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Food and feed safety, innovation
Pesticides and Biocides

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Note for agreement with Competent Authorities for Biocidal Products

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, it does not represent the official position of the Commission and 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: An interim approach for the establishment of maximum residue limits for residues of active substances contained in biocidal products for food and feed and specific migration limits in food contact materials

1. BACKGROUND AND PURPOSE OF THE DOCUMENT

(1) As the use of biocidal products may lead to residues in food or feed, Article 19(1)(e) of Regulation (EU) No 528/2012[1] (BPR) lays down that biocidal products shall be authorised provided that, in particular, where appropriate (*emphasis added*), maximum residue[2] limits (MRLs) for food and feed have been established in accordance with relevant Union legislation, or specific migration limits or limits for the residual content in food contact materials.

[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 and use of biocidal products

[2] In this note the definition of residues applies as included in Article 3(1)(h) in the BPR.

(2) In September 2009, a note[3] on the establishment of MRLs was endorsed.

(3) In July 2013, a discussion note[4] was presented on the use of biocides in food contact materials suggesting that only for those substances that are deliberately incorporated or impregnated into the final food contact material to achieve a biocidal function and keep the article free from microbial contamination, and which are also likely to migrate into food ('surface biocides'), should a specific limit[5] for those biocidal substances be set. It was indicated that the details of the procedure to coordinate the assessment of applications for product authorisation under the BPR and the setting of migration limits also had to be further elaborated.

(4) In December 2013, a discussion note[6] was presented on the general approach for MRL setting for biocidal active substances. It was suggested in this note, in order to use the limited resources in an efficient way, to develop a focused and risk-based approach to identify active substances requiring MRL setting based on proven concerns for consumers.

(5) In March 2014, the Federal Institute for Risk Assessment in Germany (BfR) together with the Commission services organised the Conference on MRL Setting for biocides[7]. During that Conference, the Commission services identified a number of open questions with regard to the establishment of MRLs such as the extent of carry-over of biocides into food and feed, the identification of critical areas with implications for consumer safety, the enforcement of MRLs and procedural aspects.

(6) In January 2015 the Committee for Medicinal Products for Veterinary Use of the European Medicines Agency (EMA) adopted a Guideline on risk characterisation and assessment of MRLs for biocides[8].

(7) In parallel to this, draft guidance documents have been developed by the Ad hoc Working Group on the Assessment of Residue Transfer to Food (ARTFood) of the European Chemicals Agency:

- on Estimating Livestock Exposure,

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[3] Reference: https://circabc.europa.eu/w/browse/4e4c2281-f7fc-4562-aae0-7d97c139d46c.
[4] Reference: https://circabc.europa.eu/w/browse/5b5b7006-4b09-48a8-aceb-ea342467e62d
[5] In the note the term limit is used for a limit or level established by a regulatory framework. Level is used to indicate quantities in food or feed in the context of scientific evaluations, technical assessment or monitoring.

[6] Reference: https://circabc.europa.eu/w/browse/2b30279e-cd1a-4749-ac08-7be39d4a7909
[7] The minutes of the BfR conference on MRL setting are available at: http://www.bfr.bund.de/cm/349/summary-report-of-the-european-conference-on-mrl-setting-for-biocides.pdf.
[8] The relevant EMA-documents are available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000512.jsp&mid=WC0b01ac05804aca04.

- on Estimating Transfer of biocidal Active Substances into Foods - Professional Uses, and
- on Estimating Transfer of biocidal Active Substances into Foods - Non-Professional Uses.

(8) In May 2015 a revised discussion note on MRLs (revision 1)[9] was presented. The purpose of this note was to discuss the way forward for the establishment of maximum residue limits for biocidal products. In particular a procedure was proposed to decide whether a limit for a residue of a substance contained in a biocidal product is required and how such a limit would be established. Member States and stakeholders were requested to send comments by 30 June 2015. In June 2015, the same note was presented to the Standing Committee on Plants, Animals, Food and Feed (PAFF). Member States were invited to send comments by 10 July 2015. In September 2015[10] a revised note (revision 2) was presented to the competent authorities for biocidal products and PAFF. Member States were invited to send comments by 10th of October 2015. In total six Member States provided comments.

