Summary Report of the European Conference on MRL Setting for Biocides

Conference report, 8 December 2014

In March 2014, the Federal Institute for Risk Assessment in Germany (BfR) together with the European Commission (COM) hosted the "EU-Conference on MRL Setting for Biocides" in Berlin. The expert conference was attended by more than 70 participants from the European Commission (DG Environment (DG ENV) and DG Health and Consumers (DG SANCO)), the European Authorities EFSA, EMA and ECHA as well as experts from Member States Competent Authorities (MSCAs).

Central topics were cross-procedural issues that have arisen under the new Biocidal Products Regulation (BPR) concerning the necessity and setting of maximum residue levels for residues occurring in food and feed following uses of biocidal products.

Since the introduction of the new European Biocidal Products Regulation (Regulation (EU) No 528/2012 (BPR)), many questions have gained further importance concerning the possible occurrence of residues of biocidal products in food and feed as well as the necessity of and procedure for setting maximum residue levels (MRLs) for biocidal active substances. The overall goal of the conference was to address these questions clarifying in particular when MRLs need to be set for biocides, how this can be accomplished in accordance with other already existing regulatory frameworks for the setting of limit values and which areas of concern should be prioritised. The aim was to identify solutions to the key policy and procedural questions with a view to develop recommendations for COM.

According to Article 19(1)(e) of the BPR, MRLs for biocidal active substances are to be established "where appropriate". When MRL setting is considered appropriate, the Regulation further stipulates that this has to occur prior to biocidal product authorisation and that MRLs then be established within the framework of one of the following EU Regulations and Directives:

Regulation (EC) No 470/2009[1] (here referred to as VMP Regulation),
Regulation (EC) No 396/2005[2] (here referred to as PPP MRL Regulation),
Regulation (EEC) No 315/93[3] (here referred to as CONTAM Regulation),
Regulation (EC) No 1935/2004[4] (here referred to as FCM Regulation) or
Directive 2002/32/EC[5] about undesirable substances in animal feed.

[1] REGULATION (EC) No 470/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin
[2] REGULATION (EC) No 396/2005 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin
[3] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food
[4] REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food
[5] DIRECTIVE 2002/32/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 7 May 2002 on undesirable substances in animal feed

The term “where appropriate” has not been further defined, leaving open questions regarding the conditions under which MRLs for biocides need to be established. Furthermore, it is unclear how biocide MRLs shall be integrated into the above mentioned existing legislations. COM stressed the need for targeted and focussed action because of limited resources in all involved parties (COM, MSCAs, IND) and proposed to find solutions to the questions of how to use existing instruments, how to deal with residues and how to organise enforcement. An efficient use of resources was considered important because of the number of active substances that can potentially lead to relevant residues in food. According to a COM statement during the conference, the number of active substances affected by MRL setting is as follows:

There is a total of about 300 notified active substances. Of these:

- about 150 potentially lead to relevant residues (e.g PT3, 4, 5, 18, 19)
- 75 have specific MRLs in PPP and/or VMP legislation
- 14 have a default MRL from PPP legislation
- 61 have no MRL so far

In preparation of the conference, important issues were compiled in a “thought starter” document (see **Fehler! Verweisquelle konnte nicht gefunden werden.**), which was agreed upon in the Preparation Committee. In this document, the scope of the conference was defined and specific questions to be addressed were described. These questions were the basis for the discussions during the conference.

2 Conference Results

The meeting started with a plenary lecture session with presentations to introduce the regulatory frameworks mentioned in article 19 of the BPR and to provide information on the involved regulatory risk assessment and MRL setting processes. These background presentations were given by representatives of the European Authorities as well as COM. The perspective of a MSCA was presented by the Netherlands, which is the only identified Member State with experience in setting MRLs for and monitoring of biocidal active substances. Short summaries of the content of each presentation are given in the following section (see “Plenary lectures: Background Presentations on the concerned Regulatory fields”).

The presentations given in this first plenary session are available on the BfR website:
http://www.bfr.bund.de/de/veranstaltung/european_conference_on_mrl_setting_for_biocides-189183.html

Following a plenary discussion in which the main overarching questions were addressed, the participants entered into detailed discussions in three Break-out Groups (BGs) with the following scopes:

BG1- How to decide whether it is necessary to establish MRLs

BG2- Adjustment and interaction of the different relevant frameworks for dual-/triple-use active substances

BG3- Options for MRL-setting for active substances that only have biocidal uses and the consequences arising thereof
The groups met twice. After the first meeting, interim results were presented to the plenary to collect comments and further input. In the light of the discussions the groups met again to conclude on remaining issues. Final results were then again presented to the plenary. The plenary discussions were integrated in the "Results of Discussion" sections for the three BGs which are provided later in the document.

2.1 Plenary lectures: Background Presentations on the concerned Regulatory fields

2.1.1 NL view on biocide MRLs (Trintje van der Velde-Koerts, RIVM)

As a MS that has a history of national biocide MRLs before the Biocides Directive entered into force, the Netherlands have experience with MRLs for a number of biocidal active substances, e.g. quaternary ammonium compounds (QAC). MRL setting in NL follows the ALARA principle (as low as reasonably achievable) in order to minimise biocide residues in or on food, feed, water or livestock. Risk mitigation measures are in place for biocidal products such as removal or coverage of food/feed before treatment, obligatory rinsing or treatments out of reach of animals. As the use of biocides should not result in residues in food all biocidal MRLs were set at the LOQ of the analytical method for the respective substance. Monitoring data from NL show that residues of biocidal active substances in food are indeed observed. For example in the years 2000 to 2012 QAC residues above the national MRL of 0.5* mg/kg (with the asterisk indicating that the MRL is set at the level of the LOQ) were detected in samples of dairy products, meat and meat products.

It was noted that MRLs are needed as the legal basis for setting up monitoring programmes and for action of food safety authorities. NL favours the ALARA principle for MRL setting and default MRLs are considered helpful. As MRLs for biocides do not fit into any of the existing frameworks (i.e. veterinary medicinal products (VMP), plant protection products (PPP), food additives, contaminants, food contact materials (FCM)), a separate biocides MRL legislation was proposed. Nevertheless existing MRLs could be taken over from other legislations, but might need to be raised to cover BP uses. Besides amending existing legislation dietary risk models as well as a procedure for MRL setting need to be developed. Also coordination of MRLs from the different legislative frameworks is suggested including a merged list of MRLs from different legislations.

2.1.2 The Biocidal Products Regulation (Karin Kilian, DG ENV)

The Biocidal Products Regulation (Regulation (EU) No. 528/2012, BPR) foresees that biocidal active substances are approved at EU level for use in one (or more) of 22 product types. Subsequently – prior to placing on the market – biocidal products are authorised nationally, by mutual recognition or by Union authorisation. Industry is responsible for submitting data allowing evaluation of active substances and biocidal products. The available data is assessed by MS, and ECHA provides scientific and technical support coordinating active substance approval and Union authorisation of biocidal products.
For active substances that were on the market before the European legislation for biocidal products came into force in 1998 a review programme was initiated with a projected end in 2024. Transitional measures allow the continued use of active substances included in the review programme until a decision has been taken.

As residues in food may occur from biocidal uses Article 19 (1) e of the BPR stipulates that "where appropriate, maximum residue limits for food and feed have to be established for active substances before products can be authorised…". Furthermore this Article lists existing relevant legislation according to which maximum residue limits may be derived. So far only the situation for biocidal active substances used in animal husbandry has been clarified under Regulation (EU) No. 470/2009.

Open questions with regard to establishment of MRLs for biocides deal with the extent of carry-over of biocides into food and feed, identification of critical areas with implications for consumer safety, enforcement of MRLs and procedural aspects. Also it must be considered how to address safety concerns with the limited resources available in MSCAs, EMA, and EFSA.

