Decision number: TPE-D-0000002475-73-05/F Helsinki, 3 May 2013

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

For sulphamidic acid, CAS No 5329-14-6 (EC No 226-218-8), 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 in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for sulphamidic acid, CAS No 5329-14-6 (EC No 226-218-8), by [redacted] (Registrant):

- Toxicity for reproduction according to OECD TG 416 (Two-Generation Reproduction Toxicity Study) in rats, oral route (gavage);
- Developmental toxicity/teratogenicity according to OECD TG 414 (Prenatal Developmental Toxicity Study) in rats, oral route (gavage);
- Long-term toxicity to aquatic invertebrates according to OECD TG 211 (*Daphnia magna* Reproduction Test), *Daphnia magna*, semi-static test;
- Long-term toxicity testing on fish (early-life stage: reproduction, (sub)lethal effects) according to OECD TG 210 (Fish, Early-Life Stage Toxicity Test), *Pimephales promelas*, semi-static test;
- Long-term toxicity testing on plants according to ISO 22030: 2005 (Soil quality - Biological methods - Chronic toxicity in higher plants), *Brassica rapa* (*Dicotyledonae* (dicots)), *Avena sativa* (*Monocotyledonae* (monocots)).

The present decision relates only to the examination of the testing proposals:

- Developmental toxicity/teratogenicity according to OECD TG 414 (Prenatal Developmental Toxicity Study) in rats, oral route (gavage);
- Long-term toxicity to aquatic invertebrates according to OECD TG 211 (*Daphnia magna* Reproduction Test), *Daphnia magna*, semi-static test;
- Long-term toxicity testing on fish (early-life stage: reproduction, (sub)lethal effects) according to OECD TG 210 (Fish, Early-Life Stage Toxicity Test), *Pimephales promelas*, semi-static test;
- Long-term toxicity testing on plants according to ISO 22030: 2005 (Soil quality - Biological methods - Chronic toxicity in higher plants), *Brassica rapa* (*Dicotyledonae* (dicots)), *Avena sativa* (*Monocotyledonae* (monocots)).

The testing proposal for fulfilling the information requirement for a reproductive toxicity study (Annex X, 8.7.3.) is addressed in a separate decision although all these were initially addressed together in the same draft decision.

The present 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.

On 7 October 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 14 February 2011 until 31 March 2011. ECHA did receive information from third parties (see section III below).

On 31 July 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.

By 30 August 2012 the Registrant did not provide any comments on the draft decision to ECHA.

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.

The Registrant did not provide any comments on the proposed amendments.

The draft decision was split into two draft decision documents: one relating to the testing proposal for a two-generation reproduction toxicity study (Annex X, 8.7.3), and one relating to the testing proposals for a Prenatal Developmental Toxicity Study, a *Daphnia magna* Reproduction Test, a Fish, Early-Life Stage Toxicity Test and a long-term toxicity testing on plants.

A unanimous agreement of the Member State Committee on the draft decision relating to the testing proposal for a Prenatal Developmental Toxicity Study, a *Daphnia magna* Reproduction Test, a Fish, Early-Life Stage Toxicity Test and a long-term toxicity testing on

plants was reached on 8 April 2013 in a written procedure launched on 27 March 2013. ECHA took the decision pursuant to Article 51(6) 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 to initiate a compliance check on the registration at a later stage.

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 rats or rabbits, 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. Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1; test method: Fish, early-life stage toxicity test, OECD 210);
and
4. Long-term toxicity testing on plants (Annex X, 9.4.6; test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants – ISO 22030).

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

5. Effects on soil micro-organisms (Annex IX, 9.4.2; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216); and

6. Long-term toxicity on terrestrial invertebrates (Annex IX, 9.4.1.; 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).

The Registrant shall determine the appropriate order of the studies taking into account the possible outcome and considering the possibilities for adaptations of the standard information requirements according to the column 2 provisions of the respective Annex and those contained in Annex XI of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **3 November 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 fulfill 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.

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 and scientific information submitted by third parties.

