Discussion document on the regulation of the use of biocides in food contact materials

THIS DOCUMENT DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION. ITS PURPOSE IS TO PROVIDE A BASIS FOR DISCUSSION ON THE REGULATION OF THE USE OF BIOCIDES IN FOOD CONTACT MATERIALS.

IT IS AN EVOLVING DOCUMENT

DRAFT FEBRUARY 2013
Scope of the issue

Regulation (EU) No 528/2012 (the biocides Regulation) establishes new rules and procedures for the authorisation of biocidal products and approval of the active substances with which they are formulated. The Regulation will apply from 1 September 2013.

The Regulation will establish a Union list of active substances approved for use in specific biocidal product types following an opinion from the European Chemicals Agency (ECHA). The second phase of the process will involve authorisation of the biocidal product itself.

Substances that require an EU level authorisation for their use in food contact materials – at present functional constituents of plastic and regenerated cellulose film – are evaluated in accordance with Regulation (EC) No 1935/2004 by the European Food Safety Authority (EFSA) and subsequently set out in the relevant measures. There is currently no EU authorisation procedure for other groups of materials and articles.

Unlike its predecessor Directive 98/8/EC, the biocides Regulation now lays down rules for treated articles (Article 58), which will include food contact materials. Thus, the placement on the market of treated articles will only be allowed after the appropriate approval of the active substance for the relevant biocidal product-type (PT) – in the case of food contact materials, PT4 (Annex V to the biocides Regulation) – and for treated articles manufactured in the EU, the authorisation of the biocidal product itself.

The biocides Regulation does not distinguish different types of materials or articles. Therefore any material or article that may constitute a food contact material will fall within its scope and whereby specific measures may be taken for the groups of materials and articles set out in annex I to Regulation (EC) No 1935/2004.

Furthermore, the biocides Regulation foresees a role for other areas of legislation concerning food and feed to set limits that may restrict the presence of the biocidal substance in food to protect consumer health, including food contact materials. The biocides Regulation provides for the opportunity to submit information on the use in a treated article and data on migration.

In light of this, a harmonised and consolidated approach for the assessment and authorisation of substances used as biocides in food contact materials is required. The aim of this draft document is to discuss and propose ways forward for the future authorisation of biocides used in food contact materials.

The approach should be taken in an effective way so as to ensure that biocides used in food contact materials do not pose a risk to consumers whilst minimising the administrative burden and avoiding duplication of work for the risk assessment bodies as well as industry.

This document discusses and considers solutions for the following key issues:

1. Types of biocides that may be present in a food contact material and proposed approach
2. How the approval/ authorisation procedure may work including EFSA’s role
3. Current status and future of biocidal substances already used in food contact materials
1. Types of biocides that may be present in a food contact material and proposed approach

Process biocides

A number of different biocides are used as components in the manufacture of food contact materials for the purpose of keeping the material or preparations which are to be processed into the final material or article free from microbial contamination during the production, storage or handing processes. They are however, not intended to be present in the final food contact material. For this reason and in this context they are termed 'process biocides'.

During the manufacture of plastic food contact materials for example, such biocides would be regarded as polymer production aids for which there is no legal requirement for authorisation to be on the positive list of substances in Annex I to Regulation (EU) No 10/2011, although non-mandatory authorisation is a possibility. For non-plastic materials and articles including regenerated cellulose film there is no positive list and therefore no such requirement either.

The incorporation of the biocide into the food contact material would be regarded as unintentional carry-over which should only occur in minute amounts where unavoidable. One way in which to deal with this could be to set a default limit e.g. 10 ppb. Additionally, industry must act under self-responsibility, where guidance on best practice, for example, could eventually be foreseen. In any case, the manufacture of the material should adhere to the general requirements of Article 3 of Regulation (EC) No 1935/2004.

The process biocides themselves however, will still be subject to the biocides Regulation. It is foreseen that the types of biocides that may be used in the process of manufacturing food contact materials will generally fall into product type 6 (preservatives for products during storage), product type 7 (film preservatives) or product type 12 (slimicides). Materials or preparations such as pre-polymer solutions, which intentionally incorporate one or more biocidal product, will themselves be a treated article. These types of biocides will not be approved under PT4 for use in a food contact material1.

