ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 6 October 2017

Addressee
[redacted]

Decision number: CCH-D-2114372331-57-01/F
Substance name: BORNAN-2-ONE
EC number: 200-945-0
CAS number: 76-22-2
Registration number: [redacted]
Submission number: [redacted]
Submission date: 12/03/2015
Registered tonnage band: 100-1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: Daphnia sp. Acute immobilisation test, EU C.2./OECD TG 202) with the registered substance;**

2. **Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Alga, growth inhibition test, EU C.3./OECD TG 201) with the registered substance;**

3. **Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: Fish, acute toxicity test, OECD TG 203) with the registered substance;**

4. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the registered substance;**

5. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance;**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.
You have to submit the information requested in this decision as follows:

a) Information request under points [1], [2] and [3] in an updated registration dossier by **15 October 2018.**

b) Information request under points [4] and [5]:

   a. If the information available from information requested under points [1] to [3] is sufficient to allow you to adapt the standard information requirements of Annex IX, Sections 9.1.5 and 9.1.6 based on an updated chemical safety assessment (CSA) in accordance with Annex IX, column 2 of section 9.1: the adaptation and, where relevant, an updated CSA addressing the information requirements in Annex IX, Sections 9.1.5 and 9.1.6, must be submitted in an updated registration dossier by **15 October 2018**

      OR

   b. If no such adaptation as stated above is available: the information requested must be submitted in an updated registration dossier by **13 January 2020.**

You also have to update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Short-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex VII, Section 9.1.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.3 by providing results obtained from the application of a quantitative structure activity relationship model ((Q)SAR):

- "*Short-term toxicity to aquatic invertebrates.001*", Meylan, W.M. and Howard, P.H. (2012), ECOSAR v1.1, result: 48 h LC50 9.303 mg/L.

ECHA has compared the QSAR information provided with the requirements set for acceptance of QSAR models in Annex XI, Section 1.3 as follows:

- Adequate and reliable documentation of the applied method is provided: whilst you have attached a (Q)SAR model reporting format (QMRF) to the IUCLID technical dossier, no (Q)SAR prediction reporting format (QPRF) has been submitted. The QPRF is prediction-specific and should be prepared by the registrant using the information in the software report and manual (ECHA Practical Guide 5 How to use and report (Q)SARs (version 3.1. July 2016)). As no QPRF has been submitted, ECHA hence considers that you have not provided adequate and reliable documentation of the QSAR method).
- Results are derived from a (Q)SAR model whose scientific validity has been established: the model is scientifically valid, however, as described below it is not suitable for the registered substance.
- The substance falls within the applicability domain of the (Q)SAR model: It is important to verify that the target substance falls within the applicability domain (AD) of the model as this indicates whether the substance can be covered by the data in the (Q)SAR training set (ECHA Practical Guide 5 How to use and report (Q)SARs (version 3.1. July 2016)). Predictions outside the AD are normally not reliable and their use is hard to justify (ECHA Practical Guide 5 How to use and report (Q)SARs (version 3.1. July 2016)). The prediction was inside the parametric domain for the model. However, the substance can be considered out of the structural domain, because the bornane- like methylene bridge of that target substance is not represented in any of the two training sets of the model. There is also a lack of close analogues which increases the uncertainty of the prediction. ECHA hence considers that the substance does not fall within the AD of the model.

- Results are adequate for the purpose of classification and labelling and/or risk assessment: ECHA notes that you have used the result obtained from this model for your PNEC derivation. As given above, the structure of the substance is not adequately represented in the training set of the model used, and there is thus considerable uncertainty with the predicted values, and consequently in the PNEC derivation. Considering the uncertainty of the prediction, and the relatively high RCRs for environment (0.7 in some exposure scenarios) reported in your CSA, ECHA considers that the prediction is not adequate for risk assessment.

In conclusion, the QSAR information submitted is not sufficient to fulfil the requirements of Annex XI, Section 1.3.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Daphnia sp. acute immobilisation test (test method EU C.2. / OECD TG 202) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.1.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *Daphnia* sp. Acute immobilisation test, EU C.2./OECD TG 202).

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Growth inhibition study aquatic plants" is a standard information requirement as laid down in Annex VII, Section 9.1.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.3 by providing results obtained from the application of a quantitative structure activity relationship model ((Q)SAR):

- *"Toxicity to aquatic algae and cyanobacteria.001"*, Meylan, W.M. and Howard, P.H. (2012), ECOSAR v1.1, result: 96 h EC50 6.951 mg/L.

