



EUROPEAN COMMISSION
DIRECTORATE-GENERAL
JOINT RESEARCH CENTRE

Directorate F – Health and Food
Food & Feed Compliance



**EXPLANATORY NOTE FOR THE PAYMENT OF FINANCIAL CONTRIBUTIONS UNDER
COMMISSION IMPLEMENTING REGULATION (EU) No 120/2014 of 7 February 2014,
amending Regulation (EC) No 1981/2006, on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the
European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms (Text with
EEA relevance)**

This document provides instructions concerning the implementation of procedures on financial contributions to the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF) as described by Regulation (EU) No 120/2014, amending Regulation (EC) No 1981/2006. The document should be understood as an explanatory note, aimed at providing technical guidance for the compliance to the said Regulation. The explanatory notes should not be understood as a legally binding text.

Regulation (EU) No 120/2014	Explanatory note
<p>Article 1, Paragraph (3)</p> <p><i>Article 3: Contributions</i></p> <p>1. For each application for a GMO containing a single transformation event, a flat-rate contribution of EUR 40.000 shall be paid by the applicant to the CRL.</p> <p>2. The CRL shall request the applicant to pay an additional contribution of EUR 65.000 where a full validation procedure of a method of detection and identification for a GMO containing a single transformation event is required in accordance with the following provisions:</p> <p>(a) Annex III to Implementing Regulation (EU) No 503/2013, when the application is</p>	<p>The contributions shall be paid to:</p> <p>European Commission</p> <p>Bank address: ING Belgium NV/SA, Avenue Marnix 24, 1000 Bruxelles, Belgium</p> <p>IBAN-Code: BE30375113754811</p> <p>BIC-Code: BBRUBEBB</p>

<p>related to:</p> <ul style="list-style-type: none"> (i) genetically modified plants for food or feed uses; (ii) food or feed containing or consisting of genetically modified plants; (iii) food produced from or containing ingredients produced from genetically modified plants or feed produced from such plants; or <p>(b) Annex I of Regulation (EC) No 641/2004 in all other cases.</p> <p>3. For each application for a GMO containing stacked transformation events, where the method of detection and identification of each single transformation event that constitutes the GMO has been validated by the CRL or where the validation is pending, the flat-rate contribution depends on the number (N) of single transformation events that constitute the GMO and shall be calculated as EUR 20 000 + (N × EUR 5 000). Only the GMO containing stacked transformation events with the highest number of single transformation events is to be considered in this calculation.</p> <p>4. For each application for a GMO containing stacked transformation events that consists of one or more single transformation event(s) for which the method of detection and identification has not been validated by the CRL or for which no validation is pending, the contribution shall be calculated as follows: Article 3(1) and 3 (2) shall apply to single transformation event(s) for which no validated method exists and Article 3(3) shall apply to the GMO containing stacked transformation events, N corresponding to the number of single transformation events composing the GMO for which a validated method exists.</p> <p>5. The CRL shall reduce the amount of the additional contribution referred to in paragraph 2, in proportion of the costs saved:</p> <ul style="list-style-type: none"> (a) where the material needed to perform the full validation procedure is supplied by the applicant; and/or (b) where the applicant provides data that refers to modules, such as DNA extraction 	<p>The following references should be clearly indicated:</p> <ul style="list-style-type: none"> 1) Beneficiary: European Commission - Joint Research Centre 2) Reference: « EURL GMFF - Unique Identifier " "(DG JRC/Dir F/GMFF/EURL – Ispra) » <p>The Applicant should immediately inform the EURL GMFF via email to jrc-eurl-gmff@ec.europa.eu in case of change of any data related to the financial identification (i.e. official name of the company, address, bank account)</p> <p>For details concerning the calculations for reduction of the contribution, please contact the EURL GMFF at jrc-eurl-gmff@ec.europa.eu</p>
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<p>protocols and species specific reference systems, already validated and published by the CRL.</p> <p>6. Where the costs of the validation of the method of detection and identification proposed by the applicant exceed by at least 50 % the amount of the financial contributions mentioned under paragraphs 1, 2 and 3, a further contribution shall be requested. The further contribution shall cover 50 % of the part of the costs exceeding the amount of the contributions referred to in paragraphs 1, 2 and 3.</p> <p>7. The contributions provided for in paragraphs 1 to 6 remain due in case of withdrawal of the application, without prejudice to Article 5(3)'.</p>	
<p>Article 1, Paragraph (5)</p> <p><i><u>Article 5: Procedure</u></i></p> <p>1. The applicant shall provide evidence that the contribution referred to in Article 3(1), 3(3) and/or 3(4) has been paid to the CRL when it submits the samples of the food and feed and their control samples to the CRL in accordance with Articles 5(3)(j) or Article 17(3)(j) of Regulation (EC) No 1829/2003.</p> <p>2. Where, as provided for in Article 3(2), a full validation procedure is required, the CRL shall notify the applicant in writing of this fact and require the payment of the amount in accordance with that provision, prior to starting step 4 (collaborative trial) of its validation process.</p> <p>3. Where, as provided for in Article 3(6), the CRL expects the costs of the validation of the detection method proposed by the applicant to exceed by at least 50 % the amount of the financial contributions referred to in Article 3(1) to (4), it shall notify the applicant in writing of the estimated amount of the further costs.</p>	<p>The proof of payment should be provided without delay to the EURL GMFF to jrc-eurl-gmff@ec.europa.eu</p>

If, within one month of the date of receipt of the notification, the applicant withdraws its application, the further contribution referred to in Article 3(6) shall not be due.

After completion of the validation of the detection method, the CRL shall notify the applicant in writing the actual and duly justified costs incurred in carrying out the validation of the method of detection and require payment of the contribution due in accordance with Article 3(6).’

4. Where, as provided for in Article 4(2), costs are incurred, the CRL shall notify the applicant in writing of the amount of the contribution due, including a justification of that amount.

5. Paragraph 5 is deleted.

6. When a reduction of the contribution is claimed in accordance with Article 4(1), the application shall be accompanied by written evidence that the conditions laid down in that Article are fulfilled. The CRL may require supplementary information where appropriate.

7. The contributions provided for in paragraph 2 and 3 shall be payable by the applicant within 45 days of the date of reception of the notification. Step 4 (collaborative trial) of the validation process shall not be started before those contributions are received.

Where the applicant has not provided proof of payment within the set time limit, and where the evaluation report referred to in point 3(e), of the Annex to Regulation (EC) No 1829/2003 has not yet been sent to the European Food Safety Authority (the Authority), the CRL shall not submit it to the Authority until the reception of the due payment. The CRL shall immediately notify the Authority that its report will be delayed, to enable the Authority to inform the applicant and take any further steps required under Articles 6(1) to (2) and 18(1) to (2) of Regulation (EC) No 1829/2003.