Procedure

APPLICATION FOR THE APPROVAL OF EXTERNAL LABORATORIES

Version 01
Date of coming into force 2009-02-15
Competent administration Laboratories Administration
Receivers Staff members of DG Laboratories
External laboratories

<table>
<thead>
<tr>
<th>Name – function / service</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written by: ir. Brigitte Pochet</td>
<td>09.02.2009</td>
<td>[Signature]</td>
</tr>
<tr>
<td>Checked by: Marina Naccarato</td>
<td>10.06.2008</td>
<td>[Signature]</td>
</tr>
<tr>
<td>Approved by: ir. Geert De Poorter</td>
<td>10.06.2009</td>
<td>[Signature]</td>
</tr>
</tbody>
</table>
List of revisions

<table>
<thead>
<tr>
<th>Revision</th>
<th>Reason and nature of revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Pochet 06/0/2009</td>
<td>Fees due for issuing approvals as from 1 March 2009</td>
</tr>
</tbody>
</table>

When the procedures were under review, it was decided that a new numbering would be applied and that the version numbers would start again from "01".
Former number of this procedure: 2007-33-LAB-agrement-P10-v01

* The period of time between the present date and the last revision shall not exceed 5 years.
Change revision number and year, if applicable. Upon approval, adjust the date of implementation taking into account the time required to inform the staff members involved.

Changes with respect to version 1 are indicated in bold, italic, blue.

Keywords: Approval – laboratory - analyses
# APPLICATION FOR THE APPROVAL OF EXTERNAL LABORATORIES

## TABLE OF CONTENTS

1. **Aim** .......................................................................................................................................................... 4
2. **Scope** .................................................................................................................................................... 4
3. **References** ........................................................................................................................................ 4
4. **Definitions and abbreviations** ............................................................................................................... 4
5. **Procedure** ........................................................................................................................................... 5
   5.1 Rules to be observed when submitting an application for approval ................................................... 5
   5.2 Paying fees for issuing the approval .................................................................................................. 6
   5.3 Submitting an application for approval ............................................................................................... 6
   5.4 Granting approval ............................................................................................................................... 7
   5.5 Renewal of the approval ...................................................................................................................... 7
   5.6 Extension of the approval ................................................................................................................... 7
6. **Reference to relevant procedures, guidelines, documents, forms or lists** ........................................ 8
   6.1 Procedures, guidelines ....................................................................................................................... 8
   6.2 Others ................................................................................................................................................. 8
7. **Annexes** ........................................................................................................................................... 8
   7.1 Annex 1: approval application form ................................................................................................... 9
   7.2 Annex 2: Estimate of the fee charged for issuing an approval (adjusted on 01/01/2009) ................. 10
APPLICATION FOR THE APPROVAL OF EXTERNAL LABORATORIES

1 Aim

This procedure describes the requirements external laboratories must meet to be eligible to approval by the Agency as well as the manner in which is handled the application for an approval as referred to in the Royal decree of 15 April 2005 on the designation of the official laboratories, laying down the procedure and the requirements for the approval of laboratories performing analyses within the framework of the control mission of the Federal Agency for the Safety of the Food Chain and implementing the Act of 15 July 1985 on the use in animals of substances with hormonal, anti-hormonal, beta-adrenergic or production stimulating effects.

2 Scope

3 References

Arrêté royal du 15 avril 2005 relatif à la désignation des laboratoires officiels, fixant la procédure et les conditions d’agrément des laboratoires qui effectuent des analyses dans le cadre des missions de contrôle de l’Agence fédérale pour la Sécurité de la Chaîne alimentaire et portant exécutions de la loi du 15 juillet 1985 relative à l’utilisation de substances à effet hormonal, à effet bêta-adrénergique ou à effet stimulateur de production chez les animaux

Loi du 9 décembre 2004 portant financement de l’Agence fédérale pour la Sécurité de la Chaîne alimentaire

Arrêté royal du 10 novembre 2005 relatif aux rétributions visées à l’article 5 de la loi du 9 décembre2004 portant financement de l’Agence fédérale pour la Sécurité de la Chaîne alimentaire

