Nanomaterials and REACH – What do I do differently?

Part 4: Exposure and Risk Assessment

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Business through Science

Traditional models to predict exposure and risk are not usually appropriate for nanomaterials because kinetics rather than thermodynamics are the driving factors. In addition, different nanoforms may not only have different hazard characteristics but can also behave differently in the workplace or environment leading to different exposure impacts. These lead onto the possibility that different nanoforms will need have different risk assessments and hence need different risk management measures.

Physico-chemical properties that impact on the risk assessment of Nanomaterials

To date, it has not been possible to identify a mode of toxicity unique to all nanomaterials, meaning that each nanomaterial must be assessed on a case-by-case basis. The research has shown that a number of factors may influence the toxicity of a nanomaterial (Table 1).

Table 1: Physico-chemical parameters that may affect exposure to nanomaterials.

Parameter	Example
Aging and weathering	As nanomaterials progress though their lifecycle, they may change their nanoform through erosion of surface treatment, increased/decreased agglomeration or coating with natural substance. These can change the reactivity and hence the risk of the nanomaterial.
Zeta potential	The zeta potential of a particle depends both on the particle and the medium in which it is suspended. This means that if zeta potential is identified as a key parameter, it should be measured in a range of media.
Agglomeration/ aggregation	If nanoforms agglomerate or aggregate they may have a higher chance of accumulating in sediment rather than being suspended in the water fraction. Naturally occurring ligands, such as humic acids can both increase or decrease agglomeration, depending on the substance characteristics.
Surface treatment	Surface treatments on the pristine nanomaterial can be changed or removed in the environment.
Intentional entrainment	Inhalation is often the most important route of exposure to humans. Entrainment as a suspension or within a solid matrix can significantly reduce exposure. Interactions with the medium can also change toxicology if the nanomaterial is released from the matrix.

Therefore, it is essential to measure all these parameters in order to be able to properly control the risk associated with the nanomaterial and accordingly, the update to REACH requires that registrants assess each variable.

Temporal aspects of the risk assessment of nanomaterials

One of the features of nanomaterials that makes it more difficult to perform a risk assessment across the whole lifecycle is the possibility of changes in the nanoform. For a simple mono-constituent substance that is liquid or highly soluble, the lifecycle is relatively simple where the hazard of the substance remains the same throughout its existence, so risk is dependent on exposure (Figure 1). With a nanomaterial it is possible to transition between different nanoforms of the same substance, each of which may have different hazard profiles. Therefore, any risk assessment across the whole lifecycle of the substance should account for these changes over time (Figure 2). It has been suggested that a nanomaterial could be viewed as a UVCB whose composition changes over time. The example given in figure 2 describes the lifecycle of a substance that is manufactured in a form that can exist as free primary particles and as agglomerates. The degree of agglomeration depends on the physico-chemical conditions the nanomaterial exists within (aerosol, suspension etc.). It may then be deliberately coated to change its properties. Each nanoform may be supplied within products to the consumer and can be

released to the environment at all points in its lifecycle. Once in the environment, both the coated and uncoated nanomaterial may be coated with natural substances (e.g. humic acids). In addition, the synthetic coating can be weathered to release the original nanomaterial.

