EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Safety of the food chain
Pesticides and Biocides

NOTE FOR GUIDANCE

This document is an attempt to provide guidance in the interest of consistency, and has been drafted by the Commission services responsible for biocidal products with the aim of finding an agreement with Member States' Competent Authorities for biocidal products. Please note, however, that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

Subject: **Q&A pairs concerning the practical implementation of the simplified authorisation procedure (SAP)**

1.- Background and purpose of the note

(1) At the 14th meeting of the Coordination Group (CG) there was a discussion about data requirements under the SAP. In this context, CG members raised the need for further guidance not only concerning the authorisation itself but also for the notification process.

(2) Until more detailed guidance is developed by ECHA, this note aims at providing a common understanding of the SAP in order to help Member States (MSs) to follow a harmonised approach that is consistent with the objectives in the biocidal products Regulation (BPR). The note is intended to be a living document to which additional Q&A pairs can be added upon discussion and agreement within the CG.

2.- Content of the note

(3) The note is structured in 3 Annexes. Annex I includes the list of agreed Q&A pairs, which is structured in five sections addressing the following:

a) Data requirements,

b) Procedural issues,

c) Assessment of the application by the evaluating Competent Authority (e-CA),

d) Post-authorisation notification to other MSs,

e) Changes to product authorisations.

(4) Annex II contains the relevant references to the SAP in Regulation (EU) No 528/2012[1] (the "BPR" hereafter) and in Regulation (EU) No 354/2013[2] (the "changes Regulation" hereafter). Annex III includes a list of other available guidance related to the SAP.

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market of biocidal products (OJ L 167, 27.6.2012, p. 1).

[2] Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

Annex I

Q&A pairs concerning the practical implementation of the SAP

Section 1.- Data requirements

(1) **Q:** What is the legal identification of an AS listed in Annex I to the BPR (e.g. category 4: traditionally used substances of natural origin)? It is only the name, or the name in combination with the EC/CAS number, as appropriate?

A: The legal identification of an AS listed in Annex I to the BPR includes both the name and, as appropriate, the EC/CAS number.

(2) **Q:** Are in-situ products eligible for the SAP when the in-situ AS is included in Annex I to the BPR?

A: The BPR does not set any limitation to in-situ products, provided that the conditions in Article 25 are met.

(3) **Q:** Is a letter of access (LoA) to the active substance (AS) data required for the authorisation of a product/biocidal product family (BPF) by the e-CA? And if the AS is listed under category 6 of Annex I to the BPR?

A: No. In accordance with Article 20(1)(b) of the BPR a LoA is not required, even if the AS is listed under category 6[3].

(4) **Q:** What information/data should be submitted by the applicant in accordance with Article 20(1)(b)(iii) of the BPR allowing the e-CA to evaluate whether or not the product/BPF meets the conditions in Article 25 of the BPR?

A: The following information/data will have to be submitted to address each condition in Article 25:

Article 25(a): Exact composition of the product/BPF;

Article 25(b): The safety data sheet (SDS) of each co-formulant (i.e. non-active substances or in-can preservatives) and of the biocidal product, as well as an assessment by the applicant concluding that the product/BPF does not contain any substance of concern (SoC) in accordance with the agreed EU guidance[4] (*see also Q&A pair 13 for some co-formulants*).

Article 25 (c): A statement by the applicant that the product/BPF does not contain any nanomaterials.

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[3] Note that the provisions regarding data protection of substances in category 6 of Annex I to the BPR in document CA-Feb13-Doc.5.1.l – Final do not apply to the SAP. Where the AS is listed under category 6, see also Q&A pair number 11.

[4] CA-Nov14-Doc.5.11-Final, available at https://circabc.europa.eu/w/browse/8f596c6c-182b-4522-856a-5ca7a6c50c96

Article 25(d): Efficacy data to demonstrate that the product is sufficiently effective according to the criteria laid down in Annex VI to the BPR[5].