(9) In November 2015 (revision 3) a revised note[11] on MRLs was presented to the competent authorities for biocidal products. In December 2015, the Commission presented the same note to PAFF. The Commission in particular pointed out in both meetings that this policy approach would be considered an interim solution based on the current legal setting. A new concept of setting limits for biocides could be further discussed in the context of the evaluation of the plant protection products legal framework and the possible review of it. The objective of the proposed policy approach is to identify the substances for which there is a potential risk. The applicants for products containing such substances will then in particular be expected to provide analytical methods. Member States and stakeholders were invited to provide comments before 15 January 2016. Comments were received of in total from six Member States and from one stakeholder.

(10) In March 2016 a revised note (revision 4) was presented on MRLs[12]. Participants were asked to send comments before the 18th of March 2016. In total one Member State provided comments.

(11) In November 2016 a revised note (revision 5)[13] was presented on MRLs to the competent authorities for biocidal products. The same note, with editorial

[9] Reference: https://circabc.europa.eu/w/browse/1315221d-970c-49b5-8163-b4e623960dd4.
[10] https://circabc.europa.eu/w/browse/52cf5c38-fa40-4af5-907a-085fbc9bb6b9.
[11] https://circabc.europa.eu/w/browse/291814b3-1702-40d8-82ab-5fd235944a4b.

[12] https://circabc.europa.eu/w/browse/2636dd53-4413-4bfb-8831-c6c1a4260251.

[13] https://circabc.europa.eu/w/browse/428268b5-491b-43fa-9a8a-c8efd496765a

amendments (revision 6), was presented to PAFF in November 2016. Participants of both meetings were asked to provide comments before 15 December 2016.

2. THE WAY FORWARD: AN INTERIM APPROACH

(12) Currently very limited data exist on the occurrence of residues in food and feed directly linked to the use of biocidal products. Moreover, no existing EU legislation is fit to set limits for the occurrence of residues of biocidal active substances contained in biocidal products linked to all relevant types of use of biocidal products. Therefore, it is important to establish an interim approach that, if necessary, should be updated to the gained experiences and data in three years. The interim approach, based on a step-wise procedure and the current knowledge and data, is proposed to help deciding in which situations and/or under which conditions it is necessary to establish limits for residues of biocidal active substances.

(13) For that purpose it is essential to clarify the responsibilities of the different actors (applicants, users of biocidal products, EU Agencies, Member States Competent Authorities and the Commission).

(14) The use of biocidal products is usually not intended to expose food or feed to active substances contained in these products. This differentiates clearly the way that biocidal products and plant protection products/veterinary medicinal products are being used. However, it is acknowledged that the use of biocidal products during the production, manufacture, processing, preparation, treatment, packing, transport of animals, plants, food or feed, may lead to the presence of residues in food or feed and those residues may in many cases be unavoidable. In accordance with the purpose of ensuring a high level of protection of human health, it is key that the interim approach provides proportionate measures to mitigate the risks of significant exposure of consumers to residues derived from biocidal use.

(15) As food or feed are in general not intentionally exposed to biocidal products, and based on the current information available on the occurrence of residues in food, it is expected that the step-wise procedure would lead to a limited number of biocidal active substances contained in biocidal products for which it is concluded that it is necessary to establish limits for residues. It is important that the interim approach will reveal those situations where exposure of consumers implies a possible risk and, therefore, requires setting limits.

(16) The consequence of the way biocidal products are being used is that residues are more likely to be found in processed or composite food rather than in unprocessed food. Residues of biocidal products may however also occur in unprocessed food. Up to now in the existing legal frameworks setting limits for residues in food focusses mainly on unprocessed food/raw products. The BPR refers to setting limits within existing legal frameworks, but it is not currently possible to address the specific situation of residues of biocidal products in processed food within those frameworks. Therefore, a practical, interim approach should be applied until this issue can be addressed in a more systematic way across legal frameworks.

(17) As indicated above one of the purposes of the BPR is ensuring a high level of protection of human health and animal health. Therefore, key points in the interim step-wise procedure should be the use pattern of biocidal products, the likelihood for transfer of active substances including their metabolites, breakdown or reaction products into food and feed, the extent to which consumers may be exposed to residues from biocidal products as well as the risk associated with this exposure.

