

SUMMARY REPORT

July 14, 2003

**Revision of the Novel Food Regulation
Summary Report Stakeholder Submissions**

This Report summarises the written comments¹ made by stakeholders following the European Commission's (the 'Commission') issuance of a Discussion Paper on the Implementation of Regulation (EC) No 258/97 of the European Parliament and of the Council of January 27, 1997 concerning novel foods and novel food ingredients (release date July 2002) (the 'Discussion Paper'). It also incorporates oral comments made by stakeholders at the January 13, 2003 stakeholder meeting organised by the European Commission (the 'Hearing').

I. General Remarks**1. General**

Many stakeholders deplore the comparatively low number of applications filed and authorisations issued under Regulation 258/97² (the 'Novel Food Regulation'), and the fact that it is therefore difficult to assess its application and to draw conclusions. One stakeholder suggests that the Novel Food Regulation has not proven to be very effective. Another view expressed is that almost each and every file has created new issues and questions to be addressed.

Many stakeholders suggest that the mechanism for authorising novel foods and novel ingredients should be simplified and improved, in particular by the introduction of strict deadlines. It is also suggested that in the interest of legal certainty and clarity, the applicant be informed from the start, which specifications must be fulfilled and which data should be submitted. It is not acceptable that more tests and studies are required during the course of the authorisation procedure. One stakeholder suggests that 'functionality' data should be excluded from the scope of the review.

Some stakeholders voiced criticism that the Commission's option paper did not include the possibility of scrapping the Novel Food Regulation altogether rather than revising it, in particular now that genetically modified foods will be removed from its scope.

Two stakeholders suggest that a business impact assessment be undertaken to analyse the different options presented by the Commission for the potential revision of the Novel Food Regulation.

¹ Comments by stakeholders on the DG SANCO web-site by February 27, 2003: Association of the European Self-Medication Industry (AESGP); Australia; Avure Technologies AB; Bundesverband Deutscher Industrie- und Handelsunternehmen für Arzneimittel, Reformwaren, Nahrungsergänzungsmittel und Körperpflegemittel (BDIH); Belgium; BEUC (the European Consumers' Organisation); Biocaps S.A.; Centre d'Expression de la Science en Afrique (CESA); CIAA; Confédération Française des Semenciers (CFS); Christian Nabrotzky; Comunidad Andina; Danish Consumer Agency; David Lindsay; Denmark; European Herbal Infusions Association (EHIA); European Federation of Associations of Health Products Manufacturers (EHPM); European Responsible Nutrition Alliance (ERNA); European Seed Association (ESA); Finland; Foodaware; France; Helen Ellery; Helsingborg Environmental Office; Ireland; Kleiner Rechtsanwaelte; Landbrugsraadet; (Name withheld); Norway; Dr Patricia Elliott; Peru; Pharmos Naturkosmetik und Heilmittel GmbH; Procter & Gamble Europe; Royal College of Physicians of London; Spain; Sweden; TNO Nutrition and Food Research, The Netherlands; Udo Kienle; United Kingdom; United Nations Conference on Trade and Development; Unilever.

² Regulation 258/97 of the European Parliament and of the Council of January 27, 1997 concerning novel foods and novel food ingredients; OJ L 43 of 1997.

Several stakeholders, mainly of non-EU origin, voice concern over the compatibility of the Novel Food Regulation with the WTO rules, in particular as regards the import of foodstuffs and food ingredients that are traditionally consumed in third countries.

One stakeholder suggests that, in addition to the revision of the Novel Food Regulation, the Commission should clarify the concepts used in the decision tree contained in Commission Recommendation of July 29, 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 the Novel Food Regulation.³

Finally, one stakeholder requests that, due to the many borderline products and new substances being used, the Commission should aim for a more co-ordinated approach, including the consideration of regulation and risk assessment of 'novel feed'.

2. Timing

Stakeholders were unanimous in urging the Commission to streamline the decision-making procedure to make it quicker, whilst not compromising on the quality and thoroughness of risk assessment and risk management process. Stakeholders in particular request the introduction of deadlines for each stage of the procedure, to apply also to the Commission and the Standing Committee for Foodstuffs. One stakeholder suggests, however, adding a clause whereby procedures may be suspended as long as an applicant has been requested to provide information.

Many stakeholders believe that putting the European Food Safety Authority ('EFSA') in charge of the risk assessment will speed up things, in particular if applications may be filed directly with EFSA, rather than with Member States' competent authorities.

