## Application for new method

**Application for certification of**

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| **Name of product** |  |
| **Application date** |  |

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| 1. | Company name (to appear on certificate): | |  | |
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| 2. | Contact person (name and title): | | | |
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| 3. | Address (to appear on certificate): | | | |
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| 4. | VAT number (for EU countries only): | | | |
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| 5. | Postal address (for billing; if different from 3.): | |  | |
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| 6. | Phone no.: |  | | |
| 7. | email address: |  | | |
| 8. | Producer (name, address, phone number, fax number, email address): | | | |
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| 9. | Name of producer quality system (e. g. ISO 9000)\* / certification body: | | | |
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| 10. | Description of method/brand: | | | |
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| 11. | Product type/catalogue number (if any): | | | |
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| 12. | Analytical parameter/microorganisms: | | | |
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| 13. | Short description of the principle of the method: | | |  |
|  | (Please enclose full method description, Encl. 1) | | | |
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| 14. | Field of application (which matrices): | | | |
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| 15. | Any reference method (number and name of the standard)? | | | |
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| 16. | Any validation data available? Please state the type of validation and the laboratory that conducted the tests (please enclose available validation reports, Encl. 2) | | | |
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| 17. | If the applicant (see Paragraph 1) is not the producer (see Paragraph 6) of the proprietary method, do the applicant and the producer have equal rights to use the available and future validation data? | | | |
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| 18. | Expert laboratory to carry out the validations (name of the laboratory, and name and email address to the contact person) | | | |
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| 19. | Do you apply for a harmonised study with AOAC INTERNATIONAL or MicroVal (microbiolgical methods)? Yes/ No | | | |
|  | Yes  No | | | |

**Ownership and confidentiality**

The members of the steering group and the members of the technical committees of NordVal International handle the application and the associated documentation with confidentiality. They may not have any economic interests in the company of the applicant or in any competing businesses. NordVal International can describe the principle of the method and the results of the validation studies in the NordVal Certificate. The applicant makes the agreement with the expert laboratory. The laboratory is approved by NordVal International.

**Procedure**

The validation of microbiological methods shall be carried out according to the NordVal International Protocol No. 1 or ISO 16140-2:2016. The validation of chemical methods shall be carried out according to the NordVal International Protocol No. 2.

* The applicant completes the application form. \*For microbiological methods documentation of certification of the production process valid for the validity period of the NordVal certificate must be attached.
* The applicant forwards the study plan to NordVal International for approval.
* NordVal International reviews and approves the study plan.
* The expert laboratory performs the comparison study.
* The applicant forwards the report of the comparison study to NordVal International.
* NordVal International reviews the report of the comparison study and forwards the conclusions thereof to the applicant.
  + If the results of the study are satisfactory, the expert laboratory can carry on with the interlaboratory study.
  + If the results are not satisfactory, there is no need to carry out an interlaboratory study as a certificate cannot be issued.
* The applicant appoints and makes arrangement with appropriate participating laboratories for the interlaboratory study.
* The applicant forwards the report of the interlaboratory study and the package insert of the product to NordVal International.
* NordVal International reviews the report and other documentation.
  + If the results of the study are satisfactory and the package insert describes the method’s performance adequately, NordVal International issues a certificate
  + If the results are not satisfactory, a NordVal certificate cannot be issued.

**Payment**

The fees for NordVal International certifications are indicated in the price list on the website.

Invoice will be forwarded along with the certificate. The NMKL host organization, Institute of Marine Research, Norway, handles the invoicing.

If NordVal International finds the results of the comparison study not satisfactory, and a certificate cannot be issued, the applicant pays 2/3 of the fee.

If NordVal International finds the results of the interlaboratory study not satisfactory, and a certificate cannot be issued, the applicant pays the entire fee.

The applicant can terminate the certification process at any time. As technical experts have to be called upon for reviews of study plan, comparison study and interlaboratory validation study, the applicant has to pay 1/3, 2/3 or 3/3, respectively, of the fee, depending on at which stage the process is terminated.

Important information about payments and invoicing for NordVal International services:

The prices listed are exclusive VAT.

For customers representing companies registered in Norway: NMKL – NordVal International is obliged by Norwegian law to add 25% VAT to the invoice.

For customers representing companies registered in other countries than Norway: the customers themselves are responsible for accounting for VAT according to their governmental laws and legislations.

Customers are encouraged to investigate whether their governmental laws allow for VAT deduction in accordance with the use of the product or its resale.

**The certificate**

The secretariat of NordVal International drafts the certificate. The certificate shall include certification number, approval date and expiry date, name and address of the applicant, a reference to the reference method, the principle of the alternative method, and the results of the validation studies. The applicant is invited to comment on the certificate. The certificate is published on the website of NMKL/NordVal International, and announced in a NMKL newsletter.

The applicant must always, and without delay, inform NordVal International of any changes that affect its ability to conform with the certification requirements. The applicant must keep record of all complaints made known to the applicant and any deficiencies found in products that affect compliance with the requirements for certification and take appropriate action.

**Renewal of certificate**

The certificate is valid for two years. The secretariat sends a renewal form 4-6 months before the certificate expires. The applicant shall specify in the form whether or not the method and the package insert have been changed since last approval. The NordVal International steering group evaluates these changes – if any – and decides to which extent new comparative and collaborative studies should be carried out.

If the reference method used for the validation has been changed since last approval the NordVal International steering group evaluates these changes and decides to which extent new comparative and collaborative studies should be carried out.

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| **Place, Date** | **Signature / e-signature** |