RAPESEED PROTEIN

ISSUE

The Irish Competent Authority has prepared a favourable initial opinion on an application for rapeseed protein under the novel foods regulation (EC) No 258/97. The Committee is asked whether it agrees with the Irish favourable initial opinion and whether it has any further comments to make on this application. The Committee's advice will form the basis for the UK's formal response.

Introduction

1. The European Commission has forwarded to Member States the Irish Competent Authority’s (CA) initial opinion on an application made by Helm AG under Article 4 (1) of Regulation (EC) 258/97, for the authorisation of rapeseed protein isolated from *Brassica napus* and *Brassica rapa* as a novel food ingredient. The novel ingredient is intended for incorporation into a range of foods, such as meal replacements, protein drinks, nutrition bars, soups and soup mixes, breakfast cereals and meat analogues.

2. The applicant states that rapeseed protein can replace soya as a source of vegetable protein in the above products.

3. The Commission is seeking the views of other Member States on the Irish CA's initial assessment of this novel ingredient. Member States can provide comments or reasoned objections to the Irish assessment within a 60 day time period.

4. The Irish assessment report is attached as Annex A and the application dossier is attached as Annex B and additional information is attached as Annex C.

The Irish CA's initial opinion (Annex A) is well summarised and draws out key points and the Committee should focus on this as a basis for carrying out its assessment. More detailed information can be found in the dossier as required.

Background

5. The Irish CA issued a favourable initial opinion for the authorisation of rapeseed protein isolated from *Brassica napus* and *Brassica rapa* from Helm AG as a novel food ingredient to be added to a range of foods.

6. Rapeseed oil can generally be extracted from the seeds of several rape varieties (*Brassica napus, B. rapa, B. juncea and B. tournefortii*) and has a long history of various uses worldwide. However, as documented in the Irish opinion, the use of rapeseed oil in food and feed was restricted initially due to the presence of glucosinolates, which made the oil unpalatable, and erucic acid, a monounsaturated omega-9 fatty acid which was found to pose a potential health risk. A new breed of rape (canola), developed in the 1970s contains very low
levels of erucic acid and glucosinolates which makes the oil suitable for food and feed use. In order to avoid any risk to human health, the erucic acid content of oils and fats intended for human consumption was restricted to 5% (Directive 76/621/EEC). Later the erucic acid content of canola-quality rapeseed oil was limited to 2% (Codex Standard 210-1999 for named vegetable oils). Rapeseed oil has a history of consumption in the EU prior to 1997. Rapeseed protein is increasingly being used in animal feed but does not have a history of consumption for human use.

7. Rapeseed protein is extracted from the pressed seed material (press cake) that remains after the oil has been removed. It is composed of soluble protein (≥85%), with insoluble protein, moisture, carbohydrate, fat and ash accounting for the majority of the remainder. The Irish CA highlights that rapeseed protein is to be added to the same range of foods to which soya protein is currently added and at similar levels, except where soya protein is explicitly specified such as in infant formula.

8. The present application for authorisation of rapeseed protein as a novel ingredient was prepared pursuant to Commission Recommendation (97/618/EC) of 29 July 1997 concerning the scientific aspects and presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients. The applicant considers that rapeseed protein be classified as a complex novel food from a non-GM source, where the source of the novel food has a history of food use in the Community (Class 2.1). The requirements for a submission for this class are as follows:

| I | Specification of the NF | X |
| II | Effect of the production process applied to the NF | X |
| III | History of the organism used as the source of the NF | X |
| IV | Effect of the genetic modification on the properties of the host organism | - |
| V | Genetic stability of the GMO | - |
| VI | Specificity of expression of novel genetic material | - |
| VII | Transfer of genetic material from GM microorganisms | - |

| VIII | Ability to survive in and colonise the human gut | - |
| IX | Anticipated intake/extent of use of the NF | X |
| X | Information from previous human exposure to the NF or its source | X |
| XI | Nutritional information on the NF | X |
| XII | Microbiological information on the NF | X |
| XIII | Toxicological information on the NF | X |

The information presented in the dossier is structured accordingly and is considered below under these schemes.

