

Certification Rules

European collective mark

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Validation of alternative analytical methods

Application to agribusiness

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The present Certification Rules and appendices were approved by AFAQ AFNOR Certification's General Manager on February 28th, 2006 and on July 30th, 2007 for new appendices 2 and 6.

Together with the representatives of users, suppliers and technical experts, AFAQ AFNOR Certification commits itself to maintain the relevance of these Certification Rules, in terms of certification process and in terms of definition of requirements considering the market context.

The Certification Rules may so be revised, completely or partially, by AFAQ AFNOR Certification, after advice of the Validation Committee.

Any revision shall be approved by the AFAQ AFNOR Certification's General Manager.

HISTORY OF MODIFICATIONS

| Modified Clause | Revision Ref. | Date | Modifications taken into account |
|----------------------|---------------|-------------------|--|
| Main document | 8 | 2006.02.28 | <ul style="list-style-type: none"> - Conformity to new AFNOR VALIDATION General Rules published when registering the AFNOR VALIDATION European collective Mark in 2005. - Updating of the mark name and updating of the name of the Certification Body - Modification of clause 3.2.3 (conditions for inviting candidates in case there is a change of the Validation Commission President) - Addition of a reference to new appendix 7 (procedure to qualify expert laboratories) |
| Appendix 1 | 6 | 2006.02.28 | - Reference to new technical validation protocols |
| Appendix 2 | 7 | 2007.08.06 | - Indication of new website www.afnor-validation.com and associated informations |
| Appendix 3 | 8 | 2006.02.28 | - Modification of the number of representatives in each college |
| Appendix 4 | 8 | 2006.02.28 | - New audit basis document |
| Appendix 5 | 8 | 2006.02.28 | <ul style="list-style-type: none"> - Modification of audit procedure - New renewal conditions |
| Appendix 6 | 9 | 2007.08.06 | - Updated application form committing the supplier to respect the deadlines in sending the documents to Afaq Afnor Certification |
| Appendix 7 | 0 | 2006.02.28 | - New appendix concerning the procedure to qualify expert laboratories (with conditions previously defined in document "Requirements revision 7") adjusted to the new requirements defined by the technical board. |
| Appendix 8 | 14 | 2006.02.28 | - Financial framework updated annually (change of reference - previously appendix 7) |

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Validation of alternative analytical methods

Application to agribusiness

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| <h1>CERTIFICATION RULES</h1> |
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** as the financial framework is reviewed each year, it is not included in the certification rules but published as a separate document which is inserted into the certification rules at the time of the review.*

These certification rules are applied in line with the AFNOR VALIDATION mark's general rules.

These certification rules have been implemented by AFAQ AFNOR CERTIFICATION so as to validate the alternative analysis methods in the area of agribusiness.

1. DEFINITIONS

An **alternative analysis method**, referred to in these certification rules as the 'alternative method', is a commercial alternative method which allows the same unit for a given product category to be analysed or estimated as that measured with the reference method. However, the alternative method also features one or more of the following criteria:

- rapid analysis and/or response,
- easy to perform and/or automate,
- analytical characteristics (detection threshold, specific character, etc.)

The term 'alternative method' encompasses the product, equipment and the technical instructions as a whole. It includes all of the ingredients, whether of a material nature or not, needed to implement the alternative method.

NB:

Under the AFNOR VALIDATION mark, it is imperative that the modus operandi of the alternative methods to detect pathogen microorganisms (*Listeria*, *Salmonella*, *E.coli* O157) comprises a confirmation stage for those results which test positive.

A **reference method** is a standardised method, when it exists, or an official method. It could also be a widely known and used method which is taken as a reference.

2. SCOPE

When applied to agribusiness, the purpose of the AFNOR VALIDATION mark is to certify that the test results obtained through the use of specific 'alternative methods' are comparable, with regard to the aims of the analysis, to those which would have been obtained if the reference methods had been applied.

These methods concern the measuring of physical properties and chemical, biochemical, biological and microbiological doses and detection levels in the area of agribusiness (including environment of the food processing industry).

The comparison is carried out by applying the references outlined in appendix 1 of this document.

The validation of an alternative method looks at the technical instructions put forward by the manufacturer, the test products and materials needed to implement the method and the area of application stated.

Validation of an alternative method is awarded on the basis of a preliminary study and an inter-laboratory study (or inter-laboratory study) whose conditions are specified in the references in appendix 1.

Periodic audits are performed to monitor the manufacturer's quality assurance system in line with the methods outlined in appendix 5 and on the basis of the audit reference guide specified in appendix 4.

The validation of an alternative method leads to the awarding by AFAQ AFNOR Certification of a validation certificate which constitutes the right to use the AFNOR VALIDATION mark. (see appendix 2)

3. GENERAL ORGANIZATION

3.1 AFAQ AFNOR Certification

AFNOR granted AFAQ AFNOR Certification, a simplified joint-stock company, an operating licence for the AFNOR VALIDATION mark.

AFAQ AFNOR Certification is responsible for implementing the AFNOR VALIDATION mark. All decisions are notified by AFAQ AFNOR Certification. They take effect the moment they are made known.

AFAQ AFNOR Certification is thereby responsible for enforcing the certification rules and all of the decisions taken with regard to these rules.

AFAQ AFNOR Certification manages the entire administration of the AFNOR VALIDATION mark, in particular:

- The setting of the Certification rules which lay down the procedures to assess and check for compliance with standards and any additional specifications,
- The management of the Validation Committee and its Technical Boards, if appropriate,
- The processing of the applications for the right to use the AFNOR VALIDATION mark,
- The organisation of the checks laid down within the certification rules and the monitoring of the conformity of the analysis methods,
- Relations with the applicants, licensees and third parties particularly with regard to making sure the AFNOR VALIDATION mark is being used correctly,
- Decisions, sanctions and their follow-up,
- Sector-based promotion and the development of the application concerned by the AFNOR VALIDATION mark

3.2 Validation Committee

A consultative body known as a 'Validation Committee' specific to the agribusiness sector is created within AFAQ AFNOR Certification.

3.2.1 Validation Committee duties

The Validation Committee has the task of producing an opinion on:

- the general operating, development, promotion and quality policy of the AFNOR VALIDATION mark,
- the draft certification rules and the certification rule reviews which have been approved,
- the decisions to be taken in compliance with the certification rules,
- the setting up of sector-based Technical Boards when necessary,
- any appeals presented by AFNOR VALIDATION mark applicants or licensees concerning the opinions produced by the Technical Boards,
- the advertising and promotional projects which concern its activity,
- the selection of monitoring and auditing bodies,
- the plans to authorize bodies,
- the examination and implementation of the recognition agreements.

The Committee can be consulted on any other issue related to the application at hand.

3.2.2 Validation Committee modus operandi

The Validation Committee produces recommendations; these recommendations are adopted by a simple majority. The Chair has the casting vote if there is a parity of votes. Any experts invited to attend the Committee meeting do not vote.

Discussions are only valid if at least half of the voting members are present or represented and if all of the colleges are represented.

Validation Committee members cannot receive any payment for the functions that they have been awarded.

The Validation Committee establishes the frequency and the dates of its meetings. A meeting is called at least once a year.

3.2.3 Validation Committee membership

The standard composition of the Validation Committee is given in appendix 3. Its members are spread over various colleges so as to ensure the balanced representation of the different parties concerned and to avoid a single interest taking predominance.

An AFAQ AFNOR Certification representative and a standardization representative appointed by the AFNOR's General Manager are ex-officio members of each Validation Committee.

The members of the Validation Committee are appointed by the AFAQ AFNOR Certification Deputy General Manager. Their mandate lasts three years; this mandate can be renewed.

The Chairman of the Validation Committee is also appointed by the AFAQ AFNOR Certification Deputy General Manager. A call for applications is previously held within the Committee's various colleges.

At the end of the chairman's three-year mandate a new call for applications is held among the members of all the Committee's colleges so that each college may put forward a representative to chair the Validation Committee.

