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P18. BIOCIDAL ACTIVE SUBSTANCES AND PRODUCTS: IDENTITY AND PHYSICO-CHEMICAL PROPERTIES EVALUATION UNDER THE BPR

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Article 3(1)(c) of Regulation (EC) No 528/2012 (BPR) defines 'active substance' as a substance (or a micro-organism) that has an action on or against harmful organisms. But what is a substance, whether active or not? According to the definition given under Regulations (EC) No 1907/2006 (REACH) and 1278/2008 (CLP), a substance goes beyond a pure chemical compound defined by a single molecular structure, but includes multiple constituents: all those that cannot be separated, such as additives (if any) and impurities.

Additives (stabilizers) are intentionally added so to prevent substance decomposition; whereas impurities are unintentional constituents, that may originate from the starting materials or be the result of incomplete reactions, side reactions or degradation. Residual solvents are to be considered as impurities, too. It shall be noted that additives and impurities can affect the behaviour of a substance and its classification, though they never contribute to naming.

In the context of the BPR, impurities are *relevant* for human health and environment, when they show additional or even more severe (eco)toxicological effects compared to the active substance itself, or *significant*, if present in quantities ≥ 0.1% w/w. Both relevant and significant impurities are to be specified.

Solvents are excluded from the REACH & CLP definition of 'substance', as far as their removal does not destabilize the substance or does not alter its composition. So, the substance specification should reflect how much solvent is practically possible to remove prior to any degradation or any alteration of the impurity profile. Nevertheless, a different approach is likely to be followed for biocides: when an active substance is a technical concentrate, i.e. manufactured and marketed in process solvent(s), it was agreed that the specification should be a strictly theoretical one, in which all solvents are removed by calculation.

In general, the specification should be for the active substance as manufactured, either as technical material or technical concentrate. An explanation on how the specification has been derived should be provided, e.g. by statistical calculations of the results from the analysis of (at least) five batches representative of the commercial-scale manufacture. Additionally, quality control data might be used to refine or support the substance specification. Eventually, for the purpose of approval as well as of future technical equivalence assessments, the reference specification is to be derived, which can be regarded as the scientific refinement of the specification originally set by the Applicant.

The unambiguous identification and naming of active substances stand as prerequisites to the BPR processes of approval and technical equivalence assessment. The correct approach to be followed depends on the substance type. The Echa's 'Guidance on substance identification and naming under REACH and CLP'– to be taken into account also for biocidal active substances, where relevant and indicated – differentiates between two main different groups: well-defined and poorly-defined substances.

Well-defined substances have a defined qualitative/quantitative composition and are grouped into mono-constituent and multi-constituent substances based on the '80% w/w rule'. Poorly-defined substances are those of unknown or variable composition, complex reaction products or biological materials (the so-called UVCB substances). While 'traditional' identification parameters suffice for mono- and multi-constituent substances, additional identifiers such as the source and the process used are needed for UVCB substances, owing to their complex origin and unknown and/or variable composition.

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A biocidal product is a mixture of active ingredient(s) and/or co-formulants in a form suitable for use. The definition given under Article 3(1)(a) of the BPR has filled a deficiency of the Biocidal Products Directive (BPD), by referring also to substances and mixtures *generating* active substances. In this way, it has been made clear that also precursors - when supplied with a biocidal intention - are to be regarded as biocidal products.

It is recognized that the active substance content in a formulation will vary from batch to batch on production, and as a result of sampling and analytical error. To account for all these variations, general limits apply to the active substance content in a biocidal product at the point of production: the same FAO/WHO tolerances already used in the context of plant protection products.

Intrinsic physical-chemical properties contribute to the characterization of an active substance and to the designation of its physical state. The physical-chemical data set offers critical in-put values for fate considerations, as well as for human health & environmental exposure assessment. Moreover, such data may be used to justify the waiving of other data/information requirements and for the correct planning of the (eco)toxicological studies, e.g. for the optimization of the experimental conditions for testing. Last but not least, physical-chemical data can form the basis for classification and labelling according to CLP Regulation, even with respect to human health and environment.

Amongst the conditions for granting an authorization, article 19 of the BPR stresses that the physical and chemical properties of a biocidal product shall be determined and deemed acceptable for the purposes of its appropriate use and transport. Data requirements vary according to the product type. If a biocidal product can be categorized as one of the FAO/WHO formulation types, the FAO Manual can be used as guidance; otherwise, a 'common sense' approach should be followed to establish which physical-chemical properties and technical characteristics are relevant for the product. Data are needed to demonstrate that the product is stable on storage under the shelf-life claimed and performs satisfactorily under practical conditions. Although it is not feasible to emulate how a formulation works in the field under whatever circumstances, tests generally provide simple models against which the (un)satisfactory performance may be judged.

Data are needed also to identify hazards of chemical, physical and technical nature, which can arise from intrinsic properties (such as flammability, explosivity and oxidizing properties) or occur indirectly, e.g. through the chemical incompatibility of the product with other materials. When a risk assessment for physico-chemical properties is needed, the main parts of the risk characterisation are normally qualitative, unlike risk characterisation for human health and the environment. Competent authorities need to consider whether the identified hazard is likely to express itself during realistic worst-case use (and, if relevant, manufacture and disposal) scenarios.

In the BPR the physical hazards of active substances and biocidal products are indicated apart and correspond exactly to the physical hazard classes for substances and mixtures, respectively, included in the CLP Regulation. The criteria and testing methods or standards are indicated in the relevant sections in Part 2 of Annex I to the CLP Regulation, through references to the 'UN Recommendations on the Transport of Dangerous Goods, Manual of Test and Criteria, UN-MTC (UN, 2009)'. Whereas the test methods for those physical-chemical endpoints not linked to classification shall be conducted according to the 'EC Methods' described in the Test Methods Regulation (Commission Regulation EC No 440/2008), based on methods recognized and recommended by international bodies, in particular OECD. Where a method is deemed inappropriate or is not described amongst the EC Methods, other methods shall be used which are scientifically appropriate, e.g. CIPAC methods.

Tests on physico-chemical properties and safety-relevant substance data should be performed at least according to international standards, i.e. carried out by laboratories complying with a relevant recognized standard (e.g. ISO/IEC 17025, ISO 9001). Therefore, Good Laboratory Practice compliance, which was required for such studies under the BPD, is no longer compulsory under the BPR.