Annex A-2


Application
Submitted to the competent authority ("CA") of the member State which is required to grant the written consent for the placing on the market of a GMO (so-called "lead CA") as or in a product to be used throughout the Community (Article 13(1), first paragraph)

Acknowledgment of receipt by lead CA
And communication of the summary of the notification ("SNIF") to the Commission and the CAs of the other member States (Article 13(1), first paragraph)

First examination by lead CA
Of whether the application contains all the information and data required by Article 13(2) (Article 13(1), second paragraph)

If yes:
Requested data is provided by the applicant

If no:
Request by lead CA to applicant for additional information (Article 13(1), second paragraph)

Assessment by lead CA
Of compliance of application with the Directive and issuance of an assessment report (Article 14(1))

If positive, the lead CA forwards the assessment report to the Commission (Article 14(2), first paragraph)

Rejection
If negative, the lead CA informs the applicant and, after minimum 15 days, the Commission* (see endnote 1) (Article 14(2), second paragraph)

Circulation by the Commission
Of the assessment report to the other member States within 30 days from receipt (Article 14(2), first paragraph)

CONTINUE
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

Discussion between objecting CAs and the Commission to resolve outstanding issue (Article 15(1))

Objections by the Commission or the member States maintained * *(see endnote 1)

Authorization for the placing on the market granted by the lead CA (Article 15(3) and 15(4))

Objections by the Commission or the member States resolved

Authorization for the placing on the market granted by the lead CA (Article 18(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”)

Regulatory Committee rejects, or does not decide on, Commission proposal

Regulatory Committee delivers a positive opinion on the Commission proposal

Commission presents the proposal to Council

Council (a) rejects, or (b) does not decide on, Commission proposal within 3 months

Commission has to (a) revise or (b) adopt its proposal

Rejection

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1 In these cases, the Commission has to consult its scientific committees, on its own initiative or at the request of a member State (Article 28(1)). The Commission may also consult the scientific committees on any matter arising under Directive 2001/18 (Article 28(2))