I. Specification of the novel food

9. The applicant’s rapeseed protein is derived only from *Brassica napus* and *Brassica rapa*. The novel ingredient is a white to off-white powder with a mild
aroma and flavour, of which more than 90% passes a US 80 mesh. The novel ingredient has a specified protein content of at least 90%, with a minimum soluble protein content of at least 85%. The Irish CA reports that Erucic acid is not detectable (LOD 0.1% of fat) in the applicant’s novel ingredient while glucosinolates are generally at or below the limit of detection (0.1 mmol/kg corresponding to approx. 40 mg/kg) and total phytates are present at ≤1.5%.

10. A detailed specification has been provided by the Irish CA on request and is attached as Annex C.

11. The Irish CA was content with this section of the dossier.

II. Effect of the production process applied to the novel food

12. Seeds of *Brassica napus* or *Brassica rapa* (non-GM) are mechanically pressed to release rapeseed oil. The remaining seed material is then purified and spray dried. Further details can be found in Annex A p2 and Annex B p 9-10.

13. The Irish CA was satisfied that the production process did not raise any concerns.

III. History of the organism used as a source of the novel food

14. The *Brassica* family of plants includes cauliflower, broccoli, Brussels sprouts and cabbage as well as plants more commonly known as rape, the seeds of which (rapeseed) contain significant amounts of oil, also known as rapeseed oil.

15. Mustard is derived from *B. juncea* or *B. nigra* from which brown and black mustard respectively are obtained. Mustard is an allergen and its presence must be declared on the labels of mustard-containing foods. This requirement does not apply to other brassicas. The applicant states that the specific rapeseed species used to produce this novel ingredient are *Brassica napus* and *B. rapa*.

16. Rapeseed oil was initially used as a lubricant for engines and also as a fuel oil for cooking and lighting, with limited food and feed uses as it had a bitter and unpalatable taste caused by particular glucosinolates and their metabolites. The high level of erucic acid, a monounsaturated omega-9 fatty acid associated with potentially negative health effects further reduced the appeal of rapeseed oil to the food and feed industry.

17. In the 1970s, a new type of rape (canola) was developed which contained very low levels of erucic acid and glucosinolates, thus making it more suitable for food and feed use. However, while rapeseed oil has a history of consumption in the EU prior to 1997, the seed protein that remains following oil extraction has not been exploited as a nutritional food source until relatively recently and there is no significant history of consumption of foods that contain rapeseed proteins.
IX. Anticipated intake/extent of use of the novel food
Annex A, p3, Annex B, p14-16

18. The novel ingredient is intended to compete with soya as a source of vegetable protein in a range of products (meal replacements, protein drinks, nutrition bars, soups and soup mixes, breakfast cereals and meat analogues).

19. The applicant provides hypothetical intake estimates for the novel ingredient in the EU, derived using 2008/2009 Euromonitor reports and proposed soya protein isolate intakes in the US. On this basis, the average intake of the applicant's novel ingredient in Europe would be 1g/person/day, with intake at the 90th percentile of approximately 2-3g/day.

20. A 'worst-case' scenario is also presented by the applicant, based on a 2011 EFSA opinion on dietary reference values for protein. Using the EFSA population reference intake (PRI) of 0.83 g/kg bw/d, the daily intake of the novel ingredient by the average (~70Kg) adult was calculated to be ≤10g/d, where 18% (0.15g/kg bw/d) of the daily protein intake came from protein added to processed food. In practice, only some of this would be rapeseed protein. To date, no tolerable upper level has been developed for protein by EFSA and intakes of twice the PRI (~1.5 g/kg bw/d) have been considered safe.

21. The Irish CA did not raise any concerns with this section of the dossier.

X. Information from previous human exposure to the novel food or its source
Annex A, p3

22. Rapeseed oil has a long established, safe history of use across the world, but the use of rapeseed protein has only recently been considered as a source of vegetable protein. The applicant has provided information on FDA GRAS notices allowing two distinct rapeseed proteins to be placed on the US market since 2010 and the applicant’s rapeseed protein since 2011.

23. The Irish CA did not raise any concerns about the information provided in this section of the dossier.

XI. Nutritional information on the novel food
Annex A, p 3-4, Annex B, p 17-21

24. The applicant states that the main nutritional component of the novel ingredient is protein (>90% in terms of dry matter).

25. The applicant demonstrates that rapeseed protein is equivalent to soya protein in terms of nutritional value (with the exception of lysine and sulphur containing amino acids) and states that it is unlikely there will be any nutritional disadvantage relating to essential and non-essential amino acid content and digestibility if soy protein was substituted for rapeseed protein. Additional information on nutritional comparisons can be found in Annex C.

