

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES**NOTIFICATIONS UNDER ARTICLE 5 OF THE NOVEL FOODS
REGULATION (EC) 258/97****Issue**

This paper provides members with information on a series of notifications that have been recently received by the European Commission for various ingredients to be marketed in the EU.

Background

1. The Novel Foods Regulation (EC) 258/97 includes a provision for applicant companies to submit a notification to the European Commission for a novel food or food ingredient that is "substantially equivalent" to a product that is already on the market. According to Article 3(4) of the regulation, this simplified procedure applies to "foods or food ingredients substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein".
2. The Agency will generally seek the ACNFP's views on such notifications, in order to confirm whether the Committee agrees that the food or food ingredient is substantially equivalent to what is already on the market, and to allow the Committee to provide any other comments. However, there is a steady stream of routine notifications from new users and producers of ingredients that have previously been authorised as novel foods (e.g. noni juice, phytosterols). These are reported to the Committee for information. The previous update (ACNFP/82/10) covered routine notifications made during August 2006-April 2007.
3. During April 2007- March 2009, the Commission received a total of fifty five notifications from companies for the marketing of noni juice, phytosterol, Argan oil and various other ingredients that are considered to meet the criteria set out above:
4. The vast majority of these are technical notifications where the "novel" product is accepted on the basis that the applicant Company intends to market exactly the same product that has already received authorisation under the novel food regulation. These are included in Table 1 for information. The remaining notifications, for new products, are listed in Table 2 and the relevant opinions are attached at Annexes 1-8. A short summary of each is also given below. As these raise no new issues compared with previous novel food applications reviewed by the Committee, they are presented for information.
5. Attached at Annex 9 is the EC's most recent published list of all notifications made under Article 5 of (EC) 258/97.

Table 1: "Technical" notifications by new operators wishing to market previously approved novel ingredients

| | Date of Notification | Notifier (Commission Number) | Product | Opinion Prepared by |
|----|----------------------|---|---|-------------------------------------|
| a. | 17 April 2007 | Bofrost Distribuzione Italia S.p.a (31r) | Beverages based on skimmed milk with added phytosterols | Notified directly to the commission |
| b. | 23 April 2007 | Linkosuo Oy (41k) | Rye bread with added phytosterols | Notified directly to the commission |
| c. | 14 May 2007 | Oy Foodfiles Ltd for Phyto-Source L.P (82) | Spreadable fats, as defined by Council Regulation (EC) No 2991/94 (1) Annex, points B and C, excluding cooking and frying fats and spreads based on butter or other animal fat. Milk based products, such as products based on semi-skimmed and skimmed milk products, possibly with the addition of fruits and/or cereals, products based on fermented milk such as yoghurt and cheese based products (fat content \leq 12 g per 100 g), where possibly the milk fat has been reduced and the fat or protein has been partly or fully replaced by vegetable fat or protein. Soya drinks. Spicy sauces and salad dressings including mayonnaise. Rye bread with flour containing \geq 50 % rye (wholemeal rye flour, whole or cracked rye kernels and rye flakes) and \leq 30 % wheat; and with \leq 4 % added sugar but no fat added with added phytosterols | Finland |
| d. | 31 May 2007 | Senoble France (57c) | Products based on fermented milk with added phytosterols | Notified directly to the commission |
| e. | 4 June 2007 | Quesos Forlasa S.A (57d) | Cheese-type products with added phytosterols | Notified directly to the commission |
| f. | 5 June 2007 | Lactalis Nestle Chilled Dairy Co. Ltd (31s) | Products based on milk with fruits and added phytosterols | Notified directly to the commission |
| g. | 9 July 2007 | Oleador (83) | Argan oil | France |
| h. | 27 July 2007 | Vivartia S.A (57e) | Products based on fermented milk with added phytosterols | Notified directly to the commission |
| i. | 7 August 2007 | Cormon Miloko Factory (31t) | Yellow fat spreads, excluding cooking and frying fats and spreads based on butter or other animal fat with added phytosterols. | Notified directly to the commission |
| j. | 10 August 2007 | Karamolegos Bakery & Confectionary Industry S.A (62a) | Rye bread with added phytosterols | Notified directly to the commission |
| k. | 16 August 2007 | Puravitta (84) | Noni Juice (Juice of the Fruits of <i>Morinda Citrifolia</i>) | The Netherlands |
| l. | 20 August 2007 | Parada (85) | Noni Juice (Juice of the Fruits of <i>Morinda Citrifolia</i>) | Poland |
| m. | 27 August 2007 | Pofit Sp.z.o.o (86) | Noni Juice (Juice of the Fruits of <i>Morinda Citrifolia</i>) | Poland |
| n. | 29 August 2007 | Pojektmanagemnt Beratung (87) | Argan oil | France |

