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Eurocolour's experiences and concerns from the registration of nanoforms under REACH

Since 1st January 2020, nanoforms must be addressed separately in registration dossiers under REACH. Besides requiring extensive data generation in a very narrow timeframe, industry faced several hurdles in fulfilling this task: from analytical impossibilities over technical pitfalls to unjustified accusations and highly questionable interpretations of the legal text.

This publication is supposed to summarize the experiences made by Eurocolour's members and highlight concerns remaining to help improve the registration process of nanoforms in the future and avoid repeating mistakes.

Pigments and fillers in focus of nanoform registrations

The definition of a nanoform within the REACH text is based on the Commission's recommendation from 2011.[1] The constituent particle size alone determines whether a material is considered a nanoform. Due to the immanent particle size of pigments and fillers providing best optical and processing properties, many of these substances fall under this definition. However, it is important to keep in mind, that these materials are only considered as nanoforms due to the wording of the definition. The particle size of these substances has not changed in decades, they are now being considered nanomaterials because of a new definition and not due to any novel nano specific properties.

Based on the current numbers for dossiers covering nanoforms published by ECHA[2] and a survey among the Eurocolour members, the majority of the registered substances with nanoforms on the market are pigments and fillers. Of 149 substances for which nano dossiers have been submitted, Eurocolour's members submitted the lead dossiers for 97 substances. The lead dossiers include not only information on the characterization of the nanoforms but also the data relevant for the hazard, exposure, and risk assessment. Thus, our members have extensive experience with the registration of nanoforms.

Insufficient timeframes and manyfold hurdles burden especially SMEs

The amended REACH Annexes[3] concerning the registration of nanoforms have been published on 3rd December 2018, giving manufacturers – in theory! – roughly 13 months to identify their nanoforms, generate requisite data for the characterization, and prepare the

[1] See publication 'Commission recommendation of 18 October 2011 on the definition of nanomaterial' 2011/696/EU, available e. g. on EUR-Lex.
[2] See presentation given at CARACAL Meeting on 5th and 6th July 2022, available on CIRCABC.
[3] See Regulation (EU) 2018/1881, available e. g. on EUR-Lex.

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registration dossiers before 1st January 2020. This is hardly sufficient in time in light of the hurdles summarized below.

Software incompatibility

To enable the registration of nanoforms, the technical means to provide respective information needed to be implemented which means IUCLID software needed to be updated by ECHA. Only with the IUCLID update to version 6.4 was it possible to submit the first dossiers including nanoforms. This update was provided on 1st November 2019. This left industry with less than two months to actually prepare the dossier updates and submit the new nano relevant information. To compound this, the guidance document on the registration of nanoforms with information on which data ECHA expects to be submitted was only published on 3rd December 2019. Considering the holidays during which ECHA is closed, this left companies with a bit over two weeks to check their dossier updates and maybe do some last-minute refinements.

Additionally, within the last two years, several more changes in the IUCLID software have been introduced. Mandatory fields were either newly introduced, changed, or deleted without any notice for users. This made dossiers which previously passed the technical completeness check incomprehensibly not being accepted during an update.

Missing guidance documents

Additionally, without guidance documents supporting the legal changes and providing supplementary information on how to identify and characterize nanoforms, industry had to make educated guesses. Based on previous research projects like NanoDefine[4], only electron microscopy can give a sufficient answer to the question whether a product fulfils the nanoform definition in most cases. This technique is not commonly available, especially for small and medium sized companies (SMEs). Therefore, SMEs needed to rely on contractor laboratories to collect the required phys. chem. characterisation for their substances. Incidentally, the contract laboratories were at capacity, amongst other reasons, due to the new nano requirements and could not be available on short notice. Worsening the situation, the late publication of the guidance documents meant that there was always the residual risk that commissioned studies would not meet the criteria or expectations of ECHA and would therefore be refused.

Communication within REACH consortia

In most cases bigger companies act as lead registrant, taking care of the hazard, exposure and risk assessment of the substance and its nanoforms. However, they can provide only limited support to their (SME) co-registrants because the phys. chem. properties of a product are often confidential business information, and each co-registrant has to collect this data for their products. As a result, communication within the registration consortia was – and still is – difficult and time consuming.