4 Definitions and abbreviations

Agency : the Federal Agency for the Safety of the Food Chain
Laboratory : the (Belgian of foreign) external laboratory that submitted the application for approval
Operator : a physical or a legal person with an activity that is subject to control by the Agency
BELAC : the Belgian accreditation body
Analysis : an analysis performed in the context of the control mission of the Agency
LABO-LIB : Access databank containing the data of laboratories
LOD : limit of detection
LOQ : limit of quantification
CCα : limit of decision
CCβ : detection capability
5 Procedure

5.1 Rules to be observed when submitting an application for approval

1. have obtained for the analyses for which the approval is sought, an accreditation that was granted in accordance with the provisions made in the Act of 20 July 1990 on the accreditation of certification and inspection bodies and of testing laboratories and the implementing decrees thereof, or an accreditation granted by a body with which the Belgian accreditation system concluded an agreement of mutual recognition;

2. agree with the participation of a representative of the Agency in the audits conducted by BELAC, as competent authority;

3. the laboratory, the person or persons under whose responsibility the analyses are performed and the persons involved in the working of the laboratory, shall not hold any direct or indirect interest in the production, the processing, the import or the marketing of the products on which are performed the analyses or categories of analyses for which the approval is granted;

4. each year, before 31 January of the current year, inform the Agency of the unit price (VAT not included) of the analyses and mention if the laboratory is subject to VAT regulations and, whenever appropriate, mention the VAT tariff that will be charged;

5. perform all types of analyses asked for by the Agency and for which the laboratory is approved;

6. for each sector of analyses, inform the Agency of the technical performance level it is able to attain (LOD, LOQ, CCα, CCβ) and mention the method (screening, confirming, …) and technique applied;

7. collect the samples at the dispatching centre (Melle or Gembloux) on the day it receives the fax from the dispatching centre and, if necessary, make two rides on one day (e.g. when a large number of microbiological analyses must be performed);

8. send a copy of the analysis reports to the Agency, in the manner prescribed by the Agency;

9. observe the time limits set between receiving the samples and sending the analysis results, according to the parameters and the analysing techniques laid down by the Minister and/or made known by the Agency;

10. store the laboratory samples for the time set and in the manner described by the law and for at least one month if the sample is not compliant or if a counter-analyses has been performed on it;

11. not divulge the information notified by the Agency;

12. take part, at its own expense, in the interlaboratory tests organised by the Agency at a national or an international level, if the Agency has made a request thereto and, more specifically, in the tests set up by the reference laboratories. The reference laboratories shall inform the Agency of the results of the interlaboratory tests;

13. comply with the instructions and the recommendations of the Agency as well as the reference laboratory designated by the King or the Minister;

14. take part in the activities set up by the reference laboratories designated by the King or the Minister, viz. the scientific trainings and the trainings set up by the Agency;
15. inform the Agency of all changes that are likely to affect the information mentioned in the approval;

16. meet the requirements with respect to traceability referred to in Article 8 of the Royal decree of 14 November 2003 on self-checking, notification requirement and traceability in the food chain;

17. in the case of a counter-analyses, make the validation file of the analysis concerned available to the Agency. Laboratories are only allowed to perform a counter-analysis if their technical performance level is at least equal to that of the laboratory where the first analysis was performed;

18. Paying fees for issuing the approval

5.2 Paying fees for issuing the approval

As from 1 March 2009 approvals will be issued on payment of a fee. In fact, laboratories are operators such as described in Article 2, 2°, of the “arrêté royal du 10 novembre 2005 relatif aux rétributions visées à l’article 5 de la loi du 9 décembre 2004 portant financement de l’Agence fédérale pour la Sécurité de la Chaîne alimentaire. »

The laboratories must, therefore, pay fees to the Agency, in accordance with article 2, 2° of this Royal decree (of 10 November 2005 on fees referred to in article 5 of the financing act of the Agency of 9 December 2004).