1. Pre-natal developmental toxicity study (Annex IX, 8.7.2)

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

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. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Registrant has proposed to perform the test on rats via the oral route. According to the test method EU B.31/OECD 414, the rat is indeed 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 therefore be performed by the oral route with the rat or the rabbit as a first species to be used.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement. ECHA stresses that third parties were invited, as specified by Article 40(2) of the REACH Regulation to submit "scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal". Other recommendations (as for example strategies for adapting an information requirement) provided by third parties cannot be regarded as information or studies per se and can therefore not be taken into consideration by ECHA. ECHA however provides the information from third parties to the Registrant. ECHA acknowledges that the Registrant may himself use and if necessary supplement under his own responsibility the argumentation and information provided by the third party in order to make use of adaptation possibilities.

A third party has recommended that the need to conduct the pre-natal developmental study be evaluated in light of the results of the existing toxicological data (and in particular of the 90-day studies) and available toxicokinetic information. However, ECHA does not regard the recommendation provided by the third party as adequate to reject the testing proposal. The information on repeated dose toxicity is not, in itself, a basis for adaptation of the information requirement for Annex X, 8.7 (column 1 or 2) or for Annex XI. Furthermore, evidence of absorption was seen in the available repeated dose toxicity studies via the oral route.

The third party alternatively proposed a waiving strategy to be considered before further tests on animals are requested. This strategy is based on a weight-of-evidence approach using *in vitro* (pre-)validated tests (embryonic stem cell test with increased applicability domain and account for metabolism, limb bud micromass culture, whole embryo culture, estrogen receptor and androgen receptor gene reporter assays) and a combination of several QSAR models. While ECHA will provide the information to the Registrant, it notes the following. Scientifically validated *in vitro* methods such as the embryonic stem cell test, the limb bud micromass culture and the whole embryo culture may provide additional information which can be assessed together with existing *in vivo* data in a weight of evidence approach. However, the mentioned in vitro tests only cover some of the reproductive toxicity endpoints, modes of action and mechanisms covered by the *in vivo* pre-natal developmental toxicity study and therefore they cannot be used on their own as replacement to testing according to OECD Guideline 414.

As a further alternative, the third party has recommended another strategy for adapting the information requirement. While ECHA will provide the information to the Registrant, it notes that, information on fertility (i.e. from a two-generation reproduction toxicity study or from an extended one-generation reproductive toxicity study) is not, in itself, a basis for adaptation of the information requirement for Annex X, 8.7 (column 1 or 2) or for Annex XI.

The third party furthermore proposed the use of the TTC concept (Threshold of Toxicological Concern) in order to evaluate if exposure is negligible. While ECHA will provide the information to the Registrant, it notes that the registration dossier indicates that exposure will occur.

Another third party has proposed yet another strategy for adapting the information requirement. The use of a nonlinear classification artificial neural network QSAR model for pre-natal developmental toxicity study. The third party has provided ECHA with a QSAR model reporting form (QMRF), a QSAR prediction reporting form (QPRF) and the outcome of the model prediction. ECHA will provide the information to the Registrant. However, ECHA notes that the result from the QSAR classification model (i.e. either "toxic" or "non-toxic") is not suitable for the purposes of classification and labelling and/or risk assessment for the endpoint for which testing has been proposed to meet the information requirement (Annexes X, 8.7). Compliance with the Annex XI section 1.3 requirements could not be established as the required information concerning the validity, adequacy for classification and labelling and documentation of the model was not provided. In addition, the submitted information suggests that the registered substance might be outside the applicability domain of the model. The QSAR Model Reporting Format (QMRF) does not provide sufficient information to deduce whether the training set was constructed from studies that cover the information requirements of the OECD 414 guideline, or important study aspects, such as the species, dose selection and number of animals used.

Another third party has proposed a further strategy for adapting the information requirement, i.e. a read-across between the registered substance and ammonium sulphamate. Although ECHA recognises that the read-across proposed by the third party might be scientifically valid, the information provided is not sufficient to fulfil Annex XI, Section 1.5 requirements. Therefore ECHA cannot reject the testing proposal on the basis of this third party comment.

c) Outcome

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

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.

