EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002673-73-05/F Helsinki, 7 June 2013

DECISION ON TESTING PROPOSALS SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For Dibenzoyl peroxide, CAS No 94-36-0 (EC No 202-327-6), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for Dibenzoyl peroxide, CAS No 94-36-0 (EC No 202-327-6), by [redacted] (Registrant):

1. Developmental toxicity (OECD Guideline 414);
2. Long-term toxicity to aquatic invertebrates (OECD 211);
3. Biodegradation in soil: simulation tests (OECD Guideline 307);
4. Biodegradation in sediment: simulation tests (OECD Guideline 308);
5. Toxicity to soil macro-organisms except anthropods (OECD Guideline 207)
6. Toxicity to soil micro-organisms (OECD Guideline 216); and
7. Toxicity to terrestrial plants (OECD Guideline 208)

This decision is based on the registration dossier as submitted with submission number [redacted] for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 18 January 2013, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the present dossier at a later stage.

On 2 November 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

ECHA held a third party consultation for the testing proposals from 16 June until 1 August 2011. ECHA did not receive information from third parties.

On 28 March 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 19 April 2012 ECHA received comments from the Registrant. On 15 June 2012, the Registrant submitted an updated dossier withdrawing the originally proposed testing proposal for stability in organic solvents.

ECHA considered the Registrant's comments received and amended the draft decision by removing the request for testing the stability in organic solvents endpoint from it.

On 18 January 2013 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 21 February 2013 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and decided to amend the draft decision.

On 4 March 2013 ECHA referred the draft decision to the Member State Committee.

On 18 March 2013, the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 24-25 April 2013, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 25 April 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Pre-natal developmental toxicity study in the rat or the rabbit via the oral route (Annex IX, 8.7.2., test method: EU B.31/OECD 414);
2. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5., test method: *Daphnia magna* reproduction test, EU C.20/OECD 211);
3. Soil simulation testing (Annex IX, 9.2.1.3., test method: Aerobic and Anaerobic Transformation in Soil simulation testing, EU C.23/OECD 307);
4. Sediment simulation testing (Annex IX, 9.2.1.4., test method: Aerobic and anaerobic transformation in aquatic sediment systems simulation testing, EU C.24/OECD 308);
5. Earthworm, acute toxicity tests (Annex IX, 9.4.1., test method: EU C.8/OECD 207); or, if long-term testing is considered appropriate, Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.1., column 2; test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei) OECD 222, or Enchytraeid reproduction test OECD 220, or Collembolan reproduction test in soil OECD 232); and
6. Effects on soil micro-organisms (Annex IX, 9.4.2., test method: Soil Microorganisms: Nitrogen Transformation Test, EU C.21/OECD 216).

The Registrant shall carry out one of the following modified test pursuant to Article 40(3)(b) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

7. Short-term toxicity testing on plants (Annex IX, 9.4.3.) test method: Terrestrial plants, growth test (OECD 208), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species), or, if long-term testing is considered appropriate, Long-term toxicity testing on plants (Annex IX, 9.4.3., column 2); test method: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030).

The Registrant shall carry out the following additional test pursuant to Article 40(3)(c) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

8. Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25/OECD 309);

The Registrant shall determine the appropriate order of the studies taking into account the possible outcomes and considering the possibilities for adaptations of the standard information requirements according to column 1 or 2 provisions of the relevant Annexes of the REACH Regulation. More specifically,

- Before conducting any of the tests mentioned above in points 3 and 4 and 8 the Registrant is advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 1.1., August 2008), Chapter R7b, Sections R.7.9.4 and R.7.9.6 and Chapter R.11.1.3 on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all three simulation tests

The Registrant shall determine the appropriate order of the studies in light of the reasoning provided above and retains the right to include fully justified adaptations for simulation testing.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **7 December 2015** an update of the registration dossier containing the information required by this decision.

Data from a second pre-natal developmental toxicity study on another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation. The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI. If the Registrant considers that testing is necessary to fulfil this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species.

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, the Registrant shall consider submitting a testing proposal for a long-term toxicity test on fish in order to fulfil the standard information requirement of Annex IX, 9.1.6.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance.

