



EUROPEAN COMMISSION
DIRECTORATE-GENERAL
JOINT RESEARCH CENTRE
Directorate F - Health, Consumers and Reference Materials
Food & Feed Compliance



Workflow for CRM sample and certificate check by the EURL GMFF in the frame of the authorisation to place GMFF on the market

CASE A: New application submitted to EFSA and applications pending at EFSA¹

- Step 1: Applicant informs the EURL GMFF (with SANTE E.3 and EFSA in copy) when the CRM can be made available.
- Step 2: The EURL GMFF informs the applicant where to send a CRM sample and the CRM certificate for the EURL GMFF check.
- Step 3: The EURL GMFF assesses the appropriateness of the CRM according to Regulation 503/2013.
- Step 4: (a) In case of appropriateness the EURL GMFF informs EFSA ("CRM is available and appropriate") with the applicant and SANTE E.3 in copy;
- (b) In case that CRM sample and/or certificate are not appropriate, the EURL GMFF informs the applicant (with SANTE E.3 and EFSA in copy) and specifies the open issue(s). The applicant has to resolve the issues and informs then the EURL GMFF (with SANTE E.3 and EFSA in copy). The EURL GMFF performs again step 3.
- Step 5: Publication of EFSA OPINION¹: EFSA awaits confirmation from EURL GMFF on CRM ("available and appropriate") before publication of opinion.

CASE B: Applications for which an EFSA overall opinion has been published²

- Step 1: As the CRMs are already publicly available, the EURL GMFF requests to obtain from the applicants corresponding CRM samples.
- Step 2: The EURL GMFF assesses the appropriateness of the CRM according to Regulation 503/2013.

¹ For applications submitted under Implementing Regulation 503/2013 and for renewal applications, checking of availability and appropriateness of the CRM is mandatory.

² For applications submitted before Implementing Regulation 503/2013, checking of appropriateness of the CRM is highly recommended.

Step 3: (a) In case of appropriateness the EURL GMFF informs SANTE E.3 ("CRM is available and appropriate") with the applicant and EFSA in copy;

(b) In case that CRM sample and/or certificate are not appropriate, the EURL GMFF informs the applicant (with SANTE E.3 and EFSA in copy) and specifies the open issue(s). The applicant has to resolve the issues and informs then the EURL GMFF (with SANTE E.3 and EFSA in copy). The EURL GMFF performs again step 2.

Whenever a new CRM batch would be released or the CRM certificate would be updated, the applicant has to inform the EURL GMFF (with SANTE E.3 and EFSA in copy). The EURL will perform steps 2 & 3.

Additional notes:

1. For a stack application, the applicant for the stack is responsible for having the CRMs of all the single events confirmed by the EURL GMFF as "available and appropriate".
2. A transition period will be applied for authorisations pending at EFSA:
 - a. For the certificates: all certificates should be available and appropriate by 31 October 2019.
 - b. For the homogeneity of the CRMs: the homogeneity of the all CRMs should be appropriate by 01 January 2020.

Contact e-mail addresses to be used:

For EURL GMFF JRC-EURL-GMFF@ec.europa.eu

For SANTE E.3 sante-consult-e3@ec.europa.eu

For EFSA: GMO_secretariat_applications@efsa.europa.eu