nanoGRAVUR

Grouping and Read Across of Nanomaterials: Objective and Needs for Environmental Hazard Assessment

Kathrin Schwirn[1], Doris Völker[1]
[1]German Environment Agency (UBA), Dessau-Roßlau, Germany

The project **nanoGRAVUR** (nanoGRAVUR: **nanostructured materials – grouping for occupational health, consumer and environmental protection and risk mitigation**) made its central objective to develop different criteria catalogues for a grouping of nanomaterials according to the respective potentials for exposure, hazard and risk. As part of the project, the developed approaches and project outcomes will be evaluated for its regulatory applicability in the area of environment, consumer and work place protection.

The grouping and read across approaches aim to close regulatory data requirements on hazard in deviation from performing standard tests. Grouping and read across approaches are already established for chemical substances. The aim is firstly to predict the physical-chemical, toxicological, and behavioural properties of chemical substances based on structural similarities. If sufficient evidence is available it should then be possible to transfer available data on the hazard information on one or several endpoints of one chemical substance to another one. This approach is intended to reduce the amount of testing necessary to determine the behaviour and effects of all individual members of a group. In addition, the number of experiments with animals should be reduced. Guidance on grouping and read across approaches have been made available by OECD[1] and the European Chemical Agency ECHA[2].
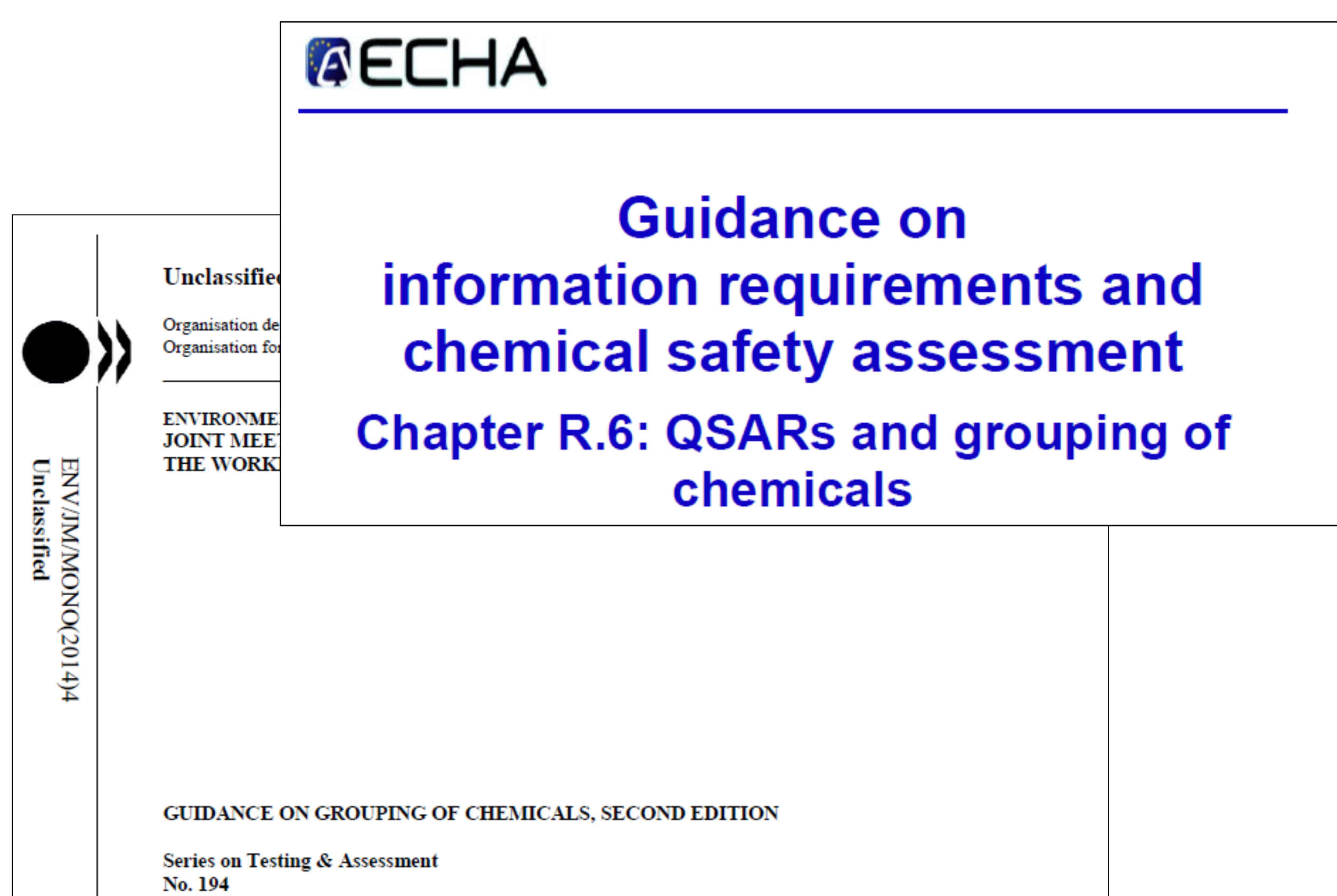

Figure 1: Guidance on grouping published by ECHA and OECD

Figure 2: Schematic presentation of approaches to fill data gaps (figure taken from OECD guidance ENV/JM/MONO (2014)4)

Given the numerous variety of manufactured nanomaterials already on the market and expected in future, the effort for the individual investigation and assessment would be enormous. Thus, the purpose is to determine whether there are differences in the eco-toxicological properties between different nanomaterials of the same substance but also between nanomaterials and their non-nano counterpart or between nanomaterials of different chemical substances, respectively. In comparison to soluble organic substances nanomaterials of the same chemical substance differ in further physicochemical parameters e.g. surface chemistry, size, shape and thus can potentially differ in their hazard profiles. In consequence, information on these intrinsic properties is needed to conclude on the possibilities of grouping and read across on. Beside intrinsic properties also so called extrinsic properties are of importance. These properties are fate related physicochemical properties which are influenced by surrounding conditions. Guidance for providing an approach on how to justify the use of hazard data between nanomaterials and within groups of nanomaterials of the same substance has been published by ECHA[3].