ECHA has compared the QSAR information provided with the requirements set for acceptance of QSAR models in Annex XI, Section 1.3 as follows:

- Adequate and reliable documentation of the applied method is provided: whilst you have attached a (Q)SAR model reporting format (QMRF) to the IUCLID technical dossier, no (Q)SAR prediction reporting format (QPRF) has been submitted. The QPRF is prediction-specific and should be prepared by the registrant using the information in the software report and manual. (ECHA Practical Guide 5 How to use and report (Q)SARs (version 3.1. July 2016)). As no QPRF has been submitted, ECHA hence considers that you have not provided adequate and reliable documentation of the QSAR method.
- Results are derived from a (Q)SAR model whose scientific validity has been established: the model is scientifically valid, however, as described below it is not suitable for the registered substance.
- The substance falls within the applicability domain of the (Q)SAR model: It is important to verify that the target substance falls within the applicability domain (AD) of the model as this indicates whether the substance can be covered by the data in the (Q)SAR training set (ECHA Practical Guide 5 How to use and report (Q)SARs (version 3.1. July 2016)). Predictions outside the AD are normally not reliable and their use is hard to justify (ECHA Practical Guide 5 How to use and report (Q)SARs (version 3.1. July 2016)). The prediction was inside the parametric domain for the model. However, the substance can be considered out of the structural domain, because the bornane- like methylene bridge of that target substance is not represented in any of the two training sets of the model. There is also a lack of close analogues which increases the uncertainty of the prediction. ECHA hence considers that the substance does not fall within the AD of the model.
- Results are adequate for the purpose of classification and labelling and/or risk assessment: As given above, the structure of the substance is not adequately represented in the training set of the model used, and there is thus considerable uncertainty with the predicted values, and consequently in the assessment of aquatic risks. Considering the uncertainty of the prediction, and the relatively high RCRs for environment (0.7 in some exposure scenarios) reported in your CSA, ECHA considers that the prediction is not adequate for risk assessment.

In conclusion, the QSAR information submitted is currently not sufficient to fulfil the requirements of Annex XI, Section 1.3.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Algae growth inhibition test (test method EU C.3. / OECD TG 201) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.2.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Algae growth inhibition test, EU C.3./OECD TG 201).

3. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Short-term toxicity testing on fish" is a standard information requirement as laid down in Annex VIII, Section 9.1.3. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.2., weight of evidence. Hence, ECHA has evaluated your adaptation with respect to this provision.

In your technical dossier under IUCLID section 6.1.1. Short-term toxicity to fish you have submitted the following two study reports in a weight of evidence approach:

- "*Short-term toxicity to fish.001*", [redacted] (2001) "Handbook of Environmental Data on Organic Chemicals", Volumes 1-2. 4th ed[redacted]. 2001, p. 421. Study: OECD Guideline 203 (Fish, Acute Toxicity Test), reliability 2, GLP compliance "not specified", *Pimephales promelas*, static. Result: 96 h LC50 110 mg/L (nominal, mortality)

- "*Short-term toxicity to fish.002*", [redacted] (2001) "Handbook of Environmental Data on Organic Chemicals", Volumes 1-2. 4th ed. [redacted]. 2001, p. 421. Study: OECD Guideline 203 (Fish, Acute Toxicity Test), reliability 2, GLP compliance "not specified", *Danio rerio*, test type "not specified". Result: 96 h LC50 > 35 mg/L - < 50 mg/L (nominal, mortality)

ECHA acknowledges that you have intended to submit the results from these two studies in a weight of evidence (WoE) approach as made possible by the provisions of Annex XI section 1.2. In addition to the information given above, you have not provided any further information on the two studies submitted in a WoE approach. ECHA notes that an adaptation pursuant to Annex XI, Section 1.2. requires sufficient weight of evidence from several independent sources of information leading to the conclusion that a substance has or has not a particular dangerous property with respect to the information requirement in question including an adequate and reliable documentation while the information from each single source alone is regarded insufficient to support this notion.

ECHA notes that the OECD TG 203, based on which the two studies have been conducted, lists four validity criteria that need to be fulfilled for a study to be valid (paragraph 6 of the guideline); 1. The mortality in controls should not exceed 10 percent, 2. Constant conditions should be maintained as far as possible, 3. Dissolved oxygen concentration must be at least [redacted] % of air saturation value throughout the test and 4. There must be evidence that concentration of the test substance is maintained and preferably it should be at least [redacted] % of the nominal concentration throughout the test.