| | Date of Notification | Notifier (Commission Number) | Product | Opinion Prepared by |
|-----|----------------------|---|---|-------------------------------------|
| o. | 11 September 2007 | Argania Gold GmbH & SARLAU (88) | Argan oil | France |
| p. | 5 September 2007 | Absim France SAS (89) | Argan oil | France |
| q. | 7 September 2007 | Frigini's Kaskade (90) | Argan oil | France |
| r. | 9 October 2007 | Arganenoel (93) | Argan oil | France |
| s. | 12 October 2007 | S.I.R.H. SA (91) | Argan oil | France |
| t. | 15 October 2007 | Noumidia Caftan International (92) | Argan oil | France |
| u. | 15 October 2007 | Leap of Faith Farms (94) | Noni Juice (Juice of the Fruits of <i>Morinda Citrifolia</i>) | UK |
| v. | 22 October 2007 | Alter Eco (98) | Argan oil | France |
| w. | 2 November 2007 | Mogador Natuprodukte (97) | Argan oil | France |
| x. | 5 November 2007 | Bio Planete (99) | Argan oil | France |
| y. | 12 November 2007 | Hajdúsági Sütödék Zrt (74a) | Yellow fat spreads as defined by Council Regulation (EC) No. 2991/94, excluding cooking and frying fats and spreads based on butter or other animal fat; milk type products such as skimmed and semi skimmed milk type products, possibly with the addition of fruits and/or cereals, fermented milk type products, such as yoghurt and cheese type products (fat content $\leq 12\text{g}$ per 100g) where the milk fat and or protein has been fully or partly replaced by vegetable fat or protein; milk based fruit drinks; salad dressings and spicy sauces; rye bread with flour containing $\geq 50\%$ rye (wholemeal rye flour, whole or cracked rye kernels and rye flakes) $\leq 30\%$ wheat and with $\leq 4\%$ sugar but no fat added with added phytosterols | Notified directly to the commission |
| z. | 14 November 2007 | Noni de Tahiti Ltd. (96) | Noni Juice (Juice of the Fruits of <i>Morinda Citrifolia</i>) | UK |
| aa. | 11 December 2007 | Health Concern BV (38b) | Yellow fat spreads, excluding cooking and frying fats and spreads based on butter or other animal fat with added phytosterols | Notified directly to the commission |
| bb. | 17 December 2007 | Perle d'Argan (101) | Argan oil | Belgium |
| cc. | 17 February 2008 | Im Kuhstiefel 19 (103) | Argan oil | France |
| dd. | 3 March 2008 | Caseificio Pinzolo Fiave Rovereto S.c.r.l (411) | Yoghurt type products with added Phytosterols | Notified directly to the commission |
| ee. | 17 March 2008 | Argana d.o.o (104) | Argan oil | France |
| ff. | 31 March 2008 | BPF Bioactive Products Faktory (105) | Noni Juice (Juice of the Fruits of <i>Morinda Citrifolia</i>) | Poland |
| gg. | 14 April 2008 | Alga Technologies Ltd. (107) | Astaxanthin rich extract from <i>Haematococcus pluvialis</i> | UK |
| hh. | 23 April 2008 | Koninklijke ERU Kaasfabrik B.V (54b) | Cheese type products with added phytosterols | Notified directly to the commission |

