

AFAQ AFNOR Certification Head office : 11 rue Francis de Pressensé – 93571 La Plaine Saint Denis CEDEX - France Offices : 116 avenue Aristide Briand – BP 40 – 92224 Bagneux CEDEX - France Phone: +33 1 46 11 37 00 Fax: +33 1 46 11 39 40 certification@afaq.afnor.org www.afnor-validation.com	Identification number 102	
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Validation of alternative analytical methods

Application to agribusiness

CERTIFICATION RULES

ANNEX 6

VALIDATION REQUEST DOSSIER

This appendix specifies the content of the dossier to be presented to AFAQ AFNOR CERTIFICATION by the applicant. The dossier must be drafted in either **English** or **French** and sent to the following address:

AFAQ AFNOR Certification
116 avenue Aristide Briand – BP 40 – 92224 BAGNEUX CEDEX - France

It includes the following chapters:

- 1- **general information** about the applicant and the approved laboratory chosen by the applicant (please see standard document A),
- 2- a **letter of commitment** from the applicant which is also signed by his legal representative in France if the applicant is outside of the European Union (please see standard document B),
- 3- **detailed identification** of the origin and the nature of all of the chemicals and materials which may be needed to implement this method and which are not supplied by the manufacturer,
- 4*- a **description of the method** which is the subject of the application and the reference method (please see standard document D),
- 5**- a **preliminary draft study** drawn up according to the guidelines in the document, '*Requirements regarding the preliminary and inter-laboratory studies carried out by an expert laboratory*'.

Only documents 3, 4 and 5 are presented to the Technical Board.

* the items in standard document D can also be included in the preliminary draft study specified in point 5

** the delivery of the preliminary draft study may be postponed. However, this document must be sent to AFAQ AFNOR Certification at least one month before the presentation date.

In the case of a modification or extension application, this must be drafted according to the model in standard document C and sent to AFAQ AFNOR Certification. If applicable, documents 1, 3, 4 and/or 5 must be filled in or modified.

The application is processed in accordance with Appendix 5.

STANDARD DOCUMENT A

GENERAL INFORMATION ABOUT THE APPLICANT

1 NAME OF THE ALTERNATIVE METHOD CONCERNED

**2 MANUFACTURER'S CORPORATE NAME
(responsible for putting the product to be validated on the market)**

- Address:

- Name of official:

- Telephone: Fax:

- E-mail:

- SIRET N° (French business registration number):

3 PRODUCTION SITE (to be completed if different from manufacturer's details)

- Address:

- Name of official:

- Telephone: Fax:

- E-mail:

4 DISTRIBUTOR'S CORPORATE NAME (to be completed if different from manufacturer's details)

- Address:

- Name of official:

- Telephone: Fax:

- E-mail:

- SIRET N° (French business registration number):

5 PRINCIPAL RAW MATERIAL SUPPLIER(S)

*All of the suppliers must be listed, as must the products that they produce. The principal raw materials are specified in chapter 2.1, Appendix 4 of the Operating rules.
 Please note: This information will remain strictly confidential.*

<p>Supplier N°1</p> <p>Name:</p> <p>Name of official:</p>	<p>Address:</p> <p>Tel:</p> <p>Fax:</p> <p>E-mail:</p>	<p>Product:</p>
<p>Supplier N°2</p> <p>Name:</p> <p>Name of official:</p>	<p>Address:</p> <p>Tel:</p> <p>Fax:</p> <p>E-mail:</p>	<p>Product:</p>
<p>Supplier N°3</p> <p>Name:</p> <p>Name of official:</p>	<p>Address:</p> <p>Tel:</p> <p>Fax:</p> <p>E-mail:</p>	<p>Product:</p>

6 APPROVED LABORATORY'S CORPORATE NAME

- Address:

- Name of official:

- Telephone:

Fax:

- E-mail:

STANDARD DOCUMENT B

**Application to be drafted on applicant's headed letter paper
(include the letter on page 7/11 if the manufacturer is outside of the European Union)**

The Deputy General Manager
AFAQ AFNOR Certification
116 avenue Arsitide Briand – BP 40
92224 BAGNEUX CEDEX
France

SUBJECT: APPLICATION FOR THE RIGHT TO USE THE AFNOR VALIDATION MARK

INCLUDED: Technical dossier

Dear Sir,

May I please ask you to process this validation application dossier for the alternative method hereafter known as:

Name of the alternative method:

Area of application requested (Scope):

In relation to the following reference method:

I hereby declare that I am familiar with the AFNOR VALIDATION mark's Certification rules (applied to agribusiness) and its appendices.