The exercising of the functions of a Validation Committee member is restricted to the person appointed. Nevertheless, each full member may appoint one substitute who has been personally appointed under the same conditions.

3.3 Validation Committee Technical Boards

The Validation Committee proposes whether specific Technical Boards should be created. It also suggests their composition, on a nominative basis, depending on the boards' responsibilities.

3.3.1 Technical Board duties

The Technical Boards have the task of producing an opinion on:

- the drafting, for their area of application, of requirements regarding the preliminary and collaborative studies carried out by an expert laboratory (please see appendix 1),
- the technical processing of the validation application dossiers,
- the technical processing of renewals.

3.3.2 Technical Board modus operandi

The Technical Boards provide AFAQ AFNOR Certification with recommendations on the decisions to be taken in application of the certification rules hereby laid down and, particularly, the follow-up to be taken with regard to the alternative method validation applications.

These recommendations are adopted by a simple majority. The Chair has the casting vote if there is a parity of votes. Any experts invited to attend the Technical Board meetings do not vote. A vote is taken automatically after the last presentation (inter-laboratory study).

Discussions are only valid if at least half of the voting members are present or represented and if all of the colleges are represented.

Technical Board members cannot receive any payment for the functions that they have been awarded.

The Technical Boards establish the frequency and the dates of their meetings in such a way as to ensure the applications are processed and any monitoring reports are studied within a timeframe which is in line with the time needed for the laboratory tests. The Technical Board meetings are convened.

The applicant has the right to have the manufacturers of alternative methods belonging to the Technical Boards excluded from the appraisal of his dossier due to reasons concerning competition. In this case, discussions are valid, without considering the manufacturers college, if at least half of the members are present or represented and if all of the colleges are represented.

3.3.3 Technical Board membership

The standard composition of the Technical Boards is given in Appendix 3. The boards are made up in such a way as to ensure the balanced representation of the different parties concerned and to avoid a single interest taking predominance.

The Technical Board members are appointed by the AFAQ AFNOR Certification Deputy General Manager. Their mandate lasts three years; this mandate can be renewed. The Chairman of the Technical Board is also appointed by the AFAQ AFNOR Certification Deputy General Manager and is done so under the same conditions.

The exercising of the functions of a Technical Board member is restricted to the person appointed. Nevertheless, each full member may appoint one substitute who has been personally appointed under the same conditions.

3.4 Expert laboratories

The studies undertaken on the alternative methods are performed and/or supervised by an expert laboratory which has been qualified by AFAQ AFNOR Certification after studying the opinion produced by the Technical Board concerned.

The approval methods for approved laboratories are specified in Appendix 7.

For each dossier an approved laboratory is selected by the manufacturer from the qualified laboratory list. The list of laboratories which have already been qualified by AFAQ AFNOR Certification is available from AFAQ AFNOR Certification.

3.5 Auditors

The auditors in charge of the audits are qualified and mandated by AFAQ AFNOR Certification.

The manufacturer may reject the auditor mandated by AFAQ AFNOR Certification once.

The list of auditors qualified by AFAQ AFNOR Certification is available from AFAQ AFNOR Certification.

4. GRANTING OF THE RIGHT TO USE THE AFNOR VALIDATION MARK

4.1 Presentation of the application

Any manufacturer, importer or distributor of alternative methods in the European Union may apply for this mark.

The manufacturer may be European or of another nationality. If the country is not a member of the European Union, the validation application must be made together with the legal representative of the manufacturer in Europe who is responsible for selling the product.

When the applicant who sells the product is not the manufacturer of the said product, the validation application is made jointly with the manufacturer. The latter commits himself to complying with these certification rules, particularly with regard to the quality assurance measures implemented by the manufacturer to guarantee the ongoing quality of the validated product.

The application must be drawn up in accordance with the instructions in Appendix 6.

4.2 Obligations of the applicant

The applicant must accept all of the conditions which appear in the AFNOR VALIDATION mark certification rules laid down in this document and in its appendices and in particular:

- undertake the checks which are his responsibility in compliance with Appendix 4,
- provide the inspection agents with the operations which are the applicant's responsibility under these certification rules and Appendix 5.

4.3 Processing of the application

The processing of the dossier is carried out according to the procedure outlined in Appendix 5.

4.4 Decisions

Subject to the opinion of the Technical Boards, AFAQ AFNOR Certification can take the following decisions:

- the granting of the right to use the AFNOR VALIDATION mark for a period of four years,
- the granting of the right to use the AFNOR VALIDATION mark for a given period at the end of which a validation confirmation process must take place according to the specific procedures put forward by the Technical Board,
- the refusal of the right to use the AFNOR VALIDATION mark while waiting for additional information to be supplied by the expert laboratory. The Technical Board may request a reference laboratory put forward by the Technical Board validates the studies.
- the refusal of the right to use the AFNOR VALIDATION mark.

4.5 Monitoring of the validated products

The licensee must regularly monitor the validated methods to ensure the certified alternative method performs correctly at all times in compliance with the measures established in Appendix 4 of these certification rules.

Any modification made to one of the processes which could lead to changes in performance must be communicated by the licensee to AFAQ AFNOR Certification.

Monitoring is undertaken by AFAQ AFNOR Certification as from the moment the right to use the AFNOR VALIDATION mark is given. Such monitoring complies with the methods outlined in Appendix 5.

AFAQ AFNOR Certification, on the basis of an opinion emitted by the Technical Board, may undertake or have undertaken an audit and/or additional studies to ascertain that the performance of the validated method remains correct in light of any complaints or disputes, etc. about which AFAQ AFNOR Certification is aware and which relate to the use of the AFNOR VALIDATION mark.

Appendix 5 specifies the procedure required to renew the method validation.

5. CONDITIONS PERTAINING TO THE USE OF THE AFNOR VALIDATION MARK

5.1 Granting of the right to use the AFNOR VALIDATION mark

Anybody who sells alternative methods on a continuous basis whose performance is equivalent to that of the reference method and who meets the requirements established in Appendix 4 may apply for the right to use the AFNOR VALIDATION mark. Such a request is hereafter referred to as an 'application' and the person making such an application is known as 'the applicant'.

The granting of the right to use the mark is given by the AFAQ AFNOR Certification General Manager in light of the application's processing result and the commitments undertaken by the applicant at this time.

When the right to use the mark is given, the beneficiary is known as the 'licensee'.

5.2 Certification - Reference to the AFNOR VALIDATION mark

For each validated method, AFAQ AFNOR Certification awards the applicant a validation certificate. This certificate is valid for a period of four years and may be renewed under the conditions specified in Appendix 5.

5.3 Restrictions to the right to use the AFNOR VALIDATION mark

The right to use the AFNOR VALIDATION mark is strictly limited to the 'alternative methods' for which it was granted, namely, the 'alternative methods', which were duly specified, from the plants, which were duly specified, and manufactured under the conditions laid down in these certification rules and Appendix 4 in particular.

In light of this and in particular:

- any modification that the licensee wishes to make to the certified 'alternative method' including a change to the trade name, a change of subcontractor, a change of premises, etc. must be the subject of an extension or modification application (please see the procedures specified in Appendices 5 and 6).
- the licensee may only refer to the AFNOR VALIDATION mark, with particular regard to his business documents (confirmation of orders, invoices, delivery slips, advertising literature, catalogues, etc.), to highlight the validated 'alternative methods'. This may only be done without there being any risk of confusing such methods with those which are not validated.

6. RECOGNITION AGREEMENTS

AFNOR is the sole body authorised to enter into agreements with other bodies regarding the AFNOR VALIDATION mark and agreements concerning the recognition of marks.

AFAQ AFNOR Certification is the sole body authorised to enter into agreements of mutual recognition with other bodies regarding analyses, audits and inspections. AFAQ AFNOR Certification can foresee the association of bodies and laboratories when the agreement is signed.

The provisions of the agreements established in this way replace or complement those of the certification rules and their appendices without affecting the other provisions which remain applicable. Any necessary derogations are established by AFAQ AFNOR Certification in light of the opinion given by the Validation Committee.

