Bundesverband
Naturkost Naturwaren e. V.

Guidelines for laboratory approval of the BNN e.V.

Applies from 01.01.2021 / Version of 09.02.2021 (changes / additions to the previous version: highlighted in YELLOW)

The results of laboratory analyses, together with the interpretation and recommendations derived from them, form the basis for many important company decisions. Therefore, the reliability of the analytical results is of central importance, especially for organic products.
Consequently, a laboratory approval for pesticide analyses of organic products has been developed in order to ensure a quality standard as uniform as possible within the framework of the BNN monitoring for fruit and vegetables with regard to analysis and evaluation of pesticide levels in organic products. The success of this measure in fruit and vegetable monitoring has awakened the need to extend laboratory approval to other product groups and, where appropriate, to other analysis parameters. For this reason, laboratory approval was put on a new basis at the beginning of 2012. After 8 years, the laboratory approval was evaluated again in 2020 and modified in some points or adapted to the experiences of the last years and current developments.

The applicability of this version of the guidelines for laboratory approval of the BNN e.V. starts as from ***01.01.2021.***

Existing approvals will be adapted to the new version during 2021. New applications and applications for renewal of approval will be carried out in accordance with this version of the guidelines from 01.10.2020.

The focus of the approval continues to be on the implementation of special competence tests, which are made obligatory by the BNN and above all take into consideration the special features of organic products (e.g. pesticide concentrations at very low levels, no announcement of test samples, verification of evaluation competencies according to BNN requirements). The basis for approval is a detailed documentary check based on clearly and unambiguously defined criteria (see "*Laboratory requirements when applying for approval*").

A laboratory approval, once granted, is in general limited to three years. Thereafter, re-approval is required, which includes a simplified document review and an evaluation of the results of the competence tests achieved in the previous three years (see "*Requirements for re-approval*"). Within the 3-year periods, defined conditions for maintaining approval must be met (see: "*Conditions for keeping laboratory approval*").

1. Application procedure

The company Lach & Bruns Partnership takes over the content-related and organisational handling of the laboratory approval on behalf of the BNN e.V. The application for laboratory approval is sent electronically to BNN-Laboranerkennung. For this purpose, the "*Registration Form_EN_BNN_2021.pdf*" and the required documents must be enclosed.
Finally, the Lach & Bruns Partnership will make a recommendation to the Bundesverband Naturkost Naturwaren (BNN) e.V. After a positive approval, the laboratory will be informed in writing about the approval, and the name of the laboratory will be published on the BNN website "www.n-bnn.de".

The costs for the application are listed in the document "Fee schedule BNN- lab approval 01.10.2020.pdf". The costs are charged in advance and are also due if the application is rejected and the contract is not concluded.

The laboratory approval within the framework of BNN e.V. consists **of two analytical areas**:

- **Pesticide analysis** (area A) and
- **Analysis of contaminants** (area B).

1.1. Area A) Pesticide analysis

Laboratory approval in this area is **modular**. The individual modules each represent different product groups.

M1: Fruit and vegetables (fresh and processed)
M2: Cereals and cereal products, rice, pulses
M3: Oilseeds and vegetable oils and fats
M4: Tea, fruit and herbal tea, dried herbs and spices
M5: Honey and bee products

1.2. Area B) Analysis of contaminants

Laboratory approval in this area is structured according to **substance groups**. These groups are - in contrast to pesticide approval - not further subdivided in terms of product groups. An approval for one of the substance groups below therefore includes all product groups.

S1: Mycotoxins
S2: Pyrrolizidine alkaloids (PA) / Tropane alkaloids (TA)
S3: Metals and other elements
S4: Phthalates and other plasticisers
S5: PAH and MOSH/MOAH
S6: Dioxins and PCBs

2. Laboratory requirements at the time of application

2.1. Area A) Pesticide analysis

1. Laboratories must have EN/ISO/IEC 17025 accreditation in the field of pesticide residue analysis for at least the following methods or groups of substances. Approval is not possible if the procedures listed below are subcontracted to other laboratories.

