Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured products. Where uptake of biocidal active substances through food is possible, the Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) requires a dietary risk assessment (DRA) as part of the active substance approval and product authorisation.

Guidance on dietary risk assessment of biocides

The former Dietary Risk Assessment Working Group (DRAWG) operating under the Biocidal Product Directive (BPD, Directive 98/8/EC) and mandated by the Biocides Technical Meeting developed draft versions of the following guidance documents:

- Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products
- Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Non-professional Uses
- Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses

Ad hoc Working Group on the Assessment of Residue Transfer to Food

With the entering into force of the BPR in September 2013, the Biocidal Product Committee (BPC) operating under the BPR mandated the Ad hoc Working Group on the Assessment of Residue Transfer to Food (ARTFood) to follow up and finalize the work of DRAWG. Like formerly done by DRAWG, ARTFood is now seeking to harmonize dietary risk assessments for biocidal products. As a result of the work of ARTFood, the first document of those listed above, the “DRAFT Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional” was published as a "pilot project" for public consultation in June 2015.

The three above mentioned documents on dietary risk assessment are closely linked to the evaluation and derivation of maximum residue limits (MRLs) in edible products derived from animals. In January 2015, the European Medicines Agency (EMA) published a new guidance on “The Risk characterisation and assessment of Maximum Residue Limits (MRL) for biocides” which came into effect on 1 August.
Therefore, dietary risk assessment should be seen in the context of MRL setting. The approach for dietary risk assessment and risk characterisation is divided into several steps which are described in the EMA guidance document mentioned in the previous paragraph.

SCC’s services

Having worked in the field of plant protection for more than 25 years, SCC has gained a wealth of experience in planning and monitoring residue studies and in performing dietary risk assessments. Not only in the context of active substance approvals under the BPD and the BPR but also at the product authorisation stage, has SCC been dealing with the assessment of residues. Thus, SCC is an experienced partner when it comes to addressing residue issues. SCC’s Biocides Department was established in the year 2000. Meanwhile, BPD and BPR dossiers have been submitted for more than 20 existing biocidal active substances, covering nearly all product types. These active substance dossiers are now followed up and defended under the BPR. In addition, SCC has filed biocidal product (family) dossiers for various active substances and product types (PTs) including applications for national BPR authorisations and Union authorisations. Our modern headquarter is located in Germany – in the culturally attractive Rhein-Nahe region, about one hour’s drive west of Frankfurt am Main. To support our international network we established Liaison Office Japan in 2007 and Office Berlin in 2014. For more information, please consult SCC’s page: http://www.scc-gmbh.de/business-units/biocides
The information regarding the topic "Dietary Risk Assessment of Biocides" displayed on this website were provided by SCC.

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SCC is located in Bad Kreuznach, Germany, an hour’s drive west of Frankfurt am Main. Please refer to SCC’s home page (http://www.scc-gmbh.de/business-units/biocides) for more information about available services relating Dietary Risk Assessment of Biocides.

Discover the world of SCC on our website: www.scc-gmbh.de

Contact us: Open Contact form or send us an email at scc@scc-gmbh.de

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