Article 25(e): Where relevant, data and an assessment of these data by the applicant concluding that the handling of the product(s) and its intended use do not require personal protective equipment (PPE) (e.g. a study demonstrating that the product is not skin sensitizer, so making the precautionary statement "wear gloves" irrelevant).

(5) **Q:** Could all this information be submitted in the form of a draft risk/efficacy assessment performed by the applicant as for other authorisation procedures?

A: Yes. Even in the absence of a specific Product Assessment Report (PAR)[6] template for the SAP, applicants are encouraged to use an adapted version of the already available PAR template within the submission of the application. Applicants should start using the SAP PAR template when it becomes available.

(6) **Q:** Where the applicant submits product-specific studies, should these studies be conducted according to the same standards or applicable guidance than for the other authorisation procedures?

A: In the absence of any derogation in the BPR, the same standards or guidance would apply. This conclusion can be adapted on a case by case basis provided that the applicant submits sufficient data allowing the e-CA to reach a robust conclusion (e.g. the product is sufficiently effective or it does not require the wearing of PPE).

Section 2.- Procedural issues

(7) **Q:** Is there under the SAP a validation phase of the application? How should the e-CA request additional information/data to the applicant?

A: No, under the SAP there is no validation phase, but just an acceptance of the application once the applicant has paid the relevant fees to the e-CA. Then the evaluation phase would automatically start, although the clock can be stopped and additional information may be requested in accordance with Article 26(4) of the BPR.

(8) **Q:** Where the applicant submits additional information, when should the e-CA restart the evaluation?

A: In accordance with the second subparagraph of Article 26(4), the e-CA shall restart the clock for a 90-day period as soon as the new information is submitted.

(9) **Q:** Several existing active substances included in the Review Programme set out under Article 89 of the BPR have been, or will be eventually, included into Annex

[5] See paragraph 5 in document CA-May14-Doc.5.5 – Final, available at https://circabc.europa.eu/w/browse/3c1b49b1-fb3d-4ae4-b2e0-3e206955cc94

[6] ECHA is working on the adaptation of the PAR template for the other authorisation procedures to the SAP.

I to the BPR[7] through Delegated Acts in accordance with Article 28(1) of the BPR. Is it possible to apply for a product authorisation under the simplified authorisation procedure before the date of approval set out in the Delegated Act including the active substance in Annex I?

A: The inclusion into Annex I of an active substance is valid as soon as the Delegated Act including the substance in Annex I enters into application. A "date of approval" is established for the application of Article 89(3) and sets a deadline for the authorisation of existing products containing this active substance on the market, for the submission of applications, and for stopping the making available on the market and use of products for which no application is submitted.

Therefore, for a new product containing an active substance included in Annex I, a company may choose :

- to place its new product on the market in compliance with the transitional rules of the Member States and apply for a BPR authorisation before "the date of approval" in accordance with the second paragraph of Article 89(2), or

- to apply directly for a BPR authorisation.

In particular, in those Member States where authorisations are required under the transitional national rules, it may be quicker and more convenient for a company to obtain directly a BPR authorisation if the product is eligible for authorisation via the simplified authorisation procedure.

(10) **Q:** Is it possible to suspend the 30 day period for notifying the intention to place a biocidal product (simplified authorisation) on the market in case issues are identified?

A: No, there is no such possibility provided in Article 27. However, in practical terms, the 30 days period defined in Article 27(1) should be counted from the time when the submitted documentation is considered complete. Then, if within the 30 days period, additional questions are raised, the notifier is informed that they cannot proceed to place the product on the market until the matter is resolved (Article 27(2), second paragraph).

In addition, Article 27(2) establishes that if a notified Member State considers that a biocidal product authorised in accordance Article 26 has not been notified or labelled in accordance with Article 27(1) or does not meet the requirements of Article 25 the matter "may" be referred to the co-ordination group. Therefore, Article 27(2) provides the possibility to have informal discussions before a formal referral is raised.

