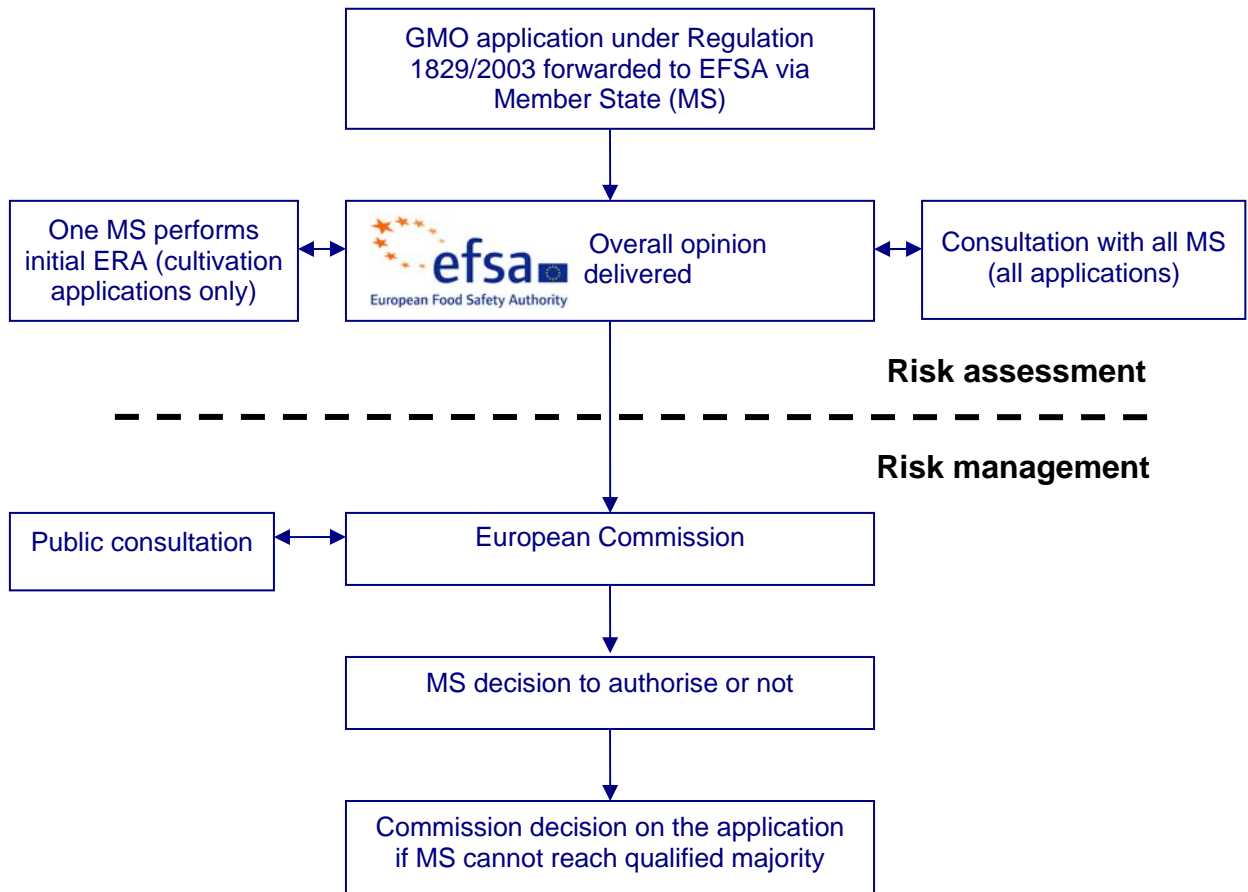


### COMMUNICATIONS DIRECTORATE

#### Authorisation procedure under Regulation (EC) No 1829/2003 (centralised procedure)

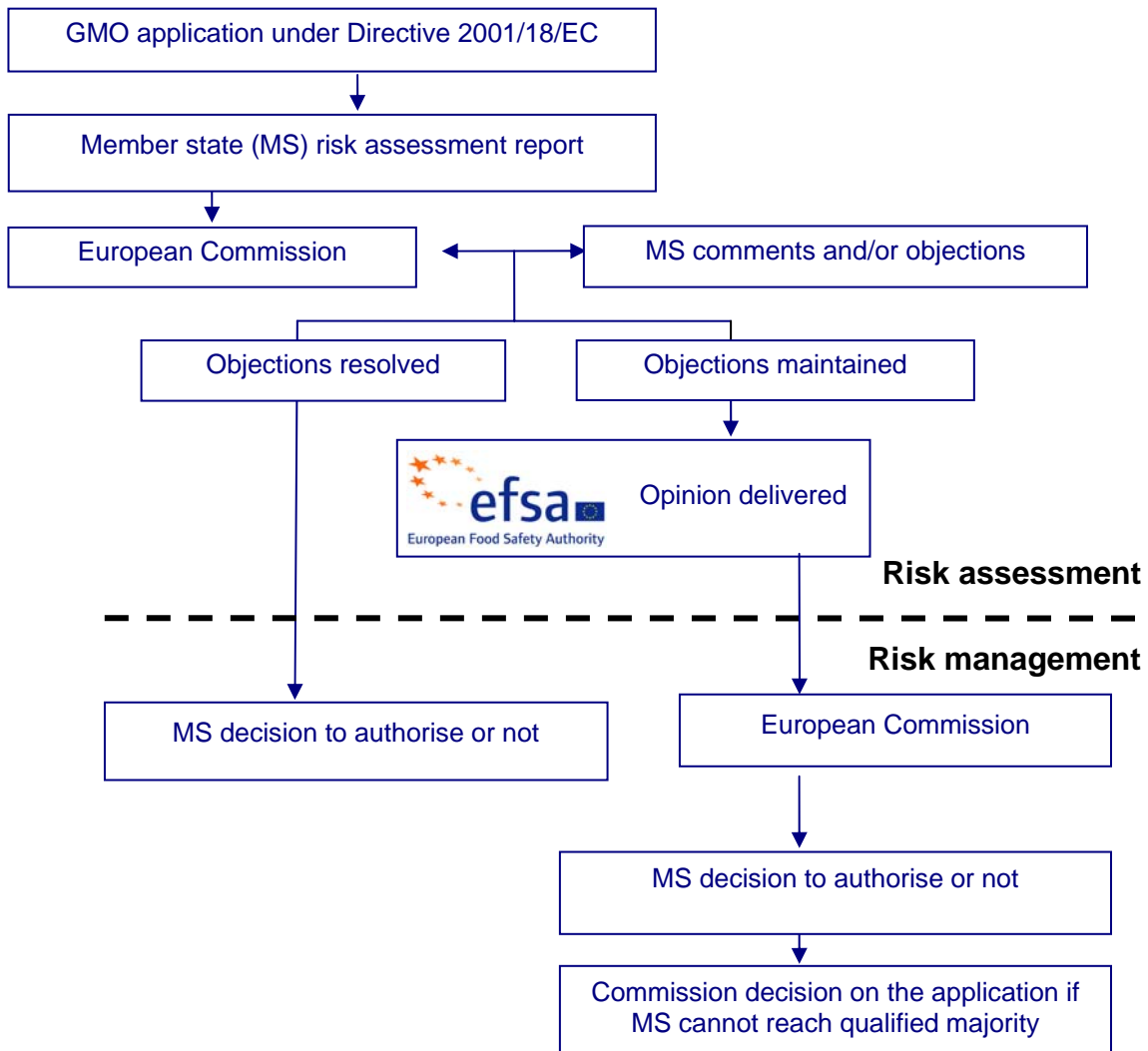


According to this procedure:

- The GMO application is sent to a Member State that immediately forwards it to EFSA, which must endeavour to deliver an opinion within 6 months.
- All Member States have full access to the application and to full studies and data presented by the applicant via EFSA's dedicated extranet.
- Member States have the possibility of raising objections and commenting on the application, including on the full data and studies presented by the applicant.
- If the application includes the cultivation of a GMO, one of the Member States is delegated to perform the environmental risk assessment.
- EFSA finalises the full scientific risk assessment of the GMO (within 6 months unless additional data are requested from the applicant) in its scientific opinion.
- EFSA forwards the opinion to the European Commission along with all other information required under Regulation (EC) No 1829/2003.
- The overall opinion is published on the websites of both EFSA and the European Commission.
- The European Commission consults the public on the overall opinion during a 30 day period.
- Based on the overall opinion, the European Commission and Member States are then responsible for taking a decision on the applicant's request.

COMMUNICATIONS DIRECTORATE

Authorisation procedure under Directive 2001/18/EC



According to this procedure:

- The GMO notification is sent to a Member State and the risk assessment of the GMO is carried out by that Member State.
- The Member State's risk assessment is sent to the European Commission which then forwards it to all Member States for their comments and input on the risk assessment (so-called "Community period").
- If objections are raised by Member States and cannot be resolved amongst Member States, EFSA is asked to provide an opinion (within 90 days) especially focusing on the points of scientific divergence between Member States.
- Based on EFSA's opinion, the European Commission and Member States are then responsible for taking a decision on the applicant's request.