I commit myself to:

- complying with the requirements of the said documents as well as the decisions taken or to be taken in application of the requirements by AFAQ AFNOR Certification when instructed by the Technical Board,
- informing AFAQ AFNOR Certification of any significant change to the organisation of manufacturing and monitoring processes and, in general, the quality assurance of the alternative method validated,
- facilitating the tasks to be undertaken by the auditors mandated by AFAQ AFNOR Certification in light of the Certification rules and its appendices,
- drafting in either English or French all of the documents concerning the products in question and the organisation of their quality assurance as well as providing an interpreting service during the audits carried out by the auditors mandated by AFAQ AFNOR Certification (if a language other than English or French were to be used),

- complying wholly and unreservedly to the decisions taken in accordance with the AFNOR VALIDATION mark's certification rules and its appendices,
- settling the amounts established in the financial framework of the AFNOR VALIDATION mark's certification rules and making any subsequent payments demanded of me in compliance with the certification rules.

I also commit myself to **respecting the deadlines decided by AFAQ AFNOR Certification (AAC) concerning the organization of technical board meetings** as follows :

1. the expert laboratory shall send the draft preliminary study document to AAC before the deadline decided by AAC (3 to 4 weeks before the meeting date)
2. the expert laboratory shall send the preliminary study report or the inter-laboratory study report or any other necessary document (such as technical sheets....) to AAC before the deadline decided by AAC (3 to 4 weeks before the meeting date)

I take notice that AAC will only put on the next meeting agenda the validation files (draft study or study report) for which the complete documents are published before the deadline. Consequently only completed studies –the results of which are known when drafting the meeting agenda – shall be part of the next meeting agenda. Any study non completed when drafting the agenda will not be presented at the next meeting. Its presentation shall be delayed to another meeting.

This procedure aims to guarantee the best organization for technical board meetings.

Yours faithfully,

(If applicable)

Date,
Manufacturer's stamp and signature

Date
Company's stamp and
signature of its legal representative

**LETTER TO BE INCLUDED IF THE MANUFACTURER IS
OUTSIDE OF THE EUROPEAN UNION
(on the manufacturer's headed letter paper)**

The Deputy General Manager
AFAQ AFNOR Certification
116 avenue Arsitide Briand – BP 40
92224 BAGNEUX CEDEX
France

SUBJECT: APPLICATION FOR THE RIGHT TO USE THE AFNOR VALIDATION MARK

INCLUDED: Technical dossier

Dear Sir,

The alternative method which is the subject of the application will be sold in France through **(1)**:

Company's full name and address:

.....
.....
.....

I authorise Mr or Mrs (named in person) to act on my behalf when in contact with AFAQ AFNOR Certification for all issues regarding the validated methods which are sold throughout Europe.

I thereby commit myself, jointly and severally with the aforementioned company, to complying with the AFNOR VALIDATION mark's certification rules as stated in the letter enclosed.

Yours faithfully,

Date
Manufacturer's stamp and signature

Date
Company's stamp and
signature of its legal representative

(1) The manufacturer must appoint a physical person who represents him in Europe

STANDARD DOCUMENT C

**Application to be drafted on applicant's headed letter paper
(include the letter on page 7/11 if the manufacturer is outside of the European Union)**

The Deputy General Manager
AFAQ AFNOR Certification
116 avenue Arsitide Briand – BP 40
92224 BAGNEUX CEDEX
France

**SUBJECT: APPLICATION FOR THE EXTENSION OF THE RIGHT TO USE THE AFNOR
VALIDATION MARK FOR AN ALTERNATIVE METHOD**

INCLUDED: Technical dossier

Dear Sir,

On the (validation date), the right to use the AFNOR VALIDATION mark was granted for the following method:

- Full trade name:
- AFNOR VALIDATION Certificate N°:
- Scope:
- Reference method:
- Manufactured in the plant,, located at (plant's complete address), which is under my authority.

STANDARD DOCUMENT D

This document must include:

1. A descriptive section which must present:
 - the principle behind the alternative method, a diagram or a photo of the method, in-depth instructions of use for the method (operating manual, technical sheet, etc.), any restrictions on the use of the method and the method's history (first manufacturing and first sale dates).
 - the area of application requested for validation,
 - the reference method's description or number, if a standard is concerned,
 - items indicating the originality and interest of the alternative method (e.g. a list of users) and approximate costs.
2. A bibliographical section which must include (if applicable)
 - a list of publications,
 - a summary of these publications which could contribute to the preliminary study as outlined in 'Requirements regarding the preliminary and inter-laboratory studies carried out by an expert laboratory'.
3. In the case of an AOAC validation, the following minimum requirements are needed:
 - the AOAC validation reference while specifying the programme followed (AOAC Official methods, AOAC Performance Tested Methods, etc.)
 - an AOAC certificate stating that the validation is still valid and has not been annulled, expired or modified since the validation date,
 - a description of the reference method used for the AOAC validation.
 - the list of products tested for the AOAC validation.