



**Agence fédérale
pour la Sécurité
de la Chaîne alimentaire**

(Federal Agency for the Safety of the Food Chain)
Administration Laboratoires (Laboratories Administration)

Procedure

Drawing up an Announcement on the Allocation of Analyses in the case of a Non-Approved Laboratory

Version	01
Comes into force on	2009/09/01
Competent administration	Laboratories Administration
Addressees	Management and staff members of the Laboratories Administration ; approved external laboratories

	Name – function / service	Date	Signature
Written by	Brigitte Pochet Attaché	2009-08-20	Sgd
Checked by	Marina Naccarato QAM	2009-08-20	Sgd
Approved by	Geert De Poorter Director general Laboratories Administration	2009-08-24	Sgd

List of revisions of the document

Revision by /date*	Reason of revision	Part of the text / scope of the revision

* The period of time between the present date and the last revision shall not exceed 5 years.

The documents are put on the central server of the Laboratories Administration. This version is considered as the version in force. Copies may be obtained from the secretariat of the Laboratories Administration.

Keywords : laboratories – analyses – approval - announcement – analysis plan

**DRAWING UP AN ANNOUNCEMENT FOR THE ALLOCATION OF
ANALYSES IN THE CASE OF A NON-APPROVED LABORATORY**

TABLE OF CONTENTS

1	AIM	4
2	SCOPE	4
3	LEGISLATION AND STANDARDS	4
4	DEFINITIONS AND ABBREVIATIONS	5
5	DRAWING UP AN ANNOUNCEMENT FOR THE ALLOCATION OF ANALYSES IN THE CASE OF A NON-APPROVED LABORATORY	6
5.1	WHEN TO DRAW UP AN ANNOUNCEMENT?	6
5.2	HOW TO DRAW UP AN ANNOUNCEMENT ?	6
5.3	INFORMING THE DESIGNATED LABORATORY	7
5.4	PROCESSING ANNOUNCEMENTS AND FOLLOW-UP	7
6	REFERENCE TO RELEVANT PROCEDURES, INSTRUCTIONS, DOCUMENTS, FORMS OR LISTS.	7
6.1	PROCEDURES / FORMS	7
7	ANNEX	7

DRAWING UP AN ANNOUNCEMENT ON THE ALLOCATION OF ANALYSES IN THE CASE OF A NON-APPROVED LABORATORY

1 Aim

The aim of this procedure is to describe the drawing up of an announcement on the allocation of analyses and the acceptance of laboratory results when no approved laboratory is available for performing analyses that have been programmed by DG Control Policy and analyses that are not listed in the Control programme.

2 Scope

Analyses pertaining to the control programme must be performed under accreditation, as prescribed by Article 11 of Regulation 882/2004/EC.

The majority of the analyses are performed by the laboratories of the FASFC or by external laboratories that have been approved in accordance with the Royal decree of 15 April 2005.

However, it is not always easy to find an accredited laboratory for all the analyses applied for within the control programme or in the event of a crisis, RASSF..., and sometimes no approved laboratory can be found.

To solve this problem, Article 10 of the Royal decree of 15 April 2005 provides for the possibility to allocate analyses to or accept the results of laboratories that do not meet the requirements laid down in Article 4 when no laboratory has been approved for a particular parameter or when the applications for analyses exceed the testing capacity of approved laboratories.

Article 4 specifically requires an accreditation for the analyses requested.

To proceed in that way, an announcement must be published in the *Moniteur belge*/Belgisch Staatsblad. The announcement should mention the period of time of the allocation, the name of one or more laboratories for performing certain well specified analyses.

3 Legislation and Standards

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 exécution 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 (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 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).

Regulation 882/2004/EC on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

4 Definitions and abbreviations

AFSCA (FASFC) announcement	Agence fédérale pour la Sécurité de la Chaîne alimentaire (Federal Agency for the Safety of the Food Chain) Announcement on the allocation of analyses and the acceptance of results – Implementation of the « 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 exécution de la loi du 15 juillet 1985 relative à l'utilisation de substances à effet hormonal, à effet anti-hormonal, à effet bêta-adrénergique ou à effet stimulateur de production chez les animaux »
Approved laboratory	Laboratory approved in accordance with the Royal decree of 15 April 2005

5 Drawing up an Announcement on the Allocation of Analyses in the case of an Non-Approved Laboratory

5.1 When to draw up an announcement ?

An announcement must be drawn up when there is no laboratory that has been approved in accordance with procedures LAB P 510 and LAB P511 to perform certain analyses that have been listed in the control programme of the FASFC.

In such cases, the designated co-ordinator shall ask the laboratory(-ies) that is(are) willing to perform the analysis for a description of the method applied and for a validation file for the analysis in question.

The co-ordinator shall examine the validation file upon receipt and no later than in the course of the 5 working days following that date.

If the validation file is satisfactory, the designated co-ordinator shall inform by e-mail the director general of laboratories and the co-ordinator in charge of legislation, who will then draw up the announcement.

The director general of laboratories decides how long the announcement will remain in force : 6 months, 1 year or 2 years according to the period of time deemed necessary for accrediting the designated laboratory for that analysis.

5.2 How to draw up the announcement ?

A form (P 520 – F01) has been prepared together with the Legal department of the FASFC.

That form (P 520 – F01) must be completed (type of analysis, matrix(matrices), period of validity of the announcement and name of the laboratory(laboratories) that will be designated.)

The date shall be added later on, when the Chief Executive Officer will have signed the document.

The announcement is then submitted for signature to the Chief Executive, as an annex to an official note that clearly explains the reasons for the publication of such an announcement for those analyses in the Moniteur belge/Belgisch Staatsblad.

5.3 Informing the designated laboratory

As soon as the announcement has been published in the Moniteur belge/Belgisch Staatsblad, the co-ordinator in charge of legislation shall send an e-mail to the laboratory informing it of the publication of the announcement and attach a pdf copy of the announcement as published to the e-mail.

5.4 Processing announcements and follow-up

The administrative assistants will file the announcements and the explanatory note sent to the Chief Executive Officer in the « AVIS » (announcements) folder in the office of the co-ordinator in charge of legislation.

The administrative assistants will insert a copy of the announcement in the file of the laboratory that is kept in a cupboard in room K04/120222.

To make sure that the expiry dates of the various announcements will be taken into account, the co-ordinator in charge of legislation will assign tasks in Outlook with a deadline set at one month before the expiry date of the announcement.

On the day of the deadline, the co-ordinator in charge of legislation will ask the co-ordinators and/or the laboratory if the announcement should or should not be prolonged.

If it is necessary to prolong the validity of the announcement, a new announcement may be produced in accordance with the procedure above.

6 Reference to relevant procedures, instructions, documents, forms or lists

6.1 Procedures / forms

Procedure LAB P 510 : application for approval of external laboratories

Procedure LAB P 511 : processing applications for approval of external laboratories

7 Annex

Form : LAB P 520 – F01 : « example of an announcement ».