It is proposed to establish a 60-day period in addition to 30 day period set by Article 27(1) to allow the possibility of reaching an agreement before a formal referral is launched (Article 35). However, it should be noted that questions have to be

[7] For instance, several food and feed active substances have been included into Annex I to the BPR during the implementation of the BPR, like vinegar, *Saccharomyces cerevisiae*, powdered egg etc.

communicated to the evaluating competent authority within the 30 days (in the established 60 days period)

Section 3.- Assessment of the application by the e-CA

(11) **Q:** Should the e-CA produce a product assessment report (PAR) summarising the evaluation of the application?

A: Yes. Although not explicitly requested by the BPR, a PAR produced by the e-CA and made available via R4BP3 would be a useful tool for the MSs notified in accordance with Article 27(1) to better understand the assessment performed by the e-CA and decide whether or not a case should be referred to the CG according to Article 27(2).

(12) **Q:** Should the e-CA discuss with other MSs the conclusions of its assessment (e.g. by making available the draft PAR) before granting the authorisation?

A: No. The e-CA shall grant the authorisation in accordance with Article 26(3) or (4) of the BPR without having to discuss the conclusions of its assessment with other MSs.

(13) **Q:** Should the e-CA check compliance with Article 95 for the suppliers of the AS(s) listed in Annex I to the BPR?

A: Only where the product/BPF contains an AS listed under category 6 of Annex I to the BPR. In that case, the e-CA has to check compliance with Article 95 of the source referred to in the draft SPC of the product and the e-CA shall only authorise compliant products[8].

(14) **Q:** Which in-can preservative ASs can be used in the biocidal product undergoing the SAP? Do they have to be included in the review program in PT6?

A: In-can preservative ASs in any biocidal product must be approved or under assessment in the review program for PT6 or included in Annex I to the BPR.

(15) **Q:** How to consider whether co-formulants that are evaluated as an AS are a SoC?

A: According to the document CA-Nov14-Doc.5.11-Final, co-formulants that are evaluated as an AS and for which a draft final CAR is available, should be considered as a SoC. However, the eCA may consider on a case by case basis that, where these co-formulants (e.g. in-can preservatives or others) do not lead to the classification of the biocidal product, these co-formulants may not be a SoC since the definition in Article 3(1)(f) of the BPR may not be met.

(16) **Q:** Aside from the information provided in the SDS(s), should information from other sources also be used in the assessment both for the AS(s) and non-active substances (e.g. C&L database or the assessment report for substances in category 6)?

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[8] In other to allow the e-CA to check compliance with Article 95, the applicant should submit the relevant documents as for the normal authorisation procedure.

A: Concerning the AS(s), the BPR only requires that it appears in Annex I and satisfies any restriction specified in that Annex so no additional information should be checked[9]. Concerning non-active substances the e-CA may also consider other sources of information in line with the agreed note for guidance on SoC (CA-Nov14-Doc.5.11-Final)[10].

(17) **Q:** If a biocidal product is classified due to the concentration of the AS(s)[11] or the non-active substances, can that product be authorised under the SAP?

A: It depends on a case by case approach. Article 25(b) and (d) requires that the product must not contain any SoC and must not require PPE, respectively. Where a classified product is considered neither to contain any SoC nor to require PPE (i.e. on account of data provided by the applicant), the product can still be authorised under the SAP.

(18) **Q:** If the data provided by the applicant is inadequate according to applicable guidance, can further information/data be required?

A: Article 26(4) of the BPR allows the e-CA to stop the clock of the evaluation phase and request additional information to the applicant. Where the additional information is submitted in time and addresses the concerns of the e-CA, then the product/BPF should be authorised. Otherwise the application should be rejected.

Section 4.- Post-authorisation notification to other MSs

(19) **Q:** What information should the authorisation holder (AH) include in a notification to another MS in accordance with Article 27(1) of the BPR?