   M1: Fruit and vegetables (fresh and processed)
   - **Pesticide multi-method:** both GC-MS/MS- and LC-MS/MS determination, e.g. EN 15662 (QuEChERS)
   - **Polar Pesticides:** at least Chlormequat, Ethephon and Phosphonic acid
   - **Phenoxycarboxylic acids** (including alkaline hydrolysis as additional step)
   - **Dithiocarbamates**, e.g. EN 12396-1,-2,-3

   M2: Cereals and cereal products, rice, pulses
   - **Pesticide multi-method:** both GC-MS/MS- and LC-MS/MS determination, e.g. EN 15662 (QuEChERS)
   - **Polar Pesticides:** at least Chlormequat and Glyphosate incl. AMPA
   - **Phenoxycarboxylic acids** (including alkaline hydrolysis as additional step)

   M3: Oilseeds and vegetable oils and fats
   - **Pesticide multi-method:** both GC-MS/MS- and LC-MS/MS determination, e.g. EN 15662 (QuEChERS)
   - **Phenoxycarboxylic acids** (including alkaline hydrolysis as additional step)

M4: Tea, fruit and herbal tea, dried herbs and spices

- **Pesticide multi-method:** both GC-MS/MS- and LC-MS/MS determination, e.g. EN 15662 (QuEChERS)
- **Nikotin**

M5: Honey and bee products

- **Pesticide multi-method:** both GC-MS/MS- and LC-MS/MS determination, e.g. EN 15662 (QuEChERS)
- **Polar Pesticides:** Glyphosate

The related evidence must be submitted (documents with technical annexes).

2. The relevant pesticide multi-method must have been established for at least three years with regard to accreditation and routine use in food testing in the laboratory with a proven track record. The laboratories must submit lists of active substances and their reporting limits, if necessary specifically per module. It is checked whether these lists and the reporting limits correspond to the state of the art.

3. The successful participation in at least three qualified ring tests or competence tests in the respective food modules (M1, M2, ...) applied for within the last 24 months is a prerequisite for approval. The results obtained, the measures derived from them and, on request, the laboratory data must be submitted. If possible, the ring tests should cover all procedures or substance groups listed in the respective modules. If this is not the case when the application is submitted, participation in the missing procedures or substance groups can be formulated as a condition to be fulfilled within a set period of time.

   All three participations must be successfully passed. This is the case if:
   - no false positive result was reported,
   - no false negative result was reported,
   - at least 75% of the reported results were evaluated as successfully passed according to the specifically defined criteria of the BNN. As a rule, the criterion of "accuracy" is the most important statement regarding laboratory competence in pesticide analysis. Therefore, as far as technically possible, a result in the range of 70 to 120 % of the spiked level is applied as success criterion. A prerequisite for this is that the respective provider of the interlaboratory test discloses the spiked levels. ***Results of interlaboratory comparisons without indication of the spiked levels can therefore usually not be considered***.

4. The test reports must indicate the reporting limits and the current EU maximum levels for identified and quantified levels of active substances. The test reports must also contain an assessment in accordance with the currently valid EU maximum levels (Regulation (EC) No. 396/2005) as well as in accordance with the current requirements of the BNN orientation value. If an assessment or interpretation is made in a test report with regard to the BNN orientation value, **the following scheme must be used** – either as an integral part of the test report or as an annex/attachment to the corresponding test report:

Evaluation of the findings according to the BNN-orientation value in the currently valid version	
Orientation value for individual substances passed (≤ 0,010 mg/kg*)	*YES / NO*
Orientation value for individual substances passed when considering the expanded measurement uncertainty of ± 50% (≤ 0,021 mg/kg*)	*YES / NO*
Maximum number of individual substances passed (max 2 single substances ≥ 0.010 mg/kg* WITHOUT consideration of the expanded measurement uncertainty of ± 50%)	*YES / NO*

* insofar as no other interpretation rules or explanations by BNN e.V. exist

Where a conversion factor is applied, the following schedule shall apply:

Evaluation of the findings according to the BNN-orientation value in the currently valid version	
Orientation value for individual substances passed, using a conversion factor (≤ 0,010 mg/kg*)	*YES / NO*
Orientation value for individual substances passed when considering the expanded measurement uncertainty of ± 50%, and by applying a conversion factor (≤ 0,021 mg/kg*)	*YES / NO*
Maximum number of individual substances passed by applying a conversion factor (max 2 single substances ≥ 0.010 mg/kg* WITHOUT consideration of the expanded measurement uncertainty of ± 50%)	*YES / NO*
Conversion factor (f. ex. according to BNN publication in the currently valid version on pesticide levels in dried organic products)	*Numerical value of the conversion factor*

* insofar as no other interpretation rules or explanations by BNN e.V. exist

5. All documents must be submitted in German or English; if necessary, a translation of all documents must be enclosed.

6. If the submitted documents are not complete or not sufficient for a final evaluation, they will be requested subsequently. Documents will be requested a maximum of twice. If, after two requests for additional documents, no complete or meaningful documents have been submitted, this will lead to a rejection of the application for approval.

