New legal regulations on nanoforms of substances in the context of the legal certainty principle

Marcin Jurewicz[1), *)] (ORCID ID: 0000-0003-1276-9696)

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Abstract: New legal regulations concerning nanomaterials in the scope of the legal certainty principle were discussed. Commission Regulation (EU) 2018/1881 of 03/12/2018 amending the REACH regulation with regard to Annexes I, III, VI-XII is the first normative act on chemicals that sets out the requirements for the registration of nanoforms of substances. The new requirements for nanomaterials will serve to implement the principle of legal certainty in this area. The presented analysis of the introduced amendments to the annexes to the REACH regulation indicates some shortcomings of the new legal regulations.

Keywords: nanoforms of substances, legal certainty, REACH regulation.

Nowe regulacje prawne dotyczące nanoform substancji w kontekście zasady pewności prawa

Streszczenie: Omówiono nowe uregulowania prawne dotyczące nanomateriałów w zakresie zasady pewności prawa. Rozporządzenie Komisji (UE) 2018/1881 z 03.12.2018 zmieniające rozporządzenie REACH w odniesieniu do załączników I, III, VI-XII stanowi pierwszy akt normatywny dotyczący chemikaliów, który ustala wymagania odnośnie rejestracji nano- substancji. Nowe wymagania dotyczące nanomateriałów posłużą do realizacji zasady pewności prawa w tym obszarze. Przedstawiona analiza wprowadzonych zmian załączników do rozporządzenia REACH wskazuje na pewne uchybienia nowych uregulowań prawnych.

Słowa kluczowe: nanoformy substancji, pewność prawa, rozporządzenie REACH.

Commission Regulation (EU) 2018/1881 of 03/12/2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) as regards Annexes I, III, VI, VII, VIII, IX, X, XI and XII to cover nanoforms of substances [1] is the first legal act in the field of chemicals that explicitly introduces requirements for the nanoforms of substances registration. Regulation (EU) 2018/1881 applies from 01/01/2020 (Article 3). These amendments apply to all new and existing registrations involving nanoforms of substances. This means that companies should update their existing registration dossiers with information related to nanoforms of substances by 01/01/2020 [2]; new registrations are required to submit their information in accordance with the new nanoforms of substances registration requirements [3]. **The purpose of Regulation (EU) 2018/1881 is to provide clarity on how nanoforms of substances are considered and demonstrated in registration dossiers so that REACH [4] can adequately address nanomaterials [5].** Introducing changes to the REACH Regulation should therefore contribute to ensuring that companies provide sufficient information to demonstrate that their nanoforms of substances are safe for human health and the environment [2]. The annexes amendments to the REACH Regulation with regard to the registration of substances with nanoforms of substances should therefore improve the knowledge on the potential effects of nanoforms of substances on human health and the environment, and, consequently, take more appropriate risk prevention measures, which is the basic aim of the regulation REACH for all chemicals. On the other hand, in terms of economic and social benefits, legal clarity and certainty are expected to have a positive impact on companies investment decisions and may improve consumer confidence in the safe use of substances with nanoforms of substances [5].

THE ESSENCE OF THE PRINCIPLE OF LEGAL CERTAINTY

The Board of Appeal of ECHA (European Chemicals Agency) emphasizes in its decisions the important role of the legal certainty principle in the area of nanomateri-

[1)] Bialystok University of Technology, Faculty of Engineering Management, Departament of Marketing and Tourism, ul. Ojca Tarasiuka 2, 16-001 Kleosin, Poland.

[*)] Autor do korespondencji; e-mail: m.jurewicz@pb.edu.pl

als [6–10]. The information requirements on nanomaterials introduced by Regulation (EU) 2018/1881 are good for implement the principle of legal certainty in this area. However, a detailed analysis of the introduced amendments to the REACH regulation annexes shows some shortcomings of the new legal regulations. The principle of legal certainty has a formal and a material aspect. The formal approach to legal certainty means that laws and court decisions must be predictable [11]. Predictability consists in a clear, understandable, as well as simple, synthetic, concise and precise formulation of legal provisions for all interested entities, including people without legal background, as the vast majority of such persons are the addressees of the law [11–13]. Predictability is also related to the stability of the legal situation, so the law should be a set of unchanging, established, independent norms.