A: The relevant requirements to carry out such notification via R4BP3 are available in the ECHA guidance on simplified authorisations[12]. This includes the translation of both the SPC in xml format and the label in the required language(s), as well as any other supporting documents[13] (e.g. where relevant, the models or drafts referred to in Article 69(3) of the BPR). The PAR produced by the e-CA should be available in R4BP within the relevant asset, so it should not be included in the notification.

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9 Except compliance with Article 95 for substances under Category 6 (see Q&A number 11).

10 With the exception referred to in Q&A pair number 13 concerning in-can preservatives and other co-formulants.

11 In accordance with Article 25(a) the restrictions in Annex I shall always be met (e.g. concentration limits for category 1).

12 http://echa.europa.eu/documents/10162/14938692/bsm_07_simplified_authorisation_en.pdf (page 24)

13 These supporting documents do not mean in any case the full data package in the application submitted to the e-CA.

(20) **Q:** Which authorisation number should appear on the label of a product notified to another MS? Is it the authorisation number in the MS of the e-CA or another number to be given by the notified MS?

A: Under the SAP, the BPR only provides for a single authorisation (and therefore a single authorisation number) in the MS of the e-CA, as the products placed on the market of other MSs are not given an "authorisation" in accordance with Article 26 of the BPR but just notified in accordance with Article 27. Therefore, the authorisation number both in the SPC and on the label should be the one established in the MS which granted the product authorisation. This should be sufficient for control purposes (i.e. check the label against the SPC available in R4BP3 – or ECHA website in future – corresponding to the authorisation number on the label).

If applicants would have to seek an additional country-specific authorisation number to be put on the label before their notification, this would create an unnecessary administrative burden that would go against the main principles of the SAP (*see recital 29 of the BPR*).

(21) **Q:** Could e-CAs use as their authorisation number the R4BP3 asset number (i.e. EU-XXXXXXX-0000) in order to avoid a wide variety of formats of authorisation numbers on one MS's market?

A: As the format of the authorisation numbers is a competence of MSs, they could use such convention if it is agreed by all MSs. This approach would also facilitate multilingual labelling of products.

(22) **Q:** Could a MS create a national register with all the products notified in accordance with Article 27(1) of the BPR?

A: The BPR is silent about this, so MSs can decide unilaterally to establish such local national registers for enforcement purposes. However, such a register would be redundant if access to this information, which is available in R4BP3 (i.e. all the notifications to a given MS can be listed), was granted to enforcement authorities. In any case, the functioning of such register cannot impose any requirements to the AH beyond those set by the BPR, such as including an additional register number on the label prior to the placing on the market of the product.

(23) **Q:** Regarding a BPF authorised under the SAP, should the AH notify the BPF authorisation (i.e. the entire family) or is the AH allowed to submit a notification for just one or more individual products of the family?

A: Article 27(1) of the BPR refers to (the individual) biocidal products that are going to be placed on the market of the notified MS. Therefore, the AH should be given the opportunity to notify all the individual products within a family or just one or more – but not all – the products within the family[14].

[14] For the sake of efficiency, a single notification could include several individual products within a given family. Until this functionality is fully supported by R4BP, ECHA will develop a temporary work around as the AH still has to notify the whole BPF in R4BP in order to notify single products.

(24) **Q:** How should the AH notify a new individual product (i.e. where the variations in composition do not only concern PPD) in the BPF?

A: A new individual product in the BPF has to be first notified to the e-CA (i.e. in accordance with article 17(6) of the BPR) and be included in the BPF authorisation. Then, the AH can proceed to notify the new product to other MSs in accordance with article 27(1) of the BPR.

(25) **Q:** Is it legally possible to notify an individual product twice (with a different trade name)?

A: No. A single product shall only be notified once, including all the trade names of that product[15]. Then the authorisation holder should ensure correspondence between the label and the SPC of the product (i.e. trade names, uses, etc..) in accordance with document CA-May14-Doc.5.6 - Final[16].