7. Finally, if the requirements for analytical competence mentioned under the above points are met, the assessment/interpretation competence with regard to pesticide levels in organic food is checked. The laboratory is informed of (fictitious) pesticide findings in organic food (depending on the module), which are to be assessed by the laboratory. Exemplary test reports are requested in which the respective assessments of the findings must be included (see above under point 4.) These assessments are checked and evaluated within the framework of the BNN laboratory approval. In addition, each laboratory must name a person responsible for the "organic" sector, who is named as contact person on the BNN website.

After completion of the reviews of the above-mentioned requirements, a recommendation will be made as to whether or not the laboratory should receive approval from the BNN e.V. office for the modules or substance groups applied for. If the application or parts of the application are accepted (e.g. only for certain modules or substance groups) the laboratory will be informed in writing and the requirements and conditions will be communicated in order to maintain the approval. If the application or parts of the application are rejected, the laboratory will be informed about the reasons for this rejection.

2.2. Area B) Analysis of contaminants

1. Laboratories must have EN/ISO/IEC 17025 accreditation in the field of contaminant analysis for the following analytical methods:
   S1: Mycotoxins:
   at least Aflatoxins / Ochratoxin A / Desoxynivalenol (DON) / Zearalenon (ZEA)
   S2: Pyrrolizidine alkaloids (PA) / Tropane alkaloids (TA)
   S3: Metals and other elements (at least lead, cadmium, arsenic und copper)
   S4: Phthalates and other plasticisers
   S5: PAH and **MOSH/MOAH**
   S6: Dioxins and **PCBs**

   The related evidence must be submitted (documents with technical annexes).

2. The respective methods must have been established for at least 3 years with regard to accreditation and routine use in food testing in the laboratory and must be verifiable. The laboratories shall submit lists of the analytes and their reporting limits for review. It is checked whether these lists and the reporting limits correspond to the state of the art. If quality criteria for the analysis of contaminants are laid down in a corresponding EU regulation, compliance with these criteria must be documented by submitting appropriate, meaningful documentation.

3. The successful participation in at least two qualified ring tests or proficiency tests for each of the following within the last 24 months: mycotoxins (at least for aflatoxins / ochratoxin A / deoxynivalenol / zearalenone), heavy metals (at least for lead, cadmium, copper), phthalates (plasticisers), PAH or MOSH/MOAH as well as dioxins/dl-PCB. The results obtained, the measures derived from them and, on request, the laboratory data must be submitted.
   All participations must be successfully passed. This is the case if at least 75% of the reported results have been evaluated as successfully passed according to the criteria of the respective ring test provider (e.g. 3 out of 4 results).

4. The test reports must indicate the reporting limits and the applicable EU maximum levels or limits for identified and quantified levels of contaminants. The test reports must also include an assessment according to the current requirements of the BNN e.V., if applicable (e.g. for plasticisers in vegetable oils).

5. All documents must be submitted in German or English; if necessary, a translation of all documents must be enclosed.

6. If the submitted documents are not complete or not sufficient for a final evaluation, they will be requested subsequently. Documents will be requested a maximum of twice. If, after two requests for additional documents, no complete or meaningful documents have been submitted, this will lead to a rejection of the application for approval.

7. Finally, if the requirements for analytical competence mentioned under the above points are met, the assessment competence with regard to organic food legislation is checked. For this purpose, exemplary test reports with defined specifications are requested and the respective assessments are evaluated (according to currently valid EU regulations or BNN guidelines/specifications). In addition, each laboratory must name a person responsible for the "organic" sector, who is named as contact person on the BNN website.

After completion of the reviews of the above-mentioned requirements, a recommendation will be made as to whether or not the laboratory should receive approval from the BNN e.V. office for the modules or substance groups applied for.