| | Date of Notification | Notifier (Commission Number) | Product | Opinion Prepared by |
|-----|----------------------|---|--|-------------------------------------|
| ii. | 29 April 2008 | Thiele Lifestyle (109) | Argan oil | France |
| jj. | 16 June 2008 | EZA Natürlich Fair (110) | Argan oil | France |
| kk. | 25 June 2008 | Arganpur (119) | Argan oil | France |
| ll. | 11 August 2008 | EFIT Srl (112) | Argan oil | France |
| mm. | 21 August 2008 | Korzonek (113) | Argan oil | France |
| nn. | 11 September 2008 | Eurofroid (114) | Argan oil | France |
| oo. | 19 September 2008 | Dale Farm Ltd. (62b) | Yoghurt drinks with added Phytosterols | Notified directly to the commission |
| pp. | 26 November 2008 | FORMOR Polska (122) | Noni Juice (Juice of the Fruits of <i>Morinda Citrifolia</i>) | Poland |
| qq. | 1 December 2008 | ArganEden SARL (115) | Argan oil | France |
| rr. | 16 December 2008 | Copram (116) | Argan oil | France |
| ss. | 12 January 2009 | Diar Argan (117) | Argan oil | France |
| tt. | 20 March 2009 | SARL Argamis (120) | Argan oil | Belgium |
| uu. | 20 March 2009 | SARL SOUSS TERROIR (121) | Argan oil | Belgium |
| vv. | 8 December 2007 | Foscon on behalf of Emsland Starke GmbH (102) | Potato protein | Germany |

Table 2: Notifications for new ingredients

| | Date of Notification | Notifier (Commission Number) | Product | Opinion Prepared by |
|---|----------------------|---|---|---------------------|
| 1 | 1 November 2007 | TNO Quality of Life for Mitsui Sugar Co Ltd. (95) | Isomaltulose | The Netherlands |
| 2 | 3 December 2007 | Aarhus Karlshamn Sweden AB (100) | Yellow fat spreads as defined by Council Regulation (EC) No. 2991/94, excluding cooking and frying fats and spreads based on butter or other animal fat; milk type products such as skimmed and semi skimmed milk type products, possibly with the addition of fruits and/or cereals, fermented milk type products, such as yoghurt and cheese type products (fat content $\leq 12\text{g}$ per 100g) where the milk fat and or protein has been fully or partly replaced by vegetable fat or protein; milk based fruit drinks; salad dressings and spicy sauces; rye bread with flour containing $\geq 50\%$ rye (wholemeal rye flour, whole or cracked rye kernels and rye flakes) $\leq 30\%$ wheat and with $\leq 4\%$ sugar but no fat added with added phytosterols | Finland |
| 3 | 8 December 2007 | Foscon on behalf of Emsland Starke GmbH (102) | Potato protein | Germany |
| 4 | 3 April 2008 | Hygieia Global/Europe (106) | Glucosamine HCl from <i>Aspergillus niger</i> for use in food supplements | Ireland |
| 5 | 30 April 2008 | KytoZyme sa (108) | Chitosan | Belgium |

| | Date of Notification | Notifier (Commission Number) | Product | Opinion Prepared by |
|---|----------------------|------------------------------|--|---------------------|
| 6 | 25 June 2008 | Vitae-Caps S.A (57) | Rice drinks with added phytosterols | Spain |
| 7 | 14 August 2008 | Hygieia Global/Europe (111) | Glucosamine sulphate NaCl & KCl from Aspergillus niger for use in food supplements | Ireland |
| 8 | 19 December | I.R.B. s.r.l. (118) | Extracts from Ajuga reptans | Italy |

(1) – Isomaltulose – Mitsui Sugar Co Ltd.

6. The applicant notified the Commission on 1st May 2007 of its intention to market Isomaltulose in accordance with Article 5 of Novel Foods Regulation (EC) 258/97. The notification was supported by an opinion from the Dutch Competent Authority (CA) that this product is substantially equivalent to Isomaltulose currently marketed by Cargill Incorporated and Sudzucker AG which was authorised as a novel food ingredient in April 2005; a copy of the opinion is attached at Annex 1 (confidential)¹.
7. **Composition:** The average concentration of the applicant's isomaltulose is 99.5% which complies with the requisite purity of at least 98% as stated in the marketing authorisations for isomaltulose. The Dutch CA has noted that although the same bacterial enzyme is used to process the ingredient there are some slight differences in the methods used to purify the isomaltulose. The Dutch CA however was of the view that the applicant's isomaltulose does not retain any chemical or biological substances that are harmful to public health and concludes that the differences in the production processes are not relevant to this assessment.
8. **Level of undesirable substances:** The applicant states it regularly tests production batches for the presence of any undesirable harmful components. The product specification allows a heavy metal content (expressed as lead) of upto 1 mg/kg and Arsenic 0.1 mg/kg. The Dutch CA was content that the limits used by the applicant are sufficiently low and notes that the limit values specified for the potential presence of micro-organisms indicate that the applicant is capable of dealing with the microbiological risks involved.
9. The Dutch CA also notes that the original application was largely based on toxicological data derived from studies in animals that were carried out using isomaltulose obtained from the applicant and Sudzucker. The Dutch CA agrees with the ACNFP's conclusion that the isomaltulose being investigated and the isomaltulose produced by Cargill are sufficiently comparable.
10. **Intended use:** Food producers can use isomaltulose as a replacement sugar in various product categories such as drinks, confectionary products (cereal products), meal replacements and sweets. The Dutch CA concludes that that applications proposed by the applicant correspond with the permitted use of Cargill and Sudzucker's isomaltulose products.
11. **Nutritional value and metabolism:** The Dutch CA is of the view that in terms of the purity of the product, its nutritional value and metabolism are equal to the isomaltulose that is already on the market.
12. **Conclusion:** The Dutch CA concludes that the isomaltulose products are substantially equivalent within the meaning of Article 3(4) of Regulation 258/97 concerning novel foods and novel food ingredients.