1. Pre-natal developmental toxicity study

Pre-natal developmental toxicity studies are part of the standard information requirements as laid down in Annexes IX and X, section 8.7.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. The dossier contains a combined repeated dose with reproduction/developmental toxicity screening study (OECD TG 422) in the rat that showed high birth rate of runts. The pups exposed to the highest levels of Dibenzoyl peroxide showed significant decrease in body weight but only at day 3 post-partum ($p<0.01$).

Consequently there is an information gap and it is necessary to generate the data for this endpoint. The Registrant did not specify the species and route to be used for testing. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out with the registered substance the following test: Pre-natal developmental toxicity study in rats or rabbits, oral route (test method: EU B.31/OECD Guideline 414).

When considering the need for a testing proposal for a pre-natal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed.

2. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on invertebrates is a standard information requirement as laid down in Annex IX, 9.1.5. of the REACH Regulation. Column 2 of Section 9.1. of Annex IX further indicates that this information requirement must be fulfilled unless the chemical safety assessment leads to the conclusion that the test is not needed. The information on this endpoint is not available for the registered substance, but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant has proposed the test to refine the predicted no effect concentration (PNEC) value for the aquatic compartment. As there is currently no data available for characterising long-term effects of Dibenzoyl peroxide on aquatic organisms and exposure of the aquatic compartment is not unlikely, ECHA considers this justification appropriate for the testing of the registered substance.

According to ECHA Guidance (Chapter R7b (version 1.1, August 2008) Figure R.7.8-4 p. 53) if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. According to the integrated testing strategy, the *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, a testing proposal for a long-term fish study needs to be submitted.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: *Daphnia magna* reproduction test (test method: EU C.20/OECD 211) using the registered substance.

3. 4. and 8. Simulation biodegradation testing (biodegradation in soil, aquatic sediment systems and in surface water)

a) Examination of the testing proposals

According to column 1 of Section 9.2. (9.2.1.2., 9.2.1.3. and 9.2.1.4.) of Annex IX of the REACH Regulation, simulation testing on ultimate degradation in surface water is a standard information requirement and simulation testing in soil and sediment are standard information requirements for substances with potential for adsorption to soil and/or sediment. The information on these endpoints is not available for the registered substance, but needs to be present in the technical dossier to meet the information requirements. Consequently, there are information gaps and it is necessary to generate the data for these endpoints.

The Registrant has submitted a testing proposal for an aerobic and anaerobic transformation in soil simulation biodegradation study (OECD 307 / EU C.23) and a testing proposal for an aerobic and anaerobic transformation in aquatic sediment systems simulation biodegradation study (EU C.24/OECD 308) to cover the endpoints of Annex IX, Sections 9.2.1.3. and 9.2.1.4.

The Registrant has submitted proposals to conduct soil and sediment simulation studies according to the OECD 307 and 308 Guidelines since Dibenzoyl peroxide was not shown to be readily biodegradable in two OECD 301 D tests. ECHA notes that the only study (OECD 301 C) which supported ready biodegradation had a Klimisch Score of 4 and can therefore not contribute to the conclusion on ready biodegradability.

ECHA notes that the proposed tests can be used to fulfil the information requirements for simulation testing on soil and aquatic sediment systems simulation testing.

For soil, the Registrant proposed the testing because soil exposure is likely via the application of sewage sludge and neither simulation biodegradation nor sewage treatment plant results being available. Additionally, adsorption is considerable and the Registrant concluded that more information on the fate of the substance is needed.

For sediment, the Registrant has proposed the testing as exposure of the sediment and water compartments is likely, adsorption is considerable and more information on the fate of the substance is needed.

To further corroborate the concern expressed by the Registrant and the inconclusive evidence from the screening studies, ECHA notes that additional evidence to further characterise ultimate degradation is provided in the conclusions of the OECD SIDS report for Dibenzoyl peroxide that indicates "*this substance is a candidate for further work, even if it hydrolyses rapidly and has a low bioaccumulation potential. The substance shows high acute toxicity to aquatic organisms and some information indicates wide-dispersive use of this substance. This could lead to local concern for the aquatic environment and therefore environmental exposure assessment is recommended.*"

Under Article 51(2), a proposal for amendment was submitted on this decision indicating that degradation simulation testing may not be warranted. The Registrant in his written comments on the proposal for amendment, proposed to remove the requests for OECD 307 and OECD 308 tests. ECHA stresses that at this stage of the procedure, testing proposals cannot be withdrawn. Furthermore, as outlined above there remain information gaps for Annex IX, Sections 9.2.1.3. and 9.2.1.4. and they need to be fulfilled (or adapted). ECHA has no reason to reject the testing proposals for the OECD 307 and OECD 308 tests as they may fulfil the current information gaps.