(26) **Q:** Should the AH always wait for a formal agreement of the notified MS to the notification before placing the product on the market of that MS?

A: No. Where the notification is submitted in time (i.e. at least 30 days before the placing on the market) and the notified MS does not express any disagreement before the placing on the market within its territory within those 30 days, that MS should be deemed to have agreed with the notification and the AH can proceed to place the product on the market.

(27) **Q:** Is an insufficient quality of the translation of the SPC a reason for the notified MS to express a disagreement? Should this be referred to the CG?

A: As a good translation of the SPC into the required language(s) of the notified MS is essential to produce the label of the notified product in such language(s), the notified MS may consider that the notification does not satisfy the requirements in Article 27(1) where the quality of the proposed translation is not sufficient. Should it be the case, the notified MS should inform the AH of that disagreement or submit the formal communication referred to in Q&A number 28 (*see below*) within 30 days from the notification.

However, since it is not really a disagreement with the e-CA, but rather disagreement with the applicant regarding the translation, it is proposed that these disagreements are not referred to the CG.

(28) **Q:** What does it mean in Article 27(2) that "the product is not labelled in accordance with paragraph Article 27(1)? Has the notified MS to check the quality of the translation of the labels?

A: Article 27(1) requires that the AH shall use the official language(s) of the notified MS in the product's labelling. As far as this requirement is met, a quality

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[15] Where the AH wants to have an additional trade name in a notified MS, the AH has to notify first the change to the eCA. See also Q&A pair number 31.

[16] "Content of label of single biocidal products with regard to the authorised uses in the SPC", available at https://circabc.europa.eu/w/browse/f818ccf3-207f-408f-a3cf-c62422fdf346

check of the translation of the labels is not expected at this procedural step. As in the context of other authorisation procedures (e.g. MR), compliance of the labels with the SPC is a matter of enforcement.

(29) **Q:** Where a notified MS considers that the product has not been notified or labelled in accordance with paragraph Article 27(1) or it does not meet the requirements of Article 25, should that MS contact the e-CA, the AH or both, before referring a matter to the CG in accordance with Article 27(2)?

A: In cases of disagreement that are referred to the CG, Article 27(2) refers to the provisions of Articles 35 and 36 of the BPR, so this procedure applies. Although not explicitly mentioned in the BPR, a prior contact could be useful as it can avoid the formal referral to the CG.

Where the identified matter concerns the requirements of Article 25, the notified MS should consult the e-CA and keep the AH informed. Where the matter concerns the notification deadlines or the translation of the authorised SPC and the label into the required language(s), the notified MS should consult the AH. These contacts are without prejudice to the formal communication referred to in Q&A number 28 (*see below*).

(30) **Q**: When a biocidal product family is authorized under the simplified authorisation procedure, and the authorisation holder notifies just one or more individual products of the family in other Member States, are the notified Member States entitled to raise formal referrals, in accordance with Articles 35 and 36 of the BPR, for products for which ~~did not received~~ a notification was not received?

A: No, the notified MS is only entitled to raise referrals on those individual products of the family for which they have received the notification.

Kommentiert [A1]: which they did not receive a notification

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~~(30)~~(31) **Q:** Where a notified MS decides to provisionally restrict or prohibit the making available on the market or use of a product on its territory, when and how should this decision be communicated to the AH?

A: Where the notification is submitted in time (i.e. at least 30 days before the placing on the market), the notified MS should inform the AH via R4BP3[17] before the placing on the market within the MS's territory.

Section 5.- Changes to product authorisations

~~(31)~~(32) **Q:** Can the AH notify/apply for a change in the notified MSs?

[17] Until this is supported by the IT tool, this could also be informed to the AH via the submission of the referral to the CG, with an explicit mention that the making available on the market or use of the product is provisionally restricted or prohibited on its territory until, where relevant, a decision pursuant to Articles 35 and 36 is taken.