¹ The UK has questioned whether this product, as a chemical substance, is eligible for the notification procedure and the FSA is awaiting a response from the Dutch authorities.

(2) Yellow Fat Spreads as defined by Council Regulation (EC) 2991/94, Milk type products such as semi skimmed and skimmed milk type products, possibly with the addition of fruits and/or cereals, fermented milk type products, such as yogurt, soya drinks and cheese type products, milk based fruit drinks, salad dressing and spicy sauces, and rye bread with added phytosterols – Aarhus Karlshamn Sweden AB.

13. The applicant notified the Commission on 3rd December 2007 of its intention to market phytosterols in accordance with Article 5 of Novel Foods Regulation (EC) 258/97. The notification was supported by an opinion from the Finnish Competent Authority (CA) that this product, derived from tall oil, is substantially equivalent to Cardiabeat phytosterol ingredient authorised for the market by Commission Decision 2007/343/EC; a copy of the opinion is attached at Annex 2 (Confidential).
14. **Composition:** In addition to esterified phytosterols and stanols, the phytosterol ingredient Vividol also contains free phytosterols, as well as mono-, di- and triglycerides. The manufacturing method for the applicant's ingredient is the same as that employed for the Cardiabeat ingredient. The results of an analysis of the composition of the sterol ingredient and sterol profile of Vividol taken from four production batches indicate that this is similar to the Cardiabeat ingredient. The Finnish CA was content that the information on composition provided by the applicant demonstrates that the product is equivalent to the requirements included in Decision 2007/343/EC.
15. **Purity and levels of undesirable substances:** Results of analyses for heavy metal residues (unspecified), PAH compounds and dioxins from two phytosterol batches of tall-oil origin were deemed acceptable for use in foods by the Finnish CA.
16. **Intended use and nutritional effect of the phytosterol ingredient:** The applicant intends to market its plant sterol ingredient to food industry companies for use in all food product groups included in Commission Decision 2007/343/EC. Vividol will replace other corresponding products enriched with phytosterols in consumer diets, hence the nutritional effects for consumers is expected to be similar.
17. **Conclusion:** The Finnish CA is of the opinion that Aarhus-Karlshamn Sweden AB's plant sterol ingredient is substantially equivalent to the Cardiabeat sterol ingredient with regards its consistency, sterol profile, purity and intended use. The Finnish CA notes that the nutritional value and metabolism of the ingredients are equivalent to the values of phytosterol and foodstuffs supplemented with them in general.

(3) Potato protein- Emsland Starke GmbH

18. The applicant notified the Commission on the 8th December 2007 of its intention to market its Potato protein in accordance with Article 5 of the Novel Foods Regulation (EC) 258/97. The notification was supported by an opinion from the German CA that this product was substantially equivalent to coagulated potato protein produced by AVEBE authorised by Commission Decision 2002/150/EC. A copy of the opinion is attached at Annex 3 (Confidential).
19. **Production process:** The production process used by the applicant and for the authorised coagulated potato protein are based on the extraction of potato juice, from which the desired potato protein fractions are separated by acid coagulation and heating. Standard food industry processes such as washing, grating, decanting, acidifying, heating, separating and drying are used.
20. **Composition/Nutritional value:** Results of analyses of the applicant's ingredient on the levels of glycoalkaloids (solanine and chaconine), total

lysinoalanine, free lysinoalanine and various constituents (minerals (Na, K, Ca, Mg, and P), amino acids) and contaminants (heavy metals, pesticides) indicate the protein content does not substantially differ to AVEBE coagulated potato protein content. The German CA also notes the two products are similar in terms of amino acid composition and levels of fat, sugar, raw fibres and minerals and therefore is content that from a nutritional perspective the applicant's ingredient can be considered substantially equivalent to the authorised coagulated protein.