[4] See NanoDefine homepage or, e. g. the JRC publication 'The NanoDefine Methods Manual' available on the JRC homepage.

Limited or incomplete feedback from co-registrants impeded joint registrations and slowed down the process of nanoform registrations. However, the reason for this is not unwillingness or inertia but the limited capacity – both in the lab and in manpower – to compile the information required in the short timeframe. The complexity of the required posed a huge challenge, especially for SMEs relying on contract laboratories.

> ***All in all, the abundance of new information requirements posed an immense hurdle for industry and sometimes also overtaxed the available resources and manpower. With such a tight timeframe, no guidance documents, and the rather late availability of the technical means to actually submit the dossiers, it was foreseeable that not all necessary information would be available in time. However, industry does not bare the blame solely for this as is often presented.***

Two-faced communication: Blame game in public, support behind the curtains

With only few nano dossiers being submitted before the 1st January 2020, it did not take long until respective headlines were published blaming industry for not complying with the legal requirements. Even when further dossiers were submitted in 2020, the public reporting hardly changed and still has not.

Wrong data basis for estimation of expected nanoforms

As a reference for the expected number of substances in nanoform, the EUON nano inventory was often used by authorities and media. However, a detailed analysis[5] by Eurocolour for the listed pigments and fillers revealed, that this database may lead to wrong conclusions when assessing the number of substances with nanoforms subject to registration: About a third of the listed entries for pigments and fillers were wrongly catalogued as a nanomaterial. The cleaned-up list matches the number of submitted nano dossiers. This is due to the different definitions and/or the different scope of lists for nanomaterials in the various national registries which serve as data sources for the EUON. In addition, Eurocolour identified several substances which have been wrongfully notified as nanomaterials to the national inventories. After detailed discussions between Eurocolour and ECHA, several of these aspects have improved.

Support for technical hurdles

Additionally, ECHA gave detailed feedback on nano dossiers that did not pass the completeness check in the first submission. At this point, issues were mostly not related to the provided information or their quality but just of technical nature: how the data and studies were

[5] See Eurocolour's publication 'Eurocolour's results of a detailed evaluation of pigments, dyes and fillers listed on EUON as nanomaterials: 30 % of entries wrong - status: November 2020' available for download.

embedded in IUCLID, how values were linked to studies, and so on. The main reason for the flurry of failed submissions was the lack of guidance documents.

Even though it would have been preferable to have a guidance document or technical manual on the new IUCLID version beforehand to avoid these tiresome corrections, this obstacle was easy to overcome. As a result, the number of successfully submitted nano dossiers rapidly increased within the first months of 2020.

> ***With all stakeholders working together to make the best of the given situation, reporting often felt one-sided and unjustly critical. It was not industry's unwillingness or laziness that led to this situation and there has never been an unidentified hazard by delayed submissions of nano dossiers.***

Implementation of the legal requirements: many demands exceed the REACH text

Irrespective of providing the necessary support and transition periods, ECHA also introduced several additional hurdles and pitfalls for registrants. Especially the set expectations on the submitted information and on the justifications for sets of similar nanoforms are not workable, not reasonable, and – most importantly – not supported by the REACH text.

Insufficient consideration of industry's concerns

Since the very beginning, during the Partner Expert Group (PEG) which is supposed to give feedback during the development of guidance documents, industry has constantly highlighted the inapplicability of the guidance document on the registration of nanoforms and that some information requirements laid down in the guidance are not supported by the REACH text, the legal basis.

A nanoform is supposed to be characterized according to REACH Annex VI, points 2.4.2 to 2.4.5 by its phys. chem. properties: its particle size distribution, its surface functionalisation or treatment, its morphology including particle shape and crystallinity, and its surface area.[6] According to REACH Annex VI

> "*A substance may have one or more different nanoforms, based on differences in the parameters in points 2.4.2 to 2.4.5.*".