Surface biocides

Some biocides are used in the manufacture of food contact materials and are intended to be present in the final article itself for example, substances used in cutting boards, storage containers, conveyor belts and fridge surfaces. Their purpose is to keep the surface of the food contact material free from microbial contamination. For this reason and in this context they are termed 'surface biocides'.

For food contact materials made from plastic (or regenerated cellulose film), such biocides are regarded as additives because they are intentionally added to the plastic to exert an effect – in this case to achieve a biocidal function – in the final material and article and are intended to be present in the final material or article. Thus at present, there is a legal requirement for such substances to be evaluated in accordance with the provisions of Regulation (EC) No 1935/2004 and that the substances must thereafter be authorised on the positive list of substances in Annex I to Regulation (EU) No 10/2011 for use at EU level. For non-plastic

1 In certain circumstances, it may be necessary to undertake a specific evaluation of such 'process biocides', particularly where the migration is demonstrated to be above 10ppb.
materials and articles, there is no equivalent positive list and therefore currently no such requirement at EU level of the substance to be used.

Since the final food contact material itself intentionally incorporates a biocidal substance, it is a treated article and falls under the scope of the biocides Regulation and the requirements contained therein. This includes the requirement for the active substance to be approved for a given product type. In the case of biocides that are used to impregnate materials which may enter into contact with food, this would require an approval under product type 4 (PT4) – the food and feed area with due consideration of its use in food contact materials and articles. In the EU, the biocidal product must also be authorised.

There are currently no biocides included in the list of authorised substances in Annex I to Commission Regulation (EU) 10/2011 as regards plastics, only those 11 that are currently on the provisional list and used in accordance with national law. The list can be found at http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/080410_provisional_list_7_211009.pdf. The substances included on the list are triclosan (2,4,4’-trichloro-2’-hydroxydiphenyl ether) and certain substances containing silver e.g. silver zeolite A.

**Food preservatives**

Some biocides are used in the manufacture of food contact materials and are intended to be present in the final material or article. However, they are also intended to be released into the food itself or have a preservative effect on the food. For this reason and in this context these types of biocides are termed 'food preservatives'.

For food contact materials, such biocides that exert an effect on the food itself would be regarded as active substances covered by Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food. In accordance with this Regulation, only those preservatives that are authorised as food preservatives in the food additives and flavourings legislation, namely Regulation (EC) No 1333/2008 and Regulation (EC) No 1334/2008, can legally be used for this function.

Furthermore, such substances as those contained within Regulation (EC) No 1333/2008 and Regulation (EC) No 1334/2008 are specifically excluded from the scope of the biocides Regulation – see Article 2(2)(f) and (g).
2. The authorisation process including EFSA's role

At present, substances that require an authorisation for their use in food contact materials i.e. functional constituents of plastic or regenerated cellulose film are evaluated exclusively in accordance with Regulation (EC) No 1935/2004 and their authorisation together with any restrictions are reflected in the relevant measure i.e. in the case of plastics Regulation (EU) No 10/2011 and in the case of regenerated cellulose film Directive 2007/42/EC. A number of biocides are currently included on the provisional list for plastics and used in accordance with national law pending their authorisation or not at EU level.

For non-plastic materials and articles there is currently no equivalent positive list and therefore no such requirement at EU level of the substance to be used.

Whereas Regulation (EC) No 1935/2004 requires that the application for the authorisation of a new substance to be included on an adopted positive list should take place in accordance with this Regulation (Article 9 onwards), the new biocides Regulation (EU) No 528/2012 sets out its own process for the approval of substances – and authorisation of subsequent biocidal products on the EU market – that may then be intentionally incorporated into or used to treat an article such as a food contact material.
In accordance with the biocides Regulation there will be a two-tier process before a biocide can be used:

I. Approval of active substance for a particular product type 4 (PT4 for food contact materials);

II. Authorisation of the biocide product where this is to be placed on the market in the EU

The biocides Regulation includes within its scope the setting of residue limits where necessary to restrict the presence of the biocidal substance in food to protect consumer health (recital 37) and goes on further to specify Regulation 1935/2004 in Article 19, whereby such a limit may be set during the authorisation of a biocidal product.