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

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A long-term toxicity test on aquatic invertebrates is a standard information requirement as laid down in Annex IX, section 9.1.5 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 provide information for this endpoint.

Furthermore, the Registrant seeks to use the outcome of the present proposed test and that of the long-term toxicity test on fish (see section 4 below) to refine the classification of his substance.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211) using the registered substance.

The registrant shall refer to the OECD guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Monograph No 23, ENV/JM/MONO(2000)6), focussing on section 3.10: ionised substances. Specifically he shall ensure that the test solutions are buffered to an environmentally relevant pH and that this is maintained throughout the study.

3. Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1)

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A long-term toxicity test on fish is a standard information requirement as laid down in Annex IX, section 9.1.6. 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 provide information for this endpoint.

Furthermore, the Registrant seeks to use the outcome of the present proposed test and that of the long-term toxicity testing on aquatic invertebrates (see section 3 above) to refine the classification of his substance.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement. The same standards as outlined under Section III 1.b) apply.

A third party has recommended that the testing proposal for a long-term toxicity test on fish be rejected based on the fact that acute toxicity for fish and *Daphnia* are similar (same order of magnitude). The third party assumes that the NOEC obtained from the long-term toxicity test on *Daphnia* proposed by the Registrant and the application of an adequate assessment factor will allow a sufficient degree of safety without the need to perform a long-term test on fish. However, ECHA does not regard the recommendation proposed by the third party as adequate to reject the testing proposal. ECHA notes the following. According to ECHA guidance (Chapter R7b (version 1.1, August 2008), Figure R.7.8-4 p. 53) if based on acute data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. There are no indications in the dossier from the short-term toxicity studies on aquatic species that the fish would be substantially more sensitive than *Daphnia* and vice versa, therefore both tests should be considered by the Registrant. Still, according to ECHA guidance, the *Daphnia* study is to be conducted first, and if based on the results of the long-term *Daphnia* study and an applied assessment factor of 50 no risks were indicated, the long-term fish testing might no longer be necessary to be conducted. Although no quantitative exposure assessment is presented in the dossier, this does not preclude the registrant from applying a testing strategy for the aquatic testing.

c) Outcome

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, the Registrant is required to carry out the proposed study: Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210) using the registered substance.

The registrant shall refer to the OECD guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Monograph No 23, ENV/JM/MONO(2000)6), focussing on section 3.10: ionised substances. Specifically he shall ensure that the test solutions are buffered to an environmentally relevant pH and that this is maintained throughout the study.

The Registrant should consider conducting the long-term toxicity testing on aquatic invertebrates (see Sections II, 2 and III, 2) before the fish, early-life stage (FELS) toxicity test. The registrant should consider the weight of evidence approach presented on figure R7.8-2 in Chapter R.7b of the ECHA Guidance on information requirements and chemical safety assessment (May 2008), and in particular the analysis of the mode of action of the substance), to determine the need for the FELS test once the chronic *Daphnia* test is available 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. The Registrant may waive the fish, early-life stage (FELS) toxicity test by providing an appropriate justification for adaptation of Annex IX, 9.1.6.1 in the registration dossier.

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.

4. Effects on terrestrial organisms (Annex X, 9.4) (Section II, points 4-6)

a) Examination of the testing proposal

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test in accordance with Article 40(3)(a) but requiring the Registrant to carry out one or more additional tests in cases of non-compliance of the testing proposal with Annexes IX, X, and XI of the REACH Regulation.

In order to fulfil the standard information requirements set out in Annex IX and X, section 9.4, the Registrant should provide information for the following endpoints: (i) effects on soil micro-organisms (Annex IX, section 9.4.2), (ii) long-term toxicity testing on invertebrates (Annex X, section 9.4.4), and (iii) long-term toxicity testing on plants (Annex X, section 9.4.6).

The Registrant has submitted a testing proposal for a long-term test on terrestrial plants in order to fulfil the standard information requirements for effects on terrestrial organisms. This test is suitable to address the information requirement of Annex X, section 9.4.6. Therefore ECHA accepts this testing proposal pursuant to Article 40(3)(a) of the REACH Regulation.

