1. **Purpose of the Document**

This document is a follow up to the document "CA-Sept12-Doc.5.1.j - Nano transition.doc" discussed during the 48th CA meeting in September 2012, which intended to start discussions on the legal status under the BPR of nano-forms of active substances which will be either included in the biocides review programme or already included in Annex I to the Biocidal Products Directive 98/8/EC ('BPD') on the day when BPR enters into application.

This document aims at proposing a way forward, with the objective of managing nanomaterials in a fair and transparent manner, and of bringing more clarity and legal certainty.

2. **Background**

The paper discussed during the 48th CA meeting presented a summary of the provisions of the BPR in relation with nanomaterials. Due to the fact that nanomaterials are excluded from the approval of an active substance unless otherwise specified, several questions were raised concerning the possibility to place on the market after 1st September 2013 nanomaterials as active substances, biocidal products containing them and treated articles that would have been treated or incorporate them, taking into account that the current review programme of existing active substances as foreseen in Regulation (EC) 1451/2007 do not indicate if the active substance notified was a nanomaterial or not.

No definition of "nanomaterial" exists in the BPD, or was commonly agreed at EU level in the past. Such a definition was only introduced in the biocides framework with the new BPR. Nevertheless, any substance, whatever its form, was already in the scope of the BPD as long as it was used as a biocidal active substance.

The Commission preliminary conclusions about the legal status as of 1 September 2013, presented during the 48th CA Meeting, were the following:
**Biocidal products**

- Substance approvals, either by virtue of transfer from Annex I to BPD or originally granted under BPR, should not mention nanomaterials unless those nanomaterials have been addressed in the substance evaluation. In consequence, biocidal products containing nanomaterials will not be eligible for product authorisation under BPR unless the nanomaterials have been addressed in the substance evaluation.

- For biocidal products containing nano-forms of new active substances, approved either by virtue of transfer from Annex I to BPD or originally under BPR, there will be no possibility to grant a transitional period for placing or keeping them on the market in the absence of authorisation granted under BPR.

- Biocidal products containing nano-forms of existing active substances under evaluation will, based on Regulation (EC) No 1451/2007 in its current form, be legally on the market, subject to national rules, even if no nanomaterial data has been submitted.

- The legal situation for biocidal products containing nano-forms of existing active substances that have been approved, either by virtue of transfer from Annex I to BPD or originally under BPR, should be clarified.

**Treated articles (ie. without primary biocidal function)**

- According to the general principle in Article 58 of BPR, articles treated with nanomaterials cannot be placed on the market unless the approval of the active substance explicitly mentions the nano-form.

- However, Article 94(1) of BPR allows the placing on the market of articles treated with active substances, including nanomaterials, subject to the submission of an application for approval by 1 September 2016. It was suggested to leave this possibility open also to nano-forms of substances under evaluation, or of substances having been approved without an evaluation of the nano-form.

3. **PROPOSED WAY FORWARD**

In view of the above-mentioned elements, and taking into account that:

- nanomaterials will be considered to be legally on the market based on Regulation (EC) 1451/2007 in its current form;

- the decision that nanomaterials are excluded from the approval of an active substance unless otherwise specified has been adopted in May 2012 with the adoption of the BPR;

- a nanomaterial will be approved under the BPR only if a specific evaluation has been carried out, in addition to the evaluation made on the non nano-form of an
active substance;
- there is a need to bring further clarity and legal certainty concerning the exact form(s) of the substances currently evaluated under the review programme of existing active substances;
- due to the current uncertainty, suppliers of active substances might currently place on the market nano-forms of these existing actives substances;
- those suppliers might not have submitted a dossier to require the inclusion in Annex I of the BPD of these nano-forms of existing active substances at the normal deadlines for submitting applications set out in article 9(2) of regulation EC 1451/2007;
- concerns exist about the safety of nanomaterials for human, animal health and the environment, and as a consequence, that there is a need to take immediate measures in order to bring clarity and legal certainty;

the Commission proposes the following approach:

1. The opportunity shall be given to persons wishing to support nano-forms of existing active substances to submit an application to require their approval under the BPR in the review programme of existing active substances.

