respect to additives required	
31	Mr. Nigel Baldwin Mananger Regulatory Affairs Europe 21 Bartons Drive UK – Yately, Hampshire GU46 6DW for OmegaTech Microforum Ring 2 D – 55234 Wendelsheim	DHA-rich Oil	Advisory Committee on Novel Foods and Processes (UK)	14 February 2001	<b>Initial Assessment report pending</b>	
32	Dr. T.G. Alistair Clemence Regulatory affairs for Maize Monsanto Services International S.A.	Roundup Ready maize line NK603	Gezondheidsraad (NL)	June 2001	<b>Initial assessment report pending</b>	

	Ave. de Tervuren 270 – 272 B – 1150 Bruxelles	Phytosterol enriched fat ingredient - <b>Diminicol</b>	Novel Food Board (FIN)	May 2001	<b>Initial Assessment Report</b> Forwarded to Member States Consultation of the SCF in parallel
33	Ms Leena Morander Teriakia Ltd. Iiluodontie 17 B 00980 Helsinki Finland				

## Attachment 2 – Table of Notifications under the Novel Food Regulation

### Notifications Pursuant to Article 5 of Regulation (EC) N° 258/97 of the European Parliament and of the Council

	Applicant	Description of Food or Food Ingredient	Scientific Evidence	Notification	Transmission to Member States
1	AgrEvo UK Limited Chesterford Park Saffron Walden UK - Essex CB10 1XL	Processed oil from genetically modified canola seed, transformation event TOPAS 19/2 and all conventional crossed	“Report on oil from a genetically modified (GM) glufosinate ammonium tolerant oilseed rape” <sup>*</sup> (ACNFP)	9 June 1997	24 June 1997
2 a	Plant Genetic Systems N.V. Jozef Plateaustraat 22 B – 9000 Gent	Processed oil from genetically modified oilseed rape seed derived from: i) male sterile MS1Bn (B91-4) oilseed rape line and all conventional crosses; ii) fertility restorer RF2Bn (B94-2) oilseed rape line and all conventional crosses; iii) hybrid combination MS1XRF2	“Report on oil from a fertility restorer line for use in a hybrid breeding programme for genetically modified (GM) oilseed rape” (ACNFP)*	10 June 1997	24 June 1997 again 28 July 1998
2 b	Plant Genetic Systems N.V. Jozef Plateaustraat 22 B - 9000 Gent	Processed oil from genetically modified oilseed rape seed derived from: i) male sterile MS1Bn (B91-4) oilseed rape line and all conventional crosses; ii) fertility restorer RF1Bn (B93-101) oilseed rape line and all conventional	“Report on oil from a fertility restorer line for use in a hybrid breeding programme for genetically modified (GM) oilseed rape” (ACNFP) <sup>*</sup> ; and “Report on oil from genetically modified oilseed rape” (ACNFP)*	10 June 1997	24 June 1997 again 28 July 1998

		crosses; iii) hybrid combination MS1XRF1				
3	Monsanto Services International S.A Avenue de Tervuren 270-272 B - 1150 Brussels	Refined oil from glyphosate tolerant oilseed rape line GT73	“Report on oil from genetically modified (GM) glyphosate tolerant oilseed rape” (ACNFP)*	10 November 1997	21 November 1997	
4	Monsanto Services International S.A Avenue de Tervuren 270-272 B - 1150 Brussels	Food and food ingredients produced from maize flour, maize gluten, maize semolina, maize starch, maize glucose and maize oil derived from the progeny of maize line MON 810	“Report on processed products from genetically modified (GM) insect protected maize” (ACNFP)*	10 December 1997	6 February 1998	
5	AgrEvo France S.A. Les Algorithmes Bâtiment Thalès Saint Aubin F - 91197 Gif-sur-Yvette Cedex	i) Starch and all its derivatives; ii) crude and refined oil; iii) all heat-processed or fermented products obtained from hominys, grits and flour (dry milled fragments) obtained from the genetically modified maize, tolerant to glufosinate ammonium, transformation event T25 and all the varieties derived from	“Report on processed products from genetically modified (GM) glufosinate ammonium tolerant maize” (ACNFP)*	12 January 1998	6 February 1998	
6	Novartis Seeds AG Schwarzwaldallee 215 CH - 4058 Basel	Food and food ingredient products derived from the original transformant Bt11 crossed with the Northrup King Company inbred line #2044 (maize), as well as from any	ACNFP* Report on grain from maize genetically modified for insect resistance	30 January 1998	6 February 1998	

		inbred and hybrid lines derived from it and containing the introduced genes			
7	Pioneer Overseas Corporation Avenue Tedesco, 7 B – 1160 Brussels	Novel foods and novel food ingredients produced from genetically modified maize line MON 809	ACNFP* Report on genetically modified (GM) insect protected maize Pioneer Hi-bred International – line MON 809	14 October 1998	23 October 1998
8	Hoechst Schering, AgrEvo GmbH Industriepark Hoechst AgrEvo-Haus K. 607 D – 65926 Frankfurt am Main	Processed oil from genetically modified oilseed rape derived from Falcon GS 40/90	BgVV** Stellungnahme zur wesentlichen Gleichwertigkeit des aus der transgenen, Glufosinat-toleranten Rapssorte Falcon GS/40/90 gewonnenen raffinierten Speiseöls	21 October 1999	8/9 November 1999
9	Hoechst Schering, AgrEvo GmbH Industriepark Hoechst AgrEvo-Haus K. 607 D – 65926 Frankfurt am Main	Processed oil from genetically modified oilseed rape derived from Liberator L62	BgVV** Stellungnahme zur wesentlichen Gleichwertigkeit des aus der transgenen, Glufosinat-toleranten Rapssorte Liberator pHoe6/Ac gewonnenen raffinierten Speiseöls	21 October 1999	8/9 November 1999
10	Plant Genetic Systems N.V. Jozef Plateaustraat 22 B – 9000 Gent	Processed oil from genetically modified oilseed rape derived from: the male sterile MS8 (DBN 230-0028) oilseed rape line and all conventional crosses; the fertility restorer RF (DBN212-0005) oilseed rape line and all conventional crosses; the hybrid combination	BgVV** Stellungnahme zur wesentlichen Gleichwertigkeit des aus der transgenen, Glufosinat-toleranten Rapssorte MS8/RF3 gewonnenen, raffinierten Speiseöls	21 October 1999	8/9 November 1999

			MS8 x RF3			
1	F. Hoffman – La Roche Ltd. Vitamins & Fine Chemicals Regulatory Affairs Bldg 241/283 CH – 4070 Basel	Riboflavin from <i>Bacillus subtilis</i> as nutrient	ACNFP* Report on Riboflavin from fermentation using genetically modified (GM) <i>Bacillus subtilis</i>	20 March 2000	26 April 2000	
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1	Mr. Jean-Pierre Clavié “Vidalou”	“Huile d’amandon de pruneau”	Agence française de sécurité sanitaire des aliments	24 July 2000	4 August 2000	
2	F – 47300 Pujols					

i\* **ACNFP** Advisory Committee on Novel Foods and Processes (UK)

\*\* **BgVV** Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin (D)