However, the Registrant has waived toxicity testing on soil microorganisms and long-term toxicity testing on terrestrial invertebrates with the justification that the data of the proposed study on terrestrial plants and the application of the Equilibrium Partitioning Method (EPM) will provide sufficient data to characterise the risks to other terrestrial organisms.

ECHA disagrees with these proposed adaptations: Firstly, and with regard to Annex IX, section 9.4.2, ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4.1 does not apply for that endpoint. The effects on soil micro-organisms need to be ascertained by performing a relevant test (EU Method C.21 or OECD 216). Secondly, and with respect to Annex X, 9.4.4, ECHA notes that in the absence of the results of the proposed long-term toxicity test on terrestrial plants and of the long term toxicity tests on aquatic invertebrates and/or fish, this justification for data waiving is not considered to be in line with the specific rules for adaptation indicated in column 2 of Annex X, 9.4 or the general rules for adaptation under Annex XI. The test proposed by the Registrant is therefore not sufficient, on its own accord, to fulfil all the information requirements outlined in Annex IX and X, 9.4, since it does not fulfil the information requirements laid down in Annex IX, section 9.4.2 and in Annex X, section 9.4.4.

Therefore there are information gaps and it is necessary to provide information for the standard information requirements of Annex IX, 9.4.2, and Annex X, 9.4.4. Consequently, pursuant to Article 40(3)(c) ECHA requires information on toxicity to terrestrial invertebrates and on toxicity to micro-organisms with the present decision.

As ECHA has noted under Section II, the Registrant shall however determine the appropriate order of the studies taking into account the possible outcome and considering the possibilities for adaptations.

If the registrant opts to carry out the proposed test on terrestrial plants (Section II, 4) first, once the outcome on that test is available, the Registrant should re-examine whether the adaptation he proposed to Annex X, 9.4.4 has become possible. If on the contrary the Registrant opts to carry out the test on terrestrial invertebrates (Section II, 6) first, the same adaptation possibility may be examined for the endpoint of Annex X, 9.4.6.

Furthermore the results of the toxicity tests on fish and/or aquatic invertebrates (Section II, 2 and 3) will allow the subsequent derivation of a PNECwater. The Registrant may consider an integrated testing strategy for soil toxicity, as recommended in section R.7.11.6., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (May 2008). This would allow the Registrant to perform an initial screening assessment in order to identify the need to perform further studies. The screening assessment should include the evaluation of the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test. Based on the result of the initial screening, one of the two long-term tests on effects of terrestrial organisms requested by the present decision (Section II, 4 and 6) could possibly be waived.

b) Outcome

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation ECHA has accepted the Registrant's testing proposal and the Registrant is required to carry out the proposed study:

- Long-term toxicity testing on plants (Annex X, 9.4.6; test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants – ISO 22030) using the registered substance.

The Registrant is also required to carry out the following tests:

- Long-term toxicity testing on terrestrial invertebrates (Annex X, 9.4.4, test method: OECD 222 or OECD 220 or OECD 232) using the registered substance.

- Test on toxicity to micro-organisms (Annex IX, 9.4.2, EU Method C.21 or OECD 216) using the registered substance.

The Registrant shall determine the appropriate order of the studies in light of the reasoning provided above, in particular keeping in mind the considerations set out in Table R.7.11.-2 of Guidance R7.c. If by following this approach an adaptation of the information requirements covered by Section II, 4. or 6. becomes possible and the Registrant includes a justified adaptation in his registration dossier, he will not be required to perform the test required by the present decision for fulfilling this endpoint.

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 studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for evaluation of the testing proposal. The Registrant 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 tests, the sample of substance used for the new 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 joint registrants of the same substance to agree to the tests proposed (as applicable to their tonnage level) and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new 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 grades, the sample used for the new studies 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 studies to be assessed.

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

ECHA 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).

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.

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Jukka Malm
Director of Regulatory Affairs