2. This opportunity shall only be open to existing active substance / product-type combinations supported under the current review programme, that is to say to existing active substance / product-type combinations already included into Annex I of the BPD, and existing active substance / product-type combinations still under examination. The opportunity has already been given to persons interested to support existing active substance / product-type combinations withdrawn from the review programme to take them over, as it covered any form of the substance, and no additional opportunity should thus be given to support them again under the review programme.

3. In case a nano-form of an active substance is supported in a dossier still under examination, this opportunity shall not be open to this(these) specific nano-form(s), but only to other nano-forms of the same existing active substance.

4. Persons wishing to support a same nano-form of an existing active substance / product type combination shall submit a joint application.

5. There is a need to clarify if some nanomaterials are currently under assessment and supported by current participants. As a consequence, the Commission will publish a notice stating that the Commission considers that no nanomaterial is currently under assessment for existing active substance / product type combinations still under evaluation by Member States. If a participant actually supports a nanomaterial, he will have to communicate this information within 3 months following the publication of the notice, giving accurate
information concerning the identity of the nanomaterial. In parallel, Rapporteur Member States can also check in the dossier submitted by participants. Any contribution received from this consultation will be studied, in order that the Commission can publish a withdrawal notice with accurate information. This withdrawal notice is the starting point to give the possibility to take over nanomaterials.

6. **It is considered that substances already included into Annex I of the BPD do not cover nano-forms of these active substances.** The withdrawal notice will automatically include these substances.

7. **Similar process and timings as in the "Draft Regulation XXX/2013 amending Regulation (EC) No1451/2007 as regards additional active substances of the biocidal products to be examined under the review programme"** will be followed as from the moment the Commission publishes a withdrawal notice (Article 3a(4) of that regulation), that is to say that:

   - These persons will have 3 months after that publication in order to send a declaration of intention to notify an AS/PT combination
   - These persons will have to submit a notification to ECHA within 18 months after the publication of the withdrawal notice. That notification should contain information requested in table II of Regulation No 1896/2000, and a proof that the substance was marketed as an active substance in biocidal products before the date of publication of the withdrawal notice
   - ECHA will provide an opinion to the Commission whether the notification can be accepted. In that case, the Commission will clarify some nanomaterials are under assessment. A specific annex could be introduced in that Regulation to clearly list which the nanomaterials are evaluated under the review programme (ex: splitting the current annex II of Regulation EC 1451/2007 into a Part A "non-nanomaterials", and part B "nanomaterials").
   - An application to require the approval of these nanomaterials will have to be submitted 2 years after the date when the Commission modified the Annex II to list the notified nanomaterials
   - The evaluating Competent Authority shall be the same as for the non-nano-form(s) of the active substance.
   - Only these nanomaterials will be allowed to remain on the market until a decision is taken on their approval.

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1 The regulation aims at giving the opportunity to support an AS/PT combination to person who failed to notify or support an active substance with the objectively justified belief that it was not in the scope of the BPD or that the use was attributed to another product-type (see the Appendix of the present document)
8. As a withdrawal notice would therefore already have been published for taking
them over, **no additional possibility will be given** to support a nano-form of an
existing active substance in case no application is submitted at the expected
submission date, the notification is rejected by ECHA, if the application is
rejected by ECHA or by the evaluating Competent Authority, or if it is withdrawn
by the participant.

If another person wishes to support that nanomaterial, it would have to be done
under the normal procedure of Article 7(1) of the BPR. Until that nanomaterial is
approved, it will not be possible to place it on the market and use it in biocidal
products.