A: No, any notification or application for a change shall be submitted to the e-CA, as the e-CA is the only CA having authorised the product and therefore the only CA that can amend the product authorisation.

~~(32)~~(33) **Q:** Where there is a change notified/submitted to the e-CA, should the AH inform all the notified MSs or can the applicant decide to only notify a few of these MSs?

A: No, the applicant shall inform all the notified MSs.

~~(33)~~(34) **Q:** According to Article 9 of the changes Regulation, MSs having been notified in accordance with Article 27(1) of the BPR shall also be notified by the AH of any notifications or applications for a change made to the e-CA. Where the agreed change(s) affects the SPC, the AH shall submit the revised SPC to each notified MS. Where one of these MSs disagrees with the revised SPC, could this be referred to the CG in accordance with Article 27(2)?

A: Article 10(2) of the changes Regulation only refers to Articles 6(3), 7(6) and 8(6) of that Regulation because these provisions concern cases in which MSs have to discuss the conclusions before the decision, whereas Article 9(2) of the changes Regulation concerns a post-amendment notification. As some changes, particularly major changes, might have a significant impact on the terms and conditions of the authorisation and for consistency with the overall aim of Article 27(2), the notified MSs should be given the possibility to refer these matters to the CG applying Article 27(2) by analogy.

~~(34)~~(35) **Q:** When should the AH submit the revised SPC to the notified MSs?

A: While the changes Regulation is silent on this, it shall be done without undue delay as the revised SPC may affect the terms and conditions for the making available on the market of the affected product.

~~(35)~~(36) **Q:** Where one of the notified MSs disagrees with the revised SPC, what are the applicable deadlines to refer the matter to the CG in accordance with Article 27(2)?

A: For consistency with the process of the initial notification in accordance with Article 27(1), it is proposed that where a notified MS does not express any disagreement within 30 days of the submission of the revised SPC, that MS should be deemed to have agreed with the revised SPC and the AH can proceed to place the product on the market in accordance with the new terms and conditions of the product authorisation.

Annex II

A. BPR provisions on the simplified authorisation procedure

Recital 29
To encourage the use of products with a more favourable environmental or human or animal health profile, it is appropriate to provide for simplified authorisation procedures for such biocidal products. Once authorised in at least one Member State, those products should be allowed to be made available on the market in all Member States without the need for mutual recognition, under certain conditions.

Recital 30
To identify biocidal products which are eligible for simplified authorisation procedures, it is appropriate to establish a specific list of the active substances that those products may contain. That list should, initially, contain substances identified as presenting a low risk under Regulation (EC) No 1907/2006 or Directive 98/8/EC, substances identified as food additives, pheromones and other substances considered to have low toxicity, such as weak acids, alcohols and vegetable oils used in cosmetics and food.

Article 20(1)(b). Requirements for applications for authorisation
(b) for biocidal products that the applicant considers meet the conditions laid down in Article 25:
(i) a summary of the biocidal product characteristics as referred to in point (a)(ii) of this paragraph;
(ii) efficacy data; and
(iii) any other relevant information in support of the conclusion that the biocidal product meets the conditions laid down in Article 25.

Article 22(1). Content of authorisation
1. An authorisation shall stipulate the terms and conditions relating to the making available on the market and use of the single biocidal product or the biocidal product family and include a summary of the biocidal product characteristics.

Article 25. *Eligibility for the simplified authorisation procedure*
For eligible biocidal products, an application for authorisation may be made under a simplified authorisation procedure. A biocidal product shall be eligible if all the following conditions are met:
(a) all the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex;
(b) the biocidal product does not contain any substance of concern;
(c) the biocidal product does not contain any nanomaterials;
(d) the biocidal product is sufficiently effective; and
(e) the handling of the biocidal product and its intended use do not require personal protective equipment.