Whilst stakeholders agree that both transparency and at least some public consultation (see below) are required, many think that this should not unnecessarily delay decision-making.

3. Simplified Procedure

The issue of simplified procedures is most disputed between stakeholders. Several options seem to appear from submissions:

- Keeping an improved version of the current notification procedure for 'substantially equivalent products' under Article 5 of the Novel Food Regulation, but possibly changing the criteria, inasmuch as 'substantially equivalent' is considered an unclear or unsuitable concept.
- Introducing a 'new' simplified procedure for certain categories of foodstuffs and food ingredients that are considered unproblematic; which categories that could be, however, is disputed. Some suggest foodstuffs and ingredients that have been safely consumed outside the EU (provided however the third country has adequate risk assessment facilities) (e.g., exotic fruits and plants if not excluded from the scope altogether and just

³ Commission Recommendation of July 29, 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; OJ L 253 of 1997.

subject to sanitary certificate), or food products that are recognised as safe elsewhere, e.g., recognised as GRAS in US). It is also argued that the simplified procedure should be applicable to foods produced with new processing techniques, because there is no valid reason why such techniques should be discriminated against.

On exotic fruits and plants, two stakeholders vigorously oppose submission to simplified procedure because experience (stevia rebaudiana, nangai nuts) demonstrates that such products have previously not been found acceptable in the regular authorisation procedure. It is also argued that genetic patterns and consumption levels between third countries and the EU may differ. Those stakeholders supporting facilitated approval of exotic food products argue that the data currently required (in particular as regards toxicity) bears no relation to the actual health risks from the products.

One stakeholder suggests the use of a simplified procedure in those cases in which novel ingredients have already passed a complete approval procedure and the approved substance be later introduced into different food applications. However, the influence of different production processes for the introduction of the novel substance into the particular food categories has to be taken into account.

For exotic plants and ingredients, it is suggested that the data required should be limited to data on origin, production, and botanical classification. Safe use could be demonstrated by third-country declarations. Notification should suffice, possibly coupled with a 60-day clearance period during which competent authorities may raise objections. Stakeholders suggest that for this novel food category in particular, the number of applications under the Novel Food Regulation bears no relation to the actual market situation in the Member States.

- Scrapping the simplified procedure altogether, coupled however with a quicker authorisation procedure, and in addition, or alternatively, ‘staged’ data requests for the different novel food categories (less data required if products have safely been consumed elsewhere; or less data required if a similar or comparable product is already on the EU market). One stakeholder remarks that such a tailor-made approach might be difficult to administer.

Supporters of a simplified or staged procedure argue that regulation should be commensurate with the risk (‘better governance’). For example, where there is evidence of a significant history of safe use in a third country, a less complex risk assessment may be appropriate. As an alternative, the procedure could be streamlined for such products by omitting individual rounds of public consultation.

4. ‘Rulings’ (Advanced Decisions)

Several stakeholders indicate that they would appreciate an instrument whereby interested parties could efficiently obtain decisions (‘rulings’) on whether or not their products are ‘novel’ foods. Two stakeholders suggest that this could be done by EFSA. Others believe that this should be done within the framework of the Standing Committee on Foodstuffs (working group on novel foods). These rulings should have legal validity throughout the EU (ideally taken at EU level) and should be subject to legal challenge. If issued by individual Member States, they should not be opposable by other Member States. There should be a right to be heard prior to issuance of such rulings.

One stakeholder maintains that the burden of proof as to whether a product is novel has to be on the manufacturer.

Two stakeholders propose establishing a publicly accessible database or network whereby they can exchange information on the novel food status of individual products.

5. Procedure for Authorisation, Member States vs. EU

All stakeholders agree that EFSA should have a prominent role under a revised Novel Food Regulation. Whilst some would like to see the actual authorisation decision taken by EFSA, most recognise and support the view that EFSA should be in charge of risk assessment, whereas public authorities should be responsible for risk management, i.e., the actual authorisation. One stakeholder suggests that pending EFSA becoming fully operational, everything should stay as is.

Stakeholders all agree that the Commission should take the actual authorisation decision at a centralised level. One Member State also requests that such centralised decision also apply to the decision to refuse marketing. However, many stakeholders believe that Member States should continue to play a role in the authorisation procedure, either during the initial assessment stage, or in the actual decision-making (Standing Committee / Novel Food Working Group). Several stakeholders suggest that in the interest of timing, the current initial assessment phase should be replaced by an EFSA assessment only.