9. The **future regulation that will amend or repeal Regulation (EC) No
1451/2007, needed for its adaptation with the entry into application of the
BPR, will establish the above mentioned provisions.**

10. Considering that specific deadlines already exists in Article 94 of the BPR to
forbid the placing on the market of treated articles with active substances not
supported by an application, **the same deadlines will naturally apply for
treated articles treated with of which incorporate a nanomaterial concerned
by the above-mentioned provisions.**

11. **The provisions of Article 95, as modified by the future amendments of the
BPR (see document " CA-Feb13-Doc.5.2a - Problems identified in new
Regulation"), will apply to nanomaterials in the following way :**

   • For **nanomaterial already under assessment (ie. theses nano-forms are
currently supported by participants),** the provisions applies as for any other
existing active substances, meaning that biocidal products containing them
can only remain on the market after 1st September 2015 if an appropriate
dossier has been submitted to ECHA under article 95 by the relevant
persons, and that relevant persons are listed in ECHA's list.

   • For **nanomaterials intended to be supported under this new procedure,**
provisions of article 95 will not apply as long as a dossier to require the
approval as not been considered as complete under this specific review
programme. Once a dossier is considered as complete, only biocidal
products containing the nanomaterial linked to the relevant persons listed
in ECHA's list will be allowed to be made available on the market.

Taking into account the above-mentioned proposals, a realistic timing for the
implementation of these provisions could be the following one:

   a. Adoption of a Regulation modifying/repealing Regulation (EC)
No1451/2007, and establishing the whole procedure: September 2013

   b. Publication of a **notice** by Commission in order to have a feedback from
participants who currently supports nanomaterials: March 2013
c. Deadline for these participants to come back and give to the Commission some information on their nanomaterial: June 2013

d. Verification of submitted information by these participants: before 1\textsuperscript{st} September 2013

e. Publication of a withdrawal notice by the Commission: September 2013

f. Deadline for making a declaration of intention to notify a nanomaterial (3 months after publication of the withdrawal notice): December 2013

g. Deadline for submitting the notifications (18 months after the publication of the withdrawal notice): March 2015

h. Deadline for ECHA to give its opinion on the acceptance of the notifications: May 2015 or July 2015 (in case the applicant has to complete its notification)
i. For notifications with a positive opinion of ECHA, adoption of a decision to include these nanomaterials in the notified list of active substances in the review programme: September 2015

j. Deadline for applicants to submit their application to request the approval of these nanomaterials (2 years after the date of inclusion into the notified list of substances in the review programme): September 2017

4. CONCLUSION

The Commission would like to receive the views of the Member States and stakeholders on this proposal.
APPENDIX

Parts of the Draft Regulation XXX/2013 amending Regulation (EC) No1451/2007 as regards additional active substances of the biocidal products to be examined under the review programme

"(1) The following Article 3a is inserted:

‘Article 3a
Procedure for the declaration of intention to notify

[...]

3. Where, following a consultation in accordance with paragraph 2, the Commission finds the request acceptable, it shall accept it and allow the notification of the active substance for the relevant product-types.

However, where the dossier submitted to the Rapporteur Member State for the relevant active substance already contains all the data required for the evaluation of the relevant product-types for which Article 4 prohibits the placing on the market, and the participant which has submitted that dossier wishes to be considered as having notified the active substance for those product-types, the Rapporteur Member State shall inform the Commission thereof, and no additional notification shall be allowed pursuant to the first subparagraph.

The Commission shall inform the Member States thereof and publish that information electronically.

4. A person intending to notify the active substance/product-type combination included in the electronic publication referred to in the third subparagraph of paragraph 3 shall declare that intention to the Commission no later than three months from the date of that electronic publication.'

(2) The following Article 3b is inserted:

‘Article 3b
Notification procedure

1. Following the declaration of intention to notify, the person referred to in Article 3a(4) shall submit a notification of the active substance/product-type
combination to the European Chemicals Agency established by Regulation (EC) No 1907/2006 (hereinafter referred to as the 'Agency') no later than 18 months from the date of the electronic publication referred to in the third subparagraph of Article 3a(3).