2.1.3 Legal aspects of relevant EU legislation related to pesticides (Almut Bitterhoff, DG SANCO)

The basic legislation on pesticides comprises of Regulation (EC) No. 1107/2009 which deals with placing of plant protection products on the market and Regulation (EC) No. 396/2005 which deals with maximum residue levels of pesticides in and on food and feed of plant and animal origin.

Pesticide MRLs, i.e. the upper legal levels of a concentration of a pesticide residue in or on food or feed, are set based on the critical GAP (Good Agricultural Practice), meaning those allowed conditions of use leading to the highest residue levels, and consider the highest estimated consumer exposure relative to body weight obtained from all European consumer groups in order to protect all (including vulnerable) consumers. Routine setting, modification or deletion of MRLs follows a clearly defined procedure involving MS, EFSA and COM. Similarly import tolerances are derived to meet the needs of international trade. For any pesticide that is not covered by the Annexes II and III of Regulation (EC) No. 396/2005 a default MRL of 0.01 mg/kg applies. Current MRLs can be found in the DG SANCO MRL database (http://ec.europa.eu/sanco_pesticides/public/?event=homepage). According to Article 12 of Regulation (EC) No. 396/2005, a review of the complete set of existing MRLs is carried out for each of the more than 300 substances (still ongoing).

For control and enforcement of MRLs a coordinated EU multiannual programme is in place and a Rapid Alert System on Food and Feed has been set up. The multiannual programme with 3-year cycles covering major dietary contributors (3x17 commodities) monitors compliance with MRLs and allows dietary exposure assessment for 166 pesticides. The 2015-2017 programme has been voted for in February 2014.

Review of Regulations (EC) No. 1107/2009 and 396/2005 is foreseen in 2015. In this context legal gaps and clarifications such as procedural aspects, dual-use substances etc. will be addressed and potential amendments considering biocides could be made in this context.

2.1.4 Legal aspects of relevant EU legislation related to contaminants and veterinary medicinal products (Frank Swartenbroux, DG SANCO)

Contaminants

Contaminants are substances not intentionally added to food. They are present in food as a result of the production, manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The regulatory framework for contaminants is laid down in Regulation (EEC) No. 315/93 and introduces maximum tolerances for specific contaminants following the ALARA principle. Moreover Regulation (EC) No. 1881/2006 lists maximum levels for certain contaminants (e.g nitrate, mycotoxins, dioxins) in foodstuffs.

Risk assessment for contaminants is performed by EFSA using the margin of exposure approach. It considers health based guidance values (e.g. tolerable daily intake, tolerable weekly intake etc.), the most important contributors and vulnerable consumer groups. Data on occurrence of contaminants is generated by MS and stakeholders. In order to protect public health, maximum levels (ML) for specific contaminants in certain food commodities (major contributors) may be established by COM, where necessary. For an initial EFSA opinion on a specific contaminant 1-3 years are projected, setting of MLs may require an additional 1-3 years.

With regard to control and enforcement of contaminants it must be considered that MLs are only set for specific contaminants in certain food commodities. Levels of contaminants detected in other commodities are assessed considering processing factors, composition of foods, or may lead to the conclusion that the food is unfit for human consumption according to Article 14 of Regulation (EC) No. 178/2002[6]. For “emerging” contaminants monitoring recommendations are followed in order to collect occurrence data for exposure assessment and potential ML derivation. Also for contaminants listed in Regulation (EC) No. 1881/2006 monitoring is foreseen.

Veterinary Medicinal Products

Basic legislation for Veterinary Medicinal Products (VMP) comprises of Directive 96/22/EC (ban of hormones) and Decision 1999/879/EC (ban of bovine somatotrophin), Directive 2001/82/EC (veterinary code), Regulation (EC) No. 470/2009 (establishment of MRLs and RPAs (Reference Points for Action)), Regulation (EU) No. 37/2010 (list of MRLs), and Directive 96/23/EC & Decision 97/747/EC (residue monitoring).

Substances having a pharmacological action, their metabolites and other substances may be transmitted to animal products and are likely to be harmful to human health. For residues of allowed substances maximum residue limits (MRLs) are set as the maximum concentration of residue in food of animal origin. For non-allowed substances in food of animal origin reference points for action (RPAs) are established, when it is deemed necessary, representing the level of residue established for control reasons.

According to Regulation (EC) No. 470/2009 risk assessment of VMPs is performed by the EMA Committee for Medicinal Products for Veterinary Use (CVMP) with data provided by the applicant or producer of the substance. If MRLs are required, they are proposed for target tissues only (muscle, liver, kidney, fat, milk, eggs, honey), based on an ADI approach. Possible outcomes of the MRL evaluation are (provisional) MRLs, the conclusion “No MRL re-

[6] REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January2002 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

quired" or "prohibited substance" (prohibition of use of the substance in food producing animals or in biocidal products for use in animal husbandry). MRLs are later used to calculate the withdrawal time needed for authorisation of a VMP. Article 10 Regulation (EC) No. 470/2009 also contains specific provisions for MRL setting for biocidal substances used in animal husbandry.

RPAs are set at the lowest residue concentration which can be quantified with a validated analytical method, i.e. they constitute a practical implementation of a zero tolerance. Substances are either covered by the existing generic EFSA RPA opinion or a specific RPA opinion is needed. Where appropriate an EFSA assessment may be requested as to whether RPAs are adequate to protect human health.

Measures for control and enforcement of VMP residues are in place. Controls focus on allowed substances in target tissues as well as on prohibited substances (zero tolerance) in all matrices in order to detect misuse. It is not recommended to apply MRLs on processed products or on composite foods. Residue monitoring plans are established with detailed prescription of species/sampling ratios and substance groups and a focus on targeted (and suspect) sampling to detect misuse.

2.1.5 Evaluation of active substances in plant protection products – Residues (Anja Friel, EFSA)

Within the framework of plant protection products data requirements and methodologies for pesticide residue assessment are identical for Regulation (EC) No. 1107/2009 and Regulation (EC) No. 396/2005.

In a first step of residue assessment for pesticides the nature of residues is derived from studies on metabolism in primary and succeeding crops and livestock, as well as food processing simulation studies. As a result residue definitions for risk assessment and for MRL enforcement are determined. In a second step the magnitude of residues is assessed from residue trials for primary and rotational crops, from animal feeding and food processing studies. A defined minimum number of trials per data set is necessary to derive median and highest residues and MRLs with sufficient certainty. There is the possibility for extrapolation of data to reduce the overall number of data to be generated.

Dietary risk assessment is performed for chronic and acute exposure using EFSA's Pesticide Residues Intake Model (PRIMo;

http://www.efsa.europa.eu/en/mrls/docs/calculationacutechronic_2.xls). Approaches for cumulative exposure are currently under development.

MRLs are established based on the most critical authorised GAP, but only if residue data requirements are sufficiently addressed and if expected residues do not pose a consumer health risk. For harmonised calculation of MRLs across the OECD countries a statistical method based calculation tool (OECD MRL calculator) is used. Pesticide MRLs are set in order to avoid trade barriers, to protect consumers, to guarantee compliance with MRL provisions for producers, to minimise residues in food (ALARA principle), and to apply the precautionary principle.

2.1.6 The MRL evaluation of pharmacologically active substances used in veterinary medicinal products (Nicholas Jarret, EMA)

Regulation (EC) No. 470/2009 lays down the Community procedures for the establishment of residue limits for pharmacologically active substances in foodstuffs of animal origin. This relates to uses of active substances used in veterinary medicines as well as in biocidal products used in animal husbandry. Within a 210 day evaluation period a pharmacologically active substance is assessed by EMA´s Committee for Medicinal Products for Veterinary Use (CVMP) including Member States consultation. MRLs for foodstuffs of animal origin are then recommended to COM and included in Regulation (EU) No. 37/2010. Possible outcomes according to Regulation (EC) No. 470/2009 are numerical (provisional) MRLs, the conclusion "No MRL required" or the prohibition of use of the substance in food producing animals or in biocidal products for use in animal husbandry. Default MRLs are not foreseen in this framework.