7. CONFIDENTIALITY - SAFEGUARDING OF DOCUMENTS

All those involved in the management of the AFNOR VALIDATION mark are bound to professional secrecy, including the members of the Validation Committee and the Technical Boards. Furthermore, they must ensure the protection of the documents with which they are entrusted against distribution, destruction, falsification and theft.

8. INFORMATION ON THE METHODS BEARING THE AFNOR VALIDATION MARK AND PROMOTION

8.1 AFAQ AFNOR Certification is responsible for managing the information on the methods and licensees which hold the AFNOR VALIDATION mark and makes sure that such information is distributed harmoniously.

8.2 AFAQ AFNOR Certification is responsible for the collective promotion of the AFNOR VALIDATION mark in Europe and abroad. Collective advertising and promotional activities for the AFNOR VALIDATION mark are defined and carried out by AFAQ AFNOR Certification within an annual general budget created in light of an opinion given by the Certification Committee of AFAQ AFNOR Certification.

The Validation Committee and the Technical Boards may be consulted on these activities.

At the expense and on the initiative of the licensees, the latter may undertake an advertising campaign for the AFNOR VALIDATION mark. This campaign would be controlled by AFAQ AFNOR Certification.

9. SANCTIONS

In the case of a licensee of the AFNOR VALIDATION mark infringing the certification rules hereby laid down, the licensee will be informed of the infringement(s) committed. The licensee has a reasonable amount of time to inform AFAQ AFNOR Certification of his remarks. After examination, one of the following sanctions may be enforced:

- suspension of the right to use the AFNOR VALIDATION mark for a given period with a request for corrective actions to be taken within a specified period,
- withdrawal of the right to use the AFNOR VALIDATION mark without affecting any action that may be taken in accordance with article 13 below.

These substantiated sanctions are communicated to the party concerned and take effect from the date of said notification.

The purpose of the suspension of the right to use the AFNOR VALIDATION mark is to deprive the licensee of the said right for a given period.

The withdrawal of the right to use the AFNOR VALIDATION mark annuls the right to use the AFNOR VALIDATION mark for the method concerned.

The type of sanction selected depends on the gravity of the infringement(s). In an emergency and, particularly, for serious infringements regarding safety obligations, AFAQ AFNOR Certification may, on a precautionary basis, enforce the provisional sanctions which are required.

In the case of the infringement not being serious, AFAQ AFNOR Certification may deliver a warning to the licensee with or without an increase in the number of inspections which are the latter's responsibility. The warning includes a request for corrective actions within a given period. The warning does not stop the licensee from using the AFNOR VALIDATION mark.

10. DISPUTES - APPEALS

The applicant or licensee may dispute a decision concerning the said party on the basis of evidence by contacting AFAQ AFNOR Certification, which submits the dossier to the Technical Board concerned for examination. The applicant or licensee is informed of the follow-up given to his dispute.

If the decision is confirmed, the applicant or licensee may appeal against the decision by sending his request to the Director General of AFAQ AFNOR Certification.

Any appeals must be presented within 15 days from the day the notification of the corresponding decision's confirmation is received. The appeals do not have a suspensory effect.

11. SUSPENSION OR WITHDRAWAL AT THE REQUEST OF THE LICENSEE

In the case of the licensee definitively ending the manufacture, sale or monitoring, under the conditions specified in these certification rules, of a certified 'alternative method', he must immediately inform AFAQ AFNOR Certification of this and provide the latter with an estimate of the outstanding stock with this method and an estimate on the time needed for such stock to be sold off.

On the basis of this information, the withdrawal of the right to use the AFNOR VALIDATION mark can be decided on under conditions specified after the Technical Board has given its opinion.

The licensee must also keep AFAQ AFNOR Certification informed of any temporary cessation of production or sale of a certified 'alternative method'.

Any temporary cessation of production or sale of a certified 'alternative method' which is considered excessive by AFAQ AFNOR Certification may, after an inquiry, lead to the suspension or withdrawal of the right to use the AFNOR VALIDATION mark for the method at hand.

12. CONVEYANCE - TRANSFER OF ACTIVITIES

The licensee must immediately inform AFAQ AFNOR Certification of any decision which leads to:

- either a change to the company's legal status, a change to the corporate name, or the merger or liquidation of the licensee,
- or, in the case of the total or partial transfer of the manufacturing of the products and materials needed for the implementation of the alternative method to another production site or in the case of a different supplier.

It is AFAQ AFNOR Certification's responsibility to examine the methods used to maintain the right to use the AFNOR VALIDATION mark for the method validated. It may consult the Technical Board prior to examining the said methods.

AFAQ AFNOR Certification may undertake a new audit and, if appropriate, additional studies.

13. MISUSE OF THE AFNOR VALIDATION MARK

13.1 Examples of misuse

Those cases which are considered as examples of misuse are those which the AFNOR VALIDATION mark is referred to, particularly for:

- 'alternative methods' whose application is still being processed or for which the right to use the AFNOR VALIDATION mark was refused or withdrawn,

- product ranges or catalogues of which only some are 'alternative methods' which bear the AFNOR VALIDATION mark,
- 'alternative methods' other than those which bear the AFNOR VALIDATION mark.
- Any other use of the AFNOR VALIDATION mark outside of its scope.

13.2 Legal action

Aside from the sanctions laid down in article 9, any misuse of the AFNOR VALIDATION mark, whether committed by a licensee or a third party, gives AFNOR or AFAQ AFNOR Certification the right, under current legislation, to take any legal action it deems necessary.

14. FINANCING

The services related to the management and promotion of the AFNOR VALIDATION mark constitute:

- an registration fee - charged to each company - as well as the application dossier processing fee which is paid for in one installment by the applicant when the application is made (this payment is not reimbursable even if the right to use the AFNOR VALIDATION mark is not granted or the dossiers are abandoned during the aforementioned process),
- the audits and any samples or tests carried out as part of the inspections specified in Appendix 5,
- an all inclusive annual licence for the promotion, legal protection and development of the AFNOR VALIDATION mark,
- annual management corresponding to the general operating of the AFNOR VALIDATION mark.

A fee, which is updated annually by AFAQ AFNOR Certification, incorporates a breakdown of the amounts due for these services and the payment methods (please see the financial framework available from AFAQ AFNOR Certification).

15. APPROVAL

These certification rules and the appendices were approved by the Deputy Director General of AFAQ AFNOR Certification on 30.07.2007.

They can be modified by AFAQ AFNOR Certification at the suggestion of the Validation Committee and/or AFAQ AFNOR Certification and, in all cases, after an opinion has been given by the Validation Committee.

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CERTIFICATION RULES

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| <p>APPENDIX 1</p> <p>CERTIFICATION REFERENCES</p> |
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The certification references used as part of the AFNOR VALIDATION mark when applied to **agribusiness** are:

1 For the general case of microbiological analysis in food processing industry:

- **Standard EN ISO 16140** – Microbiology of food – Protocol for the validation of alternative methods
- **Requirements regarding the preliminary and inter-laboratory studies carried out by an expert laboratory:** this is a document drafted by the AFNOR VALIDATION Technical Board for microbiology and applies in addition to the EN ISO 16140 standard. It constitutes an application guide for this standard and contains specific measures which apply to the AFNOR VALIDATION mark. It is updated each time a modification is made by the corresponding Technical Board and/or by AFAQ AFNOR Certification.
After each update, it is distributed to the approved laboratories which have been qualified, the corresponding Technical Board and the manufacturers and/or distributors with validated methods.

Furthermore, until the end of 2005, the previous document entitled 'Requirements regarding the preliminary and collaborative studies carried out by an expert laboratory' (Revision 7) may apply to the processing of new dossiers and the renewal studies for the inter-laboratory study part.

2 For the case of the antibiotic residue detection methods and other molecules with a similar effect:

Standard EN ISO 16140 does not apply.

The applicable protocol is that one specified in the document drawn up by the Technical Board and with the reference '**Requirements regarding the preliminary and inter-laboratory studies carried out by an expert laboratory** / application to antibiotic residue detection methods and other molecules with a similar effect'.