21. **Metabolism:** No information on metabolism are available for either product, however the German CA is of the view that because both products consist of denatured protein mixtures from potatoes, no substantial differences in their metabolism can be expected.
22. **Intended use:** The applicant's ingredient is to be used as a food ingredient in a similar way to the authorised ingredient. The main food categories it is intended for include meat and baked goods (particularly in deep-frozen form), along with salad dressings, sauces, ice-cream and snacks. The German CA notes that the applicant can use its ingredient at a maximum of 2-3% in these products and that it is also required to inform other companies who use their ingredient of this maximum use level.
23. **Level of undesirable substances:** The German CA notes from the documents submitted by the applicant that their ingredient has lower levels of glycoalkaloids (total), lysinoalanine (total and free) than the limits specified in Decision 2002/150/EC.
24. **Conclusions:** The German CA is of the view that the applicant's ingredient is substantially equivalent to the authorised coagulated potato protein in terms of its composition, nutritional value, intended use and level of undesirable substances. The German CA points out that the applicant must adhere to the labelling requirements under Article 2 of Commission Decision 2002/150/EC which states that the designation "potato protein" shall be displayed on the labelling of the product as such or in the list of ingredients of foodstuffs containing it.

(4) Glucosamine Hydrochloride from *Aspergillus niger* for use in food supplements- Hygieia Global Health

25. The applicant notified the Commission on 3rd April 2008 of its intention to market its Glucosamine HCl from *Aspergillus niger* in accordance with Article 5 of Novel Foods Regulation (EC) 258/97. The notification was supported by an opinion from the Irish CA that this product is substantially equivalent to shellfish-derived glucosamine hydrochloride currently on the market. A copy of the opinion is attached at Annex 4 (confidential).
26. **Composition:** The applicant provided results of analyses of IR absorption, H NMR, C NMR and mass spectroscopy to demonstrate that the structure of glucosamine HCl from *A. niger* and shellfish is identical. The production process for the two products is the same except for the starting material resulting in a white crystalline powder of greater than 98% purity. The results of analysis on three batches of glucosamine HCl from both sources reveal almost identical values for a variety of parameters.
27. **Nutritional value and metabolism:** The applicant provides a table of nutritional data that shows levels of fat, protein, carbohydrate, calories etc. are identical for glucosamine HCl from both sources.
28. **Intended use:** The applicant intends to market fungal glucosamine HCl in food supplement form at dosages similar to its existing shellfish counterpart. Although there is no established formal RDI for glucosamine HCl, the most widely accepted intake level is up to 1,500 mg per day.

29. **Levels of undesirable substances:** The specifications for glucosamine HCl derived from shellfish and *A. niger* sources are similar, with additional tests for Ochratoxin A conducted on the fungal sourced material as some strains of *A. niger* may produce that toxin. The tests for microbial contaminants yield identical results for product derived from both sources.
30. **Conclusion:** The Irish CA concludes that Hygieia glucosamine HCl derived from *A. niger* is substantially equivalent to glucosamine HCl from shellfish that is already on the EU market in supplement form. This is subject to labelling of products containing the fungal ingredient and the ingredient is produced to the specifications outlined in the application and used only in food supplements, in accordance with Directive 2002/46/EC.