Evaluation of a substance is subdivided in safety and residue evaluation as described in Volume 8 of the publications "The Rules governing medicinal products in the European Union" (http://ec.europa.eu/health/documents/eudralex/vol-8/index_en.htm). Safety evaluation is focussed on deriving an ADI based on consideration of toxicological, pharmacological and microbiological effects. For residue evaluation data from comparative metabolism studies, total residue depletion studies, and marker residue depletion studies are required to identify the nature and magnitude of residues in edible tissues of the target species. Additionally validated analytical methods suitable for residue control have to be provided.

The calculation of consumer residue intake is based on residue levels at different time points after administration of the active substance considering a fixed basket of food of animal origin. MRLs are then derived from the residue levels at the time point at which the theoretical maximum daily intake falls below the ADI. The final MRL will take into account the proportion of ADI already used by other uses including veterinary drug uses in other species, pesticide and biocide uses and the need to maintain an unused portion of the ADI for future uses. There is also the possibility to extrapolate MRLs from one foodstuff to another foodstuff of the same animal species or from one or more species to another species.

Guidance on risk characterisation and assessment of MRLs for biocides has been drafted by a group of CVMP and DRAWG (Dietary Risk Assessment Working Group of the Biocides Technical Meeting; recently refounded as ARTFood under the head of ECHA) members. In a stepwise approach external exposure of livestock animals is estimated and compared to a trigger value (4 µg/kg/day, based on the trigger of 0.1 mg/kg feed under Regulation (EC) 1107/2009). In case this threshold is exceeded MRL evaluation starts with a Worst Case Consumer Exposure (WCCE) estimate with the possibility to refine it, e.g. based on absorption considerations. If comparison of the WCCE to the ADI indicates that exposure reduction measures are needed to bring exposure below the ADI MRLs will be needed for control purposes. In certain cases MRL setting may also be necessary even if WCCE is below the ADI.

Residue data requirements for MRL evaluation are based on those that exist for VMP active substances, although deviations are possible based on scientific justification. In many cases residue data will be needed.

Currently the draft guideline is reviewed based on comments received during the public consultation period. Major concern was the trigger value that was considered too low, so that almost all biocidal substances for use in animal husbandry would require MRL evaluations. It is discussed to base the triggering event on the (refined) WCCE estimate rather than on the external exposure estimate of the animal.

2.2 Results of discussions in Breakout groups (including plenary discussions)

2.2.1 Results of discussion in Break-out group 1

Scope: How to decide whether it is necessary to establish MRLs

There was a wide consensus that MRLs should be set for biocidal active substances with uses that lead to residues in food. Besides ensuring consumer safety and trade of food commodities, they are also necessary to control the correct use of risk mitigation measures that may be required as a result of product authorisation.

Because of the number of active substances affected, COM voiced concerns that the system may become overloaded by too many MRL applications at a time and proposed to implement a prioritisation whereby MRL setting would be focused on active substances with uses of concern for human health. This was seen critically by many participants who saw the prioritisation itself as a resource-intensive process, because the concern to human health can only be identified in a dietary risk assessment. At the same time participants agreed with the need for some type of prioritisation if a large number of active substances is identified for which MRLs need to be set.

As a solution, it was proposed to start by setting an appropriate default MRL for all active substances with the potential to lead to residues in food. In a second step, active substances for which the default MRL is not appropriate would be identified and specific MRLs be set for them. This approach was generally regarded to be quick to implement and protect consumer health by ensuring that all active substances with the potential to lead to residues in food have an MRL (thereby covering even active substances and uses that have not yet undergone an MRL evaluation) while at the same time it saves resources by focusing MRL setting on a smaller number of active substances. It would also be in line with the plant protection products framework which also has a default MRL and which already applies to dual-use biocides.

However, many participants identified a number of practical concerns regarding the approach ranging from trade problems arising from a default that is too low to questions about the available options to identify in practice the active substances that need specific MRLs.

2.2.1.1 Default value approach

Discussion

Participants decided that critical areas where biocide uses can lead to residues of concern in food can be identified by first looking at the product type the use belongs to. Product types that may lead to residues in food are for example 3, 4, 5, 6, 18, 19 and 21. The default value should apply at least to active substances in those product types and possibly others.

Concerns were voiced that a default that is too low would keep many biocidal products off the market because their residues exceed the default even though they are safe from a consumer health standpoint. It may not be possible to adjust the uses of these biocides in order to lead to lower residues without sacrificing their efficacy. IND stated that the purpose of using biocides is to ensure food safety, i.e. contribute to food hygiene. In their opinion, the benefit of using the biocidal product overrules the potential risk from residues in food. In the case of disinfectants, adequate efficacy is indispensable for the protection from bacterial growth, another health concern.

In addition, a low default might lead to an increase in recalling food batches that contain residues above the default although they are safe for consumption. To highlight the issue, it was reminded that it is current practice in the plant protection products field to take food off the market, if the default of 0.01 mg/kg food is exceeded.

Another matter is that for a number of active substances no validated analytical methods might be in place beforehand to enforce a default of 0.01 mg/kg.

Due to these concerns, COM proposed to introduce the default with a sufficiently long transitional period until it comes into force. This would solve some of the problems mentioned and would also put some pressure on industry to provide data as experience in the plant protection products field shows.

On the other hand, in the plenary discussion it was mentioned that if a default MRL is set, it must be checked for health concerns because for some active substances it may be too high. Moreover, it needs to be decided whether the same default should apply to all food items. It must be considered that the VMP legislation does not have a default value. Therefore, a default value does not apply to VMP and similarly not to biocidal products used in animal husbandry.

Conclusion

The majority agreed on the following way forward. A default is set with a transitional period until it applies. No agreement was reached for which product types the default should finally apply. During the transitional period, it is determined which value is appropriate as a default (e.g. LOQ) and for which active substances specific MRLs need to be set. For the identified active substances MRL applications need to be submitted which might be accompanied by further data (e.g. residue trials data) needed for a full MRL assessment.

2.2.1.2 Identifying substances for which specific MRLs need to be set

Discussion

Many questions arose regarding the available options to identify substances for which specific MRLs need to be set and on how to prioritise them. During the discussion, the following possible procedures were identified:

- Collect data that already exist from quality control and/or other self-monitoring programmes in the food industry as well as from Member States' monitoring programmes

- Screen active substances using the methods described in the guidance documents developed by DRAWG/ARTFood
- Set up additional, targeted monitoring programmes focused specifically on the goal to identify substances for which specific MRLs need to be set

Use of existing data

Industry associations (e.g. FoodDrinkEurope) should be approached regarding the possibility to collect existing quality control data from industry. In addition, distribution of a questionnaire to industry was suggested to find out about the various use areas of biocidal products. Member States' monitoring data seem at the moment to be available only from the Netherlands and only for a limited number of active substances. This makes it difficult to extrapolate findings to all MS across the EU.

Use of guidance documents

Critical voices stated that the methods of the guidance document on livestock exposure were based on very conservative, worst-case assumptions that would trigger an MRL evaluation for nearly every biocidal use. However, such an employment of unfavourable conditions reflects the absence of information on exposure parameters. The methods of the guidance document on food were criticised for already requiring too many data in the screening step. Nonetheless, many voices were in favour of using the guidance documents due to lacking alternatives and because they provide a clear procedure, but called for further works on the details of their methodology. Another advantage of using the guidance documents is that they can be implemented soon, allowing quicker decisions regarding MRL setting and allowing IND to move forward with data generation. Using the monitoring programme on the other hand would give information on relevant residues late in the process.

Use of monitoring data

The practicability of using monitoring data was questioned. Its usefulness regarding identifying residues specifically of biocides was not clear, since monitoring cannot distinguish between the sources of residues from dual-use products (Do they come from plant protection products, biocides or other products?). The implementation of a monitoring programme was also considered difficult and potentially resource-intensive in particular because in setting up such a monitoring programme, the following points would have to be considered:

- Monitoring of all active substances that can lead to residues in food in all relevant food commodities requires the availability of validated analytical methods for each active substance that cover the relevant food commodities and have a sufficiently low LOQ (some methods may not be that sensitive).