3 For any other cases:

If a method is not within the scope of the specific documents which are applicable to the AFNOR VALIDATION mark, the Technical Board will adjudicate on a case by case basis on the experimental conditions which relate to the application of standards.

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| 5 | 2000-07-31 | | | | | | | | |
| 6 | 2006-03-15 | | | | | | | | |
| 7 | 2007-08-06 | | | | | | | | |



Validation of alternative analytical methods

Application to agribusiness

CERTIFICATION RULES

APPENDIX 2

HOW TO REFER TO THE AFNOR VALIDATION MARK

VALIDATION CERTIFICATE

For each validated method, AFAQ AFNOR Certification awards the applicant an AFNOR VALIDATION mark certificate on the basis of the validation certificate models drawn up by the Technical Board concerned.

The manufacturer/distributor must have free copies of the validation certificates available for users.

TECHNICAL INSTRUCTIONS OF THE VALIDATED METHOD

The technical instructions sheet must at least indicate the following characteristics:

- certificate number delivered by AFAQ AFNOR Certification,
- certificate's expiry date,
- scope of the AFNOR VALIDATION mark (these three items appear on the first page of the certificate supplied by AFAQ AFNOR Certification).

This technical sheet must be identified by the manufacturer so as to allow the reviews to be indicated on the document. AFAQ AFNOR Certification will list the reference identified on the validation certificate.

PRELIMINARY AND INTER-LABORATORY STUDIES' SUMMARY REPORT

AFAQ AFNOR Certification and/or the manufacturer/distributor may send users (who so desire) further information to that contained in the validation certificate. This can be done, in particular, through the preliminary and inter-laboratory studies' summary report which is drafted by the approved laboratory according to the model drawn up, if appropriate, by the Technical Board concerned.

LIST OF CERTIFIED METHODS

AFAQ AFNOR Certification publishes and distributes on a periodic basis after each Technical Board meeting the list of validated methods. Such distribution is not controlled. For each method this list comprises the contact details of the manufacturer/distributor/production site, the commercial reference of the method, the aim of the test (detection/enumeration and analysis sought), the initial validation date as well as the possible renewal and/or extension dates and the expiry date.

WEBSITE

AFAQ AFNOR Certification has created the following website dedicated to the AFNOR VALIDATION mark: www.afnor-validation.com (in English) or www.afnor-validation.org (in French)

All general information as well as details relating to validated methods (such as updated list, certificates, resumes of studies) can be downloaded from this website.

CONDITIONS PERTAINING TO THE USE OF THE AFNOR VALIDATION MARK

This paragraph deals with the AFNOR VALIDATION logo reproduction methods, the reference to the AFNOR VALIDATION mark, the labelling of the validated products as well as the information given to the buyer of the validated products on those characteristics which are validated.

Without affecting the sanctions laid down in article 13 of these Operating rules, any erroneous statement could expose the licensee to legal action for fraud and/or misleading advertising.

Logo



The AFNOR VALIDATION logo must be placed by the manufacturer on the products' technical sheet and it may be placed directly on the products and/or their packaging in compliance with the **user chart** drawn up by AFAQ AFNOR Certification. Any other support documents which refers to the validated product - such as documents and advertising, etc. - may also refer to the AFNOR VALIDATION mark.

Compulsory labelling regarding the logo:

Communication on information relating to the certification of products and services is the subject of legislation: the reason for this is to make the meaning of labels and certification marks, etc. transparent to consumers and users.

Article R 115-10 of the French consumer law therefore stipulates that:

When certification is referred to in the advertising, marking or presentation of any product as well as in the commercial documents of any kind which refer to certification, the following information must be given to the consumer or user:

- the name or the corporate name of the certifying body or its collective certification mark as well as its address,
- identification of the reference serving as a basis for certification,
- essential certified characteristics.

In compliance with this article, the manufacturer must indicate on the products' technical sheet - and, if he so desires, on the products and/or their packaging or any other documents referring to the AFNOR VALIDATION mark (support documents which are identified as secondary) - **the following information as a minimum requirement next to the logo:**



XXX aa/bb – cc/dd*

ALTERNATIVE ANALYTICAL METHODS FOR AGRIBUSINESS

Certified by AFAQ AFNOR Certification

www.afnor-validation.com

** this concerns the reference provided by AFAQ AFNOR CERTIFICATION for each validated method.*

To meet the requirements of article R115-10 concerning the essential certified characteristics and the address of the certifying body, **the validation certificate, identified as a primary support document, will include the following information:**



XXX aa/bb – cc/dd*

ALTERNATIVE ANALYTICAL METHODS FOR AGRIBUSINESS

Analytical performances certified

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

www.afnor-validation.com

These labelling methods have **immediate effect** for all of the methods validated after the publication of these certification rules. For those methods which were already validated at the time these rules were published, this labelling obligation is **postponed** to the **next** renewal of the validation.

DELABELING CONDITIONS

Any suspension or withdrawal of the right to use the AFNOR VALIDATION mark prohibits the use of this mark and any reference to it. Similarly, those products which are accidentally noncompliant must also be delabeled.

In these cases, therefore, the AFNOR VALIDATION mark must no longer appear on the products, their packaging, documents, advertising or any other support document used by the manufacturer.

Each licensee must implement a product delabeling procedure. The manufacturer/distributor must inform in real time the user clients of any decision to withdraw, suspend, modify or extend the certificate awarded by AFAQ AFNOR Certification for its method.

| | |
|---|--|
| 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 |
| | Revision number Implementation date |
| | 7 2002-05-15 8 2006-03-15 |



Validation of alternative analytical methods

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CERTIFICATION RULES

APPENDIX 3

STANDARD COMPOSITION OF VALIDATION COMMISSION AND TECHNICAL BOARDS

VALIDATION COMMISSION

- 1 Chairman (member of the Validation Commission)
- 1 secretary from AFAQ AFNOR Certification
- 1 standardization representative – AFNOR Standardization Department

"PUBLIC AUTHORITIES" COLLEGE **2 to 4 representatives**

composed of representatives from ministries involved

"MANUFACTURERS" COLLEGE **5 to 7 representatives**

including at least 4 representatives of manufacturers/retailers members* of SYDIALE/EFED

** These representative should be holders of AFNOR Validation mark or should request AFNOR Validation mark before 1 year (except the case where there is no Technical Board)*

"METHODS' USERS" COLLEGE **4 to 6 representatives**

composed of representatives of industrial laboratories, public laboratories and private laboratories

"TECHNICAL INSTITUTES" COLLEGE **5 to 7 representatives**

Including as an example :

- 1 representative of of Food industries technical centres
- 1 representative of Food Industries Association
- 1 representative of Food Safety Agency
- 1 representative of Scientific Research Centre
- 1 representative of Accreditation Body
- 1 representative of regional public laboratory
- 1 representative of the Pasteur Institute

TECHNICAL BOARD

- 1 Chairman (member of the technical committee)
- 1 secretary from AFAQ AFNOR Certification
- 1 standardization representative – AFNOR Standardization Department

"MANUFACTURERS" COLLEGE

5 to 8 representatives

including at least 5 representatives of manufacturers/retailers members* of SYDIALE/EFED

** These representative should be holders of AFNOR Validation mark or should request AFNOR Validation mark before 1 year*

"METHODS' USERS" COLLEGE

5 to 8 representatives

composed of representatives of industrial laboratories, public laboratories and private laboratories

"TECHNICAL INSTITUTES" COLLEGE

7 to 9 representatives

Including representatives from **ministries** involved

Including 5 to 8 **non governmental** representatives (Food associations, technical centres, accreditation body,...)

| | |
|--|--|
| AFAQ AFNOR Certification Head office: 11 rue Francis de Pressensé – 93571 LA PLAINE SAINT DENIS CEDEX Office : 116 avenue Aristide Briand – BP 40 – 92224 BAGNEUX CEDEX 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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| |
|--|
| <p>APPENDIX 4</p> <p>QUALITY REQUIREMENTS FOR THE MANUFACTURER</p> |
|--|

0 SUBJECT, SCOPE AND NORMATIVE REFERENCES

Subject

This appendix specifies the obligations related to the quality system and to the production process of alternative methods, that the manufacturer (applicant or holder of the AFNOR VALIDATION mark) shall commit itself to implement within the framework of these certification rules.