26. The Irish CA did not raise any concerns with this section of the dossier.
XII. Microbiological information on the novel food
Annex A, p4

27. The Irish CA was content that the microbiological specifications presented by the applicant for its rapeseed protein are satisfactory and are sustained by batch analysis results. Additional data were provided by the applicant clarifying the status of yeast and moulds, Annex C.

28. The Irish CA was content with this section of the dossier.

XIII. Toxicological information on the novel food

29. The Irish opinion highlights that the applicant bases the safety of rapeseed protein on the fact that its protein content, which accounts for more than 90% of the ingredient, has an amino acid profile similar to soya protein, which in turn has a considerable history of safe food use. In addition, any undesirable substances known to occur naturally in rapeseed are either absent or at such low levels that they can be considered not to pose a safety risk in the context of the intended uses. The Irish CA agrees with the applicant’s comparative approach and considers that vegetable protein from soya or rapeseed protein will be metabolised similarly.

30. The applicant has referred to a number of toxicological studies on rapeseed protein isolates (not the applicant’s novel ingredient). The Irish CA states that none of the studies provided any cause for concern, although two 90-day rat feeding studies showed weak evidence of an anti-thyroid effect at high intake levels (up to 20% in the diet, or greater than 11 g/kg bw/day) which would not be unexpected considering the presence of glucosinolates or their metabolites in the test materials.

31. The applicant has also addressed the possible presence of undesirable secondary plant metabolites (glucosinolates, allyl isothiocyanate or AITC derived from glucosinolates, phenolics (sinapine), phytates and erucic acid) in its rapeseed protein. The Irish CA reports that these residues are either not detected, as is the case for AITC, or are controlled at low levels and therefore their presence in rapeseed protein are at levels which are not of toxicological concern.

32. The Irish CA did not raise any concerns with this section of the dossier.

XIII. Allergenicity

33. Mustard is derived from Brassica juncea or Brassica nigra from which brown and black mustard seeds respectively are obtained. Mustard is one of fourteen known food allergens that must be labelled when used in food production under EU legislation. The applicant states that its rapeseed protein will be isolated only from Brassicus napus and Brassica rapa and not the Brassica species from which mustard is derived. To note: International Standards states that rapeseed oil can generally be extracted from B. juncea (brown mustard), B. napus or B. rapa or B. tournefortii. Although the applicant states that the novel ingredient will only be derived from B. napus and B. rapa and not B. juncea, the dossier does
not describe how the applicant will ensure that the seed cake starting material is not derived from the mustard species.

34. The applicant states that the main mustard allergens identified are Sin a 1, a 2S albumin from *Sinapis alba* (yellow mustard) and Bra j 1, a 2S albumin from *Brassica juncea* (oriental mustard) (EFSA, 2004b). Both proteins are seed storage proteins. In EFSA's view, there is no general allergic cross-reactivity between different *Brassicaceae* species. However, an IgE and IgG cross-reactivity between BnIII, a 2S albumin from *Brassica napus* seeds, and Sin a 1 has been observed (Monsalve et al., 1997). An IgE cross-reactivity to oilseed rape and mustard was also noted in groups of Finnish children suffering from atopic dermatitis (Puumalainen et al., 2006; Poikonen et al., 2009).

35. The applicant states that under these circumstances, it may be prudent to inform individuals with mustard allergy about the potential unsuitability of foods formulated with canola protein isolate. The applicant has also mentioned that it is recognised that such precautionary labelling would restrict the availability of certain foods to allergy sufferers and there is no hard evidence that such restriction is justified.

36. The Irish CA highlights that because the applicant has presented in its dossier referenced studies to demonstrate that there is limited if any cross-reactivity between mustard and non-mustard Brassica family members and that the applicant does not intend to prepare the novel ingredient from the mustard family of Brassica, mustard allergen labelling is not required.

37. The Irish CA was satisfied with this section of the dossier.

**COMMITTEE ACTION REQUIRED**

38. The Committee is asked whether it agrees with the initial opinion from the Irish CA and whether it wishes to make any comments on the application.

Secretariat

November 2011

Annexes attached

Annex A Initial Opinion on rapeseed protein from the Irish Competent Authority (PROTECT – REGULATORY).


Annex C Additional information supplied by the applicant