If the application or parts of the application are accepted (e.g. only for certain substance groups) the laboratory will be informed in writing and the requirements and conditions will be communicated in order to maintain the approval. If the application or parts of the application are rejected, the laboratory will be informed about the reasons for this rejection.

3. Conditions for keeping laboratory approval

3.1. Area A) Pesticide analysis

For each approved module (M1, M2, M3, M4, M5) and calendar year, participation in a competence test of an external provider, which is precisely specified and named by BNN e.V., is binding. If BNN e.V. conducts its own competence test in one of the 5 modules, the obligation to participate in an external competence test does not apply to the respective module in that calendar year. The required participation in the interlaboratory comparison will be communicated to the laboratories at least 2 months before the start of the respective competence test. The laboratories must actively register themselves with the external proficiency testing provider and bear the costs themselves. Participation in ring tests / proficiency tests other than those designated by the BNN e.V., is not relevant for laboratory approval and therefore does not have to be reported.

Each laboratory must submit the following documents for the respective approved modules by **15 March of each calendar year** without being asked:

- Results and evaluations as well as any necessary quality assurance measures according to the participation in the interlaboratory comparisons or competence tests specified by BNN e.V. from the previous calendar year.

On the same date (15 March of each calendar year), information must be provided on whether significant changes relevant to the approval have occurred (e.g. change in essential personnel functions, use of new instrumental equipment, changes in the scope of analytical methods, changes in the scope of active substances of multi- or group-methods, ...).

BNN Competence Tests
If the BNN performs its own laboratory competence test for the respective module combination, participation in it is obligatory for all laboratories approved for the respective module. A fee is charged for the organisation, implementation and evaluation (see " Fee schedule BNN- lab approval 01.10.2020.pdf").

The participation(s) in the competence tests prescribed by BNN e.V. or carried out by the association itself must be successfully passed. This is the case if:

- no false positive result was reported,
- no false negative result was reported,
- at least 75% of the reported results were evaluated as successfully passed according to the specifically defined criteria of the BNN. As a rule, the criterion of "accuracy" is the most important statement regarding laboratory competence in pesticide analysis. Therefore, as far as technically possible, a result in the range of 70 to 120 % of the spiked level is applied as success criterion.

In case of repeated failure to meet the requirements, re-approval is not possible after the 3-year period.

3.2. Area B) Analysis of contaminants

By 15 March of each calendar year, each laboratory must submit the following documents for the respective approved groups of substances without being asked:

Results and evaluations as well as any necessary quality assurance measures of participation in corresponding external competence tests from the previous calendar year. Documents must be submitted for **at least one competence test of the substance classes**

- Mycotoxins (at least for Aflatoxins / Ochratoxin A / Desoxynivalenol, Zearalenon),
- PA (pyrrolizidine alkaloids) or TA (tropane alkaloids): annually alternating,
- Metals (at least for lead, cadmium, arsenic, copper),
- Phthalates (plasticisers),
- PAH resp. MOSH/MOAH: annually alternating,
- Dioxins and PCBs,

if an approval exists for the respective substance class.

At least 75% of the reported results must have been successfully passed according to the specifically defined criteria of the competence test provider. As a rule, "comparability" is the relevant criterion (z-score evaluation with the requirement $|z| \leq 2$).
If this requirement is repeatedly not met, re-recognition is not possible after the 3-year period.

On the same date (15 March of each calendar year), information must be provided as to whether significant changes relevant to approval have occurred (e.g. changes in essential personnel functions, use of new instrumental equipment, changes in the scope of analytical methods, etc.).

4. Requirements for re-approval

After 3 years from the date of approval granted by the BNN, the laboratory must submit updated documentation as part of a re-approval procedure. This includes all items listed at "Laboratory requirements at the time of application" with the exception of the participation in ring tests. When assessing the application for re-approval, the results of participation in the interlaboratory tests/competence tests specified by the BNN e.V. from the past three years as well as the results of participation in the competence tests organised and carried out by the BNN itself are taken into consideration in particular.

After completion of the reviews of the above-mentioned requirements, a recommendation will be made as to whether or not the laboratory should receive approval for the modules or substance groups applied for from the office of BNN e.V. for a further 3-years period. The laboratory will be informed in writing and the requirements and conditions to be followed to maintain the recognition will be communicated. In case of refusal, the laboratory will be informed about the reasons.