These obligations constitute the system of reference which will serve as a basis for the audits defined in appendix 5.

The “manufacturer of alternative method” is the company which guarantees the formulation and monitoring of the operational characteristics of the alternative method.

The “product” as referred in standard EN ISO 9001, is an alternative method composed by the product together with the equipment and instructions for use. This includes all ingredients, material or otherwise required for the implementation of the alternative method.

Scope

The quality system of the manufacturer shall comply with requirements of standard EN ISO 13485 (with restrictions mentioned in the table in chapter 1) as well as to the specific requirements related to AFNOR VALIDATION mark as specified in chapter 2.

In chapters extracted from standard EN ISO 13485 the words “medical device” are to be replaced by “alternative method” as defined in the present certification rules.

Whenever the supplier is working with subcontractors for the production and/or control of the functional characteristics of the alternative methods, these subcontractors shall also comply to the requirements specified in this appendix.

Normative references

| | |
|--------------|---|
| EN ISO 9001 | Quality management systems - Requirements |
| EN ISO 13485 | Medical devices – Quality management systems – Requirements for regulatory purposes |

1 OBLIGATIONS CONCERNING THE QUALITY SYSTEM

The following clauses of standard EN ISO 13485 are applicable (only titles are mentioned in the table below. Please refer to the standard for contents)

| Clause | Title in standard EN ISO 13485 | Applicability |
|----------|---|---------------|
| 4 | Quality Management System requirements | applicable |
| 4.1 | General requirements | |
| 4.2 | Documentation requirements | |
| 4.2.1 | General requirements | |
| 4.2.2 | Quality Manual | |
| 4.2.3 | Control of documents | |
| 4.2.4 | Control of records | |
| 5 | Management Responsibility | applicable |
| 5.1 | Management Commitment | |
| 5.2 | Customer focus | |
| 5.3 | Quality policy | |
| 5.4 | Planning | |
| 5.4.1 | Quality objectives | |
| 5.4.2 | Quality Management System planning | |
| 5.5 | Responsibility, authority and communication | |
| 5.5.1 | Responsibility and authority | |
| 5.5.2 | Management representative | |
| 5.5.3 | Communication | |
| 5.6 | Management review | |
| 5.6.1 | General | |
| 5.6.2 | Review input | |
| 5.6.3 | Review output | |

| | | |
|------------------|---|--------------------------|
| 6 | Resource management | |
| 6.1 | Provision of resources | |
| 6.2 | Human resources | |
| 6.2.1 | General | applicable |
| 6.2.2 | Competence, awareness and training | |
| 6.3 | Infrastructure | |
| 6.4 | Work environment | |
| 7 | Product realization | |
| 7.1 | Planning of product realization | applicable |
| 7.2 | <i>Customer-related processes</i> | <i>Non applicable</i> |
| 7.3 | Design and development | applicable |
| 7.3.1 | Design and development planning | |
| 7.3.2 | Design and development inputs | |
| 7.3.3 | Design and development outputs | |
| 7.3.4 | Design and development review | |
| 7.3.5 | Design and development verification | |
| 7.3.6 | Design and development validation | |
| 7.3.7 | Control of design and development | |
| 7.4 | Purchasing | applicable |
| 7.4.1 | Purchasing process | |
| 7.4.2 | Purchasing information | |
| 7.4.3 | Verification of purchased products | |
| 7.5 | Production and service provision | See details below |
| 7.5.1 | Control of production and service provision | applicable |
| 7.5.1.1 | General requirements | |
| 7.5.1.2 | Control of production and service provision- Specific requirements | |
| 7.5.1.2.1 | Cleanliness of product and contamination control | |
| 7.5.1.2.2 | <i>Installation activities</i> | <i>Non applicable</i> |
| 7.5.1.2.3 | Service activities | applicable |

| | | |
|-----------|---|-----------------------|
| 7.5.1.3 | <i>Particular requirements for sterile medical devices</i> | <i>Non applicable</i> |
| 7.5.2 | Validation of processes for production and service | applicable |
| 7.5.2.1 | General requirements | |
| 7.5.2.2 | <i>Particular requirements for sterile medical devices</i> | <i>Non applicable</i> |
| 7.5.3 | Identification and traceability | applicable |
| 7.5.3.1 | Identification | |
| 7.5.3.2 | Traceability | |
| 7.5.3.2.1 | General | |
| 7.5.3.2.2 | <i>Particular requirements for active implantable medical devices and implantable medical devices</i> | <i>Non applicable</i> |
| 7.5.3.3 | Status identification | applicable |
| 7.5.4 | <i>Customer property</i> | <i>Non applicable</i> |
| 7.5.5 | Preservation of products | applicable |
| 7.6 | Control of monitoring and measuring devices | |
| 8 | Measuring, analysis and improvement | See details below |
| 8.1 | General | applicable |
| 8.2 | Monitoring and measurement | |
| 8.2.1 | Customer satisfaction | |
| 8.2.2 | Internal audit | |
| 8.2.3 | Monitoring and measurement of processes | |
| 8.2.4 | Monitoring and measurement of product | |
| 8.2.4.1 | General requirements | |
| 8.2.4.2* | <i>Particular requirements for active implantable devices</i> | <i>Non applicable</i> |
| 8.3 | Control of nonconforming products | applicable |
| 8.4 | Analysis of data | |
| 8.5 | Improvement | |
| 8.5.1 | Continuous improvement | |
| 8.5.2 | Corrective action | |
| 8.5.3 | Preventive action | |

2 ADDITIONAL SPECIFIC REQUIREMENTS

The following requirements shall be applied in addition to the requirements specified in clause 1.

2.1 Definitions

A "**main raw material**" is a specific material directly affecting the method's capacity.

(for example: antibodies in the case of an immunological method, major ingredients in the case of a medium, etc),

An "**associated raw material**" is a material affecting the method's capacity indirectly.

(for example: wash buffer, formats for the methods in a solid phase, etc.),

2.2 Period of validity

The method used to calculate the period of validity for each type of product shall be documented.

2.3 Identification and traceability

A/ Identification

Identification of the finished products is contractually mandatory, applying the specifications in appendix 2 of the present certification rules.

B/ Traceability

The manufacturer shall give a definition for the notion of batches for the main raw materials and for the products. The manufacturer shall ensure the traceability of the raw materials and products.

2.4 Control of processes

A/ Subcontracting

If a manufacturer subcontracts all or part of the production, either in case of unexpected circumstances (e.g. volume of work, need for additional technical knowledge or temporary disability) or in a general way (under permanent contracts with subcontractors), these activities shall be mandated to a competent subcontractor.

A subcontractor is said to be competent if he is in conformity with the present requirements for the specified activities

B/ Special processes

The manufacturer shall ensure that the records relating to the quality of special products identify the following items :

- The work instructions used
- The date of use of the special process
- The identity of the person using special process

2.5 In-house inspections

The manufacturer shall :

- define what the main raw materials and associated raw materials are,
- justify the relevance of the inspections plans which are implemented.

A/ Procedures concerning the main raw materials

- The manufacturer shall define a specification for each main raw material.
- The manufacturer shall draw up a system of reference allowing him to specify the performance level of each main raw material using reproducibility tests.

The frequency of the in-house inspections is :

- at least 1 inspection per batch received,
- if goods are stored, at least 1 inspection per batch or per aliquot of batches after storage and before manufacture

The main raw materials may be identified by codes so as to conserve, vis-à-vis the auditor, the anonymity of the raw materials being used.

Exceptions :

- if the main raw material stems from a supplier, the manufacturer may obtain guarantees from the latter,
- should it be proven technically impossible, the reproducibility tests will be carried out on the finished product.