ECHA notes that in the respective endpoint study records you have not provided information on any of the above validity criteria, and you have also not indicated whether the validity criteria have been fulfilled. Therefore, the information provided in the study summaries is not sufficient for ECHA to decide on the validity of these data.
ECHA notes that while you have indicated that a weight of evidence approach has been submitted, you have not provided any explanation or justification on how the sources of information/studies that you have provided enable to conclude on the endpoint.

Furthermore, in the endpoint summary of Short-term toxicity to fish in IUCLID you have given an LC50 of 50 mg/L as the "Key value for chemical safety assessment". You provide no discussion in your technical dossier nor in the Chemical Safety Assessment on why you consider this value suitable to be used to conclude on this endpoint. ECHA notes that the relative values/weights of different pieces of the provided information needs to be assessed as indicated in ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.4., Section 4.4 (version 1.1, December 2011). In particular relevance, reliability and consistency of results/data and coverage (completeness) need to be considered.

As indicated above since you have not provided any explanation or justification on how the sources of information/studies, which you have provided enable to conclude on the endpoint or how you have selected the effect value used for the CSA, ECHA notes that adequate and reliable documentation as required according to annex XI section 1.2. is missing and it is not possible to to conclude with adequate confidence on the property of the registered substance with respect to the information requirement for Annex VIII, Section 9.1.3.

Therefore, the general rules for adaptation laid down in Annex XI, Section 1.2. of the REACH Regulation are not met and your adaptation of the information requirement is rejected.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) fish acute toxicity test (test method EU C.1. / OECD TG 203) is the preferred test to cover the standard information requirement of Annex VIII, Section 9.1.3.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, acute toxicity test (test method: EU C.1./OECD TG 203).

4. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.5., column 2. You provided the following justification for the adaptation: "*In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms*."

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.5., column 2 because as discussed in sections 1. to 3. above, the acute aquatic data you have used as basis for PNEC derivation and the current Chemical Safety Assessment (CSA) for environment cannot be considered reliable. Consequently the CSA including the exposure assessment and risk characterisation sections cannot, with the available information, be used to adapt this information requirement.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) *Daphnia magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

5. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement [according to Annex IX, Section 9.1.6., column 2. You provided the following justification for the adaptation "*In accordance with column 2 of REACH annex IX, further degradation testing does not need to be conducted as the chemical safety assessment does not indicate a need for further investigation".*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2 because as discussed in section 5. above, with the current information gaps the CSA cannot be used to show that there is no risk to the environment and that no further testing is needed.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) fish early-life stage (FELS) toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

However, the FELS toxicity test according to OECD TG 210 is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215), as it covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), *Chapter R7b, Figure R.7.8-4).*

Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects over a longer exposure period, or which require a longer exposure period of time to reach steady state (ECHA *Guidance Chapter R7b,* version 4.0, June 2017).

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration for aquatic toxicity testing (sections 1 to 5 above)

Before conducting the tests requested above under points 4. and 5., you shall consult the ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R7b, Section R.7.8.5 to determine the necessity to conduct the long-term toxicity testing on aquatic invertebrates and on fish.

Concerning the order of studies to be conducted, you may first fulfil the information requests made for short-term aquatic studies under points 1., 2., and 3. above and subsequently update the CSA according to Annex I of the REACH Regulation.

If you come to the conclusion that no further investigation of chronic effects on aquatic organisms is required, you shall update your technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.5 and 9.1.6. taking into account the new information submitted for the short-term aquatic studies as requested by the present decision and the exposure assessment and risk characterisation.

On the other hand, if after the update of the CSA you come to the conclusion that the long-term toxicity tests are still required to refine the risk assessment, you should consider the Integrated Testing Strategy (ITS) for aquatic toxicity as described in ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4). According to the ITS, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially less sensitive than other trophic levels (i.e. fish, invertebrates, algae), long-term studies may be required on both fish and invertebrates. In such case, according to the ITS, the long-term *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

Deadline to submit the requested information in this decision

In the draft decision communicated to you, the time indicated to provide the requested studies and submit the study results to ECHA in a dossier update was 27 months from the date of adoption of the decision. In the proposal for amendment (PfA) made by a Member State Competent Authority (MSCA), it was proposed to split the deadline into two timelines since the long-term aquatic studies requested in points [4] and [5] are conditional to the short-term aquatic studies requested in points [1], [2] and [3]. The MSCA proposed a deadline of 12 months if only the short-term aquatic studies requested in points [1], [2] and [3] will be performed, and a deadline of 27 months if all aquatic studies requested in points [1], [2], [3], [4] and [5] are to be performed.

ECHA accepted this MSCA PfA and the draft decision has been modified, accordingly.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 21 February 2017.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA did not receive any comments by the end of the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-55 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.