(18) Biocidal products may be necessary and sometimes essential for ensuring the hygiene of food and feed commodities and processed food and feed, in particular to ensure the compliance with microbiological criteria established for commodities and processed products. Taking this into account, to achieve the purpose of the BPR of ensuring a high level of protection of human health, the interim policy approach should find the right balance between two objectives:

(a) Limiting consumer exposure to residues of active substances contained in biocidal products, and

(b) Ensuring microbiological safety by having effective tools to control organisms to the extent that they cannot cause harm to human or animal health.

(19) Some Member States' comments in the context of the setting of limits for biocidal active substances would imply amending primary legislation such as Regulation (EC) No 396/2005.

(20) As an evaluation of that Regulation is foreseen in the coming years, the establishment of MRLs for active substances contained in biocidal products would require amendments to the Regulation, including the introduction of measures concerning exposure to the same substances from multiple sources. These amendments will be considered in the context of the evaluation of that Regulation and its possible review but it is not possible to introduce those measures now.

(21) This note therefore proposes a policy approach compatible with the current legal setting and can be considered as an interim approach until the evaluation and possible amendment of the current regulatory framework has been finalised.

(22) The experience gained and data gathered whilst implementing the interim approach, should feed into the forthcoming evaluation of Regulation (EC) No 396/2005 in respect to its application to biocidal active substances. In addition, the interim approach should be updated, as appropriate, taking into account experience and any further data gathered in a period of three years after its adoption.

(23) Following agreement on the interim approach proposed in this note, further discussion will take place on the details of its implementation in relation to the existing legal framework referred to in Article 19(1)(e) of the BPR.

2.1 Consumer exposure unlikely: no further action is required for substances belonging to certain product-types

(24) The question of residues should be further explored, when active substances under normal conditions of biocidal use (i.e. the conditions of authorisation of the biocidal products) can lead to residues in food or feed.

(25) Since the use of biocidal products belonging to product-types 3, 4, 5, 18, 19 and 21[14] is more prone to lead to the presence of residues in food or feed, a risk-based approach should concentrate on these products.

(26) On the other hand, the use of biocidal products belonging to product-types 1, 2, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 20 and 22[15] would not be expected to lead to the presence of residues in food or feed. Where there are indications that i) measurable residue levels can be found in food as a result of the use of the biocidal product for which authorisation is requested, and ii) the applicant fails to demonstrate that these residue levels do not pose a risk to health[16], such biocidal products should be considered as requiring MRLs.

2.2 Likely consumer exposure: no further action is required for substances for which limits established under other legislation are considered safe or for which no maximum limits are required

(27) The question of residues should be further explored[17], when active substances under normal conditions of use (i.e. the conditions of authorisation of the biocidal products) can lead to measurable residue levels in food[18].

(28) There should be no need to establish specific limits for active substances in the following categories, if safety limits have not been deemed necessary or have been established already under existing legislation:

(a) substances included in the EU list of approved food or feed additives[19], or substances normally used as food and/or feed and listed as a food or feed item in Annex I of Regulation (EC) No 396/2005[20],

[14] Biocidal products of product-types 3, 4, 5, 18 and 19 concern disinfectants used for veterinary hygiene purposes, for the disinfection in the food and feed area, for the disinfection of drinking water, and products used for the control of arthropods.

[15] This are biocidal products not covered by the products covered in footnote 14.

[16] The risk for health can be considered in relation to the Health Based Guidance Value established for this active substance.

[17] Policy development is on-going in order to address the risks associated with a cumulative exposure of consumers to the same active substance by different sources of use.

[18] There is no need to point out the occurrence of hazardous substances in this paragraph as these are specifically addressed by Article 5 of the BPR.

(b) substances included in Annex I to BPR[21] or Annex IV[22] of Regulation (EC) No 1907/2006 or Annex IV of Regulation (EC) No 396/2005[23],

(c) micro-organisms approved under Regulation (EC) No 1107/2009 or under the BPR, when it is concluded in the assessment report that the organism is sufficiently well defined to establish it has no toxicity or infectivity to humans, and that it does not produce/contain any toxin that could adversely affect consumer health[24],

(d) consumer exposure to the active substance linked to use as a biocidal product is considered as negligible compared to other uses in the food chain and/or natural background[25].