An index-linked basic fee of €45,33 is due per application for approval. This sum covers the cost for administration and file processing. In addition will be charged a fee for the examination of the application. This fee amounts to €31,73 per 30 minutes and is index-linked.

The time estimated necessary to treat an approval application file may vary from 1 to 8 hours according to the activities of the laboratory, on the one hand, and the “quality” of the documents supplied, on the other hand.

An invoice mentioning the total amount due will be sent as soon as the file has been treated. This amount must be paid before the approval can be issued.

Annex 2 gives an estimate of the cost of an approval. The total amount covers a period of 5 years, except if the laboratory should ask for an extension of the approval during that time. In that case, file processing costs will be charged as well.

5.3 Submitting an application for approval

When the laboratory has taken note of the requirements to be met with a view to approval, it shall submit an application for approval to the FASFC – DG Laboratories by means of a registered letter, in duplicate; to that end, it shall fill out the form added as Annex I that is available on the website of the Agency : secteurs professionnels, administration des laboratoires.

The laboratory shall add to this application a complete file containing the following pieces

1. a copy of the accreditation certificate (issued by the Belgian accreditation system BELAC or by a body with which the Belgian accreditation system concluded an agreement of mutual recognition) and a copy of the relevant technical annex;
2. a copy of the most recent audit report drawn up by the accreditation body and, in the case of an extension, also a copy of the intermediate or renewal audit report;
3. a list of the analyses and matrices for which the laboratory seeks approval;
4. a list of the analyses and matrices the laboratory is capable of performing apart from the approval (if any);
5. a copy of the statutes of the laboratory.
The application for approval shall also be sent by Email to agrementlabo@afsca.be, mentioning as subject: «application for approval: <name of the laboratory>, accreditation number XXX)».

Upon receipt of the electronic application for approval, DG Laboratories shall send an acknowledgment of receipt to the laboratory, within 10 working days, as well as the tables retrieved from the LABO-LIB databank that must be corrected and/or completed and that mention the parameters and the matrices for which the laboratory seeks approval or that it is capable of performing apart from the approval (if any).

The following fields shall be accurately filled out:

1. Parameters
2. Matrices
3. Technical performance level for each sector of analysis (LOD, LOQ, CC\(_\alpha\), CC\(_\beta\))
4. Delivery time for analysis results, as from the receipt of the sample
5. Maximum analysis capacity per month
6. Unit price (VAT not included)
7. Accreditation

These tables shall be returned by Email to agrementlabo@afsca.be

5.4 Granting approval

If the administrative and technical inquiries appear to be favourable and if the fee due for issuing the approval has been paid, approval is granted for a period of 3 years. The laboratory is informed thereof by means of a letter sent within 2 months at the latest. The decision is published in the Moniteur belge/Belgisch Staatsblad and on the website of the FASFC.

If the administrative and technical inquiries appear to be unfavourable, the laboratory is informed thereof by means of a letter motivating the decision and sent by registered mail. The options for appeal are described in the procedure LAB P10: “Handling Approval Applications of External Laboratories”, under 4.3.2.

5.5 Renewal of the approval

The application in view of the renewal of an approval shall be submitted 3 months before the date of expiry of the approval in force. The same procedure shall be followed as when applying for an approval.

5.6 Extension of the approval

In the course of the period of validity, a laboratory may ask for an extension of its approval. To this end, the laboratory must follow the same procedure as when submitting an application for approval.

The extension shall be granted for the duration of the approval in force.