B/ Procedures concerning the associated raw materials

The manufacturer shall define a specification for each associated raw material, as well as procedures for monitoring these specifications.

C/ Procedures concerning the possible detection of the signal
(methods integrating a physical measurement)

The 3 main phases of the detection are :

- the physical principle of detection,
- the processing of the signal,
- the processing of the information.

For each of these phases, the manufacturer shall :

- document their performance level,
- define the monitoring operations.

D/ Procedures concerning the products

The manufacturer shall draw up a system of reference for the in-house inspection of the suitability of each product and shall justify its relevance.

The system of reference will incorporate at least :

- the detection limit,
- the specificity,
- the signal detection threshold, if required.

An in-house inspection frequency of 1 inspection per batch is desirable.

2.6 Delivery

The manufacturer shall ask each authorized representative to update the records related to the distribution of alternative methods and ensure that these records are kept available for any inspection.

2.7 Quality records

The manufacturer shall keep all quality records during a period at least equivalent to the period of validity of the alternative method he has defined. This period cannot be inferior to one validation cycle (starting from the date of granting AFNOR Validation)

The manufacturer shall set up and update quality records related to each batch of alternative methods corresponding to the traceability referred to in clause 2.3 and identifying the quantity produced and the quantity distributed. The batch registration shall be verified and authorized

Note : one batch may contain only one alternative method

2.8 Statistical techniques

The manufacturer shall set up and update procedures in order to ensure that sampling methods are regularly controlled using reports on non conforming products, quality audits reports, complaints (Cf. 2.10) and any other appropriate item.

2.9 Modifications

The quality system shall include the management of modifications concerning :

- the main raw materials,
- the processes,
- the products.

Any modification having a direct influence on the suitability of the method shall be declared to AFAQ AFNOR Certification, whether a modification of protocol or of materials .

See appendix 5 for the related procedures.

2.9 Customer complaints

All information returned to the manufacturer, including customer complaints and products sent back, must be documented, investigated and interpreted. The information shall be circulated according to procedures defined by a specific person.

The manufacturer shall update all records concerning investigations on complaints. When an investigation states that upstream activities have influenced the complaint, a copy of the report shall be sent to the persons in charge of these upstream activities.

| 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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| | <table border="1"> <thead> <tr> <th>Revision number</th> <th>Implementation date</th> </tr> </thead> <tbody> <tr> <td>7</td> <td>2002-05-15</td> </tr> <tr> <td>8</td> <td>2006-03-15</td> </tr> </tbody> </table> | Revision number | Implementation date | 7 | 2002-05-15 | 8 | 2006-03-15 |
| | Revision number | Implementation date | | | | | |
| 7 | 2002-05-15 | | | | | | |
| 8 | 2006-03-15 | | | | | | |



Validation of alternative analytical methods

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CERTIFICATION RULES

APPENDIX 5

PROCESSING AND FOLLOW-UP PROCEDURE

AFAQ AFNOR CERTIFICATION MONITORING METHODS

1 VALIDATION APPLICATION FOR AN ALTERNATIVE METHOD

1.1 Filing of the application

The applicant sends the validation application dossier as outlined in Appendix 6 of the certification rules to:

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

The applicant must include an independent expert laboratory of his choice, whether public or private, in the application. This laboratory must be qualified by AFAQ AFNOR Certification for the area in question (qualification procedure available from AFAQ AFNOR Certification).

AFAQ AFNOR Certification can take on the management of the call for tenders aimed at laboratories and/or the compliance with the conditions stated in the call for tenders according to methods which are available from the company.

This laboratory has the task of undertaking and/or supervising the preliminary study and the inter-laboratory study of the alternative method put forward for validation.

In the case of subcontracting a part of the tests for the preliminary study, the expert laboratory must indicate in its preliminary draft study the amount to be subcontracted as well as the name of the subcontractor.

1.2 Registration of the dossier by AFAQ AFNOR CERTIFICATION

AFAQ AFNOR Certification registers all validation application dossiers and provides an acknowledgement of receipt in return. The technical processing of the dossier can only occur if the dossier is complete.

1.3 Processing of the dossier

The validation application dossiers are processed from a technical perspective by the Technical Board concerned.

The dossiers are not processed anonymously. Technical Board members are bound to professional secrecy.

The applicant has the right to have the manufacturers of alternative methods belonging to the Technical Boards excluded from the appraisal of his dossier due to reasons concerning competition. This can occur at any stage during the presentation of the study results.

The technical processing of the dossier by the Technical Board occurs in three stages according to the protocol based on the EN ISO 16140 standard (please see Appendix 1):

- 1st stage** Presentation of the preliminary draft study.
- 2nd stage** Presentation of the preliminary study results and a inter-laboratory draft study.
- 3rd stage** Presentation of the inter-laboratory study results to the Technical Board (and possibly the audit report if AFAQ AFNOR Certification so wishes).

The aim of the preliminary study is to assess the alternative method put forward for validation compared to the reference method in accordance with the technical protocol specified in Appendix 1. This study leads to the drafting, by the expert laboratory, of an assessment report for the alternative method which is presented to the Technical Board experts.

The aim of the inter-laboratory study (or collaborative study) is to determine the variability of the results obtained in a number of laboratories using identical samples and to compare these results with those obtained at the time of the preliminary study, in accordance with the technical protocol specified in Appendix 1.

The expert laboratory is responsible for leading the inter-laboratory study. It also has the task of gathering and processing the results obtained and drafting a report which is presented to the Technical Board experts.

Prior to each presentation before the Technical Board, the expert laboratory must send the projects and study reports on the date set (approximately one month before the meeting) to AFAQ AFNOR Certification so that the latter can distribute the said documents among the Technical Board members.

The study projects and reports are presented to the Technical Board by the expert laboratory representative who may be accompanied by the manufacturer's representative.

The Technical Board studies and assesses the content of the projects and reports.

For each study, reviewers are appointed during the first stage by the Technical Board. These reviewers, who are selected within the Technical Board (from among all of the colleges), will study those dossiers for which they are responsible in more depth. They will be able to contact the expert laboratory prior to the meetings so as to obtain any additional information and allow the latter to provide any additional information required prior to the Technical Board meeting. During the meeting, the reviewers will give a brief spoken account of the studies presented by the expert laboratory.

A maximum period of one year between each stage of the dossier's technical processing procedure is permitted.

An in-depth description of the methods used to process the studies is given in the document entitled: 'Requirements regarding the preliminary and inter-laboratory studies carried out by an expert laboratory' (please see Appendix 1).

1.4 Manufacturer audit

While the inter-laboratory study is carried out, AFAQ AFNOR Certification has an audit on the manufacturer's premises undertaken to make sure that the latter has a quality assurance system which complies with the requirements in Appendix 4. These audits are performed under the responsibility of AFAQ AFNOR Certification.

If the manufacturing of the alternative method is the result of assembling principal raw materials, of which some are produced offsite, the auditor pays particular attention to the supplier(s)'s monitoring methods. If the subcontractor(s) has/have a certificate based on the standards EN ISO 9001 or EN ISO 13485 for the production of the abovementioned principal raw materials, a copy of the certificate must be given to AFAQ AFNOR Certification. Otherwise, AFAQ AFNOR CERTIFICATION decides on whether it is worth undertaking an audit among the subcontractors (nature, duration and frequency to be specified during the dossier's processing, based on an analysis of risk).

Information on the audit results may be given by AFAQ AFNOR Certification in the Technical Bureau during the third stage (please see § 1.3).

AFAQ AFNOR Certification may call upon the two reviewers if an inconclusive appraisal has been given by the audit report. In this case, these reviewers receive the audit report and present their opinions to the Technical Board at the same time they give their opinions on the results of the inter-laboratory study.

Audits are undertaken either in English or French. If the documents are in another language, AFAQ AFNOR Certification and/or the auditor may demand a translation.