(29) However, MRLs should be established if there are indications that (i) measurable residue levels can be found in food as a result of the use of the biocidal product for which authorisation is requested and (ii) the applicant fails to demonstrate that these residue levels do not pose a risk to health[26].

(30) Expert judgement may be needed to decide in specific cases where deviation from this principle is considered necessary by an authority

(31) It is important to note that the residues of biocidal active substances referred in paragraph 28, subparagraph a, have to be within the defined ranges in which these substances are allowed to be added as food or feed additive.

(32) Substances contained in biocidal products may also be used as veterinary medicinal products (VMPs) or plant protection products (PPPs). When specific limits have already been established under legislation for residues for this type of use, it can be assumed that there is no consumer risk if active substance residue levels in food resulting from biocidal use remain below these limits. The respect of these limits can be estimated and evaluated as a part of the process of an application and evaluation for product authorisation. Further consideration is

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[19] Regulation (EC) No 1333/2008 on food additives and Regulation (EC) No 1831/2003 on additives for use in animal nutrition..

[20] This approach is in line with Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005 (SANCO/11188/2013, 13 June 2013), reference: http://ec.europa.eu/food/plant/pesticides/guidance_documents/docs/sanco-2013-11188_en.pdf.

[21] Active substances contained in the biocidal product eligible for the simplified authorisation procedure (Article 25(a) of BPR).

[22] Substances that are considered to cause minimum risk because of their intrinsic properties (Article 2(7)(a) of REACH)

[23] Active substances of plant protection products for which no MRLs are required (Article 5 of Regulation (EC) No 396/2005).

[24] See footnote 24

[25] See footnote 24; residues that are negligible compared to other uses may still lead to an increase of overall risk because of an increase of the overall exposure,

[26] See footnote 16.

required in order to ensure any future modification of such an existing limit takes account of the cumulative exposure by use as VMP or PPP and biocidal use.

(33) Those existing limits will however have been set in most cases for specific food commodities (for example meat, milk or apples).

(34) The application of a biocidal product occurs at different stages of the supply chain. Furthermore, food can be exposed to biocidal products during or after its processing and before or after mixing/blending. Consequently, residues from biocidal products may be expected to be detected and of relevance in processed or composite food products.

(35) When biocidal products are used before processing of food and those foods are then concentrated, dried or diluted, use of a concentration or dilution factors may be appropriate in order to be able to judge the appropriate limits in these processed food products. The appropriate limit in composite foods can likewise be calculated from the composition of the food of primary commodities. When a biocidal product is used during the processing stage, account should be taken of the possibility that several uses of the same biocidal product may occur. It is emphasised that further discussion will need to take place in general on the need to establish limits for processed and composite products. As indicated in paragraph 20 an evaluation of the legal framework for plant protection products is foreseen in the coming years.

2.3 Likely consumer exposure via food with the potential for appreciable risk: the question of the need of setting a limit for residues should be further explored

2.3.1 Active substances used as surface biocides[27] in food contact material: the FCM approach

(36) Regulation (EC) No 1935/2004 on food contact materials (FCM) provides the possibility to establish limits on the migration of constituents into or on to food. Risk assessments are performed by the European Food Safety Authority (EFSA). Further discussion is required on the details of the procedure by which these migration limits will be established.

2.3.2 Active substances used in animal husbandry: the VMP approach

(37) For biocidal products used in animal husbandry and for which an MRL evaluation is considered necessary for the active substance, Article 10 of Regulation (EU) No 470/2009 specifies that a limit shall be established through

[27] See paragraph 3 for definition of surface biocide.

this regulation[28]. The risk assessment is performed by EMA. The data requirements for the applications are included in the EMA Guideline on risk characterisation and assessment of MRLs for biocides[29].

(38) Further discussion is required with EMA on the level of the fee applicable and the procedures to establish a limit for active substances contained in biocidal products used in animal husbandry.

