

Guidelines for laboratory approval by Bundesverband Naturkost Naturwaren (BNN) e.V. (Federal Association for Natural Foods and Natural Products inc. soc.)

Editorial revision 01 September 2015

The results of lab analyses together with the interpretation and derived recommendations form the basis for many far-reaching company decisions. Therefore, reliability of the analysis results has central meaning, also and especially for organic products.

Consequently, a laboratory approval in context of the analysis and interpretation of pesticide contents in context of the BNN monitoring of fruit and vegetables has been developed for pesticide analyses of organic products in order to ensure a quality standard as uniform as possible. The success of this measure for fruit and vegetable monitoring has prompted the need for expansion of the lab approval to also include other product groups and, as applies, additional analysis parameters. For this reason the lab approval will be set on a new basis in the beginning of the year 2012.

The evaluation of the analytical competence thus far has depended in its focus on an assessment of the labs' participation in lab competence tests by appropriate providers. This will now be expanded by conducting special aptitude tests that are bindingly required by BNN and which most of all take the particularities of organic products into account (e.g. pesticide contents in very low concentrations, no advance notice for test samples).

Basis for the approval continues to be an elaborate document review by means of clearly and unequivocally defined criteria (see "*Lab requirements for application*"). Approval also includes the review of the interpretation competence.

A lab approval once granted is generally limited to three years. Thereafter a re-approval is necessary, which includes a simplified document review as well as an evaluation of the results achieved in competence reviews in the preceding three years (see *Requirements for re-approval*). Within the 3-year periods, defined requirements for maintaining the approval have to be fulfilled (see: *Requirements for maintaining the lab approval*).

The lab approval in the framework of BNN is a modular system consisting of two columns: Column A) Parameter groups, and Column B) Food groups.

These are sectioned as follows:

A1: Pesticides

A2: Contaminants (e.g. mycotoxins, heavy metals, PAH, softeners ...)

A4: Dioxins and dioxin-like PCB (polychlorinated biphenyls)

The following parameter groups are currently not being offered yet:

A3: *Microbiological and molecular-biological parameters*

B1: Fresh fruit and vegetables

B2: Processed fruit / vegetable (e.g. raisins, dried fruit, dried vegetables, juices, etc.)

In case of an application and consequent BNN approval for module combination Pesticides (A1) / Fresh Fruits and Vegetables (B1), the combination A1/B2 (Pesticides / Processed Fruit and Vegetables) is consequently granted, too.

B3: Cereals and cereal products, rice, oil seeds as well as vegetable oils and vegetable fats
 B4: Tea and fruit teas, spices
 B5: Food on animal basis (meat, sausage products, eggs, milk and dairy products ...)

Approval can be applied for and granted optionally, however a relation between the two columns must always be present (e.g. A1/B1: Approval for pesticide analytics in fresh fruit and vegetables; sole approval for A1 "Pesticides" is not possible.)

Lab requirements for application

Module A1: Pesticides

1. Labs must have a method-accreditation according to EN/ISO/IEC 17025 in the field of pesticide residue investigation for at least the following analytical procedures:
 - **Pesticide multi-method:** using both GC- as well as LC-MS/MS detection, e.g. ASU §64 LFBG L-00.00-34 (DFG S 19) or L-00.00-113 (BfR method) or L-00.00-115 (QuEChERS)
 - **Inorganic total bromide**, e.g. EN 13191-2 or ASU § 64 LFBG L-00.00-36
 - **Dithiocarbamates**, e.g. EN 12396-1,-2,-3 or ASU § 64 LFBG L-00.00-35
 - at least one of the following group or individual methods:
 - Ethephon**
 - Chlormequat/Mepiquat**
 - Phenyl urea** (urone and its respective aniline metabolites) or
 - Phenoxy alcan carbon acids** / Acidic herbicides (including their respective derivatives and metabolites if relevant).

The corresponding verifications are to be submitted (certificates with technical annexes.)