(5) Chitosan- KytoZyme sa

31. The applicant notified the Commission on the 30th April 2008 of its intention to market Chitosan from a fungal source (*Agaricus bisporus* and *Aspergillus niger*) in accordance with Article 5 of the Novel Foods Regulation (EC) 258/97. The notification was supported by an opinion from the Belgian CA that this product was substantially equivalent to Chitosan derived from shells of crustaceans that is currently used as a food supplement. A copy of the opinion is attached at Annex 5 (Confidential).
32. **Production and arguments:** The applicant's novel ingredient is derived from *A. bisporus*, an edible mushroom and *A. niger*, used in the production of citric acid. The applicant has provided information on the specification of *A. bisporus* (dry matter and production intermediates) including tests carried out on production intermediates for various heavy metals. The Belgian CA is content as to the suitability of the raw material, including with regard to heavy metals. The applicant has also provided detailed specifications (values for dry matter, minerals, heavy metals, salmonella etc) for the raw material *A. niger* and its production intermediate. The figures have been confirmed by tests carried out. The applicant has compared the data for the raw material with those for foodstuffs and concludes that the raw material is suitable to be used in foodstuffs. The Belgian CA was satisfied that the raw material is suitable to be used in foodstuff.
33. The production method comprises acid hydrolysis in several stages, a washing process, the elimination of fat and a drying process. The applicant has provided detailed information on the different stages of production employed to obtain chitin from both raw materials. The applicant states that the process is quite similar for both except that the process for removing fat is used only for the raw material *A. bisporus*.
34. **Conclusion:** The Belgian CA was content that processes employed consist of classical stages which are acceptable for use with regard to foodstuffs. It was of the view that chitosan derived from fungi is identical, in terms of purity, to the chitosan derived from crustaceans. The degree of purity is >84.8%. The Belgian CA was content that the analyses provided by the applicant show that the product complies with the specifications set out in the application and that the preparations are equivalent at this level. It was noted that chitosan, whether derived from *A. bisporus* or *A. niger*, complies with relevant legislation. Additional tests on chitosan derived from *A. bisporus* and *A. niger* was compared to the chitosan derived from crustaceans. The preparations complied with the specifications for protein, fat, glucans and components of ash. The nutritional profile of chitosan from crustaceans and the applicant's ingredient show that there is a relatively high degree of correspondence at this level between the two types of preparation.

(6) Rice drinks with added phytosterols- Vitae-Caps s.a.

35. The applicant notified the Commission on the 25th June 2008 of its intention to market rice drinks with added phytosterols in accordance with Article 5 of the Novel Foods Regulation (EC) 258/97. The notification was supported by an opinion from the Spanish CA that this product was substantially equivalent to rice drinks with added phytosterols currently marketed by Teriaka Ltd. and authorised by Decision 2008/36/EC. A copy of the opinion is attached at Annex 6 (Confidential).
36. **Composition:** In November 2005, the Spanish CA gave Vitae Caps a favourable opinion that its phytosterols and phytosterols esters were substantially equivalent to authorised phytosterols and phytosterol esters. The Spanish CA notes that the phytosterols and phytosterols esters produced by Vitae Caps comply with those specifications and purity criteria established in the European Commission's Decisions on the use of vegetable sterols in foods (2004/333/EC, 2004/334, 2004/845/EC, 2008/36/EC, 2008/58/EC and phytosterol fractions per Decision 2007/343/EC).
37. **Nutritional value and metabolism:** The applicant notes its phytosterols and phytosterol esters are expected to have the same metabolic effects as previously approved products (compete for absorption with both dietary and endogenously produced cholesterol).
38. **Intended use:** The applicant intends to use its phytosterol in rice drinks in the same way as Teriaka's product, as authorised (Decision 2008/36/EC). The specifications which the ingredient must comply with are in Decisions 2004/333/EC, 2004/334/EC and 2006/58/EC.
39. **Levels of undesirable substances:** The Spanish CA notes that the phytosterols and phytosterol esters produced by Vitae Caps S.A comply with current dietary quality requirements in terms of heavy metals, contaminants and microbiology. HACCP schemes are used to control product safety and quality.
40. **Conclusion:** The Spanish CA was content that substantial equivalence has been established for Vitae Caps phytosterol ingredient. It noted that conditions established in Decisions 2007/343/EC which authorises the marketing of phytosterols or phytostanols, and 2008/36/EC which authorises the marketing of rice beverages with added phytosterols or phytostanols must be complied with.