The Registrant has not proposed a test for fulfilling the endpoint of Annex IX, Section 9.2.1.2. In addition to the explanation for not further examining degradation in the water compartment (see above) the Registrant provided the following adaptation for not conducting the surface water simulation biodegradation test:

> *'In addition, dibenzoyl peroxide was determined to be hydrolytically unstable under acidic, neutral and basic conditions, with a half-life of less than 1 day under environmental conditions (25°C). Benzoic acid, the main breakdown product present in the hydrolysed solutions at each test pH is known to be readily biodegradable as it is used as reference substance during screening tests for ready biodegradability. According to 67/5848 EEC regulation, a substance can be considered as readily biodegradable if there is scientific evidences showing that the substance of interest can degraded (biotic and abiotic degradation) in the aquatic environment up to 70% in 28 days. Based upon the aforementioned information, we can safely assume that the substance is degraded during this cut-off period. Besides, abiotic degradation will involve the apparition of benzoic acid which is readily biodegradable. Thus, dibenzoyl peroxide should be considered as readily biodegradable. (based on three 301 tests; two 301 D and one 301 C)*
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> *Sediment and water compartments exposition is likely. However, based upon the adsorption potential of the substance of interest, simulation biodegradation tests would be recommended and so are proposed in order to get more information of the fate of the concerned substance in sediment compartment. Nevertheless, the substance was assessed as hydrolytically unstable at environmental condition, as a consequence no further assessment of the (bio) degradation is proposed in the water compartment.'*

Soil compartment can be exposed via the application of sewage sludge. From the production plant, the release of organic peroxide into the sewage is very limited, not to say completely negligible. The waste water from production plant is usually treated: at least a physical/chemical treatment, which will neutralize potential residual organic peroxide and that can be followed by a biological treatment. So it can be expected that organic peroxides won't be present in sludge. Nevertheless, as neither simulation biodegradation test results, nor measures in treatment plant sewage are available, a simulation biodegradation test in soil is proposed in order to cover these issues.'

Both OECD 301 D and 301 C tests are not considered equivalent to a simulation biodegradation test. Furthermore, as indicated above, the Registrant has not demonstrated that the registered substance is readily biodegradable. In addition he has not justified why surface water would not be an appropriate medium for testing (Column 2 of Section 9.2. of Annex IX). Therefore, there remains an information gap for Annex IX, Section 9.2.1.2. that needs to be fulfilled.

The above-mentioned proposal for amendment suggested that if any further degradation simulation studies should be conducted, it would be more relevant to consider OECD 309 (Annex IX, 9.2.1.2). The Registrant in his written comments on the proposal for amendment proposed to conduct a chronic *Daphnia* toxicity study (OECD 211) first, and then based on the results of the OECD 211 study, to perform the OECD 309 study. ECHA agrees that as there is an information gap for Annex IX, 9.2.1.2. the OECD 309 should be requested. As the dossier also contains data gaps and testing proposals for Annex IX, 9.2.1.3. and 9.2.1.4., the OECD 309 test (Annex IX, 9.2.1.2) is therefore requested in addition to the tests proposed by the Registrant. The Registrant shall determine the appropriate order of the studies in light of the reasoning provided in the following paragraph and retains the right to include fully justified adaptations for simulation testing in appropriate media on that basis:

- The assessment of the vP criterion as per Annex XIII of the REACH Regulation can be based on data from simulation testing. The impact on the chemical safety assessment (CSA) by the results of a first simulation test and, if appropriate, other required tests shall be evaluated before proceeding with the required other simulation tests. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance. The Registrant is advised to consult the REACH guidance on information requirements chemical safety assessment Chapter R.11.1.3. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment. If by following this approach an adaptation of information requirements covered by Section II, 3 or 4 or 8 becomes possible and the Registrant includes a justified adaptation in his registration dossier, he will not be required to perform the respective test pursuant to the present decision.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed studies: Aerobic and anaerobic transformation in soil – simulation biodegradation test (Annex IX, 9.2.1.3.; test method: EU C.23/OECD 307) using the registered substance and Aerobic and anaerobic transformation in aquatic sediment systems – simulation biodegradation test (Annex IX, 9.2.1.4; test method: EU C.24/OECD 308) using the registered substance.