2. The respective pesticide multi-method must be verifiably established since at least 3 years at the lab regarding the accreditation and in routine application for food testing. For the review the labs will present lists of the active substances and their detection limits. It will be reviewed, if these lists and the detection limits conform to the state of the art. The lists are to be submitted separately for all applied for food modules (B1, B2, ...). The range of active substances in context of the multi-method(s) must be clearly defined and include at least 300 active substances, which are proven to be validated or verified for analytical quality assurance by the lab in the context of its activities.
3. Successful participation in qualified ringtests or competence tests respectively in each of the applied for food modules (B1, B2, ...) is a prerequisite for approval. For fresh fruit and vegetables (B1, including automatically B2) at least three successful participations within the last 18 months are required, for modules B3 and B4 two participations within the last 24 months are sufficient. The results achieved, the measures derived and lab data, if requested, must be submitted.

All three participations must have been passed successfully. This is the case if:

- no wrong positive value has been reported,

- no wrong negative value has been reported,
 - at least 75% of the reported results have been evaluated as passed according to the respective specifically defined criteria of BNN (e.g. 3 of 4 results). As a general rule, the trueness-criterion is considered most important related to the assessment of the laboratories' competencies in pesticide residue analysis. As a conclusion, a laboratory's result is considered satisfying in case of covering a range of 70 – 120% of the spiked pesticide level. The achievement of satisfying results should be (of course) technically achievable. Consequently, an important prerequisite for the application of the trueness-criterion is the publication of the spiked levels by the corresponding ring test provider. Ring test reports and thus the corresponding results of the participating laboratory can therefore not be considered for the BNN approval in general, in case of the publication of the spiked levels is NOT provided.
4. The detection limits and the valid EU maximum contents for identified and quantified contents of active substances must be shown in the test reports. Labs outside of the EU must also state the respectively valid EU maximum contents. The test reports must further contain an evaluation according to the current requirements of the BNN reference value.
 5. All documents must be submitted in German or English language, as applies a translation of all documents has to be enclosed. If the submitted documents are not complete or not adequate for a conclusive evaluation, they will be requested in supplementation. A supplemental request for documents will be made maximally two times. Insofar as no complete or definitive documents are submitted after the two-time request for supplementation, such will lead to a rejection of the application for approval.
 6. If the requirements for analytical competence as set forth in above paragraphs are fulfilled, the interpretation competence relating to pesticide contents in organic foodstuffs will be reviewed in the last step. For this purpose three example test reports with defined prerequisites will be requested from the lab and the respective interpretations will be assessed. Moreover, a person responsible for the "organic" field must be named by every lab. The responsible person will be interviewed (generally by phone) in order to evaluate competence in this aspect. The review and thus also approval of the interpretation competence of laboratories outside of the German-language area will only be made, if there are no language barriers, which means that it will be done if the lab staff who is responsible for the organic evaluation has competent knowledge of the German or English language.

After conclusion of the reviews as to aforementioned requirements, a recommendation will be made whether the lab should receive approval from the offices of BNN e.V. for the applied module combinations or not. If the approval is granted for the application or parts of the application (e.g. for certain module combinations) the lab will be notified in writing and requirements and sanctions to be observed for maintaining the approval will be communicated. If the application or parts of the application is refused the lab will be notified of the reasons.

Module A2: Contaminants

1. Labs must have a method accreditation according to EN/ISO/IEC 17025 in the field of contaminants analytics for at least the following analysis procedures:
 - a. **mycotoxins** (at least for 2 subgroups):
aflatoxins / ochratoxin A / deoxynivalenol (DON) / zearalenone (ZEA) / fumonisins B1 and B2 / toxin T-2 and HT-2
 - b. **heavy metals** (lead and cadmium)
 - c. at least one of the following group or individual methods:
nitrate
phthalates (plastic softeners)
polyaromatic hydrocarbons (PAH)

The corresponding verifications are to be submitted (certificates with technical annexes.)

The following module-combinations (group of analytes / food groups) are recommended for application (together) and are thus evaluated as one approval:

Combination 1:

A2 (Contaminants) – **B1/B2** (Fresh fruits and vegetables including dried fruits)

→ relevant analytes like f. ex. Aflatoxins B+G, Ochratoxin A, Heavy Metals (Pb and Cd), Nitrate

Combination 2:

A2 (Contaminants) – **B3/B4** (Cereals and cereal products, rice, oil seeds, vegetable oils and fats / tea, fruit teas, spices) → relevant analytes like f. ex. Mycotoxins, Heavy Metals (Pb and Cd), Phthalates, PAH

Combination 3:

A2 (Contaminants) – **B5** (Food on animal basis like f. ex. milk, meat and meat products, fish and fish products) → relevant analytes like f. ex. Aflatoxin M1, Heavy Metals (Pb and Cd), Phthalates, PAH

For each application and the annual fee, a corresponding charge of one A/B module will have to be paid. In case of approval for more / additional combinations, the charge will be the sum of all combinations for which the laboratory applies.