Modus operandi of the audits

If appropriate, the companies must provide AFAQ AFNOR Certification with a copy of the relevant quality assurance certificate. The certificate must clearly specify that the scope of the certificate includes the manufacturing of the validated method and it must also mention the restrictions to the validity of said certificate.

1st case: The company is not certified according to one of the following standards: EN ISO 13485 or ISO 9001,

Or, the company is certified according to one of these standards but the production unit associated with the validated method (or in the process of validation) is not.

A two-day audit is carried out on the site for admission. This audit can be reduced to one day if the main manufacturing stages are subcontracted to a site which is already certified.

The audit reference guide is the one outlined in Appendix 4.

The auditors who carry out the audits are qualified by AFAQ AFNOR Certification.

If the company so desires, a local auditor (or the same auditor as the quality assurance certifying body) may be mandated by AFAQ AFNOR Certification for this

company's audits. However, in this case, the cost incurred to approve this auditor is at the company's expense.

2nd case: The company is certified according to the ISO 9001 standard for the production unit associated with the validated method (or in the process of being validated).

The quality assurance certifying body must be recognised by AFAQ AFNOR Certification.

A one-day audit is carried out on the manufacturing site.

The audit reference guide will include the chapters from Appendix 4, which complement the ISO 9001 standard (requirements specific to the EN ISO 13485 standard and requirements specific to the AFNOR VALIDATION mark).

3rd case: The company is certified according to the EN ISO 13485* standard, for the production unit associated with the validated method (or in the process of validation).

The quality assurance certifying body must be recognised by AFAQ AFNOR Certification.

There is no audit on the manufacturing site **at the time of admission**.

The requirements specified in chapter 2 of Appendix 4 (requirements specific to the AFNOR VALIDATION mark) will not be checked **at the time of admission**.

** the quality assurance certificates emitted according to the EN ISO 13485 standard (2001 version) will be taken into consideration during the transitional period specified for the application of the new version of the standard (2003). At the end of this transitional period, only those certificates emitted according to the EN ISO 13485 standard (2003 version) will be considered to reduce the auditing process.*

1.5 DECISION

After each stage, the Technical Board provides AFAQ AFNOR Certification with an opinion on the follow-up to be given to the application being processed.

After the 3rd stage (presentation of the inter-laboratory study results and assessment of the audit report) and when the Technical Board's opinion is favourable, the Technical Board may specify the validation restrictions as well as the details to be contained in the specification sheet (operating manual) of the method put forward by the manufacturer.

The aforementioned details, if appropriate, are attached to the alternative method's validation certificate. The validation certificate is drafted by AFAQ AFNOR Certification in line with the model specified by the Technical Board and sent to the manufacturer following an opinion emitted by the Technical Board concerned.

The decision to award a certificate is taken by the AFAQ AFNOR Certification Director.

2 EXTENSION OR MODIFICATION OF THE VALIDATION

Any modification likely to lead to a change in the performance of the alternative method (change of one or more components, raw material supplier, manufacturing process, production site, specification sheet, etc.) must be made known to AFAQ AFNOR Certification.

The processing methods are the following:

2.1 Modification of one of the principal raw materials

The modification is studied by an expert laboratory which draws up a diagnosis and gives its opinion on the nature of the additional studies to be undertaken. This opinion is presented to the Technical Board.

2.1 Modification of one of the associated raw materials

The modification is noted and sent directly to AFAQ AFNOR Certification, which sends the dossier to the Technical Board members for an opinion. A presentation is given by the manufacturer to the Technical Board if requested by the latter.

In both cases, the information must be given in English or in French and communicated by the distributor if such a distributor exists.

2.3 Another modification concerning the validated method

Any other modification made to the validated method (in the protocol, the area of application, etc.) must be communicated beforehand to AFAQ AFNOR Certification, which then decides:

- either to implement an extension study if the change is significant,
- or to take the modification into account without any additional study if it is insignificant.

In all cases, the modification request is subject to the Technical Board's opinion. The Board decides on whether the right to use the AFNOR VALIDATION mark may be maintained without an additional study, if appropriate.

2.4 Use of an automatic device

The following specifications apply:

- If the use of an automatic device is not an obligatory part of the method, the automatic device cannot be validated. The qualification of the automatic device is the user's responsibility: this is due to a metrology problem.
- If the automatic device reproduces a validated protocol fully, an extension is not needed.

- If the automatic device requires a modification to the protocol, the extension deals with this modification of the protocol.

2.4 Modification concerning the production site or subcontracting

In accordance with chapter 12 of the certification rules, it is up to AFAQ AFNOR Certification to ascertain the need for an additional audit and, if appropriate, an additional study.

3 MONITORING OF THE VALIDATED METHOD

AFAQ AFNOR CERTIFICATION organises the monitoring of the conformity of the alternative methods with the validation criteria as soon as the methods are validated.

Standard monitoring consists in:

- periodic audits whose frequency and duration are specified in chapter 3.1,
- every four years, a renewal study whose methods are specified in chapter 3.2.

The renewal study's processing methods are specified below.

3.1 Manufacturer monitoring audits

If appropriate, the companies must provide AFAQ AFNOR Certification with a copy of the relevant quality assurance certificate for the production site. The certificate must clearly specify that the scope of the certificate includes the manufacturing of the validated method and it must also mention the restrictions to the validity of said certificate.

If appropriate, the companies must also supply a copy of the quality assurance certificate of the subcontractor sites which produce the principal raw materials.

**1st case: The company is not certified according to one of the following standards:
EN ISO 13485 or ISO 9001,**

Or, the company is certified according to one of these standards but the production unit associated with the validated method is not.

A one-day audit is carried out on the production site every two years when it is being monitored.

The audit reference guide is the one outlined in Appendix 4.

2nd case: The company is certified according to the ISO 9001 standard for the production unit associated with the validated method.

The quality assurance certifying body must be recognised by AFAQ AFNOR Certification.

A one-day audit is carried out on the production site every four years when it is being monitored.

The audit reference guide will include the chapters from Appendix 4, which complement the EN ISO 9001 standard (requirements specific to the EN ISO 13485 standard and requirements specific to the AFNOR VALIDATION mark).

3rd case: The company is certified according to the EN ISO 13485* standard, for the production unit associated with the validated method.

The quality assurance certifying body must be recognised by AFAQ AFNOR Certification.

A one-day audit is carried out on the production site every four years when it is being monitored.

** the quality assurance certificates emitted according to the EN ISO 13485 standard (2001 version) will be taken into consideration during the transitional period specified for the application of the new version of the standard (2003). At the end of this transitional period, only those certificates emitted according to the EN ISO 13485 standard (2003 version) will be considered to shorten audits.*

3.2 Renewal study

The **applicant** (manufacturer or distributor) selects an **expert laboratory** (from the list of laboratories qualified by AFAQ AFNOR Certification) which will undertake this renewal study.

The expert laboratory presents in a meeting with Technical Board members the items outlined below (numbered 1 to 6) concerning the alternative method.

Two reviewers for the method are appointed from among the Technical Board members prior to the presentation by the expert laboratory, if possible. Ideally, these appointments take place during the previous session.

The **six item** list which makes up the renewal dossier presented by the expert laboratory during an initial meeting is indicated below. :

3.2.1 A reminder of the alternative method, including the following sections:

- date the AFNOR VALIDATION mark was first awarded and the previous renewal date(s)
- principle behind the method
- technical sheet in the form of a diagram
- reference method(s) against which the alternative method was compared
- updated technical sheet as well as all of the previous technical sheets which have been in place since the previous validation or renewal with an indication of the modifications

The applicant must provide the expert laboratory with these versions of the technical sheets

- specific characteristics (validation scope, any restrictions on the use of the method, etc.)
- overview of the results obtained during the initial validation and any renewals and extensions
- an account of any modifications made to the alternative method which may have given rise, or not, to an extension of validation

The applicant must provide the expert laboratory with an in-depth account of all of the modifications made since the last validation, renewal or extension.

3.2.2 A bibliographic study including, if appropriate:

- A list of publications which have appeared since the last validation or renewal of the method

The items of information are provided, on the one hand, by the applicant and, on the other hand, are the outcome of bibliographical research carried out by the expert laboratory. They may be complemented by information from the reviewers.