- An appropriate sampling plan needs to be developed that specifies which food commodities to sample (raw, processed, simple, composite, representative model matrices as is done for food contact materials?) and when to sample food (during production or at point of sale?)

- In the case of quantifiable residues decision is needed on whether the use(s) had been in compliance with label instructions or not. Moreover, it has to be determined whether more than one contamination may have occurred along the production chain with the same active substance, summing up in the finished food.
- Decision is needed who will develop, coordinate, implement and in particular finance the monitoring programme. Suggestions to divide implementation among the Member States were seen critically by COM and some Member States, as there is no legal basis for this task and because some Member States simply do not have enough resources.

It was reported that there are 61 active substance in the review programme that are notified for residue-relevant PTs and that do not have further uses in other regulatory areas. For these 61 active substances, monitoring would have to be conducted. At first sight, this seemed manageable. However, considering that a large number of food commodities will have to be sampled for each active substance, the feasibility of representative monitoring was questioned. Therefore, COM proposed to rank these 61 active substances, giving each a priority for monitoring.

Two basic approaches for prioritisation were proposed:

- Use available information on the specific use pattern (e.g. frequency and amount of use, market shares) and the formulation of the biocidal product as well as the available information on toxicity (ADI, ARfD) and the physical-chemical properties of the active substance.

- Perform a screening-type assessment based on modelling as described in the guidance documents first. Monitor those active substances that do not pass the screening threshold.

In discussing the specific use pattern and the toxicity as criteria for prioritisation, the question arose whether a distinction could also be made based on acute or chronic risk. The group agreed that there are biocidal products that have only a chronic or only an acute risk, and that this depends on the toxicity of the active substance as well as the use pattern and resulting consumption of the biocidal products. Biocidal products with acute risks were considered to be more severe in the short term and should therefore be given a higher priority. The difficulty lies in determining whether a biocidal product has an acute or chronic risk without performing a full dietary risk assessment. Acute risk depends not only on the acute effects of the active substance, but also on the consumed amounts of the specific commodities under consideration. It is difficult to say which commodities are affected without knowing standard applications and conducting residue trials accordingly. In addition consumption figures (e.g. “large portion” in case of acute risk) on (semi)processed foods are widely unavailable.

Conclusion

The three options identified for collecting data on active substances all have advantages and disadvantages. No clear agreement has been reached on whether they should be used in combination or one option should be chosen. Nonetheless, before developing projects to collect existing data or set up a targeted monitoring programme, their feasibility should be

weighed carefully taking into consideration the points raised during the discussion. In addition, the guidance documents have to be further developed and finalised.

In general, monitoring data should only be used for the purpose of prioritisation, but not for setting specific MRL values.

2.2.2 Results of Discussion in Break-out Group 2

Scope: Adjustment and interaction of the different relevant frameworks for dual-/triple-use active substances
The majority of participants in the group had a pesticide background (15) and/or a biocide background (9), four participants were working in the VMP area and only one participant was dealing with contaminants (CONTAM).

2.2.2.1 Necessity of biocide MRLs and default value approach

The majority of the group felt that in general there is a need to set MRLs for biocidal active substances. However, cases were identified, where no MRL would be necessary because e.g. no residues are envisaged in food and feed or toxicological reference values are not deemed necessary for the substance and its residues. This is in line with other regulations, e.g. for PPP MRLs, where MRLs in products of animal origin might not be required at all if a trigger for residues in animal feed is not met, or for the pesticides included in Annex IV of the PPP MRL Regulation which do not require MRL setting. Some participants referred to the wording in the biocide legislation saying “MRLs for biocidal active substances are to be established where appropriate” (Art. 19(1)e of the BPR) and interpreted this in a way, that MRLs are only necessary if they are needed to ensure consumer safety. The majority of participants replied that they consider MRLs appropriate in all cases where detectable residues in food and feed might be expected due to the product type (PT) and area of use of the BP. If “detectable” means “> 0.01 mg/kg” or “> LOQ” needs to be further discussed and also depends on the decision on default MRLs. Notwithstanding, single substances might require MRLs below 0.01 mg/kg to ensure consumer safety. Examples from the pesticide MRL regulation are known (e.g. fipronil or abamectin in milk). Values below 0.01 mg/kg can only be set if there are analytical methods capable of detecting these low residue levels. If it is not possible to set safe and detectable values, the respective use would not be authorised.

In the VMP Regulation MRLs are set for specific substance/commodity combinations, while for all not mentioned combinations or veterinary medicinal substances a zero tolerance applies. In the PPP Regulation MRLs are also set for specific substance/commodity combinations, but for all not mentioned combinations or pesticidal active substances the default value of 0.01 mg/kg applies. For biocidal uses, commodities likely to get in contact with the product in most cases are not specified at product authorisation level (disinfection products are authorised e.g. for the use on surfaces; food items, that can come in contact with these surfaces can not be determined beforehand).

Some participants were of the opinion that default MRLs are not needed for biocidal active substances. Others felt that default values would be helpful in enforcement as a legal basis to refer to. They would allow handling of residues of biocidal active substances used worldwide even if these are not authorised or used within the EU. Default values were also considered to ensure that users adhere to the ALARA principle and to good practice.

The group identified several purposes of MRL setting for biocidal active substances in general. MRLs could serve as a legal tool for monitoring/enforcement, guarantee consumer safety and are required to facilitate international trade. It was, however, pointed out that MRLs are not suitable to identify misuses in case of dual-/multiple-use substances.

2.2.2.2 Legislation recommended for setting biocide MRLs (focus on dual-/triple-use active substances)

The issue was discussed, whether MRLs for dual-/triple-use active substances should preferably be set in one or in different legislations. The setting of biocide MRLs in different existing legislations was regarded as the pragmatic solution which might be achieved in not too distant future allowing to get started soon, although it would be desirable to have all MRLs in one piece of legislation.

Since the group considered the setting of biocide MRLs in different existing legislations being the most pragmatic solution, the question was then discussed which existing MRL regulations would be the most suitable for that purpose.

For biocides used in the presence of livestock, COM already decided to include MRLs required to cover residues from such BP uses in updated VMP legislation (together with VMP MRLs): Article 10 of the VMP Regulation provides for the establishment of MRLs for active substances intended to be used in biocidal products used in animal husbandry.

However, currently no default MRLs are foreseen in this regulation, although for biocides such an approach was favoured by the majority of the group. Consideration of default MRLs also for VMP should be further discussed in future.

Concerning all other biocide uses no decision was taken yet on EU level. The group identified the PPP MRL Regulation as a possible option. One advantage of this solution would be that many active substances used in BP are also used in PPP and thus are covered by this regulation anyway. Default MRLs are used in this regulation in case no specific MRLs are available for certain substance/commodity combinations. However, the need was identified to extend the list of commodities for which MRLs are set, before biocide MRLs could be included in this regulation. BPs are often applied during processing and consequently MRLs should be set for processed products and not only for raw products as currently done in PPP MRL Regulation.

The group considered also the other legislations mentioned in the BPR with regard to their applicability for inclusion of biocide MRLs.

Both the FCM and the CONTAM legislation were considered less suitable for the inclusion of biocide MRLs. Maximum levels for contaminants are established based on occurrence data and technical feasibility. Contaminants are not the result of intended uses and are not regulated before occurrence in the food. On the other hand, biocide residues in food are the result of intended uses and can be regulated before entering the food chain. Hence the difference in terminology of “contaminants” and “residues” results. Due to this difference in basic principles biocide MRLs seem not to fit in the CONTAM legislation.

FCM legislation is also not fully suitable for the inclusion of biocide MRLs. For some types of material (e.g. plastic materials) legally binding positive lists are available, for others only recommendations exist. Only for few of the listed FCM also specific maximum concentrations in food are regulated. In case specific values exist, only one value per substance is established, which then applies to all kinds of raw or processed food commodities. Biocide MRLs will have to cover a much broader area than FCM and inclusion of biocides in the FCM legislation would not be a solution for the majority of biocides. However, it should be noted that the FCM legislation will be applicable for PT4 biocides used in food contact materials (according to COM a new specific measure for this is already under development).

