

Workflow for the CRM appropriateness check by the EURL GMFF in the frame of the authorisation to place GM food and feed on the market

Definitions: As referred to in Articles 5(3)(i) and 17(3)(i) of Regulation (EC) No 1829/2003:

- CRM or certified reference material: *any material or substance, one or more of whose property values are certified for calibration or quality control of methods. It is accompanied by a certificate that provides value of the specified property, its associated uncertainty and a statement of metrological traceability*
- Detection method: event-specific quantitative detection method(s) of the genetically modified material.

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

Step 0: Completeness check: EFSA checks the submission of the applicant's letter stating the availability of the CRM

Step 1: EFSA sends the validity letter to the applicant (start of the risk assessment phase) with the EURL GMFF and DG SANTE E.3 in copy.

Step 2: (a) The EURL GMFF has received from the applicant the detection method and the corresponding CRM/s and proceeds to Step 5.

OR

(b) The EURL GMFF has not received the detection method and/or the corresponding CRM/s → the EURL GMFF informs the applicant of the missing item/s (with SANTE E.3 and EFSA in copy) asking the applicant to provide the timeline by when these item/s will be available and informing the applicant where to send the CRM. In addition, the EURL GMFF asks EFSA to activate the stop-the-clock (StC) mechanism². EFSA accepts the request made by the EURL GMFF and activates the StC mechanism.

Step 3: The applicant informs the EURL GMFF (with SANTE E.3 and EFSA in copy) when the missing item/s will be sent.

Step 4: Upon reception of the missing item/s, the EURL GMFF informs EFSA and asks to re-activate the clock. EFSA reactivates the clock.

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

² StC activated by the EURL GMFF for analytical reasons does not affect EFSA progress on risk assessment and vice versa.

Step 5: The EURL GMFF checks the appropriateness of the CRM/s according to Regulation 503/2013 within 3 months from the receipt of the CRM/s.

Step 6: (a) In case of appropriateness of the CRM/s, the EURL GMFF informs EFSA ("CRM XXX for GM event YYY is available and appropriate in relation with application number ZZZ") with the applicant and SANTE E.3 in copy;

OR

(b) In case the CRM is not appropriate, the EURL GMFF informs the applicant (with SANTE E.3 and EFSA in copy) specifying the open issues and asks EFSA to activate the StC mechanism (Step 2b). The applicant has to resolve the issues and then informs the EURL GMFF (with SANTE E.3 and EFSA in copy) (as in Step 3). The EURL GMFF performs again Step 4, Step 5 and Step 6.

CASE B: Applications for which an EFSA opinion has been published¹

Step 1: As the CRM/s are already publicly available, the EURL GMFF requests to obtain from the applicant/s corresponding CRM samples.

Step 2: The EURL GMFF assesses the appropriateness of the CRM according to Regulation 503/2013.

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

(b) In case the CRM is not appropriate, the EURL GMFF informs the applicant (with SANTE E.3 in copy) and specifies the open issues. The applicant has to resolve the issues and then informs the EURL GMFF (with SANTE E.3 in copy). The EURL GMFF performs again step 3.

Whenever a new CRM batch is released or the CRM certificate is updated, the applicant informs the EURL GMFF (with SANTE E.3 in copy). The EURL GMFF performs steps 2 & 3.

Additional note:

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".

Contact e-mail addresses to be used:

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

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

For EFSA: GMO_secretariat_applications@efsa.europa.eu