Article 26. Applicable procedure
1. Applicants seeking the authorisation of a biocidal product meeting the conditions of Article 25 shall submit an application to the Agency, informing it of the name of the competent authority of the Member State that it proposes should evaluate the application and providing written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

2. The evaluating competent authority shall inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.
Upon receipt of the fees payable under Article 80(2), the evaluating competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.
3. Within 90 days of accepting an application, the evaluating competent authority shall authorise the biocidal product if satisfied that the product meets the conditions laid down in Article 25.
4. Where the evaluating competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.
The evaluating competent authority shall, within 90 days of receipt of the additional information, authorise the biocidal product if satisfied, on the basis of the additional information submitted, that the product meets the conditions laid down in Article 25.
The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. In such cases, where fees have been paid, part of the fees paid in accordance with Article 80(2) shall be reimbursed.

Article 27. Making available on the market of biocidal products authorised in accordance with the simplified authorisation procedure
1. A biocidal product authorised in accordance with Article 26 may be made available on the market in all Member States without the need for mutual recognition. However, the authorisation holder shall notify each Member State no later than 30 days before placing the biocidal product on the market within the territory of that Member State and shall use the official language or languages of that Member State in the product's labelling, unless that Member State provides otherwise.
2. Where a Member State other than that of the evaluating competent authority considers that a biocidal product authorised in accordance with Article 26 has not been notified or labelled in accordance with paragraph 1 of this Article or does not meet the requirements of Article 25, it may refer that matter to the coordination group established in accordance with Article 35(1). Article 35(3) and Article 36 shall apply mutatis mutandis.
Where a Member State has valid reasons to consider that a biocidal product authorised in accordance with Article 26 does not meet the criteria laid down in Article 25 and a decision pursuant to Articles 35 and 36 has not yet been taken, that Member State may provisionally restrict or prohibit making available on the market or use of that product on its territory.

B. Provisions on the simplified authorisation procedure in the changes Regulation

Article 9. Biocidal products authorised in accordance with Article 26 of Regulation (EU) No 528/2012
1. Where the authorisation has been granted in accordance with Article 26 of Regulation (EU) No 528/2012, the authorisation holder or its representative shall notify each Member

State, on the territory of which the biocidal product is made available, of notifications or applications made to the reference Member State in accordance with Article 6, 7 or 8 of this Regulation.
2. Where a reference Member State has agreed with a revised summary of the biocidal product characteristics, the authorisation holder or its representative shall submit the revised summary to each Member State on the territory of which the biocidal product is made available in the official language(s) of that Member State.

Article 10. Coordination group, arbitration and derogation from mutual recognition
1. A Member State concerned may propose to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation in accordance with Article 37 of Regulation (EU) No 528/2012.
2. Where, regarding matters other than those referred to in paragraph 1, the Member States concerned do not reach an agreement on the conclusions of the assessment report or, where relevant, on the revised summary of the biocidal product characteristics in accordance with Article 7(6) or 8(6), or a Member State concerned has disagreed in accordance with Article 6(3), the reference Member State shall refer the matter to the coordination group referred to in Article 35 of Regulation (EU) No 528/2012.
Where a Member State concerned is in disagreement with the reference Member State, the former shall give a detailed statement of the reasons for its position to all Member States concerned and to the applicant.
3. Articles 35 and 36 of Regulation (EU) No 528/2012 shall apply to matters of disagreement referred to in paragraph 2.

Annex III. Other available guidance relevant for the simplified authorisation procedure

- Practical guide on biocidal products Regulation on Simplified authorisation (click here).

- CA-Sept13-Doc.6.2.e-Final: Handling of applications for product registration submitted under the BPD for which the evaluation has not been completed by 1st September 2013 (click here).

- CA-May14-Doc.5.5-Final: Consideration of storage stability, stability and shelf-life data in the context of applications for product authorisation under the simplified procedure (click here).

- "Biocides Submission Manual; Application instructions: Simplified authorisations" (click here).