EFSA confidentiality assessment & sanitisation | Procedural steps



Regulation (EU) 2019/1381 ("Transparency Regulation"), which has been in application since 27 March 2021, strengthens the principle of transparency of the risk assessment process in the food chain. Among several regulatory innovations, it stipulates the proactive public disclosure of all information supporting any request for a scientific output to be delivered by EFSA, with the exception of duly justified confidential data.

This infographic outlines the main procedural steps of confidentiality decision-making and content sanitisation.

SUBMISSION OF APPLICANT CONFIDENTIALITY REQUEST [OPTIONAL] EFSA sends a request for clarification to the applicant. **NOTIFICATION OF EFSA DRAFT DECISION** [OPTIONAL] Applicant makes comments. **NOTIFICATION EFSA** OF FINAL DECISION [OPTIONAL] Applicant sends confirmatory application. When a confirmatory application is submitted, EFSA puts on hold the implementation of its related confidentiality decision. The EFSA decision on the confirmatory application

EFSA • **CONTENT SANITISATION/ APPLICANT** | **IMPLEMENTATION**

Ombudsman.

The process of masking or unmasking scientific data, studies and other information, including personal data in accordance with the final confidentiality decision.

may be challenged before the General Court of the European Union. Alternatively, a complaint regarding the decision may be brought before the European

• PUBLICATION OF NEWLY SANITISED VERSION



EFSA can review the decision in case the scientific output identifies foreseeable effects on human health, animal health or the environment.



