ANNEX A-3

REGULATION 258/97: EC ADMINISTRATIVE PROCEDURE FOR GRANTING CONSENTS FOR NOVEL FOODS AND NOVEL FOOD INGREDIENTS

Application
submitted to the competent authority ("CA") of the member State where the Novel Food should be placed on the market for the first time (so-called "lead CA") with copy to the Commission (Article 4(1), first paragraph)

90-day period between receipt of complete application and initial assessment report.
The applicant may be asked for additional data.

The CA that has received the application (a) notifies the Commission the competent food assessment authority responsible for preparing the initial assessment report or (b) asks the Commission to arrange with another MS for its competent food assessment

The Commission forwards a copy of the summary provided by the applicant to the other member States (Article 6(2) second paragraph)

Initial assessment by lead CA
of whether the application complies with the criteria of Article 3(1) and contains a labelling proposal in accordance with Article 8, and issue of a report which concludes on whether a further assessment is needed or not (Article 6(3))

An additional assessment is required
An additional assessment is not required

Normally the Commission consults the SCF (now EFSA) (Article 11). The applicant may be asked for additional data

The lead CA forwards the initial assessment report to the Commission which circulates it to the other member States (Article 6(4))

Request for further information, comments or reasoned objections by the Commission or the member States

No request for further information, comments or reasoned objections by the Commission or the member States

60-day period from date of circulation of assessment report to make objections or reasoned objections (Article 6(4))

Authorization
for the placing on the market taken by CA that received the application (Article 4(2))

Commission presents a draft decision to the Regulatory Committee
*before being issued, each Commission act has to be agreed among the services (Directorate Generals) concerned (so-called "inter-service consultations")