In reverse, that means if two commercial products exhibit the same parameters, they consist of the same nanoform. However, based on ECHA's guidance documents several more factors are supposed to be taken into account, contradicting the REACH text. Industry's concerns regarding the applicability of the whole guidance and the legal justification of these claims were simply ignored.

[6] See REACH Regulation (EC) No. 1907/2006, Annex VI, Note 2, sub-section 2.4.2 – 2.4.5.

While a guidance document is not legally binding and is only supposed to support in the implementation, it is much more complicated. Hence, the guidance document and ECHA's expectations were discussed in several meetings between Eurocolour and ECHA even after the PEG process was finished and the guidance was published. While some aspects regarding data quality due to analytical infeasibilities were acknowledged, the fundamental issue of differentiating products or grades with the same phys. chem. properties into two separate nanoforms remains. However, this is fundamental for joint submissions and also important when evaluating read-across approaches for the hazard, exposure and risk assessment.

New mandatory requirements without a legal basis

ECHA has introduced new information demands which are not supported by the legal text. This is seen rather critical as ECHA has no legislative authority. At the same time, there is no benefit from this new information. Even though the REACH text does not require all these additional demands, by introducing compulsory fields for this information into IUCLUD, ECHA has made these requirements mandatory. If no data are provided, the dossier cannot be submitted as it will not pass the completeness check.

Frequent changes in submission rules impede dossier updates

The latest IUCLID updates since 2020 also came up with incomprehensible changes and introduction of new field that were neither announced nor explained in detail. Dossier submitters had to find out by trial and error when a dossier was to be submitted. As error messages usually do not contain relevant hints where the problems lie, a time-consuming search is the consequence. Thus, even small dossier updates can lead to excessive workload. Instead of encouraging frequent updates, improving the data quality and quantity constantly, such pitfalls achieve the opposite. A more transparent communication on technical changes in the software may solve this issue easily.

> **By introducing new information demands without a legal basis, contradicting statements in the given REACH text, coupled with inadequate communication of unnecessary and constant changes in the technical systems, ECHA impeded – and currently still hinders – the registration of nanoforms in many ways while industry struggles to fulfil unreasonable and unjustified expectations.**

Unacceptance of analytical data/proofs

Related to the refusal of ECHA to accept that only a difference in the phys. chem. parameters leads to a new nanoform is the unacceptance of analytical data. Industry needs to provide sufficient data to demonstrate that either the same nanoform is present or in case of a set of similar nanoforms, that the hazard, exposure, and risk assessment can be performed jointly. But so far, ECHA did not accept any justification including the argument of a common hazard, exposure, and risk potential based solely on similarities in phys. chem. properties.

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Same properties also mean same hazard and risk potential

So far, data demonstrating that the same phys. chem. characterizers for two commercial products or grades produced by one or more manufacturers are not accepted as sufficient to show similarity in hazard/exposure and risk outcome. ECHA clearly states in its guidance documents that e. g. two manufacturers cannot produce the same nanoform and several more restrictions are introduced. But as parameters like the particle size or the surface treatment primarily influence the product properties, these parameters are closely monitored by manufacturers. As a result, products competing for the same market usually have similar particle size distributions – irrespective of where, how or by whom they were manufactured. This is also reflected in the REACH text where it is clearly stated that only the parameters in points 2.4.2 to 2.4.5 are decisive for the differentiation of a nanoform. Due to the lack of any legal or scientific justification and no clear benefit, it is not comprehensible why ECHA contradicts REACH in this case.

Concept of set of similar nanoforms fails due to ECHA's impracticable expectations

In cases of dossiers with sets of similar nanoforms, the justification for the set formation has been rejected in many cases at the beginning of the nanoform registrations and is now again challenged in the first dossier evaluations. Inability to differentiate into different nanoforms based on the phys. chem. parameters was not deemed sufficient to justify the set. Supplementary data demonstrating similar behaviour in biological media or other toxicological studies for nanoforms representing boundary compositions of the proposed set, were also challenged to be sufficient for the whole set. Currently the impression is created that only if each individual (!) product or grade on the market is fully characterized – not only for its phys. chem. properties but also the full toxicological profile – a joint assessment would be accepted.