Furthermore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following as additional study: Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25/OECD 309), using the registered substance.

The Registrant shall determine the appropriate order of the studies in light of the reasoning provided above and retains the right to include fully justified adaptations for simulation testing.

5. Earthworm, acute toxicity test

Short- and long-term toxicity testing on terrestrial invertebrates are standard information requirements as laid down in Annexes IX, section 9.4.1. and X, section 9.4.4. of the REACH Regulation. Furthermore, Column 2 of section 9.4 of Annex IX indicates that long-term testing shall be considered already on the Annex IX level for substances that have a high potential to adsorb to soil or that are very persistent. As neither short- or long-term toxicity information is available for the registered substance, it needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant has proposed an earthworm acute test (OECD 207) to cover the endpoint in question. Short-term toxicity testing on terrestrial invertebrates is a standard information requirement as laid down in Annex IX, section 9.4.1. of the REACH Regulation. The Registrant has justified the testing proposal for this endpoint by the following statement: *"According to claimed uses of Dibenzoyl peroxyde and to its lyfe cycle, terrestrial exposure is likely. At the moment no data is available for characterizing Dibenzoyl peroxide effects on organisms inhabiting terrestrial compartment. Soil compartment can be exposed via the application of sewage sludge. From the production plant, the release of organic peroxide into the sewage is very limited, not to say completely negligible. The waste water from production plant is usually treated: at least a physical/chemical treatment, which will neutralize potential residual organic peroxide, and that can be followed by a biological treatment. So it can be expected that organic peroxides won't be present in sludge. Nevertheless, as neither toxicity test results, nor measures in treatment plant sewage are available, toxicity tests on sediment (*Note: the Registrant probably means 'terrestrial'*) organisms are proposed in order to cover these issues."*

ECHA considers that presently it is not possible to determine whether results obtained from the proposed short-term test (Annex IX, 9.4.1) could be used to adequately justify an adaptation of the standard information requirement of Annex X, 9.4.4 for long-term testing. Additionally, ECHA notes that long-term tests are suitable to simultaneously address the information requirement of Annex X, section 9.4.4 and Annex IX, section 9.4.1. Therefore, the Registrant is granted the option to carry out a long-term test as an alternative to the short-term test on terrestrial plants that the Registrant proposed.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out one of the following studies: Short-term toxicity to invertebrates (Annex IX, 9.4.1); test method: Earthworm acute toxicity test (Eisenia fetida/Eisenia andrei), (OECD 207), or, if long-term testing is considered appropriate, Long-term toxicity to terrestrial invertebrates (Annex X, 9.4.4); test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei) OECD 222, or Enchytraeid reproduction test OECD 220, or Collembolan reproduction test in soil OECD 232).

Furthermore, ECHA would like to acknowledge the presence of a short-term earthworm test in both the registration dossier and the OECD SIDS report. Whereas the study was of reliability score 2 in the latter, the Registrant has assigned a lower reliability score for the purposes of his registration dossier due to insufficient information on the validity of the study results. As indicated in Annex I, 0.5., it is the responsibility of the Registrant to take into account available information from assessments carried out under other international and national programmes.

6. Effects on soil micro-organisms

Effects on soil micro-organisms is a standard information requirement as laid down in Annex IX, section 9.4.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance, but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant has proposed a Soil Microorganisms: Nitrogen Transformation Test (OECD 216) to cover the endpoint in question. The Registrant has justified the testing proposal for this endpoint as exposure of the terrestrial compartment is likely via application of sewage sludge and there is currently no available data to characterise the substance's effects on terrestrial organisms (see statement above).

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Soil Microorganisms: Nitrogen Transformation Test (Annex IX, 9.4.2, Effects on soil micro-organisms, test method: EU C.21/OECD 216).

7. Toxicity testing on plants

Short- and long-term toxicity testing on plants are standard information requirements as laid down in Annexes IX, section 9.4.3 and X, section 9.4.6 of the REACH Regulation. Furthermore, Column 2 of section 9.4 of Annex IX indicates that long-term testing shall be considered already on the Annex IX level for substances that have a high potential to adsorb to soil or that are very persistent. As neither short- or long-term toxicity information is available for the registered substance, it needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to generate the data for the endpoints.