Figure 3: ECHA`s recommendations for grouping nanomaterials

Based on OECD expert consultation features that complicates the grouping and read across approaches of nanomaterials include i) insufficient characterisation of nanomaterials, ii) insufficient information on the fate of nanomaterial during testing, and iii) lack of standard preparation protocols and testing procedures for the determination of physicochemical parameters and assessment of the bioavailability and effects of nanomaterials based on theses parameters, and iv) case studies that illustrates the importance of selected parameters for the prediction and transferability of hazard data.
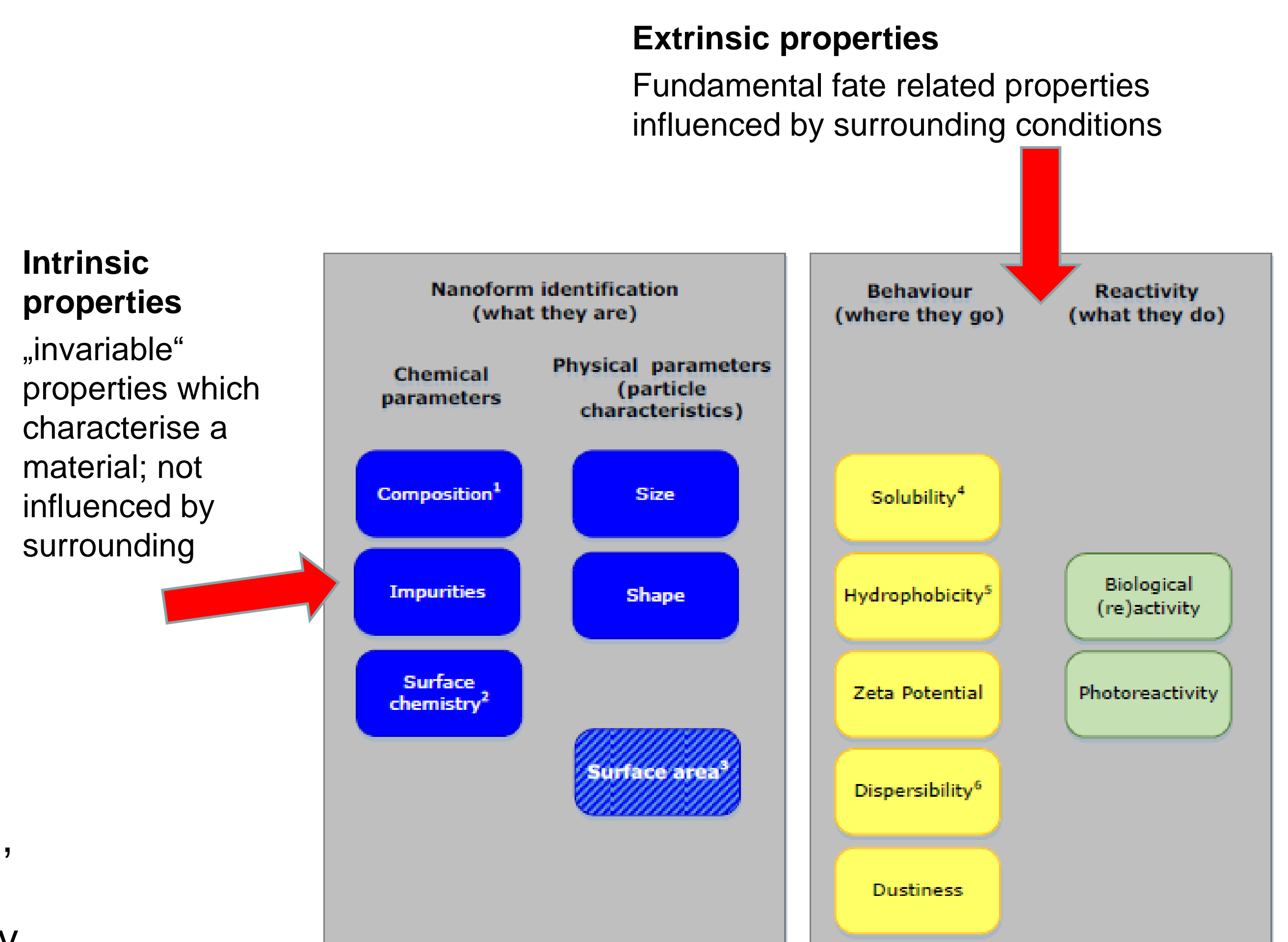

Figure 4: Intrinsic and extrinsic properties which need to be considered for grouping and read across for nanomaterials hazard information (figure taken from reference 3)

[1] OECD Guidance on Grouping of Chemicals, Second Edition: ENV/JM/MONO (2014)4
[2] ECHA Guidance on Information requirements and chemical safety assessment, Chapter R.6: QSARs and grouping of chemicals, May 2008
[3] ECHA Guidance on Information requirements and chemical safety assessment, Chapter R.6: QSARs and grouping of chemicals, Appendix R.6-1 for nanomaterials applicable to the Guidance on QSARs and Grouping of Chemicals, Version 1.0, 2017