> ***More and more data are demanded but at the same time expert judgement and conclusions based on existing and newly generated scientific data are not being accepted by ECHA. This contradicts not only the idea behind the introduction of the concept of sets of similar nanoforms, and the REACH text as legal basis for all actions, but also the purpose of REACH itself as stated in Article 1. This is not proportional, does not bring added benefit and does not serve the aim of the REACH Regulation: ensuring a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.***

Our conclusion

The concept of registering nanoforms falls behind industrial reality. As a consequence, authorities tried to let the reality look like what was expected instead of adhering sound scientific data. But one should not tangle unrealistic expectations with the scientifically based

reality. Introducing new requirements and obligations will not change the nature of nanoforms on the market and will not bring any benefit – especially when these new requirements are bare of a legal basis and even contradict the legal text.

The current REACH text allows thorough assessment of nanoforms. But if two materials cannot be differentiated into two separate nanoforms based on their phys. chem. characterizers, it must be scientifically acceptable that they are by all means the same nanoform with the same hazard, exposure and risk profile. Artificially inflating the number of nanoforms without any legal justification only strains industry's capacities in the EU which is needed elsewhere e. g. to fulfil the high goals set out by the EU Green Deal and it does not change the fundamental fact that based on all available evidence[7] nanomaterials do not exhibit any new hazardous properties and do not need to be treated differently than bulk materials.

Therefore, Eurocolour promotes

- **Greater inclusion of industry's concerns in the development of legislation and guidance documents – industry's voice is not being heard. A token inclusion brings no benefit and is unacceptable.**
- **Higher acceptance of scientific data – science does not bend to political agendas**
- **Realistic timeframes necessary – Diligence and correctness must take precedence over time pressure and speed**
- **Facing and solving fundamental problems instead of case-by-case discussions**

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About Eurocolour:

Eurocolour e. V. is the umbrella association for manufacturers of pigments, dyes, fillers, frits, ceramic and glass colours, and ceramic glazes in Europe.

[7] See data submitted in the REACH dossiers containing nanoforms and scientific publications like e.g. H. F. Krug, *Nanosafety Research—Are We on the Right Track?*, Angew. Chem. Int. Ed. (2014), 53: 12304-12319, link.

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Our concerns

- Information demands exceed the legal text basis of REACH by far. Guidance documents, IUCLID, and the first draft decisions by ECHA all ask for information without legal basis, nor scientific reason.
- Scientific justifications for formed sets of similar nanoforms or for the boundary composition of single nanoforms are not accepted without clear justification.
- Given time frames have been unrealistic and could not be met when sound scientific data needed to be generated. This is an especially high burden for SMEs who often do not have all the analytical equip in-house but have to rely on contract laboratories.
- The published Guidance Documents are of limited usefulness and applicability as they do not reflect the legal requirements and include many unclarities. Additionally, constant changes in IUCLID without any information for users hamper the submission of updated dossiers.

Our demands

- Greater inclusion of industry's concerns in the development of legislation and guidance documents – industry's voice is not being heard. A token inclusion brings no benefit and is unacceptable.
- Higher acceptance of scientific data – science does not bend to political agendas
- Realistic timeframes necessary – Diligence and correctness must take precedence over time pressure and speed
- Facing and solving fundamental problems instead of case-by-case discussions

Our proposed actions

- Align information requirements in guidance documents and in IUCLID with the legal text. A nanoform is defined by the characterizers laid down in REACH Annex VI, Note 2, subsection 2.4.2-2.4.5 and nothing else.
- Accept that materials with the same phys. chem. parameters also have the same hazard, exposure, and risk profile, thus, facilitating defining boundary compositions for individual nanoforms and justifications for sets of similar nanoforms.
- Improve communication with industry, e. g. by providing more transparency by publishing patch notes for IUCLID updates or by granting an appropriate deadline in case a dossier evaluation revealed the need to additional data to be generated

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