Whilst some would like the application filed directly with EFSA, others suggest that it be filed with the Commission, which would forward it to the Member States; others again suggest that the applicant should have the choice to file his/her application with either a Member State or the Commission, either of which would forward it to the other parties concerned. One stakeholder suggests keeping the system as is.

One stakeholder suggests that during the initial assessment phase to be conducted by EFSA, the applicant should have the right to participate in hearings with EFSA scientists. Prior to final adoption and publication of the assessment report, the applicant should be informed of the EFSA conclusions in order to allow for objections. Similarly, the applicant should have participation rights during the risk management stage (within comitology).

It is said that EFSA is particularly suited to collect and assess exposure data in those cases in which the same or similar novel food ingredients are used in different food applications.

6. Legal Recourse

All stakeholders agree that legal recourse against a decision to authorise or not authorise a novel food should be guaranteed. It should also be possible to challenge advance 'rulings' (see above).

II. Scope

In addition to the individual items below, some stakeholders submit that the exclusive list of foodstuffs in Article 1 (2) (a) – (f) that are considered ‘novel’ within the terms of the Novel Food Regulation has its limitations and has led to many problems in the Regulation’s day-to-day application. Three stakeholders seem to follow the Commission’s Option 1, to make minor amendments to the existing definition only, mainly for the reason that a completely new definition would possibly create new interpretation difficulties. However, one of these stakeholders also suggests that if categories are used, those should have some sense in also distinguishing between the data requirements and the procedures to be followed for the individual categories. Another of the three stakeholders suggests adding a category ‘other novel foods’ to cover new techniques that may come up in the future.

Others suggest exploring whether the enumerated list should not be replaced by a positive list of what is not novel, or by a more general definition, or by making the current list indicative rather than exhaustive. A general definition would potentially serve to ensure that foods produced with future new technologies would be included in the scope of a revised Novel Food Regulation.

For example, one suggestion is to consider the Australian and New Zealand definition, whereby ‘novel food’ means a non-traditional food (which does not have a history of significant human consumption by the community in Australia or New Zealand) for which there is insufficient knowledge in the community to enable assessment of safe use in the form or context in which it is presented, taking into account:

- (a) The composition or structure of the product;
- (b) Levels of undesirable substances in the product;
- (c) Known potential for adverse effects in humans;
- (d) Traditional preparation and cooking methods; or
- (e) Patterns and levels of consumption of the product.

Another stakeholder proposes determining the scope of the Novel Food Regulation by two categories:

- Foods and food ingredients with a new or intentionally modified structure with no established history of safe food use (e.g., products obtained by chemical synthesis);
- Foods not hitherto used and food ingredients consisting or isolated from a source (animal, plant, alga, fungus or bacteria) with no established history of safe food use (e.g., microbial source of proteins).

Yet another stakeholder who argues that in the future the majority of novel non-genetically modified foods placed on the market are likely to be associated with a claim, proposes that a novel food might be defined as a food not previously available to consumers in the EU using the process or in the form in which it is intended to be marketed, and/or for which some claim is being made by the manufacturer. As to the criteria for authorisation, such foods would have to demonstrate a benefit to the consumer; the scientific basis of the claim would have to be justified; and any section where there could be risks would need to be defined and appropriately labelled. Should there be legislation on claims, a separate Regulation on novel foods might become redundant.

One stakeholder demands more clarity as to the coverage of substances isolated from plant-derived ingredients.

It is also argued that the May 15, 1997 cut-off date should not preclude food products marketed prior to this date from undergoing an evaluation if this is considered necessary from a scientific point of view, in particular if similar foods were authorised and were made subject to specific marketing conditions as novel foods thereafter (example of Benecol vs. Unilever yellow fat spreads).

1. Partially GM

As the Commission has decided to propose separate legislation for foodstuffs from genetically modified organisms or derived therefrom, this issue is outside of the scope of this Summary Report. However, it was noted during the Hearing that clarification is needed as to the applicability of legal regimes for those food products that are partially 'novel' and partially genetically modified.

2. Whole Animals/Cloned Animals

Many stakeholders demand the inclusion of whole animals (e.g., insects, larvae, arachnids) in the scope of the Novel Food Regulation, whilst one stakeholder submits that the case for inclusion is weak because no evidence is presented that there could be associated health risks. Several stakeholders also demand the inclusion of cloned animals and food products derived therefrom (including dairy products), including from conventional offspring of those cloned animals. One stakeholder asks for the coverage of mutagenic treatment of reproductive cells.