(7) Glucosamine sulphate NaCl & KCl from *Aspergillus niger* for use in food supplements- Hygieia Global Health

41. The applicant notified the Commission on the 14th August 2008 of its intention to market Glucosamine sulphate NaCl & KCl from *Aspergillus niger* for use in food supplements in accordance with Article 5 of the Novel Foods Regulation (EC) 258/97. The notification was supported by an opinion from the Irish CA that this product was substantially equivalent to food supplements already on the EU market containing a shellfish counterpart. A copy of the opinion is attached at Annex 7 (Confidential).
42. **Composition:** The applicant has demonstrated through infrared absorption, ¹H NMR, ¹³C NMR and mass spectrum that structure of glucosamine sulphate potassium from both *Aspergillus niger* and shellfish is almost identical. The production process is the same except that the starting material for the fungal product is *Aspergillus niger* biomass, a by-product of citric acid production. Results of tests on three batches of glucosamine sulphate potassium from shellfish and *Aspergillus niger* demonstrated a very similar composition.
43. **Nutritional value and metabolism:** Glucosamine sulphate NaCl and KCl is a single molecule and the applicant demonstrates that the source of the raw

material (shellfish or fungal) has little or no impact on the final nutritional value of the ingredient.

44. **Intended use:** Glucosamine sulphate KCl from *Aspergillus niger*, like existing shellfish-derived glucosamine is to be used in food supplement only. The applicant notes there is no established formal RDI for glucosamine sulphate KCl and while recommendations vary, the most widely accepted intake level is up to 1,500 mg per day.
45. **Levels of undesirable substances:** *Aspergillus niger* is not known to be toxic or pathogenic for humans and the release specifications for glucosamine sulphate NaCl and KCl from both the shellfish and fungal sources are similar. Certain strains of *Aspergillus niger* however, have been known to produce Ochratoxin-A, but additional tests carried out by the applicant yielded satisfactory results. The tests for microbial contaminants yielded identical results for products derived from both sources.
46. **Labelling:** The applicant provided a proposed label which includes “Derived from *A. niger*” prominently displayed among other details.
47. **Conclusion:** The Irish CA was content that substantial equivalence has been established between Hygieia Health Company’s glucosamine product from *Aspergillus niger* and food supplements containing shellfish-derived glucosamine currently on the market.

(8) Extracts from *Ajuga reptans*- I.R.B. s.r.l

48. The applicant notified the Commission on the 19th December 2008 of its intention to market extracts from cell cultures of the plant *Ajuga reptans* in accordance with Article 5 of the Novel Foods Regulation (EC) 258/97. The notification was supported by an opinion from the Italian CA that this product was substantially equivalent to extracts derived from *Ajuga reptans* that is currently used as a food supplement. A copy of the opinion is attached at Annex 8 (Confidential).
49. The Italian CA considered information on the results of the metabolomic analysis performed on hydroalcoholic extract of *Ajuga reptans* cell culture and information on the production process for the cell culture.
50. The applicant provided a detailed description of the production process to obtain the *Ajuga reptans* cultures, starting from the culture of the fraction from the samples of fresh *Ajuga reptans* vegetable. The culture was obtained by varying the proportion of various components and cultural conditions such as nitrogen (organic and inorganic), micronutrients, growth hormones, the photoperiod, the temperature of *in vitro* culture etc. By selecting appropriate culture conditions, the company is able to obtain *in vitro* cell culture with a phytochemical profile similar to those produced by *Ajuga reptans* grown spontaneously.
51. Phytochemical analysis has been carried out using TLC highlighting the presence of different compounds by a colorimetric reaction using detectors for functional groups. Analysis has also been conducted using the “metabolic approach” which is based on evaluation of the natural crude extract without further fractionation.
52. Teupolioside with various derivatives, verbascoside and derivatives, rosemary acid and derivatives, caffeic acid and derivatives were identified in the phytochemical extract from cell culture. All of these compounds are normally present in the plant grown in the open. A comparative analysis on extracts from fresh shoots of the plant and the culture-derived extracts show the overlap in the phytochemical profile between cell culture and plant is not 100% however on the basis of the results it is reasonable to assume substantial equivalence between the two extracts.

53. The metabolomic analysis using HPLC-MS showed two main differences between the two kinds of extracts. Cell culture extracts accumulate a significantly higher amount of phenylpropanoid metabolites and others; they also tend to accumulate a significantly lower amount of all other metabolites. However the analysis performed did not find substances belonging to class of compounds that were undesirable or different from those produced by the plant *in vivo*.
54. The Italian CA concluded that *Ajuga reptans* cultured *in vitro* is substantially equivalent to the same species of *Ajuga reptans* growing naturally provided the extracts are obtained using the culture conditions described in the dossier and the extracts are used in food supplements only.