As an outcome of the group's discussion, biocide MRLs should preferably be implemented in the VMP and PPP MRL Regulations. If for the biocidal active substance in question MRLs already exist in one or both of these regulations due to dual-/triple-use situations, these are recommended to be used as a starting point for biocide MRL setting. The existing MRLs might be either default MRLs or specific MRLs. Part of the risk assessment for each biocidal product is the evaluation of the levels of residues that might occur in food and feed based on a sufficient data set. Depending on the outcome of this assessment, the conclusion is drawn whether the existing MRLs are still sufficient to accommodate the needs of the BP use, or the MRLs need to be raised in some or all commodities, or suitable exposure reduction measures can be identified to ensure that MRLs are not exceeded. Attention should be paid to possible discrepancies of the residue definition on which the existing and the proposed MRL rely, and to the consequences of adding MRLs for existing and new (processed) commodities for the other frameworks (dietary risk assessment, processing requirements). For example, for VMP no MRLs are derived for processed meat/milk products and no processing data are required in that context. For BP uses MRLs are needed for processed foods, also for substances that already have MRLs set in the VMP area on raw commodities.

2.2.2.3 Harmonisation of necessary evaluation procedures

The point was raised that ways for deriving MRLs and criteria for evaluating their safety for consumers should be aligned as far as possible. For this purpose, aspects of the other legislations were considered very helpful.
For instance it was illustrated that some use scenarios for BPs that might lead to residues resemble those of process contaminants, so that the contaminants legislation might be able to deal with specific problems that have not yet been solved for biocides. Also the Food Additives Framework contains elements which might be useful in the evaluation of biocidal uses, e.g. the dietary risk assessment modelling.
The FCM regulation was considered a valuable source of information when it comes to selection of commodity groups or perhaps also matrix groups for which biocide MRLs will be set and analytical methods have to be established.
It was concluded that different frameworks should be checked with regard to the assessment approaches for residues from biocidal uses, while the inclusion of MRLs should rather be restricted to the PPP and VMP legislation.

2.2.2.4 Identified problems arising from MRLs being set in different frameworks

A couple of problems may arise from (i) the parallel existence of several MRL Regulations which partly overlap and (ii) the inclusion of MRLs for substances/uses belonging to different legal frameworks (such as BP, PPP and VMP) in one MRL legislation.

“Fixed percentages”

A problem was identified with MRLs which have originally been set for a VMP and need to be raised due to additional BP uses. Such MRLs would no longer allow to control the withdrawal period of a VMP.

When MRLs are currently set for VMP, which contain active substances that are used in PPPs also, a certain share of the ADI (55 %) is “reserved” for those pesticide uses and consumer exposure from the VMP use is tolerated only up to a level of 45 % ADI. This share might need reconsideration when BP uses additionally need to be taken into account. Moreover, the view was expressed that a fixed share like this does not offer maximum flexibility and might lead to difficulties when uses change or additional uses become relevant later on. When splitting the ADI for MRL setting purposes in different legislative areas it must also be born in mind that the non-professional BP uses, for which MRLs are not set but dietary exposure might arise, have to be considered to ensure the ADI will not be exceeded. Despite of intensive discussions no agreement was reached on this point.

The point was also raised that ways for deriving MRLs and criteria for evaluating their safety for consumers should be aligned as far as possible within one regulation (e.g. for VMP and BP).

Commodity groups

The point was made that in cases where apparently different MRLs have been established for the same substance/commodity combination in two regulations, the definition of the commodities has to be checked closely and harmonised. As an example, discrepancies were noted for the commodity “meat” in the VMP and PPP MRL Regulations with respect to the assumed fat content (pure meat vs. 10 % fat).

The group briefly discussed the selection of commodities or commodity groups relevant for biocide MRL setting, but felt it was outside the scope of this conference to propose representative commodities or extrapolation possibilities to derive group MRLs. It was agreed that because of BP use patterns and because of the multiple entries possible along the food production chain, processed products have to be included. It was noted that the DRAWG (Dietary Risk Assessment Working Group) which has recently been re-founded as ARTFood, has already started to discuss the issue in the context of guideline development.

The definition of food commodities was regarded as a key element for MRL setting for biocides. In particular, it must be considered that biocide residues may mainly be introduced into processed and composite foods, which are not included in the PPP and VMP regulations.

Because of the large number of affected food commodities, it should be discussed whether it is useful to set MRLs for specific commodities or for food groups (e.g. similar to FCM for fat, water, acid food).

Residue definitions

It was discussed that also the residue definition which is used for an active substance might vary in the different legislations. For instance, in VMP and PPP, metabolites of active substances which occur during animal and/or plant metabolism might be part of the residue definition, while the same substances were not considered relevant for biocidal uses. “Global” residue definitions are desirable that apply uniformly to different legislations.

Aggregation of residues

Situations were identified in which an aggregated assessment might be required, namely if the same substance is repeatedly used for different purposes along the food chain (e.g. VMP, PPP, BP…) and residues add up. Decision is needed who would be in charge of conducting aggregated assessments and of proceeding an MRL application if required.

2.2.2.5 Discussed solutions

The parallel existence of several MRL Regulations requires intensive coordination and communication efforts between the different legal frameworks. For this reason possibilities of setting up an “Overview List” with MRLs stemming from all the relevant frameworks were discussed. When drawing up a comprehensive data base for MRLs from different legislations and aligning MRLs as far as possible, harmonisation will probably be required concerning commodity definitions and residue definitions and the use of default MRLs for VMP.

It was also considered useful to state the origin of an MRL listed in such a comprehensive data base (e.g.: use as biocide PT4) and to identify a fall-back MRL. In the case of dual-/multiple-use it is expected that the highest MRL will be the leading MRL. If the use underlying this highest MRL is no longer supported, a lower level will suffice. Having this fall-back MRL precludes immediate re-evaluation of the MRL, but most of all fits the ALARA principle.

The group proposed to establish a Coordinating Committee on EU level. Tasks of this committee could be to provide an overview list and/or a comprehensive data base for MRLs from different legislations and to set up coordinated procedures for MRL setting and monitoring. The committee should ensure that any MRL decision considers all relevant existing MRLs, also including CXLs (CODEX MRLs). CXLs should get incorporated in EU legislation, as long as no unacceptable risks for European consumers have been identified. Implications of EU MRLs being set at higher levels than CXLs may have to be explored. Examples were noted for different MRLs in different legal frameworks for the same substance/commodity combination (example: abamectin in sheep muscle, kidney, liver and fat has different MRLs in VMP and PPP MRL Regulations), which should normally not occur and be sorted out before establishing the MRLs in question. A coordinating committee could help preventing such discrepancies in future.

2.2.2.6 Development of guidance documents

The group pointed out that guidance might be needed to explain to all involved parties in which framework the MRL for a specific biocidal use has to be put. Development of guidance was also encouraged to lay down the evaluation criteria for consumer risk assessment of biocide MRLs. It was proposed to make use of the best suited pieces of evaluation from all legal frameworks.

2.2.2.7 Monitoring and enforcement

The group briefly discussed recommendations that could be given for biocide monitoring. In the current situation with only very few monitoring/enforcement data on biocides already available, a broad monitoring was considered a helpful starting point to get an overview of the residue situation. However, the group felt that the first results should not be enforced for a certain transitional period of time, since data gathering would partly take place prior to authorisation and evaluation of the substances. If default MRLs were introduced, those defaults should remain preliminary and exceedances should trigger substance specific re-evaluation and setting of specific MRLs in the transitional period rather than taking-off-the-market of the products (if no acute concern for consumer safety is shown).