2. The respective methods must be verifiably established since at least 3 years at the lab regarding the accreditation and in routine application in food testing. The labs will present lists of the analytes and their detection limits for review. It will be reviewed, if these lists and the detection limits conform to the state of the art. The lists are to be submitted separately for all applied for food modules (B1, B2, ...). The quality criteria according to the requirements of the Directives (EC) No. 401/2006 (mycotoxins), (EC) No. 1882/2006 (Nitrate) and the Guidelines 2001/22/EC (heavy metals) and 2005/10/EC (PAH) (respectively corresponding with the current amending regulations / directives or succession requirements) have to be adhered to and must be verified.
3. Successful participation in at least two qualified ringtests or competence tests each for mycotoxins and heavy metals as well as successful participation in at least one ring/lab competence test in the field of nitrate or phthalates or PAH in the respectively applied combinations 1 and/or 2 and/or 3 (see above) within the last 24 months are prerequisites for the approval (insofar offered). The results achieved, the measures derived and the lab data, if requested, must be submitted.

All participations must have been passed successfully. This is the case when at least 75% of the reported results have been evaluated as passed according to the respective specifically defined criteria of ring test provider (e.g. 3 of 4 results).

4. The detection limits and the valid EU maximum contents or threshold values for identified and quantified contents of contaminants must be shown in the test reports. Labs outside of the EU must also state the respectively valid EU maximum contents. The test reports must further contain an evaluation according to the current requirements of the BNN reference value, to the extent that these are applicable (e.g. for softeners in oils.)
5. All documents must be submitted in German or English language, as applies a translation of all documents has to be enclosed. If the submitted documents are not complete or not adequate for a conclusive evaluation, they will be requested in supplementation. A supplemental request of documents will be made maximally two times. Insofar as no complete or definitive documents are submitted after the two-time request for supplementation, such will lead to a rejection of the application for approval.
6. If the requirements to the analytical competence as set forth in above paragraphs are fulfilled, the interpretation competence relating to bio foodstuffs will be reviewed in the last step. For this purpose, example test reports with defined prerequisites will be requested from the lab and the relevant interpretations will be assessed. Moreover, a person responsible for the "organic" field must be named by every lab. The responsible person will be interviewed (generally by phone) in order to evaluate competence in this aspect.

After conclusion of the reviews as to aforementioned requirements, a recommendation will be made whether the lab should receive approval from the offices of BNN e.V. for the applied module combinations or not. If approval is granted for the application or parts of the application (e.g. for certain module combinations) the lab will be notified in writing and requirements and sanctions to be observed for maintaining the approval will be communicated. If the application or parts of the application is refused the lab will be notified of the reasons.

Module A3: Microbiological and molecular-biological parameters

Not yet defined.

Module A4: Dioxins and dioxin-like PCB

Possible module-combination (group of analytes / food groups):

A4 Dioxins and dioxin-like PCB - **B5** Food on animal basis

1. Labs must have a method-accreditation according to EN/ISO/IEC 17025 in the field of the determination of mass concentrations of PCDDs and PCDFs as well as dioxin-like PCB and non-

dioxin-like PCBs in vegetable and animal oils and fats as well as in food products. The corresponding verifications are to be submitted (certificates with technical annexes.)

