The application procedure for smoke flavourings primary products differs from other flavourings. The authorisation procedure and administrative steps are set down in Regulation EC 2065/2003. Specific quality criteria for the testing are described in Regulation EC 627/2006. Scientific data requirements are specified in EFSA’s scientific guidance documents. Applications for the renewal of an existing authorisation should be submitted to the European Commission (EC).

**Legend:**
- Applicant
- Member State
- EC
- EFSA

- Application procedure for smoke flavourings primary products

The application procedure for smoke flavourings primary products differs from other flavourings. The authorisation procedure and administrative steps are set down in Regulation EC 2065/2003. Specific quality criteria for the testing are described in Regulation EC 627/2006. Scientific data requirements are specified in EFSA’s scientific guidance documents. Applications for the renewal of an existing authorisation should be submitted to the European Commission (EC).

- Potential applicant requests for general pre-submission advice (optional)

- For renewals only: potential applicant notifies list of intended studies and receives renewal pre-submission advice

- Potential applicant notifies studies commissioned or carried out as of 27 March 2021

- Applicant submits application via e-submission system to Member State authority or to the EC in case of renewal

- The Member State Authority or the EC tasks (mandate) EFSA and makes the application available to EFSA

- Receipt of the application by EFSA and completeness check

- EFSA validates the application

- EFSA launches public consultation on the application dossier

- EFSA performs thorough risk assessment

- EFSA Panel adopts the scientific output

- EFSA publishes the scientific output

- Based on EFSA’s opinion the EC prepares a draft specific measure

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*EFSA aims at providing its 1st feedback on Completeness check within 30 working days after receipt of the application. In case certain parts of the application need modification or completion in order to be considered valid, EFSA requests the missing information to the applicant.

**In certain cases, the application might be declared as non-valid (see EFSA administrative guidance for further information).**

**In case of a request of additional information, the scientific risk assessment process is put on hold until the requested additional information is supplied by the applicant.