The set up of an EU harmonised monitoring programme was considered an important prerequisite for starting monitoring actions. Furthermore, responsibilities should be assigned for setting up the monitoring programme and for data collection. While the monitoring is likely to be conducted by Member States authorities, auto-controls by food business operators would be required in addition, because food business is responsible for the residue situation in marketed food. Ways should be discovered to make also these data available to risk managers and risk evaluators.

Monitoring is costly and focusing on the most relevant areas of concern might therefore be required. The group recommended that such areas are selected based on potential risks. This refers to both the potential consumer risk and the risk for potential MRL exceedance. Criteria need to be established to identify such situations. First indication of a possible risk would be the use in certain product types (PT) that are known to come in contact with food and feed. The market share of a biocidal substance was also discussed as an indication of relevance for monitoring. However, it was not clear how this would help in situations, where residues are contained in imported food products.

2.2.3 Results of discussion in Break-out group 3

Scope: Options for MRL-setting for active substances that only have biocidal uses and the consequences arising thereof

2.2.3.1 Necessity of biocide MRLs

There was general agreement that MRLs should be set for biocides. However IND disagreed to set MRLs by default, instead MRLs should be set only in case a consumer risk is identified during the assessment. As to the question of interpreting “where appropriate” (BPR, Article 19(1)(e)) the group agreed that an MRL should be established when residues in food may occur and the assessment shows that an MRL is needed. This MRL evaluation should be based on the use patterns of the respective biocidal product similar to the assessment performed for PPP.

The group agreed that MRLs are set in order to ensure consumer safety as well as to avoid trade barriers. The majority also considered MRLs important with regard to the precautionary principle and best practices to ensure that biocidal substances will not be overused. However, it was noted that compliance to best practice when several uses exist can only be ensured for the most critical use. Moreover MRL setting will contribute to transparency as in-

formation on existing uses must be available for derivation of MRLs and an update of dietary risk assessment for the respective biocidal substance will be performed.

The group agreed that uses of single-use biocidal active substances (that may nevertheless be applied in several biocidal product types) do not generally differ from dual-/triple-use substances. Therefore, these substances should not be assessed differently from dual-/triple-use substances if they have the same biocidal uses.

2.2.3.2 Default value approach

The majority of the group considered the application of default MRLs appropriate, which could be revised on a case by case basis. Introduction of defaults would avoid the need to perform MRL evaluations for all concerned substances upfront. It would help keeping timelines for biocide procedures, i.e. MRLs would be in place prior to product authorisation.

In contrast, IND considered default values inappropriate as in their opinion MRLs would be only necessary in case a risk for consumers is identified. As many biocidal products in food industry are applied to surfaces and not directly to food, the need for default MRLs was questioned. IND was very concerned that foods may have to be taken off the market in case default values were set that cannot be met. IND considered default MRL setting for biocidal active substances disproportionate.

Since the use of biocidal products is not defined by crops or commodities and since one use (e.g. on food preparation surfaces) might lead to residues in a variety of food commodities it was discussed to set matrix-specific MRLs (oil-based matrix, high water content matrix etc.) to avoid setting MRLs for the numerous single commodities included in a composite food.

For the majority of the group default values of 0.01 mg/kg or LOQ as applied for PPP generally appeared appropriate, though the inherent toxicity of residues would have to be considered for very toxic substances in order to protect consumers. Moreover, experts from the enforcement sector indicated that a (provisional) default value of 0.01 mg/kg may not be practicable for enforcement purposes in all cases, so that default MRLs may have to be amended depending on the definition of residues, matrix (e.g. high water content, oil-based, difficult matrices) or analytical method requirements (e.g. LOQ > 0.01 mg/kg).

A revision of default values would depend on information available (e.g. data on toxicity, analytical methods, explanation of best practices as to why default cannot be met etc.) and might lead for example to higher values or to the conclusion „No MRL necessary“.

Furthermore, the question was raised how to handle cases where default MRLs apply for existing biocidal substances that are still under evaluation in the review programme and for which products are not yet authorised. In these cases, a transitional period for single-use biocides (if legally possible) may be necessary before applying the default MRLs. Moreover, a transitional period for dual-use biocides with existing pesticide default MRLs may be even more critical. It will need to be carefully considered how a commodity-based MRL (based on PPP uses) can be combined with a non-commodity related MRL (resulting from BP uses). The duration of the transitional period needs to be discussed.

2.2.3.3 Monitoring and Enforcement

There was consensus that once MRLs are set, they must be enforced. As in most MS no monitoring programmes are in place for biocides yet it is recommended to introduce a separate system for biocides or extend existing monitoring programmes.

Resources should be used efficiently considering tight budgets and resources in the MS. The possibility to combine mandatory enforcement and industry self controls (Hazard Analysis and Critical Control Points, HACCP) was discussed. However, it remains unclear to what extent industry performs regular checks and how the results could be obtained (e.g. by establishing a respective legislation based on company size, amount of production).

The group identified several issues that need to be considered when setting up an enforcement programme for biocides or when extending existing monitoring programmes:

- The definition of commodities should consider processed foods with composite foods posing a particular challenge.

- The sampling procedure should be adjusted to biocidal requirements. Samples may be obtained from within the food production chain up to the food as it is consumed. It was suggested to start monitoring food in trade; however, enforcement at food production level would be preferred.

- Uses and matrices should be prioritised for enforcement, e. g. focus on dairy products and meat (PT3, 4, 18 uses)

- The availability of multi-residue analytical methods (detection of several substances at a time in one matrix, methods for all required matrices) would ease the enforcement.

- EU and national reference laboratories for biocides as well as monitoring laboratories may need to be established. Alternatively, existing reference laboratories e.g. for pesticide residues could be appointed.

2.2.3.4 ALARA principle

The term “ALARA” (“as low as reasonable achievable”) refers to the principle applied e.g. in PPP legislation, that MRLs are set based on the residues resulting from the uses and use conditions to be authorised, always provided the dietary risk assessment does not indicate a risk for consumers. This applies even if the resulting ADI utilisation is very low. In contrast, in VMP legislation, MRL setting is based on a certain part of the ADI which can be utilised.

For single-use biocidal substances it was noted that the ALARA principle appears to be the most appropriate principle for setting MRLs since residues in food from the use of biocides are not wanted. A participant raised the question whether an application of biocidal products e.g. in food industry is really necessary in all cases or could be substituted by non-chemical methods. IND pointed out the benefits of biocidal products for ensuring food hygiene.

It was agreed that MRLs should not lead to exceedance of 100 % of the ADI. Applying the ALARA principle will ensure that residues for each biocidal use will be as low as possible and

critical uses in different PTs can easily be combined for dietary risk assessment. Moreover, a single-use biocidal substance may also be used as a PPP and/or VMP in the future which may lead to additional MRLs and it still must be ensured that the ADI will not be exceeded by all uses.

Following the ALARA principle does not necessarily mean that an MRL needs to be set, as an MRL assessment may also come to the conclusion that “no MRLs are necessary” for a specific substance use. IND was concerned that a default MRL would be applicable for non-toxic substances. However, others noted that a separate Annex listing non-toxic active substances, e.g. many natural food ingredients, similar to Annex IV of the PPP MRL Regulation may be helpful.

For VMPs the ALARA principle is not applied, so this may also be the case for all biocides used in animal husbandry in the future with MRLs being set under the VMP Regulation. However, it was pointed out that so far all PT3 biocides (veterinary hygiene products) are also used in other PTs. Therefore it is unlikely that for biocides used in animal husbandry residues will be allowed that utilise the ADI already up to 100 % as room is needed to cover residues from other PTs. Nevertheless the two different principles, ALARA and the VMP approach using up to 100 % of the ADI, might be applied in parallel for one biocidal active substance used in different PTs.