The Registrant has proposed a toxicity to terrestrial plants (OECD Guideline 208) test to cover the endpoint in question. The Registrant has justified the testing proposal for this endpoint as exposure of the terrestrial compartment is likely via application of sewage sludge and there is currently no available data to characterise the substance's effects on terrestrial organisms (see statement above).

ECHA considers that presently it is not possible to determine whether results obtained from the proposed short-term test (Annex IX, 9.4.3) could be used to adequately justify an adaptation of the standard information requirement of Annex X, 9.4.6 for long-term testing. Additionally, ECHA notes that long-term tests are suitable to simultaneously address the information requirement of Annex X, section 9.4.6 and Annex IX, section 9.4.3. Therefore, the Registrant is granted the option to carry out a long-term test as an alternative to the short-term test on terrestrial plants that the Registrant proposed.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For short-term toxicity testing, ECHA considers three species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with one monocotyledonous species and two dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. Alternatively, for long-term toxicity testing, ECHA considers six species as the minimum and testing shall be conducted, as a minimum with two monocotyledonous species and four dicotyledonous species. The Registrant should consider if testing on additional species is required to cover the information requirements.

Therefore, pursuant to Article 40(3)(b) of the REACH Regulation the Registrant is required to carry out the proposed study under modified conditions: Short-term toxicity to plants (Annex IX, 9.4.3.); test method: Terrestrial plants, growth test (OECD 208), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species), or may, as alternative to the short-term test, opt to carry out one of the following studies: Long-term toxicity testing on plants (Annex X, 9.4.6.); test method: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030).

8. Further note on testing requirements 5, 6 and 7: Sequence of terrestrial testing

Prior to conducting any of the above-mentioned terrestrial toxicity tests (5-7), the Registrant shall take into account the "*Guidance on information requirements and chemical safety assessment*" related to integrated testing strategy for terrestrial toxicity testing in order to determine the sequence in which the tests are to be conducted. Table R.7.11-2, Chapter R.7c, page 131 indicates that, for a soil hazard category 2 substance, a risk characterisation ratio (PEC/PNEC) based on the Equilibrium Partitioning Method (EPM) should be calculated, together with a confirmatory short-term soil toxicity testing to the most sensitive organism group, as indicated from aquatic toxicity data. Only if the PEC/PNEC ratio is above 1 or there is an indication of risk from the confirmatory short-term soil toxicity testing, the Registrant should proceed with additional short-term studies. In other cases, only one short-term is adequate, unless the Registrant wishes to perform all three tests. This integrated testing strategy applies for soil hazard category 2 chemicals (no high persistence, very toxic to aquatic organisms) such as the one registered.

According to the above-mentioned Guidance, the PNEC screen is calculated through EPM on the basis of aquatic toxicity data only. Intrinsic properties of soil microbial communities however are not addressed through the EPM extrapolation method. Thus, the hazard to soil microbial communities need to be evaluated as a standard information requirement under Annex IX. 9.4.2. Therefore, ECHA concludes that the application of an integrated testing strategy could only be applied to the need to perform either a long term toxicity test for soil invertebrates or plants, or to perform both of them, and that the effects on soil micro-organisms need to be ascertained by performing a relevant test (EU Method C.21 or OECD 216).

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrants.

9. Deadline for submitting the information required under Section II

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 24 months from the date of adoption of the decision. In follow-up to the proposals for amendment an additional test was included amongst the tests requested by the decision. ECHA considers that 24 months may not suffice to conduct sequential simulation testing. An additional 6 months are adequate for such sequential testing. Therefore the timeline was extended to 30 months. The decision was modified accordingly.

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new study/studies meet real information needs. Within this context, your dossier was sufficient to confirm the identity of the substance to the extent necessary for assessing the testing proposal. You must note, however, that this information, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the proposed test(s), the sample of substance used for the new study/studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all the joint registrants of the same substance to agree with the test(s) proposed in the testing proposal (as applicable to their tonnage level) and to document the necessary information on its composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study/studies 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 by each registrant. If the registration of the substance by any registrant covers different technical grades, the sample used for the new study/studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
Jukka Malm
Director of Regulatory Affairs