**Secretariat
April 2009**

Annexes attached:

- Annex 1:** Opinion on the substantial equivalence of Isomaltulose to be placed on the market by Mitsui Sugar Co Ltd (Confidential)
- Annex 2:** Opinion on the substantial equivalence of Yellow fat spreads as defined by Council Regulation (EC) No. 2991/94, excluding cooking and frying fats and spreads based on butter or other animal fat; milk type products such as skimmed and semi skimmed milk type products, possibly with the addition of fruits and/or cereals, fermented milk type products, such as yoghurt and cheese type products (fat content \leq 12g per 100g) where the milk fat and or protein has been fully or partly replaced by vegetable fat or protein; milk based fruit drinks; salad dressings and spicy sauces; rye bread with flour containing \geq 50 % rye (wholemeal rye flour, whole or cracked rye kernels and rye flakes) \leq 30 % wheat and with \leq 4 % sugar but no fat added with added phytosterols to be placed on the market by Aarhus Karlshamn Sweden AB (Confidential)
- Annex 3:** Opinion on the substantial equivalence of Potato protein to be place on the market by Foscon (Confidential)
- Annex 4:** Opinion on the substantial equivalence of Glucosamine HCl from *Aspergillus niger* to be placed on the market by Hygieiea Global/Europe. (Confidential)
- Annex 5:** Opinion on the substantial equivalence of Chitosan to be placed on the market by KitoZyme sa (Confidential)
- Annex 6:** Opinion on the substantial equivalence of rice drinks with added phytosterols to be place on the market by Vitae-Caps s.a. (Confidential)
- Annex 7:** Opinion on the substantial equivalence of Glucosamine NaCl and KCl from *Aspergillus niger* to be placed on the market by Hygieiea Global/Europe. (Confidential)
- Annex 8:** Opinion on the substantial equivalence of extracts from *Ajuga reptans* to be placed on the market by I.R.B. s.r.l (Confidential)
- Annex 9:** List of notifications made to the EC under Article 5 of regulation (EC)258/97.

CONFIDENTIAL

Opinion on the substantial equivalence of Isomaltulose to be placed on the market by Mitsui Sugar Co Ltd

**Secretariat
February 2009**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

CONFIDENTIAL

Opinion on the substantial equivalence of Yellow fat spreads as defined by Council Regulation (EC) No. 2991/94, excluding cooking and frying fats and spreads based on butter or other animal fat; milk type products such as skimmed and semi skimmed milk type products, possibly with the addition of fruits and/or cereals, fermented milk type products, such as yoghurt and cheese type products (fat content \leq 12g per 100g) where the milk fat and or protein has been fully or partly replaced by vegetable fat or protein; milk based fruit drinks; salad dressings and spicy sauces; rye bread with flour containing \geq 50 % rye (wholemeal rye flour, whole or cracked rye kernels and rye flakes) \leq 30 % wheat and with \leq 4 % sugar but no fat added with added phytosterols to be placed on the market by Aarhus Karlshamn Sweden AB

**Secretariat
February 2009**

CONFIDENTIAL

Opinion on the substantial equivalence of Potato protein to be place on the market by Foscon

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February 2009

CONFIDENTIAL

**Opinion on the substantial equivalence of Glucosamine HCl from
Aspergillus niger to be placed on the market by Hygieiea Global/Europe.**

**Secretariat
February 2009**

ACNFP/92/x Annex 5

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES
CONFIDENTIAL

Opinion on the substantial equivalence of Chitosan to be placed on the market by KitoZyme sa

Secretariat
February 2009

ACNFP/92/x Annex 6

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES
CONFIDENTIAL

Opinion on the substantial equivalence of rice drinks with added phytosterols to be place on the market by Vitae-Caps s.a.

Secretariat
February 2009

ACNFP/92/x Annex 7

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES
CONFIDENTIAL

Opinion on the substantial equivalence of Glucosamine NaCl and KCl
from *Aspergillus niger* to be placed on the market by Hygieiea
Global/Europe

Secretariat
February 2009

ACNFP/92/x Annex 8

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES
CONFIDENTIAL

Opinion on the substantial equivalence of extracts from *Ajuga reptans*
to be placed on the market by I.R.B. s.r.l (Confidential)

Secretariat
April 2009

ACNFP/93/10 Annex 9
ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

**List of notifications to the EC under Article 5 of regulation
(EC) 258/97.**

Secretariat
April 2009