3. Traditional Breeding, Varieties of

Whether new foodstuffs or ingredients derived from traditional breeding should be included within the scope of the Novel Food Regulation is disputed. Several stakeholders submit that this would be unpractical, unnecessary (because of safety required according to Regulation 178/2002), and a large administrative burden because of the 3,000 or so varieties that are registered annually. Others argue that traditional breeding that was previously conducted largely to eliminate toxicants is now conducted for a variety of nutritional purposes and may therefore result in significant changes of known foodstuffs (e.g., increase of antioxidants). These, the argument continues, would go unassessed if such foods continue to be excluded from the scope of the Novel Food Regulation. Such result would be illogical and unjustified. One stakeholder would like to have included only those products from traditional breeding that amount to intentional significant modifications to their nutritional composition. Finally, one stakeholder requests the Commission to provide further analysis as to why products from traditional breeding should remain outside the scope of the Novel Food Regulation, and yet another requests the Commission not to completely rule out the inclusion of products from traditional breeding.

One stakeholder suggests that the Novel Food Regulation should become applicable if new species are used that were not previously used in European breeding.

4. Novel Food Production Techniques

There is also disagreement as to whether foods obtained through new production techniques should be within the scope of the Novel Food Regulation. It is conceivable that the concept is ill understood by some. Indeed, under the current Novel Food Regulation it is the food so obtained that is assessed, not the production technique as such. Under Option 3 of its Discussion Paper, the Commission had, however, proposed the inclusion of production techniques as such, regardless of whether or not they result in a significant change of the foodstuffs produced.

Several stakeholders submit that subjecting foods obtained from novel production techniques to the Novel Food Regulation would halt or impede innovation. In any event, producers are obliged (Regulation 178/2002) to ensure the safety of their products. An add-on pre-

marketing assessment would therefore be superfluous. Also, the mere fact that only one application under Article 1 (2) (f) had ever been submitted showed that this category was redundant.

In addition, the term ‘significant change’ used in (f) is considered difficult to manage. ‘Significant change’ should potentially therefore be replaced by ‘significant change in composition or molecular structure regardless of whether the production process is new or not’; or ‘significant change’ should include microbial and chemical contamination and the category be widened to ‘have implications for public health; or ‘significant change’ should be eliminated altogether.

It is also suggested that any changes in nutritional value could be dealt with by appropriate labelling, thus eliminating the need for (f).

Some also submit that whilst it may be useful to have some regulatory review of novel processes, this may better be done under a separate legal regime (see Directive 1999/2/EC⁴ on irradiation of foodstuffs).

Still others believe that foods produced from novel production techniques should continue to remain within the scope of the Novel Food Regulation because, for example, new techniques have given rise to safety concerns in the past (contamination of Italian and Spanish olive pomace oil, chiefly by PAHs). It is suggested, unfortunately without specification, that ‘other legitimate factors’ should be considered in the evaluation of novel production techniques.

It is also suggested that new enzymatic processes should be considered novel production techniques under the Novel Food Regulation.

Two stakeholders seem to support the approach, taken in the Commission’s Option 3, but one seems unsure whether the Novel Food Regulation is suitable for this purpose. Others suggest that novel techniques that do not result in a change of the food might be dealt with in a simplified procedure, e.g., by self-declaration.

5. History of Safe Consumption

Whether and how ‘history of safe consumption’ should be used as a criterion in either the determination of whether a product is ‘novel’ or whether it is ‘safe’ remains hotly disputed. The following positions emerge:

- History of safe consumption elsewhere should bring products outside the scope of the Novel Food Regulation. Regulation 178/2002⁵ suffices to deal with the safety aspects of those foodstuffs.
- History of safe consumption in other jurisdictions should count for the assessment. Stakeholders demand guidelines or a definition for this category. Another stakeholder suggests that history of safe consumption is demonstrable by declarations issued by those countries in which the products were traditionally consumed.

⁴ Directive 1999/2/EC of the European Parliament and of the Council on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation; OJ L 66 of 1999.

⁵ Regulation 178/2002 of the European Parliament and of the Council of January 28, 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; OJ L 31 of 2002.

- Two stakeholders submit that now that the Food Supplements Directive⁶ (Directive 2002/46) has been adopted, history of safe consumption as food supplement should count as history of safe consumption under the Novel Food Regulation (see also discussion on food supplements below). Other stakeholders dispute this conclusion. One stakeholder takes a differentiated view, suggesting that the level of intake of a food supplement should determine whether consumption as food supplement qualifies as history of safe use.
- Approval in other countries should count for the assessment of applications.
- A clear set of criteria should be developed to demonstrate history of safe consumption.