The biocides Regulation also provides for the opportunity to submit information on the use in a treated article both at the stage of approving an active substance (Article 4(3)(d)) and at the stage of authorising a biocidal product (Article 19(2)(b)). As part of the requirements for information on active substances, it allows for data on migration into food to be submitted where relevant in the case of treatment of food contact materials (Annex II, 8.16.7).

In the context of the above, it is prudent and desirable to have one overall approval and authorisation procedure for biocides in a food contact material that will:

✓ Ensure the biocide is safe for use in food contact materials including a specific assessment to allow for the setting of an SML;
✓ Minimise administrative burden both for risk assessment bodies and industry;
✓ Avoid duplication of effort, particularly as regards plastic materials and articles whilst taking the opportunity to ensure the safe use in other materials and articles;
✓ Respect the legal restrictions of both the biocides legislation and food contact materials legislation.

As the new biocides Regulation now includes food contact materials within its scope, it is proposed that the overall assessment and approval of substances and the assessment and authorisation of biocidal products to be incorporated into food contact materials will be carried out under the framework of Regulation (EU) No 528/2012. However, it is also proposed that an additional or complementary assessment will be required to ensure the safety for this specific use and the setting of an SML where substances are approved and biocidal products authorised, under the food contact materials framework legislation 1935/2004.

Regulation (EU) No 528/2012 lays down a number of conditions to meet for the authorisation of a biocidal product once a substance is approved for the appropriate product type. Article 19(1)(e) requires that where appropriate maximum residue limits for food are established with respect to active substances contained in a biocidal product in accordance with Regulation (EC) No 1935/2004.

However, a key point to consider is that an FCM may be manufactured in a third country and imported into the EU without any evaluation of a biocidal product taking place, since according to Article 58(2) of the biocides Regulation, only approval of the active substance
used in the biocidal product for the relevant product type, is required and not authorisation of
the biocidal product. This potentially leaves a gap for the complete scrutiny and assessment of
using a biocidal substance in a food contact material.

It is therefore suggested that the assessment of the use of an active substance specifically in a
food contact material should be undertaken within the scope of the first stage of approving an
active substance. This renders greater control at an earlier stage of the process and no matter
where the food contact material is manufactured, the use of the substance will have been
assessed.

Where the application for approval is for use in PT4, the applicant would have to submit
sufficient data to enable the specific assessment of use in a food contact material e.g.
appropriate migration data to complement the approval process to demonstrate safe use in the
food contact materials and to enable the setting of an SML. If this information is not
submitted, the substance can still be approved under PT4 but its specific use in a food contact
material would be automatically excluded.

In reality, during the initial substance approval stage it is likely more often than not that data
would not be submitted to support a specific use in a food contact material. However, a
mechanism should be available to rescind the automatic exclusion at a later point in time
should data be provided and a specific assessment for use in food contact materials undertaken.

Whereas the approval of a substance in PT4 would be set out in a Commission Implementing
Regulation under the legal framework of Regulation 528/2012 on the basis of an Opinion
from ECHA, its use in food contact materials would only be allowed with the complementary
setting of an SML under the legal framework of Regulation 1935/2004 (Article 5(e)), set out
in a new measure on food contact materials (see below), on the basis of an Opinion from
EFSA\(^2\).

Involvement of bodies to provide risk assessment

It is foreseen that at EU level, a peer review of the assessment undertaken by a Rapporteur
Member State (RMS), is organised by ECHA, within the Biocidal Products Committee and
that the outcome of this assessment /peer review forms an ECHA opinion on the active
substance or biocidal product, where an application is made at EU level.

As regards food contact materials, Article 7 of Regulation (EC) No 1935/2004 determines that
provisions liable to affect public health shall be adopted after consultation with EFSA. It is
appropriate therefore that EFSA should be involved in the process whereby an assessment is
needed specifically to evaluate the use of a particular substance in food contact materials. This
should be undertaken once the bulk of the assessment work has been carried out by ECHA i.e.
evaluating the toxicological data.

\(^2\) Other restrictions may also have to apply, for example use of the substance to be restricted to a particular type
of material.
Regulation (EC) No 1935/2004 does not set out a specific process for the setting of an SML nor provide for detailed modalities of EFSA’s involvement. It is thus proposed that the general modalities set up in Regulation 178/2002 for EFSA’s involvement should apply.