2.3.3 Active substances currently or formerly used as plant protection products: the PPP approach

(39) For active substances that are currently or formerly used as PPPs, the 0.01 mg/kg default limit established by Regulation (EC) No 396/2005[30, 31] would apply in the absence of more specific MRLs.

(40) However, recent developments have demonstrated that it will be difficult to comply with the default values set under existing legislation for residues of certain active substances contained in biocidal products and this can be also the case where MRLs are set under Regulation (EC) No 396/2005. This is illustrated in the case of quaternary ammonium compounds (QACs) that come within the definition of plant protection products. Although they are no longer used for plant protection purposes, the statutory limit set under plant protection legislation applies, with residues above the limit being found in processed and composite food products, following the use of biocidal products containing QACs[32].

(41) In such cases a specific MRL can be established by Regulation (EC) No 396/2005 for the active substance, based on information submitted by stakeholders and authorities. The MRL should sufficiently protect consumers on the possible exposure to residues due to the use of the substance in biocidal products, as low as reasonable possible and based on good practice for the use of the specific biocidal product(s).

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[28] Limits should be set for all relevant food-producing animal species that may be exposed to the biocidal active substance in accordance with the principles set for pharmacologically active substances intended for use in veterinary medicinal products in Regulation (EC) 470/2009.

[29] See footnote 8.

[30] Fish and fish products are mentioned in Annex I of Commission Regulation (EU) No 752/2014 but footnote entry 5 (page 24) of this regulation suspends the application of the levels in the Annex to fish, fish products and any other marine and freshwater food products until individual products have been identified and listed within this category.

[31] Article 18(1) of Regulation (EC) No 396/2005 specifies that the products covered by Annex I shall not contain, from the time they are placed on the market as food or feed, or fed to animals, any pesticide residue exceeding […] 0,01 mg/kg for those products for which no MRL is set out in Annexes II or III, or for active substances not listed in Annex IV unless different default values are fixed for an active substance in accordance […].

[32] See Commission Regulation (EU) No 1119/2014 of 16 October 2014 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzalkonium chloride and didecyldimethylammonium chloride in or on certain products.

2.3.4 Different limits established for the same substance under different legislation

(42) Where different limits have been established for a substance, it is necessary to clarify what limit should apply for biocidal active substances contained in biocidal products.

(43) Considering that each limit is established by using scientific data with the objective of ensuring a high level of consumer protection, the highest limit[33] should be applied when different limits have been established.

2.3.5 Active substances not covered by the legislation on FCMs, PPPs, or VMPs

(44) Biocidal products may contain substances for which no limits have been established or are applicable, whether specific or default. According to the proceedings of the Conference on MRL Setting for biocides of March 2014 about 60 of the notified biocidal active substances have no MRL set so far.

(45) Article 19(e) of Regulation (EU) No 528/2012 specifies that "where appropriate" MRLs for food and feed have to be established. Therefore, MRLs should be considered to be established in situations where i) measurable residue levels in food would arise from the envisaged use (as an indicator of significant exposure) and ii) the applicant fails to demonstrate that these residue levels do not pose a risk to health.

(46) The conclusions of the Conference on MRL Setting for biocides of March 2014 suggest setting MRLs for biocidal substances by applying the legislation on plant protection products including the default value approach. In this context it is important to note that the scope of Regulation (EC) No 396/2005 concerns commodities in or on which pesticide residues may be present. The definition of pesticide residues in Article 3(2)(c) of this Regulation does not apply to substances that are "biocides only", i.e. substances being used in a biocidal product that are not and were not in the past used in plant protection products. Therefore, Regulation (EC) No 396/2005 cannot be used to set MRLs for biocidal substances that are not and were not in the past used in plant protection products.

(47) Thus, for the interim approach, and until the Regulation (EC) No 396/2005 may be amended, when it would be necessary to establish limits for residues of biocidal active substances not covered by the legislation on FCMs, PPPs or VMPs, reliance on Council Regulation (EEC) No 315/93 (contaminants) or Directive 2002/32/EC (undesirable substances in feed) is necessary and the following approach would be followed.

[33] The highest limit is the limit providing the highest level for residues of a substance which may be accepted in food.