6. 'To a Significant Degree'

Another subject of criticism in the wording of the present Novel Food Regulation which remains disputed is the term 'to a significant degree' of Article 1 (2) first sentence Novel Food Regulation, and the way it is currently interpreted by the Commission (availability in the general food supply chain, for example supermarkets, rather than through specialty channels, such as pharmacies, distance or structured selling, or health food stores).

Stakeholders submit that this criterion should not be negatively determined by the outlet in which a product is sold. In some countries this was a matter of mandatory regulation; in other cases a question of marketing techniques. Rather, it would seem more reasonable to permit interested parties to submit their evidence of consumption level and to take a decision based on merit. Local production in Europe and traditional consumption and distribution should also be considered to disqualify a product as 'novel'. The length of time a product has been on the market pre May 15, 1997 should also be part of the equation. One stakeholder proposes limiting past consumption to the last 30 years, and disregarding consumption in ancient times.

Stakeholders also request written guidelines on what constitutes 'to a significant degree', to include rules on consumption data.

Particular difficulties with the current interpretation of significant use seem to arise for a large number of supplement ingredients (see also below) (those used pre May 15, 1997 in the UK and the Netherlands seem not recognised by other Member States). Clearly, and in contrast to the foregoing, some stakeholders firmly believe that use as food supplements should not count as evidence for significant consumption, or history of safe use.

⁶ Directive 2002/46/EC of the European Parliament and of the Council of June 10, 2002 on the approximation of the laws of the Member States relating to food supplements; OJ L 183 of 2002.

7. Food Supplements / Food Fortification / Claims

Stakeholders demand clarity as to the coverage of plants and plant extracts, and medicinal ingredients, possibly by means of guidelines. Ingredients that were previously used in food supplements should not be considered ‘normal’ ingredients and used without further evaluation. They should be considered ‘novel’ with respect to foodstuffs. However, this should not impede their use in food supplements. Placing on the market of new food supplements or food supplement ingredients should either remain with the remit of the Novel Food Regulation or should be explicitly excluded from its scope and consequently included in EU legislation on food supplements.

One stakeholder submits that most Member States seem to view novel ingredients for supplements as within the scope of the Novel Food Regulation, as long as the Food Supplements Directive does not explicitly list those substances. Indeed, one stakeholder confirms this. The previous stakeholder submits that its industry is faced with the problem that certain substances are not totally restricted to supplements and could also be used in functional and fortified foods. As it is likely that considerable time will pass before substances other than vitamins and minerals are subject to the positive lists under the Food Supplements Directive⁷ (Directive 46/2002), a procedure for obtaining recognition across the EU for existing and new substances is needed.

8. Food vs. Additive

Several stakeholders remark that there have been cases where it was difficult to determine whether a particular product was a food ingredient or a food additive. They suggest that when submitting applications, applicants should clearly define the uses of their product. Those uses should be explicitly stated in the application and possibly in the authorisation decision. Where a product serves both nutritional as well as technological purposes, the product should undergo authorisation under both regulatory regimes.

Other stakeholders suggest the drafting of guidelines to determine the classification of active substances, and additives used as supplements (e.g., lycopene).

⁷ Directive 2002/46/EC of the European Parliament and of the Council of June 10, 2002 on the approximation of the laws of the Member States relating to food supplements; OJ L 183 of 2002.

9. Minerals

One stakeholder suggests the inclusion of minerals in the scope of the Novel Food Regulation.

III. Criteria for Authorisation (Health Benefits / Nutritionally (dis) advantageous) / Monitoring / Labelling / Claims

1. Criteria for Authorisation

There are few comments on the existing three criteria (no danger to consumer; no misleading of consumer; no difference from foods or ingredients they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous). These seem to be considered as adequate. However, one stakeholder submits that the third criterion makes little sense in relation to such foods and ingredients that have no traditional EU counterpart, such as exotic fruits and plants.

Whilst several stakeholders argue that the novel food assessment is a purely safety oriented assessment that should disregard any health benefits attributable to a novel food, others admit that, particularly for novel foods intended for certain population groups, some nutritional disadvantages may be largely outweighed by the positive aspects of the particular food. For those food groups, incorporating health benefits into the assessment is crucial for the outcome of the authorisation procedure.

One stakeholder requests that the issue of benefits of novel foods be more clearly addressed in future legislation.