It was recommended that MRL assessment should start with the identification of critical uses across the product types (similar to critical GAPs for pesticides), followed by the identification of residues resulting from these critical uses (ALARA). It should also be kept in mind that for different uses of the same biocidal substance exposure of different food commodities may occur. Therefore, a standardisation of critical uses might be very difficult because the use patterns of biocides are highly variable (when and where to use the biocidal product). Also, it was pointed out that the aggregation of residues within the complete food production chain must be considered. However, only relevant residues that cannot be removed by RMM should be included. Finally MRLs are set based on the critical use. It was also noted that if a biocidal use would result in lower residues compared to other acceptable uses RMM may be difficult to enforce.

2.2.3.5 Into which legislation should single-use active substances be integrated?

Article 19(1)(e) of the BPR mentions several legislations into which MRLs for single-use active substances should be integrated. Again the group emphasised that similar substance uses should be treated in an equal way and discussed the options given in Article 19(1)(e) of the BPR:

- The VMP Regulation covers all biocides used in animal husbandry and this decision was not further challenged. For biocides beyond uses in animal husbandry the regulation was not considered applicable.

- The scopes of the FCM Regulation for food contact materials and Directive 2002/32/EC for undesirable substances in animal feed were also considered too limited to cover all biocidal uses.

- The PPP MRL Regulation was favoured to include biocides as many biocidal active substances are already regulated in this piece of legislation. It also exhibits limitations, but might be appropriate after extensive amendment (see also further questions below).

- Application of the CONTAM Regulation was discussed and several aspects were highlighted:

    - It is not clear whether the legal definition of contaminants as given in the CONTAM Regulation excludes biocides (similar to PPP and VMP that are also not considered contaminants). Legal advice is recommended to answer this question.

    - Within the contaminant framework MS are responsible for providing data on residues in food. This is in contrast to the data requirements within the biocidal framework where the applicant is asked to provide residue data.

    - MRL setting will only occur after residues in food have been detected. However, the BPR foresees that MRLs must be set prior to product authorisation.
    - No default values are applied for contaminants.
    - MRLs would only be set for relevant commodities.
    - Timelines do not fit the requirements of BPR.

Another possibility would be to introduce a completely new legislation specifically for biocide MRLs. The group agreed that a new legislation would only be welcomed in case one comprehensive MRL regulation would be established for all substances (PPP, BP, VMP).

2.2.3.6 Conclusion

MRLs for single-use biocidal substances applied in animal husbandry are regulated in the VMP Regulation. For single-use biocidal substances that are not used in animal husbandry an amended PPP MRL Regulation possibly is the most suitable choice.
This conclusion is in line with the recommendations of COM in the plenary discussion to integrate potential biocide MRLs into existing legislations.

2.2.3.7 Open points identified by the group

Prior to integrating biocide MRLs into the existing PPP MRL Regulation the following points need to be addressed:

- For which commodities should MRLs be set? A “simple” solution would be welcomed, proposal: grouping of food commodities including proposals for representative commodities used for extrapolation (e.g. matrix). Consider FCM simulants as possible starting point.

- Different default MRL values may apply for different food groups (e.g. based on analytical matrices).

- Are existing residue definitions appropriate for biocides? E.g. it may be necessary to include additional degradation products of the active substance that occur during biocidal use to existing residue definitions from other frameworks.

- Dietary intake models for biocides need to be developed.

- Methods for cumulative exposure assessment should be developed (considering several biocidal PTs, PPP and VMP uses etc.).

3 Conclusions

Background presentations introduced the basic principles of substance evaluation and/or MRL setting under different legislations, namely in the areas of biocidal products (BP), plant protection products (PPP), veterinary medicinal products (VMP), food additives and contaminants. The ALARA principle turned out to be applied throughout most legislations, while risk assessment varies strongly from one to the other legislative framework. Concerning MRL setting, differences in timelines, procedures and involved parties were noticed. Some legal frameworks set default MRLs in the absence of specific regulations, others do not. The Netherlands were identified as the only MS having already experience in MRL setting for biocides on a national level. They also set up a monitoring programme for biocides. According to their experiences biocide residues may indeed occur in food at levels above the LOQ for certain product types (PTs). To deal with this situation, either adequate risk mitigation measures or sufficiently high MRLs need to be established.

The first conclusion of the meeting was that MRLs are required for biocidal active substances, at least in those cases where residues in food are likely to occur from the envisaged uses. This is mainly expected for disinfectants (PT 3-5), preservatives (PT 6, 8, 12), pest control agents (PT 18-19), and antifouling agents (PT 21). Due to limited resources, priorities for MRL setting need to be identified. Substances which are potentially relevant for MRL setting could be identified by applying screening-type risk assessments (according to the guidance developed by ARTFood) and/or by using information from surveillance/monitoring. Prioritisation would be driven by phys-chem properties and toxicity (ADI and ARfD) of the substance, with acutely toxic substances having a higher priority in the short term. In addition to potentially relevant substances also potentially critical areas of use could be identified based on the PT, frequency and amount of use and phys-chem properties of the BP.

MRLs facilitate international trade, ensure consumer safety, provide a tool for direct action by food safety authorities and help to control the effectiveness of risk mitigation measures. The meeting recommended that biocide MRL setting adheres to the ALARA principle. The majority of participants also favoured the implementation of default MRLs where no numerical MRLs were established, at least for substances likely to occur in food. For substances used in both PPP and BP, defaults apply already. Default values constitute a good starting point for biocide MRL setting. As soon as sufficient data is available to substantiate MRL setting, the default can be revised as appropriate. Biocide MRLs will have to be enforced. A transitional period is recommended for the implementation of a default MRL during which only food is withdrawn from the market which might pose a risk for consumers. The transitional period should be used to extend multi-residue analytical methods to biocides and to collect monitoring data. In this way, it is possible to gain a broad overview of the residue situation and set-up tailored, harmonised monitoring programmes. While monitoring will focus on the food in

trade in the first place, food business operators are in charge of food surveillance at all food production levels.

Concerning the question in which regulation(s) to integrate biocide MRLs, the meeting looked at substances used as biocides only and at dual-/triple-use substances, which already fall under existing pieces of legislation (PPP, VMP or others). A new stand-alone MRL regulation for biocides was not recommended. As the best possible solution a comprehensive MRL regulation was identified taking on board all substances occurring in food (PPP, BP, VMP etc.). This was, however, not considered a feasible solution. The meeting therefore favoured the integration of biocide MRLs into existing MRL legislation, as this would be the fastest and most pragmatic approach. The decision already taken on EU level was not challenged: MRLs to be set for BP uses in animal husbandry have been integrated in the updated VMP regulation. A need for alignment of evaluation criteria was identified in this context. MRLs to be set for other BP uses should best be integrated in the PPP MRL Regulation, because this provides most synergies. Nevertheless this regulation would need further amendments to satisfy the needs of BP MRLs. It was emphasised that MRLs for similarly used substances should be put in the same piece of legislation and that MRL setting should be aligned as far as possible for all substances covered by one regulation. To gain the best possible overview of all MRLs which are applicable for food from all legislations, the meeting proposed a combined list and/or common data base as well as a Coordinating Committee ensuring better coordination and communication between legal frameworks. Furthermore, guidance was considered necessary on how to assess the potential aggregation of residues along the food chain, if a certain substance is used for different purposes at different steps of the production process.

Appendix 1

European Conference on MRL-Setting for Biocides

Thought Starter

Prioritising areas for MRL-setting for biocides and identifying consequences of integrating biocide MRLs into existing legislation

1 Foreword

This thought starter has been drafted in preparation of the upcoming European Conference on MRL-Setting for Biocides, which is to be held at the German Federal Institute for Risk Assessment on 18th-19th March 2014. The thought starter is meant to define the scope of the conference and describe the specific questions to be addressed. Please note that food con-tact materials are not within the scope of this conference, but will be discussed separate-ly, possibly at a follow-up event. The Commission is currently involved in ongoing discus-sions on how to handle this issue.

The overall goal of the conference aims at addressing the question of residues in biocidal products defining in particular when MRLs need to be set for biocides and what areas of concern should be prioritised with a view to develop recommendations for the European Commission.

