

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

REFINED ECHIUM OIL

Issue

The Committee is invited to consider the response provided by Croda Chemicals Ltd to the comments raised at the September meeting and discuss whether this provides sufficient information for the Committee to conclude its evaluation of this novel food ingredient.

Background

1. At the September 2006 meeting, Members considered an application from Croda Chemicals Ltd for the approval of a refined echium oil from *Echium plantagineum* as a novel food ingredient (ACNFP/79/3).
2. A letter detailing the ACNFP's comments on this application was sent to the applicant on 16 October (see Annex 1) and these are summarised below:

- I. **Protein analysis** – The Committee noted that the application dossier assessed allergenicity on the basis that Cytochrome C allergen is equivalent to total protein content and the whole protein profile of the novel ingredient (NI) had not been identified. The Committee therefore requested that analysis be carried out in order to provide details of the protein composition.

The Committee also noted that the test materials used for the protein analysis were emulsions of oil samples in water and asked for information on the preparation of the corresponding standards.

- II. **Anticoagulant effect** – The Committee noted that people receiving anti-coagulant therapy are advised to avoid consuming foods rich in long chain n-3 fatty acids and therefore, raised concerns that such people may not be adequately informed about the nature of the NI.
- III. **Estimated daily intake (EDI)** – The Committee noted that the EDI had been calculated only in terms of stearidonic acid and agreed that the EDI of the refined echium oil itself should also be presented.
- IV. **Nutritional implications** – The Committee was not convinced by the claims that stearadonic acid represents a significant alternative source of EPA. Members considered the marketing of foods containing the NI could be nutritionally disadvantageous to consumers, if these products were consumed in preference to foods containing EPA and DHA.
- V. **Labelling** – The Committee was of the view that the average consumer would not understand what 'STA' is and therefore suggested that the

wording “STA (stearadonic acid)-rich oil from Echium plantagineum” should be replaced with a description that is more intelligible to the final consumer.

- VI. **HACCP** – Members highlighted that the HACCP certificate provided in the application dossier is for the manufacture of fish oil concentrates and refined vegetable oil for use in animal feeds and therefore questioned whether the HACCP system in place is also applicable to the manufacture of echium oil for food use.
3. The applicant responded to these comments on 2 November (**see Annex 2**). The secretariat wishes to highlight the following points:

- I. **Protein Analysis**- The applicant explains that the method employed to detect protein is the Bradford assay, which has a sensitivity of 10µg/ml. The material analysed was an emulsified water/oil mix which was produced by ultrasonic probe without the addition of emulsifying agents. The samples were allowed to partition and the aqueous phase was taken for analysis. Protein standards were prepared in aqueous solution.

The applicant points out that the results presented in the application dossier (Table 1.b 1.2-1) demonstrate that this method can detect protein when it is present in the crude echium oil sample and that the refining process for the NI removes this protein.

The applicant has provided no more detailed breakdown of the proteins that might be present in the oil at low levels (below the limit of detection of the Bradford assay), and states that a 1.6g portion of the oil will contain less than 16µg of total protein.

- II. **Anticoagulant Effect** – The applicant calculates that the maximum amount of EPA that might be theoretically produced from ALA and STA in the echium oil, even in high level consumers, is well below the 3 g/day threshold of EPA and DHA that has been set by other regulatory bodies for the prevention of changes to platelet function and bleeding time, and well below the amounts administered in studies assessing the effects of combined administration of anticoagulants and EPA / DHA. The applicant is therefore of the view that at the proposed levels of use, the NI is not expected to increase the risk of bleeding in individuals receiving anticoagulant therapy.
- III. **Estimated Daily Intake (EDI)** – The applicant has recalculated the intake figures and reported that the greatest mean and 97.5th percentile all user intakes of echium oil (on absolute basis) are found in male adults, at approximately 9 g and 17 g person/day, respectively. On a body-weight basis, children were identified as having the highest intakes of any population group, with mean and 97.5th percentile all-user echium oil intakes of 0.4 and 0.8 g/kg body weight/day respectively.
- IV. **Nutritional Implications** – The applicant states that no health claims are made within the dossier and that the regulation of health and nutrition claims is not the subject of their novel foods application. The applicant has not

addressed the possibility that foods supplemented with echium oil might displace other foods rich in EPA and DHA from the diet.

- V. **Labelling** – The applicant proposes that at a minimum the term “refined echium (vegetable) oil”, be included on the ingredient list of the final food and that, in addition to normal fat labelling requirements, the stearadonic acid content and total omega-3 fatty acid content be included in the nutrition panel of the final food.
- VI. **HACCP** – The applicant notes that the principles of HACCP and traceability are common to both feed and food and are laid down in Community legislation on the hygiene of foodstuffs and feed materials and confirms that the certified HACCP system equally applies to the production of food grade oils, including the NI.

Committee Action Required

- 4. The Committee is asked whether the applicant’s response provides sufficient information and adequately addresses its concerns.
- 5. If so, the Secretariat proposes to draft an opinion incorporating the ACNFP’s comments on Croda Chemicals Ltd application which will be discussed at the next Committee meeting in March.
- 6. If not, the Committee is asked to indicate what additional information would be required.

Secretariat
January 2007

Annexes attached:

ANNEX 1 Letter of 16/10/06 to the applicant with the Committee’s comments

ANNEX 2 Response from the applicant of 02/11/06

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Letter to the applicant with the Committee's comments (16 October 2006)

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Response from the applicant (2 November 2006)