In addition to the existing criterion that a novel food should not mislead the consumer, one stakeholder requests that the consumer should also not be provoked into making unreasonable choices.

Possible over-consumption of certain novel food ingredients should be addressed, possibly through monitoring and communication.

2. Labelling / Claims

There seems to be agreement among stakeholders that there is scope for labelling within the Novel Food Regulation over and above the labelling rules contained in Directive 2000/13,⁸ but that any labelling has to comply with the horizontal requirements stipulated in Directive 2000/13. Questions are posed concerning the need for ethical labelling (cloned animals and products derived therefrom) and traceability issues. However, once the Community has adopted legislation on health claims, clarity is required as to whether such claims are to be part of the authorisation process under the Novel Food Regulation or whether they have to be assessed separately (in parallel) under the future regime on health claims. Also, some suggest that labelling under the Novel Food Regulation should be limited to specific health related aspects (specific population groups). According to one stakeholder, warnings should only be allowed where the food product has actual benefits. One stakeholder suggests that the new

⁸ Directive 2000/13/EC of the European Parliament and of the Council of March 20, 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs; OJ L 109 of 2000.

ingredients should be declared and information on novel food approval and the date thereof should be provided on the label.

Some stakeholders see a role for EFSA to play in the verification and assessment of labelling and claims, others not. The latter believe that labelling should be outside the scope of the Novel Food Regulation and should be the sole responsibility of the applicant.

3. Monitoring

Several stakeholders advocate monitoring within the framework of the Novel Food Regulation and suggest that EFSA should be in charge of instructions on monitoring, or the follow-up to monitoring. One stakeholder requests monitoring and follow-up along the lines undertaken for pharmaceuticals and demands that any authorisation decision under the Novel Food Regulation be provisional. It is also commented that monitoring is integrated somewhat into the additives legislation and that the UK has an on-going research project on feasibility of market monitoring.

It is also pointed out that post-market monitoring is extremely expensive. One stakeholder submits that monitoring should be a case-by-case decision.

IV. Data Protection / Exclusivity / Form of Decision / Applicant

1. Decision vs. Regulation

Stakeholders are divided on the question whether the authorisation decision should take the form of a Decision (applicable only to the person addressed) or whether it should be issued by means of a Regulation (generally applicable).

Stakeholders favouring the 'Regulation' path argue that protection of investors' interests can be achieved through patent protection. It is also argued that there is no reason why authorisations under the Novel Food Regulation should take a different form from those granted under the additives legislation.

Stakeholders supporting 'Decisions' argue the improved possibility for enforcement/responsibility and monitoring, the obligation to submit new scientific findings, and better protection of investment. Also, Regulations, due to their greater protection for the individual applicant, are better suited to stimulate investment and thereby innovation in new products. Regulations may be acceptable to some if the return on investment is otherwise guaranteed, i.e., through a fee sharing regime ('royalties'), payment of risk assessment through public funds, or the granting of exclusivity for a number of years (e.g., five years).

One stakeholder who supports the Decisions option points out that there would be little gain through the use of Regulations because the person wanting to benefit from a product authorised under a specific Regulation would presumably still have to demonstrate that his/her product is the same as the one previously authorised. In the same spirit, with a different conclusion however, one stakeholder supporting the use of Regulations suggests that the second 'applicant' nevertheless has to submit a 'notification of suitability' for the assessment by the competent authority based on the characteristics of the product originally authorised, regardless of the novel food category involved.

Some stakeholders advocate a diversified approach, according to which 'Decisions' should only be issued in those cases where there is a specific commercial benefit, or where this is

necessary to evaluate precisely the level of expected consumption and the risks connected with the marketing. Finally, other stakeholders admit that in limited cases, Regulations (e.g., exotic fruits) or an extension of Decisions to identifiable third parties may be acceptable.

On exotic fruits, one stakeholder believes that even in such case Regulations may not be suitable because it would be difficult to find a volunteer first applicant who would have to bear the cost of the application which later would benefit all subsequent importers.

Finally, one stakeholder suggests that if Decisions are used, equivalent products could go through a simplified procedure to limit administrative burden. However, the first applicant would possibly have to enjoy some form of exclusivity period.

The use of Decisions would also presuppose that the conditions for marketing attached to approved food ingredients and labelling would be also binding on third parties, the food producers using the ingredients, and the actual users of the new production techniques.