In that respect, the focus is to identify solutions to key policy and procedural questions. Im-portant scientific issues may be identified, but are not to be discussed in detail. Scientific issues are within the scope of a number of guidance documents that have been/are currently being developed:

- CA-Dec10-Doc.6.2b - Livestock exposure TNsG.doc
- EMA CVMP 90250 2010_Guideline RC RA of MRLs biocides.pdf (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/12/WC500119802.pdf)
- TMII2012-Tox-item3b-DRAWG DRAFT PROPOSAL.DOC
- TMIII_tox_item 3b - DRAWG DRAFT PROPOSAL_non-prof use_27.08.2013_clean.DOC

We are looking forward to fruitful discussions. If you have specific examples you consider helpful for the discussion of the questions, please provide them at the conference.

2 Background

According to Article 19(1)(e) of the Biocide Regulation (EU) No 528/2012, maximum residue levels (MRLs) for biocidal active substances are to be established “where appropriate”. When MRL-setting is considered appropriate, the Regulation further stipulates that it occurs prior to

biocidal product authorisation and that MRLs then be established within the framework of one of the following EU Regulations and Directives: Regulations (EU) No 470/2009 , (EC) No 396/2005 , (EEC) No 315/93 , (EC) No 1935/2004 or Directive 2002/32/EC . The term "where appropriate" has not been further defined, leaving open questions regarding the conditions under which MRLs for biocides need to be established. Furthermore, it is unclear how biocide MRLs shall be integrated into the above mentioned existing legislation.

3 Workshop Goal

The overall goal of the conference aims at addressing the question of residues in biocidal products defining in particular when MRLs need to be set for biocides and what areas of concern should be prioritised

The workshop should focus on:

- elaborating on the meaning of the term "where appropriate" as used in Article 19(1)(e) of Regulation (EU) No 528/2012
- identifying the need for setting MRLs for biocidal active substances
- identifying (known) critical areas of concern for MRL-setting
- exploring possibilities for generating residue data for MRL-setting
- discussing ways to integrate biocide MRLs into existing legislation as stipulated in Article 19(1)(e) of Regulation (EU) No 528/2012 and the consequences arising thereof

4 Break-out groups

The workshop will start with a number of presentations introducing the legal and assessment background regarding MRL-setting for biocides. The workshop questions will be addressed in a plenary discussion as well as in three break-out groups. In the following, the specific questions to be addressed are outlined.

Each break-out group will start with a brief discussion of the questions from the plenary discussion. After that, each group will discuss the questions of their specific topic.

Please note that workshop participants will be assigned to the break-out groups and will be contacted by the organisers prior to the conference. Preferences will be considered, but cannot be guaranteed.

4.1 Plenary discussion

- Why should MRLs need to be set for biocides (e.g. to ensure consumer safety, ensure correct use of biocidal products)?
- How can biocide MRLs be enforced?

- What does Article 19(1)(e) of the Biocide Regulation mean by the term “where appropriate”?

4.2 Break-out group topic 1

Scope: How to decide whether it is necessary to establish MRLs

Main questions to be addressed

Question 1: What are the known critical areas where biocide uses can lead to residues in food which may be of concern for consumers?

Question 2: What strategies can be used to identify areas where biocide uses can lead to residues of concern in food? E.g.:

2.1 Monitoring data from routine testing or targeted projects (official food safety control); quality control data, self-control, best practices (food business operators, industry)?

2.2 Screening-type residue assessment (performed by Applicant and Authorities) based on guidance documents currently under development/discussion?

Question 3: How to prioritize active substances for MRL setting once it has been decided that there is a need to set an MRL?

3.1 How many active substances/product types are affected? How many biocidal products are affected?

Question 4: Could risk management measures be employed to avoid having to set MRLs? (e.g. guidance for good practice, implementation of HACCP (Hazard Analysis and Critical Control Points) taking into account specific critical points in the production process).

Question 5: What is the risk of chronic exposure to residues of active substances/biocidal products compared to the risk of acute exposure?

5.1 Are there biocidal products that have only a chronic or only an acute risk?

5.2 Can they be prioritised differently?

5.3 What does it imply in terms of consumer protection and risk mitigation measures? Can biocidal products with chronic vs. acute exposure be managed differently?

4.3 Break-out group topic 2

Scope: Adjustment and interaction of the different relevant frameworks for dual-/triple-use active substances

Main questions to be addressed:

Question 1: Would it be possible to use existing specific MRLs for a substance?

1.1 How to deal with cases where MRLs already exist but not for (all) relevant species/commodities or where existing MRLs are too low to cover the biocidal use or too high to detect biocidal misuse?

1.2 Under which conditions would it be impossible to use the existing specific MRLs established for plant protection products and/or veterinary medicinal products for biocidal active substances (case of dual/triple uses)?

1.3 How to deal with international trade and current international limits (Codex ? OECD?...) ?

Question 2: Would it be possible to maintain existing default MRLs for all substances not having specific MRLs?

2.1 How to deal with cases of residues below the default MRL which are either of concern for consumers or where NGOs see a problem with residues?

2.2 What are the consequences of applying the default MRL of 0.01 mg/kg to those biocidal active substances that fall under the scope of Regulation (EC) No 396/2005 be-cause they are/have been used in plant protection products? (Note that this is already the case.)

Question 3: What further questions need to be addressed in the future in order to integrate biocide MRLs into the mentioned existing legislations? (see Annex)

Question 4: How can substances be handled that are used in different areas (e.g. animal husbandry, food industry, food contact materials)? Can MRLs for all uses be set in one legislation or do different legislations apply according to the use?

4.4 Break-out group topic 3

Scope: Options for MRL-setting for active substances that only have biocidal uses and the consequences arising thereof

Main questions to be addressed

Question 1: According to which principle should MRLs for single-use biocidal active substances be set (e.g. residues as low as reasonably achievable with the authorised use (ALARA) as in the framework of PPP; based on maximally 100% utilisation of ADI as in the framework of VMP)?

Question 2: Would it be appropriate to establish a default MRL (e.g. 0.01 mg/kg from the PPP area or LOQ or other), which could then be revised if necessary – on a case by case basis - for substances which have been proven to cause higher residues in food and for which appropriate data is available?

Question 3: Into which of the legislations mentioned in Article 19(1)(e) of the BPR should MRLs for single use substances be mainly integrated?

3.1 Could the contamination legislation be used? This would imply that no default limit would be set (as is the case for pharmacologically active substances used in VMPs).

MRLs would only be set if there is significant exposure and only for the specific food product concerned. In addition, MRLs would not be set prior to product authorisation as required for biocides, but only after detection in routing monitoring. In that case two different systems would coexist for biocidal active substances: one for substances with a dual/triple use, and one for biocides that are not and have never been PPPs and/or VMPs.

3.2 Would any of the other legislations be more appropriate?

3.3 For biocidal uses that do not fit any of the existing legislations, is it possible to introduce a new legislation specifically for biocides?

Question 4: What further questions need to be addressed in the future in order to integrate biocide MRLs into the mentioned existing legislations? (see Annex)

4.5 Annex: Further questions already identified by the preparation committee

1 How do regulatory frameworks have to be adjusted in order to use existing specific MRLs for a substance (e.g. amending the list of food commodities)?

2 Procedural issues

- Establishment of a central co-ordinating unit
- Setting up of communication channels to co-ordinate between the different agencies and procedures
- How to ensure that MRLs are set in time for product authorisation?
- Who will decide whether MRLs for VMP, PPP, contaminants or biocides cannot be set, because the ADI is exceeded?

3 Scientific issues

- Which dietary risk assessment model is suitable (e.g. the food additive model because it covers processed and combined foods as well as single and raw commodities)?
- What are the requirements for residue studies and how are they evaluated?
- For which food commodities do MRLs have to be set?
- How to perform aggregate risk assessment, i.e. uses in different biocide product types as well as in other regulatory fields?

Appendix 2

Presentations

The presentations given in the plenary session are available in full on the BfR website: http://www.bfr.bund.de/en/event/european_conference_on_mrl_setting_for_biocides-189196.html