With specific reference to Article 29, a permanent/standing Commission mandate to EFSA could be set up to provide a basis for EFSA conducting assessment work to complete the evaluation where necessary and fulfil the requirements of Regulation 1935/2004. Details of dossier requirements, verification of correct information, timeframes and in general the relationship between ECHA and EFSA would need to be clarified. The input from EFSA is foreseen after the main part of the work by the RMS and ECHA has been conducted.

To facilitate the process, EFSA could provide guidance specifically to help applicants provide relevant data i.e. to supplement Annex II, 8.16.7 of Regulation 528/2012. This would help an eventual decision to be made on whether the substance is safe in a food contact material or not and what restrictions apply. The guidance could form part of the ECHA guidance currently under draft.

Possible legislative changes

In order to achieve the objectives set out above, a new measure could be considered specifically for the use of biocides in food contact materials. The measure would incorporate the following aspects:

1. For the purposes of ‘completing’ the approval procedure under the biocides Regulation, a new measure on food contact materials would lay down the process for the application and setting of an SML for surface biocides to be used in a food contact material. Together with an appropriate mandate, this would ensure that EFSA are involved in the process and that the use of the biocide specifically in a food contact material can only be allowed with the agreement of an SML, on the basis of an EFSA opinion and under the framework of Regulation (EC) 1935/2004.

2. The new measure would feature an annex containing a list of biocidal substances together with the relevant SML. Only once the relevant SML is established can the approval procedure be completed for the use of the biocide substance specifically in the food contact material. The legal basis for the establishment of an SML should be Article 5(e) of Regulation (EC) 1935/2004.

3. Amendment of Commission Regulation (EU) 10/2011 (on plastics) and Commission Directive 2007/42/EC (on regenerated cellulose film) to specifically exclude surface biocides from the scope of these measures. This means that:
   a. The principal procedures for the approval of biocidal substances in all food contact materials would be the same for all food contact materials, including for plastics and regenerated cellulose film;
   b. The authorisation procedure for all relevant substances except surface biocides will continue to take place in accordance with Regulation (EC) 1935/2004 and the agreed authorisations and associated restrictions will be reflected in the associated measures (e.g. monomers for plastics).
4. Amendment to Regulation 528/2012

It is proposed that active substance used as a surface biocide in a food contact material should be specifically approved for such use under PT4.

The use in food contact materials would be automatically excluded. Active substances could however still be authorised under PT4 without the relevant migration data being provided and assessment but in this case its until such a time that the relevant data is provided and appropriate assessment and setting of SML carried out.

To that effect, the data requirements listed under item 8.16.7 of annex II of regulation 528/2012 should be clarified.

Summary of proposals

- A new measure on food contact materials to:
  - Exclude surface biocides from scope of current legislation on plastics (Reg 10/2011) and regenerated cellulose film (Directive 2007/42/EC)
  - Lay down the process for setting an SML for biocides
  - List of approved surface biocides together with restrictions including SML
- Amend Regulation (EU) No 528/2012, Annex II to clarify that information on migration into food is needed for active substances to be incorporated into FCMs
- Substances to be used as surface biocides in food contact materials to be specifically approved for such use
- Use in food contact materials to be excluded under PT4 unless specific assessment for use in food contact material has taken place
- Main toxicological evaluation to be undertaken by RMS/ ECHA. Complementary assessment by EFSA to evaluate use in food contact material and propose SML

3. Current status and future of biocidal substances already used in food contact materials

At present, a number of biocides are used in plastic food contact materials, including Triclosan as well as a number of silver-based substances. They have been assessed by EFSA but their use in plastics has not been agreed and authorised at EU level and to date they remain on the 'provisional list', which allows their use at national level. See http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/080410_provisional_list_7_211009.pdf.

Triclosan

Triclosan was evaluated by the Scientific Committee on Food (SCF 2000) and the European Food Safety Authority (EFSA 2004) for use in food contact materials and classified in SCF List 33 with a restriction of 5 mg/kg of food. Potential uses beyond household articles like cutting boards, kitchen utensils and food storage containers exist (e.g. conveyor belts, machinery, work surfaces and transport containers used in food processing).
Under the current Biocides Directive 98/8/EC, Triclosan has been used as an active substance for a number of biocidal product types e.g. PT7 for film preservatives. It is therefore an existing active substance for several product types and is subject to the ongoing review programme being carried out under the biocides framework for these product types.