2. Data Protection / Exclusivity

Stakeholders argue that data protection is necessary, possibly over and above the rules contained in Regulation 1852/2001.⁹ This should include unpublished scientific data (e.g., clinical studies), product formulations, manufacturing processes as such, and other sensitive data.

One stakeholder recommends including a provision equivalent to Article 19 of the proposed Regulation on Feed Additives (COM (2002) 153 final).¹⁰

It is suggested that applicants receive a minimum of five, but possibly 10 years exclusivity to their data (from date of filing or date of authorisation?) to ensure an acceptable return on investment.

3. Applicant

Stakeholders are divided on who should qualify as applicant. Some believe that anyone should be entitled to make an application, in particular if the authorisation is handed down in the form of a Regulation, whilst others would like to see applications restricted to the manufacturer of the product (because he is the only one who can ultimately be held accountable), possibly extended to the person responsible for marketing in the Community, and possibly the manufacturer of the processing equipment should Article 1 (2) (f) be maintained. One stakeholder submits that it would be preferable to keep the chain consistent rather than have it vary from product to product. One stakeholder requests that applications should also be possible for applicants which do not have an EU representative.

⁹ Commission Regulation (EC) No 1852/2001 of September 20, 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; OJ L 253 of 2001.

¹⁰ Proposal for a Regulation of the European Parliament and of the Council on additives for use in animal nutrition - COM/2002/0153 final - COD 2002/0073; OJ C 203 E of 2002.

V. Transparency / Public Consultation

All stakeholders support transparency. However, their opinions vary on public access to individual parts of the application and the extent of consultation. The following proposals emerge:

- Publication of summary of dossier;
- Publication of entire dossier (excluding commercially sensitive information);
- Publication of initial assessment report, comments possible;
- Every comment to receive response in order to obtain credibility of the system;
- Targeted stakeholder comment;
- Same approach as for genetically modified foods under new proposed legislation;
- UK ACNFP approach, but no public consultation;
- Regulation 178/2001 gives large access to EFSA documents anyway, this is sufficient for transparency purposes;
- Transparency to be ensured through consumer representatives within EFSA structure;
- Two public consultations;
- Public consultation prior to final approval for limited time;
- Access to outcome of discussions of novel food working group of Standing Committee on Foodstuffs;
- Widest degree of openness and consultation possible but without disclosure of confidential information.

VI. Conclusion

Most stakeholders commented on the issues raised in the Commission's Discussion Paper. No major other issues were raised.

There is general agreement that the novel food authorisation procedure, if maintained, must be shortened and streamlined.

Improvement and greater clarity are required as regards the scope of the Novel Food Regulation, either by streamlining the categories of Article 1 (2) or by introducing a more general definition of novel food. There seems scope for the discussion of widening the coverage of the Novel Food Regulation to whole and cloned animals and products derived therefrom, products from traditional breeding if they are nutritionally significantly different from their predecessors, and minerals.

A number of issues are hotly disputed, namely the maintenance of a simplified procedure (applicable to which categories, data and other evidence required), and the form which the authorisation should take (Decision vs. Regulation).

Most stakeholders support provision for labelling within the framework of the Novel Food Regulation.

There are many different proposals as regards transparency and public consultation.

VII. Recommendations

1. Scope / Definition of Novel Food

Taking advantage of the future exclusion of GMOs from the scope of the Novel Food Regulation, some limited restructuring of Article 1 (2) of the Novel Food Regulation (in particular (e)) may add to its clarity.

It may be worthwhile to explore whether, in view of the fast moving technical and scientific knowledge and development, foods and ingredients obtained by traditional propagating or breeding practices should, in specific cases (e.g., induced mutation), be included within the scope of the Novel Food Regulation.

2. Simplified Procedure

A simplified procedure (currently Article 5 of the Novel Food Regulation: notification and simultaneous marketing) would serve to advance the marketing of specific classes of novel foods. Provided the regular procedure is substantially accelerated (*e.g.*, to six months), a simplified procedure would seem largely superfluous. Even the use of the simplified procedure requires in practice some lead time due to the need to obtain an opinion of a national body on 'substantial equivalence'.

We would caution against installing different types of 'regular' procedures for different product classes as suggested by some stakeholders, because such an approach is likely to create difficult scoping issues. It is the applicant who would have to decide under which procedure he submits his product. The risk of having it incorrectly classified and submitted under the incorrect procedure and thereby losing precious time would be entirely upon him. In view of the limited number of applications filed to date, there is not yet an established 'case law' to rely upon for classification purposes.