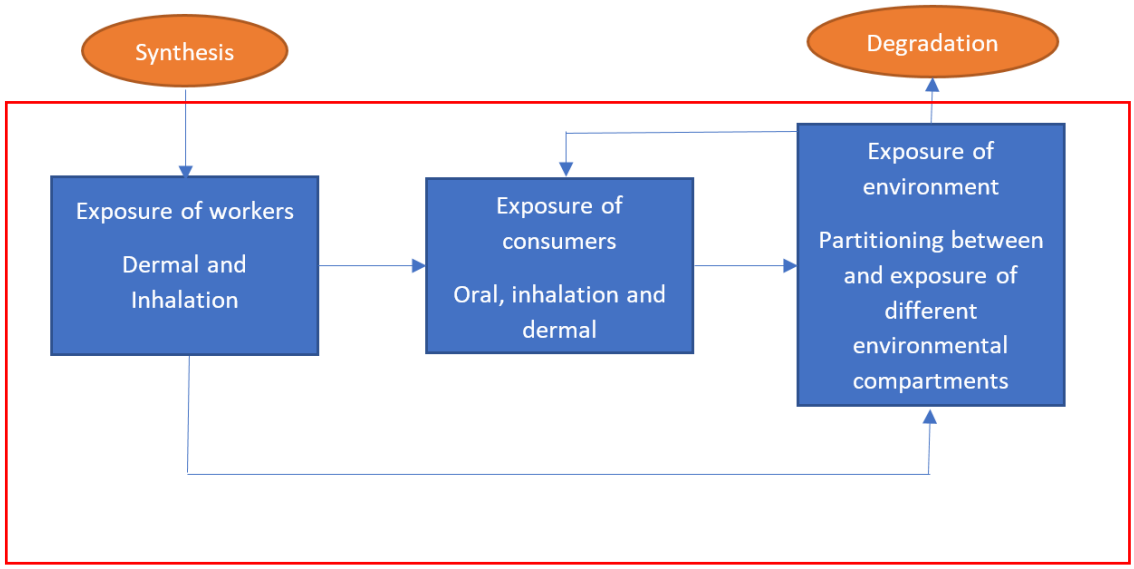

Figure 1: Simplified lifecycle of a mono-constituent, liquid substance. The red box shows the extent of the risk assessment across the lifecycle of the substance. The blue boxes show the separate exposures that must be individually assessed as part of the overall risk assessment.

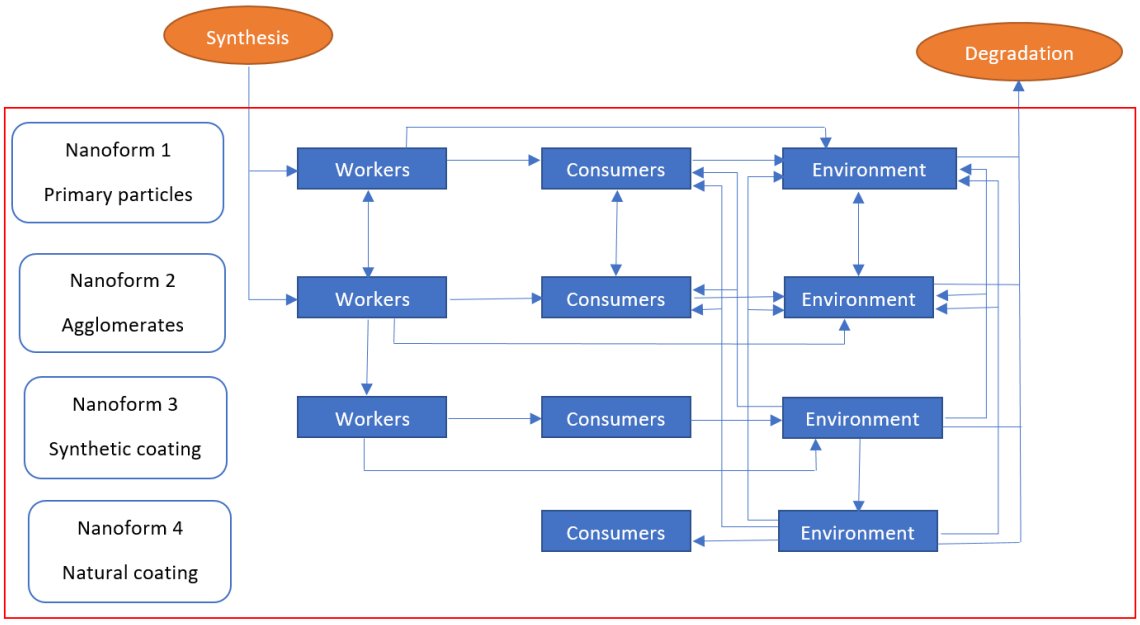

Figure 2: A lifecycle of a theoretical nanomaterial showing the added complexity of performing a risk assessment for a nanomaterial

The update to REACH requires that the whole life-cycle of the substance is included in the registration dossier, so knowledge of how nanoforms interconvert will be required. The update also increases the possibility that exposure scenarios for the nanoforms will be included in extended safety data sheets, meaning that downstream users will need to be aware of any intentional or unintentional changes to

the nanoform during their use of the substance and whether the supplied exposure scenarios are applicable to them or not.

Yordas Services

Yordas Group has actively supported a number of projects at the cutting edge of risk assessment of nanomaterials, such as MARINA. As part of the NanoMONITOR project we have undertaken exposure measurement programs in rural and urban scenarios.

We are able to support clients with performing their exposure and risk assessments as part of REACH registrations or other global regulations. If a client needs to prove compliance with exposure scenarios or other occupational exposure obligations we can design and support these programmes.

To discuss your requirements with a member of our expert team, call us on +44(0)1524 510278 or email info@yordasgroup.com.