However, Triclosan is not currently supported in the review programme for PT4 and can therefore not be placed on the market for such uses under Directive 98/8/EC. There are transitional measures foreseen both for biocidal products and in addition, for the treated articles incorporating these products. Article 94 of the biocides Regulation states that those treated articles on the market on 1 September 2013 may, until the date of a decision concerning the approval for the relevant product-type of the active substance contained in the biocidal product with which they are treated, or which they incorporate, continue to be placed on the market provided that an application for the approval of the substance in the relevant product type is submitted by 1 September 2016.

Hence, those food contact materials that incorporate Triclosan as a surface biocide and that are on the market on 1 September 2013, may continue to be made available provided an application is submitted by 1 September 2016 under the biocide Regulation to support the use of Triclosan as a surface biocide (PT4). Otherwise those food contact materials can no longer be placed on the market after 1 September 2016. If an application is made and an approval is not granted, the food contact materials would also need to be withdrawn from the market within 180 days after this decision or before 1 September 2016, whichever is the later.

In addition, in accordance with Article 93 of the BPR, biocidal products containing Triclosan, and used as a surface biocide (PT4) could be made available on the market in accordance with national rules until 1 September 2017, if they already were on the market before 1 September 2013, in accordance with the provisions of the food contact materials legislation. After 1 September 2017, these products could only continue to be made available on the market in accordance with national rules if an application for product authorisation has been submitted before that date and until the date of the decision granting the authorisation. This is relevant where food contact materials are manufactured in the EU.

### Silver containing substances

Concerning silver, EFSA has evaluated the use of various silver releasing biocides in food contact materials in 2004 and in 2005 allocating a group specific migration limit (SML) of 0.05 mg Ag/kg food. Silver zeolite A is used to control microorganism growth on the food contact material and to thereby preserve the article. Glass matrices containing silver, magnesium, phosphorus and/or calcium and/or boron and/or aluminium and/or sodium and/or silicon oxides are glasses may be used as additives for food contact plastic materials.

Some of the silver substances, including silver zeolite A, which are on the 'provisional list', allowing their use in food contact materials at national level are supported for PT4 under the biocides review programme and eventually their inclusion in PT4 will be confirmed or not. If it is confirmed, they will continue to be allowed to be used in food contact materials together with an appropriate SML etc, taking into account existing EFSA opinions where they continue to be relevant. Until a decision is taken, as per the transitional measures foreseen for treated articles which have been treated with or intentionally incorporate these silver
compounds, food contact materials that are available on the market on 1 September 2013 can remain on the market.

For the other silver substances, like silver chloride coated onto titanium oxide, they are not supported for PT4 under the biocides review programme. As for Triclosan, an application will therefore have to be submitted under the biocide Regulation for their use in PT4 by 1 September 2016 otherwise they can no longer remain on the market after this date. An application for product authorisation where food contact materials are manufactured in the EU would also need to be received by 1 September 2017.

Other substances

For materials and articles other than plastics and regenerated cellulose film, there is no requirement to authorise substances and hence there may be other biocidal substances that are used in the final article of other types of food contact material. If such articles are already on the market on 1 September 2013, they may remain on the market until 1 September 2016 by which time an application for the approval in PT4 will need to be received and a subsequent decision made. Alternatively, if the substance is one that happens to be currently supported for PT4 and it is concluded that it can be continue to be used for PT4, an additional assessment for its use in the relevant food contact material would also need to be completed.

Anyone wishing to place a food contact material on the market after 1 September 2013 for the first time incorporating an active substance not approved or supported for PT4 will have to first make an application for the use of the substance in PT 4 first and subsequently an application for authorisation of the biocidal product where the food contact material is manufactured in the EU.

The table below shows the substances currently on the provisional list and a column to indicate those that are currently approved for PT4 and under the review programme.