2. The respective methods must be verifiably established since at least 3 years at the lab regarding the accreditation and in routine application for food testing. The requirements related to the performed analysis, which are laid down in corresponding regulations and documents (f. ex. Regulation (EU) Nr. 252/2012 , RL 2002/69/EG und Doc. SANCO 11562/2013, respectively corresponding with the current amending regulations / directives or succession requirements), must be met and they must be verifiable.
3. Successful participation in at least two qualified ringtests or competence tests of the relevant food module B5 within the last 24 months is a prerequisite for approval. The results achieved, the measures derived and lab data, if requested, must be submitted. All two participations must have been passed successfully. This is the case if at least 75% of the reported results have been evaluated as passed according to the applied assessment criteria of the corresponding proficiency test organisation.
4. All documents must be submitted in German or English language, as applies a translation of all documents has to be enclosed. If the submitted documents are not complete or not adequate for a conclusive evaluation, they will be requested in supplementation. A supplemental request for documents will be made maximally two times. Insofar as no complete or definitive documents are submitted after the two-time request for supplementation, such will lead to a rejection of the application for approval.
5. If the requirements for analytical competence as set forth in above paragraphs are fulfilled, the interpretation competence relating to pesticide contents in organic foodstuffs will be reviewed in the last step. For this purpose example test reports with defined prerequisites will be requested from the lab and the respective interpretations will be assessed. Moreover, a person responsible for the "organic" field must be named by every lab. The responsible person will be interviewed (generally by phone) in order to evaluate competence in this aspect.

After conclusion of the reviews as to aforementioned requirements, a recommendation will be made whether the lab should receive approval from the offices of BNN e.V. for the applied module combinations (A4/B5) or not. If the approval is granted for the application the lab will be notified in writing and requirements and sanctions to be observed for maintaining the approval will be communicated. If the application is refused the lab will be notified of the reasons.

Requirements for re-approval

Upon the expiration of 3 years after the approval granted by BNN, the lab has to submit updated documents on the relevant analysis methods in context of a re-approval procedure. This includes all items listed in "*Lab requirements for application*". In specific, the results of the participations in ring/competence tests from the past three years as well as the results of the participation in competence tests organised and conducted by BNN will be evaluated.

After conclusion of the reviews as to aforementioned requirements, a recommendation will be made whether the lab should receive approval from the offices of BNN e.V. for the applied for module

combinations for another three years or not. The lab will be notified in writing and requirements and sanctions to be observed for maintaining the approval will be communicated. In case of rejection the lab will be notified of the reasons.

Standing requirements for maintaining the lab approval

Every lab must present the following documents unrequested for each accepted module combination (e.g. A1/B1 "Pesticides in fresh fruit and vegetables") by the 1st of March of each calendar year:

- results and analyses for the participations in relevant ring or competence tests from the previous calendar year;
- overview of planning for the participation in relevant ring or competence tests in the current calendar year.

On the same due date a declaration has to be filed whether, and if so, which significant changes that are relevant for the approval (e.g. change of important staff positions, use of new instruments, changes in the analytical scope of methods, changes in the range of active substances of the multi or group methods,...)

If BNN conducts a lab competence test for the respective module combination, participation therein is obligatory once a year for all labs that have been accepted for the respective module combination. A fee will be charged for organisation, implementation and evaluation (see "*Fees*".)

The participation(s) must be passed successfully. This is the case if:

- no wrong positive value has been reported,
- no wrong negative value has been reported,
- at least 75% of the reported results have been evaluated according to the respective specifically defined criteria of BNN as successfully passed. (e.g. 3 of 4 results). As a general rule, the trueness-criterion is considered most important related to the assessment of the laboratories' competencies in pesticide residue analysis. As a conclusion, a laboratory's result is considered satisfying in case of covering a range of 70 – 120% of the spiked pesticide level. The achievement of satisfying results should be (of course) technically achievable. Consequently, an important prerequisite for the application of the trueness-criterion is the publication of the spiked levels by the corresponding ring test provider. Ring test reports and thus the corresponding results of the participating laboratory can therefore not be considered for the BNN approval in general, in case of the publication of the spiked levels is NOT provided.

In non-fulfillment of above aspects (results and planning of external round-robin tests; notification of relevant changes; unsuccessful participation in BNN competence tests) the lab will be given the opportunity for subsequent improvement. In case of repeated non-fulfillment of the requirement aspects (despite written request in each case) re-approval is not possible after the expiration of the 3-year period.

Fees

In the context of the lab approval by BNN e.V. the following fees will be incurred (all prices in addition to sales tax, see the document "Fee Rules for lab approval by BNN e.V.").