- An overview produced by the expert laboratory on the basis of these publications which includes information on the method's performance
- The outcome to the external validations undertaken by bodies other than AFAQ AFNOR Certification (date, body, nature of the validation protocol, indication of the reference method)

The applicant must give the reports concerning these validations to the expert laboratory, which has them available for the Technical Board during the presentation.

3.2.3 A summary and analysis of user complaints regarding the method

If appropriate, the applicant must provide the expert laboratory with the items needed to bring to the attention of the Technical Board the anomalies detected which have led to modifications to the protocol or the exclusion of matrices, for example.

Furthermore, audits are carried out on the method's production site on behalf of AFAQ AFNOR Certification at the time of the validation application and during monitoring on a regular basis (please see Appendix 4).

A chapter on complaints appears in the audit reference guide. Information concerning the complaints recorded since the last validation or renewal (type, importance, processing) may be sent to the Technical Board in the form of a summary if proposed by AFAQ AFNOR Certification and the auditor and if such information undermines the method's performance.

The complaints gathered by AFAQ AFNOR Certification will also be sent to the expert laboratory to be included in the dossier.

3.2.4 Stock-take of the modifications made since the previous validation

- In the **technical reference guide** of the AFNOR VALIDATION mark (a document which outlines the protocol used to undertake the preliminary and inter-laboratory studies by the expert laboratory, please see Appendix 1)
- In the **reference method** against which the alternative method was compared for subsequent validation

3.2.5 Presentation of any modifications foreseen for the alternative method itself

The expert laboratory draws up a diagnosis and gives its opinion on the need to carry out an additional study.

The new draft technical sheet (supplied by the applicant) must appear in the dossier.

If the applicant foresees an extension to the method's validation (major modifications made to the method or the application protocol, or change to the validation's area of application), the procedure which relates to the extension methods applies simultaneously.

3.2.6 Additional draft validation study

If appropriate (please see the following chapters), the additional studies to be carried out will be suggested in line with the validation reference guide's requirements.

The Technical Board examines all of these parameters and gives one of the following opinions:

IF NO MODIFICATION HAS BEEN MADE IN THE TECHNICAL REFERENCE GUIDE OF THE AFNOR VALIDATION MARK OR IN THE REFERENCE METHOD AND IF THE MODIFICATIONS (IF ANY) TO THE ALTERNATIVE METHOD DO NOT UNDERMINE THE METHOD'S PERFORMANCE AND IF THE ANALYSIS OF THE COMPLAINTS AND THE BIBLIOGRAPHICAL EXTRACTS DO NOT UNDERMINE THE METHOD'S PERFORMANCE:

- ☛ the Technical Board grants the renewal of the Validation for a period of four years without any additional studies (as long as the dossier presented is complete)

IF THERE HAS BEEN A MODIFICATION TO THE AFNOR VALIDATION MARK'S REFERENCE GUIDE:

- ☛ the Technical Board requests the undertaking of an additional study*, so as to meet all of the new requirements.

** the evaluation of the importance of the modifications and the definition of the additional studies to be performed is the Technical Board's responsibility.*

IF THERE HAS BEEN A MODIFICATION TO THE REFERENCE METHOD:

- ☛ the Technical Board demands that the validation study* is carried out either fully or partially.

** the evaluation of the importance of the modifications and the definition of the additional studies to be performed is the Technical Board's responsibility.*

IF MODIFICATIONS TO THE ALTERNATIVE METHOD ARE PRESENTED:

a) In the case of (a) significant modification(s) which affect the method:

- modification of principal material (= specific material directly affecting the method's capacity - for example: antibodies in the case of an immunological method, major ingredients in the case of a medium, etc), or
- significant modification of the protocol (including the introduction of an automatic device affecting the protocol).

- ☛ The Technical Board requests the undertaking of an additional study based on the diagnosis established by the expert laboratory.

b) In the case of (an) insignificant modification(s):

- modification of an associated raw material (= material affecting the method's capacity indirectly - for example: wash buffer, formats for the methods in a solid phase, etc.), or
- insignificant modification of the protocol (including the introduction of an automatic device which fully reproduces the validated protocol).

- ☛ After studying the documents in a session, the Technical Board may grant the renewal of the validation without an additional study.
If the Technical Board considers that the modification affects a principal raw material (and not an associated material) or that the modification is likely to affect the method's capacity, processing will occur according to case a).
If considered useful, the Technical Board may request additional information which will be studied at the following session.

c) If the method comprises a software program for the processing of the results, and the program has been modified:

- ☛ The expert laboratory must check whether the results obtained during initial validation or renewal are altered through the use of the updated program. In the case of a modification to the results, the Technical Board requests the undertaking of an additional study based on the diagnosis established by the expert laboratory.

IF ANY COMPLAINTS OR BIBLIOGRAPHICAL EXTRACTS ARE LIKELY TO UNDERMINE THE METHOD'S PERFORMANCE:

- ☛ The Technical Board requests the undertaking of additional validation studies or additional documentary support to be provided so as to prove that the performance remains satisfactory in relation to the AFNOR VALIDATION mark.

If several of these cases are recent, the Technical Board puts forward additional studies (preliminary and/or inter-laboratory) while considering all of the parameters.

At the end of reaffirmation, a **summary report** will be drafted by the expert laboratory. It will comprise a summary of the various sections presented as well as an overview of the additional studies performed, if any.

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|---|----------------------------------|--|
| 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 | |
| | Revision number | Implementation date |
| | 7 8 9 | 2002-05-15 2006-03-15 2007-08-06 |



Validation of alternative analytical methods

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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.*

| | | |
|---|---|-----------------|
| Supplier N°1 Name: Name of official: | Address: Tel: Fax: E-mail: | Product: |
| Supplier N°2 Name: Name of official: | Address: Tel: Fax: E-mail: | Product: |
| Supplier N°3 Name: Name of official: | Address: Tel: Fax: E-mail: | Product: |
| | | |

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.

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| | Revision number | Implementation date |
| | 0 | 2006-03-15 |



Validation of alternative analytical methods

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CERTIFICATION RULES

APPENDIX 7

PROCEDURE TO QUALIFY EXPERT LABORATORIES

The expert laboratories must be **accredited** by COFRAC (French Committee for accreditation) or by any other accreditation body recognised by COFRAC for the analytical programme concerned.

The approved laboratory must send to AFAQ AFNOR Certification, so as to be **qualified**, a document with the following minimum information:

- 1 - Laboratory name, address, telephone, fax, E-mail, official's name.
- 2 - General area of expertise, number of employees by area of expertise, number of analyses per year.
- 3 - Accreditation(s): indicate the accreditation programme(s), provide the accreditation certificate and its technical appendix (this appendix must mention the reference method for the analysis corresponding to the area of qualification) (please see 4).
- 4 - Area of qualification requested: one reference method corresponds to one area.
- 5- Items allowing the Technical Board to judge whether the laboratory is capable of implementing the applicable validation protocol as outlined in Appendix 1 of the certification rules.
As an example, the laboratory will have to present the following items (non-exhaustive list): experience in the organisation of inter-laboratory studies, access to a culture collection comprising the main species and serotypes to be tested at the time of the studies, capacity to stress bacteria according to the required methods, skills in statistics, etc.

This document is presented by the candidate laboratory's representative during a Technical Board session. The Technical Board gives its opinion on whether the laboratory qualifies.

If this opinion is positive, the approved laboratory is invited by AFAQ AFNOR Certification to attend a subsequent Technical Board session as an observer so as to become familiar with the issues raised during the meetings and how dossiers are presented within the Technical Board.

At the end of this observation session, the AFAQ AFNOR Certification Director General qualifies the laboratory.

A qualified approved laboratory does not have to present a dossier for each specific study, unless the study is outside of the area of qualification which was originally requested.

If the laboratory loses its accreditation, it will automatically lose its AFNOR VALIDATION qualification.