3. (Advanced) Ruling Procedure

A 'Ruling' procedure whereby potential applicants may seek clarification on whether or not their product is novel does not exist under the current EU regulatory framework, but experience shows that introduction of such procedure at European level is necessary. In cases of doubt, it is currently the Member States who counsel applicants on whether a food or ingredient is novel or not. Other Member States may not accept that assessment, thereby creating marketing uncertainty for manufacturers. Trying to overcome this uncertainty with simple submission of the national opinion to the Commission and the EU Member States as is currently the case does not provide any legal certainty to the applicant. No formal decision on the file is taken at EU level. The current practice of turning to individual Member States may also undermine the credibility of the system ('forum shopping').

It is recommended that the 'Ruling' procedure follow the same procedure and have the same duration as the normal authorisation procedure because input from EFSA, stakeholders and Member States should be ensured for acceptance and legal certainty. At the end, a Commission Decision on the file should be issued.

4. Authorisation of Novel Foods

a) Procedure

The assessment of whether a food or ingredient is novel and safe is a technical/scientific assessment. The authorisation procedure should ideally reflect the character of this assessment.

Therefore, rather than providing for a Regulatory Committee procedure for authorisation of novel foods with possible referral to the Council,¹¹ the possibility could be explored whereby the Regulatory Committee procedure could be replaced by an Advisory Committee Procedure (the Commission taking the authorisation decision after the Committee has delivered an opinion; no referral to Council). Experience with the Novel Food Regulation (no file has yet been submitted to Council for decision because of a preceding lack of qualified majority in the Regulatory Committee) suggests that the assessment of novel foods is of good quality and that it would therefore be sufficient for individual Member States to give their comprehensive input during the assessment phase. In addition to their individual input during the assessment phase, the Advisory Committee procedure would allow Member States to continue having a 'collective' input at the end of the procedure, because the Advisory Committee Procedure obliges the Commission "*to take utmost account of the opinion delivered by the Committee*".¹² Such change from Regulatory Committee procedure to Advisory Committee procedure¹³ may help to speed up the processing of novel food applications.

b) Form of Decision

It is recommended to authorise novel foods via a Decision rather than by means of a Regulation. Any provisions that should be of general application rather than applicable to the applicant only (e.g. labelling of foods with novel ingredient; concentration of novel ingredient in final food product) could be adopted within the framework of a separate Regulation (one Regulation for all novel foods). Any time a new novel food is authorised, the Commission would amend this Regulation.

Continuing the current practice of authorisations by means of Decisions is recommended because this is thought to best protect the applicant who may have had substantial investments in the development and launch of the novel food. Development and marketing of novel foods has significant prospects in Europe. The innovative power of industry should not be inhibited by having competitors copy products and profit from an authorisation issued to another manufacturer.

It is also thought that such approach is best to protect the public interest because enforcement, possibly necessary post-market monitoring of specific novel foods, and control of daily intake of specific novel foods would be much easier that way.

In order to respond to criticism that such 'exclusivity' by means of a Decision would not be warranted in specific cases, in particular where the development cost is negligible, or the administrative burden would be very high because many applicants may seek authorisation of the very same product (e.g. exotic foods), it may be advisable to allow for joint filings of

¹¹ Articles 7 and 13 of the Novel Food Regulation. Article 13 provides for a Regulatory Committee procedure in accordance with Decision 87/337; the latter repealed by Decision 1999/468 (OJ L 184 of 1999). For Regulatory Committee procedure, see Article 5 of Decision 1999/468.

¹² Article 3 (4) of Decision 1999/468.

¹³ Article 3 of Decision 1999/468.

applications by several manufacturers or importers ('consortia') – thereby allowing sharing of the cost for filing; and/or consideration of variable authorisation periods – whenever the authorisation would expire, other operators could also market the product because it would no longer be considered as 'novel'.

5. Data

There is clearly a need for better specifying (possibly in an Annex to the Novel Food Regulation) which data must be submitted in the course of an application, and which data is qualified.

Data and scientific assessments from third countries should be recognised if they are equivalent to EU data. Consumption data from third countries should qualify as evidence for safety unless consumption and preparation of the product are traditionally different in the third country.

From a public safety standpoint, it seems justifiable to demand a scientific assessment of allergy potential and toxicity in all cases.

It is recommended to allow previous use of a novel food (ingredient) as food additive at least those that are allowed as '*quantum satis*' to count as evidence for safe use if the concentration in the novel food is the same or lower compared to the previous use as additive and the projected daily intake remains at the same level.