<table>
<thead>
<tr>
<th>PM ref.</th>
<th>Name of the substance</th>
<th>Supported in review programme as PT 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>86430</td>
<td>20%w/w Silver chloride coated onto 80% (w/w) titanium dioxide</td>
<td>No</td>
</tr>
<tr>
<td>86432</td>
<td>Silver-containing glass (silver-magnesium-calcium-phosphate-borate)</td>
<td>No</td>
</tr>
<tr>
<td>86432/20</td>
<td>Silver containing glass (silver-magnesium-aluminium-phosphate-silicate), silver content less than 2%</td>
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</tr>
<tr>
<td>86432/40</td>
<td>Silver containing glass (silver-magnesium-aluminium-sodium-phosphate-silicate-borate), silver content less than 0,5%</td>
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</tr>
<tr>
<td>86432/60</td>
<td>Silver containing glass (silver-magnesium-sodium-phosphate),silver content less than 3 %</td>
<td>No</td>
</tr>
<tr>
<td>86434</td>
<td>Silver sodium hydrogen zirconium phosphate</td>
<td>Yes</td>
</tr>
<tr>
<td>86437</td>
<td>Silver Zeolite A (Silver-zinc-sodium-ammonium-aluminosilicate), silver content 2 – 5%</td>
<td>Yes</td>
</tr>
<tr>
<td>86437/50</td>
<td>Silver-zinc-aluminium–boron–phosphate glass, mixed with 5-20% barium sulphate, silver content 0,35 – 0,6 %</td>
<td>No</td>
</tr>
</tbody>
</table>
### Summary of proposals

- **Triclosan** and a number of silver substances not currently approved for PT4 will be allowed to remain on the market pending an application for their approval in PT4 by 1 September 2016. If no application is made by this date, the food contact materials will have to be removed.

- An assessment of their use in PT4 will be made once an application is received for the substance. If the decision is favourable and the restrictions such as SML remain relevant, they can be used as surface biocides in food contact materials on the EU market. If the decision is not favourable they would need to be removed.

- Silver zeolite A, as well as silver zinc zeolite A and silver sodium hydrogen zirconium phosphate can remain on the market and can continue to be used as a surface biocide in food contact materials until the conclusions of the review programme.

- Food contact materials other than plastics that use these or other substances as surface biocides that are on the market on 1 September 2013 can remain on the market pending an application for their approval in PT4 by 1 September 2016 – or additional food contact materials assessment if supported or approved for PT4.

- An approval for PT4 and assessment for use in the food contact material would need to be undertaken for new material-substance combinations placed on the market after 1 September 2013 before they can be placed on the market.

<table>
<thead>
<tr>
<th>PM ref.</th>
<th>Name of the substance</th>
<th>Supported in review programme as PT 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>86438</td>
<td>Silver zinc zeolite A (silver-zinc-sodium-alumina-silicate-calcium metaphosphate), silver content 1 – 1,6 %</td>
<td>Yes</td>
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<tr>
<td>86438/50</td>
<td>Silver zinc zeolite A (silver-zinc-sodium-magnesium-alumino-silicate-calcium-phosphate), silver content 0,34 – 0,54 %</td>
<td>Yes</td>
</tr>
<tr>
<td>93930</td>
<td>Triclosan</td>
<td>No</td>
</tr>
</tbody>
</table>
Annex: Overview of suggested process

FCM = food contact material

1. The applicant submits a dossier to a rapporteur MS via ECHA. In the case of surface biocides for use in FCM, sufficient information should be submitted on migration to allow for a complementary assessment.
2. The rapporteur Member State carries out the bulk of the assessment of the substance on the basis of the dossier and then submits an assessment report to ECHA within 1 year.
3. Within 270 days of receipt of the evaluation by the Member States, ECHA prepares and submits an opinion to the Commission. This is then used to form an opinion from the Standing Committee on Biocides.
4. Where the substance is to be used as FCM and there is data on migration EFSA is given the task to specifically evaluate the safe use of the substance in the FCM. Data would need to be shared between ECHA and EFSA.
5. EFSA gives an opinion on use of substance in FCM. This is then used to form an opinion from the Standing Committee on the Food Chain and Animal Health to set an SML.
6. The Commission issues either an Implementing Decision and the substance cannot be used for PT4 or an Implementing Regulation to positively include its use in PT4.
7. The active substance is included in the EU list of approved active substances for PT4. Its use in FCM is automatically excluded unless the relevant assessment has been done and SML set.
8. Where it is to be used in an FCM, an SML is reflected in a new measure on FCM.
9. If the relevant data to set an SML is not given at the time of the active substance approval, the exclusion of FCM use in PT4 can be rescinded at a later date if an when the relevant data is submitted, evaluation done and SML set.