The notification shall be made through the Register for Biocidal Products referred to in Article 71 of Regulation (EU) No 528/2012 of the European Parliament and of the Council *.

2. The notification shall be submitted in IUCLID-format. It shall contain all the information referred to in points I to 3 and the table in Annex II to Regulation (EC) No 1896/2000, and proof that the substance was on the market as an active substance of a biocidal product falling under the relevant product-type on the date of the electronic publication referred to in the third subparagraph of Article 3a(3).

3. Unless a Rapporteur Member State has already been designated for the active substance in question, the notifier shall indicate to which competent authority of a Member State it intends to submit a dossier, and provide written confirmation that that competent authority agrees to evaluate the dossier.

4. Upon receipt of a notification, the Agency shall inform the Commission thereof, and inform the notifier of the fees payable under the Regulation adopted pursuant to Article 80(1) of Regulation (EU) No 528/2012. If the notifier fails to pay the fee within 30 days from the receipt of that information, the Agency shall reject the notification and inform the notifier thereof.

5. Upon receipt of payment of the fees, the Agency shall verify within 30 days whether the notification complies with the requirements of paragraph 2. If the notification does not comply with those requirements, the Agency shall grant the notifier a period of 30 days in which to complete or correct the notification. After the expiry of that 30-day period, the Agency shall, within 30 days, either declare that the notification complies with the requirements of paragraph 2 or reject the notification, and inform the notifier thereof.

6. Appeals against decisions of the Agency taken pursuant to paragraph 4 or paragraph 5 shall lie with the Board of Appeal established by Regulation (EC) No 1907/2006. Article 92(1) and (2), and Articles 93 and 94 of Regulation (EC) No 1907/2006 shall apply to such appeal procedures. An appeal shall have suspensive effect.

7. The Agency shall without delay inform the Commission of whether the notification complies with the requirements of paragraph 2 or has been rejected.’

(3) The following Article 3c is inserted:
1. Where an active substance is considered notified in accordance with the second subparagraph of Article 3a(3), or where the Agency informs the Commission in accordance with Article 3b(7) that a notification complies with the requirements of Article 3b(2), the Commission shall accept the notification and:

(a) where the active substance/product-type combination concerned is not included in Annex II to this Regulation, include the active substance/product-type combination therein and, where relevant, the active substance in Annex I to this Regulation;

(b) where the active substance/product-type combination concerned is included in Annex II to this Regulation but has been the subject of a Commission decision not to include it in Annex I or IA of Directive 98/8/EC, annul that decision.

2. Where a declaration of intention to notify has not been received within the deadline referred to in Article 3a(4), where a notification has not been received within the deadline referred to in Article 3b(1), or where the Agency informs the Commission in accordance with Article 3b(7) that a notification submitted in accordance with Article 3b(1) has been rejected, the Commission shall inform the Member States thereof and publish that information electronically.

(6) In Article 4, the following paragraph 4 is added:

‘4. By way of derogation from paragraphs 1 and 2, biocidal products containing an active substance for which the Commission has published electronically the relevant information in accordance with the third subparagraph of Article 3a(3) for the relevant product-types may be placed on the market in accordance with Article 16(1) of Directive 98/8/EC until the date when the Commission has taken a decision to include the active substance/product-type combination in Annex II in accordance with point (a) of Article 3c(1) or to annul a previous non-inclusion decision in accordance with point (b) of Article 3c(1), or for a period of six months from the date when the Commission has published electronically the relevant information in accordance with Article 3c(2).’

(7) In Article 9, the following paragraph 3 is added:

‘3. By way of derogation from paragraph 2, for active substance/product-type combinations listed in Annex II in accordance with point (a) of Article 3c(1), or for which a decision has been annulled in accordance with point (b) of Article 3c(1), applications for approval of an active substance in accordance with Article 7 of Regulation (EU) No 528/2012 shall be submitted no later than two years from the date of the decision adopted in accordance with points (a) or (b) of Article 3c(1).’