*Extensions are also granted on payment of a fee, in accordance with Annex 2 that gives an estimate of the cost. In that case, only the amount for file processing will be charged.*
6 Reference to relevant procedures, guidelines, documents, forms or lists

6.1 procedures, guidelines

LAB P 511 Handling approval of external laboratories

6.2 Others

7 Annexes:

LAB F 510-1
LAB D 510-2
7.1 Annex 1 : approval application form

Application for approval

in the context of the Royal decree of 15 April 2005 on the designation of the official laboratories, laying down the procedure and the requirements for the approval of laboratories performing analyses within the framework of the control mission of the Federal Agency for the Safety of the Food Chain and implementing the Act of 15 July 1985 on the use in animals of substances with hormonal, anti-hormonal, beta-adrenergic or production stimulating effects

<table>
<thead>
<tr>
<th>NAME OF THE LABORATORY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ADDRESS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FAX :</th>
<th>TELEPHONE :</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PERSON IN CHARGE OF THE LABORATORY</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The laboratory declares having taken note of the requirements laid down in procedure LAB P 510 that must be met with respect to the application for approval and commits itself to comply with those requirements.

The laboratory commits itself to collect the samples at the dispatching centre in Melle – Gembloux * on the day that it receives the fax from the dispatching centre, and, whenever necessary, to make two rides a day (e.g. when a large number of microbiological analyses must be performed).

The laboratory, the person or persons under whose responsibility the analyses are carried out and the persons involved in the working of the laboratory do not hold any direct or indirect interest in the production, the processing, the import or the marketing of the products on which the analyses or categories of analyses are performed and for which an application for approval is made.

The laboratory seeks approval for the analyses mentioned in the table annexed.

Annexes :

1. a copy of the accreditation certificate (issued by the Belgian accreditation system BELAC or by a body with which the Belgian accreditation system concluded an agreement of mutual recognition) as well as a copy of the relevant technical annex ;
2. a copy of the most recent audit report drawn up by the accreditation body and, in the case of an extension, also a copy of the intermediate or renewal audit report;
3. a list of the analyses and matrices for which the laboratory seeks approval ;
4. a list of the analyses and matrices the laboratory is capable of performing apart from the approval (if any).
5. a copy of the statutes of the laboratory

Date : Name and signature of the person in charge of the laboratory :

The application for approval shall be sent by registered mail and in duplicate to the Federal Agency for the Safety of the Food Chain, DG Laboratoires, CA-Botanique, Food Safety Center, 4ème étage, boulevard du Jardin botanique 55 in 1000 Bruxelles and shall also be sent by Email to agrementlabo@afsca.be

(* Please circle the dispatching centre where you want to collect the samples)
### Annex 2: Estimate of the fee charged for issuing an approval (adjusted on 01/01/2009)

<table>
<thead>
<tr>
<th>half-hour</th>
<th>File processing fee (€)</th>
<th>overall amount (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>31,73</td>
<td>77,06</td>
</tr>
<tr>
<td>2</td>
<td>63,46</td>
<td>108,79</td>
</tr>
<tr>
<td>3</td>
<td>95,19</td>
<td>140,52</td>
</tr>
<tr>
<td>4</td>
<td>126,92</td>
<td>172,25</td>
</tr>
<tr>
<td>5</td>
<td>158,65</td>
<td>203,98</td>
</tr>
<tr>
<td>6</td>
<td>190,38</td>
<td>235,71</td>
</tr>
<tr>
<td>7</td>
<td>222,11</td>
<td>267,44</td>
</tr>
<tr>
<td>8</td>
<td>253,84</td>
<td>299,17</td>
</tr>
<tr>
<td>9</td>
<td>285,57</td>
<td>330,9</td>
</tr>
<tr>
<td>10</td>
<td>317,3</td>
<td>362,63</td>
</tr>
<tr>
<td>11</td>
<td>349,03</td>
<td>394,36</td>
</tr>
<tr>
<td>12</td>
<td>380,76</td>
<td>426,09</td>
</tr>
<tr>
<td>13</td>
<td>412,49</td>
<td>457,82</td>
</tr>
<tr>
<td>14</td>
<td>444,22</td>
<td>489,55</td>
</tr>
<tr>
<td>15</td>
<td>475,95</td>
<td>521,28</td>
</tr>
<tr>
<td>16</td>
<td>507,68</td>
<td>553,01</td>
</tr>
</tbody>
</table>

**Basic fee:** 45,33 €, index-linked  
**Fee for one half-hour - class A agent:** 31,73€, index-linked