(48) The applicant has to provide sufficient information[34] to identify the relevant residues in representative food/feed commodities in which residues of the substance are most likely to occur[35] and to provide related analytical methods to detect residues in those food/feed commodities. The provided analytical methods should be in-house validated[36].

(49) As a next step, Member States and other parties[37] are encouraged, on the basis of the food/feed commodities identified and of the analytical methods provided, to collect occurrence data whether residues occur of the substance in food or feed and to help decide whether it is necessary to establish a limit.

(50) When a Member State or a stakeholder, based on collected data, considers that a limit should be set, it should inform the Commission. The Commission, based on the provided information, may decide to trigger the appropriate procedure for setting limits under Council Regulation (EEC) No 315/93 (contaminants) or Directive 2002/32/EC (undesirable substances in feed). This implies that EFSA will be asked to provide an scientific advice and, if necessary, a limit will be set in accordance with the opinion of the Standing Committee on Plants Animals Food and Feed.

It is emphasised that maximum levels adopted under Council Regulation (EEC) No 315/93 and Directive 2002/32/EC will be set, based on the available information, as low as reasonably achievable. This implies that the exposure of consumers to residues caused by biocidal products will be as low as reasonably achievable.

(51) Finally, it shall be noted that if a Member State considers that, in the period between the authorisation of a product and the possible setting of limits in accordance with the procedure described in this section 2.3.5, food or feed is unsafe because of the occurrence of residues, this Member State can take appropriate actions to protect public and animal health pursuant to Article 14 ("food") or 15 ("feed") of Regulation (EC) No 178/2002[38]. With applying Article 14 or 15 the Member State can ensure that a high level of protection of human

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[34] This is in line with the responsibility of applicant to provide the relevant information and in accordance with point 5.3 of Annex II and Annex III of the BPR.

[35] The monitoring of biocidal residues will require resources with regard to sampling and laboratory analysis. By determining the critical use areas of the biocidal products for the occurrence of residues, if possible, in a joint approach with the users of the product, for example food businesses, Member States can focus monitoring on those products in which most likely residues will occur.

[36] This implies that an applicant is not required to provide an analytical method valid ated by a national or a EU reference laboratory. If a competent authority has serious doubts about the appropriateness of the analytical method it could be submitted to a EU reference laboratory for verification.

[37] Also applicants and stakeholders are encouraged to collect and submit occurrence data on residues in food and/or feed,.

[38] Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (Official Journal of the European Union, L 31 of 1.2.2002).

health is ensured during the period of gathering of information to determine whether there is a need for setting limits, and if necessary, the appropriate level.

Final considerations

(52) The processes of establishing MRLs or migration limits for substances used in food contact materials should ideally take place between the adoption of the decision on the approval of the active substance and the biocidal product authorisation.

(53) In cases where it would not be possible to complete these processes by the time of product authorisation, in accordance with Article 22(q) of the BPR, it may be necessary to include in the biocidal product authorisation a condition[39] that data need to be submitted for the establishment of an MRL or a migration limits. If the data are not provided within the set deadline in the authorisation, the authorisation may be withdrawn.

(54) When specific limits have already been established for residues of the active substance, they should be applied for the use of these active substances in biocidal products[40].

(55) Food is subject to controls on residues. The setting of a limit for residues of active substances contained in biocidal products in food implies that Member States have to monitor these residues in the relevant commodities.

(56) Following this agreement on the interim approach further details of the procedures have still to be developed (e.g. on food contact materials and veterinary medicinal products). After some experience has been gained with the new procedures, these may be laid down in a Commission Notice on the interpretation and implementation of Article 19(1)(e) of the BPR.

(57) Finally, it should be noted that Council Regulation (EEC) No 315/93, Directive 2002/32/EC, and Regulation (EC) No 470/2009 do not provide specific rules on data protection and data-sharing.

[39] It is proposed that Member States and the Commission will agree on a format for this type of condition to be included in the biocidal product authorisations, so there is a harmonised approach across the EU.

[40] Exposure to the same substances from multiple sources may occur. This should be considered in the context of the evaluation of the Regulation (EC) No 396/2005, see paragraphs 20-22.