Moreover, based on the principle of legal certainty, the legal system should be coherent.

This means that constituting it set of legal norms should be rational and internally ordered, the norms of this system should be applied in a uniform and impersonal manner [11].

Right holders must therefore not be uncertain as to their rights and obligations [13]. Normative acts should be formulated in such a way that units have the possibility to unambiguously determine the rights and obligations resulting from the normative act, and to take appropriate actions [11]. The law should be required to let the recipient know what action or omission the legislator expects from him.

The subject to which the law refers should be able to foresee the effects of facts (states of affairs) determined by law, including acts (actions and omissions) of his own and other entities [14].

From the perspective of the legal certainty principle, it is also important that legal acts have an appropriate legal basis and form. Consequently, the binding nature of any act producing legal effects must derive from a provision of EU law which determines the legal form to be adopted by that act and which must be clearly stated therein as its legal basis [11].

The presented list of features forming the formal approach to legal certainty is also taken into account in the Interinstitutional Agreement of 22.12.1998 on common guidelines for the Community legislation quality [15]; this agreement, as stated in recitals 1–2, aims to guarantee a high level of EU legal acts.

According to the substantive aspect, legal certainty is recognized in the context of the legal regulations rationality and court decisions (at the stage of law creation and its application); it means acceptability, i.e. the possibility of their acceptance by a given community [11]. Legal entities should therefore be able to rely on legal provisions as something that is trustworthy and provides a sense of security [14]. Therefore, it means taking into account the principles that make up the rule of law concept, in particular the feeling of legal security of citizens, citizens' trust in the state and the law it enacts, non-retroactivity of law, rightly acquired rights protection, maintaining appropriate *vacatio legis* (the period between the publication of a legal act and its entry into force), the right to a fair trial, proportionality [16]. A legal norm must also be rationally justified in order to gain the acceptance of legal entities [11].

Moreover, the fact of conducting public consultations, especially real ones, significantly influences the acceptability level of a given decision [16]. The importance of public consultations as a tool to improve lawmaking was emphasized in the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission of April 13, 2016 on better law-making [17].

This agreement in point 19 concludes that public consultation is an integral part of the informed decision-making process and essential to improving the quality of the law-making process. Public consultations may be real when the authorities do not exclude the inclusion of comments collected in the course of these consultations, or illusory when the authorities intend to take into account only comments that are irrelevant from their perspective or do not intend to take into account any [16].

NEW LEGAL REGULATIONS WITH REGARD TO THE REGISTRATION OF NANOFORMS OF SUBSTANCES AND THE PRINCIPLE OF LEGAL CERTAINTY

The key amendments introduced by Regulation (EU) 2018/1881 in relation to the registration of nanomaterials are: nanoforms of substances definition, provisions on grouping of nanoforms with similar properties into "sets of similar nanoforms" and amendments to individual annexes [18]. The definition of nanoform according to Annex VI introductory text – states that "nanoform of a substance" is a natural or manufactured material containing particles in a free state, or in the form of an aggregate or agglomerate in which at least 50% or more of the particles in the numerical particle size distribution have one or more dimensions in the range 1–100 nm; as an exception, nanoforms are also fullerenes, graphene flakes and single-wall carbon nanotubes with at least one dimension below 1 nm.

In this context, "particle" means a piece of matter with defined physical boundaries, "agglomerate" denotes a set of weakly related particles or aggregates where the final size of the outer surface is close to the sum of the surface areas of the individual components, and "aggregate" means a particle containing strongly bonded or fused particles.

Grouping nanoforms into 'sets of similar nanoforms' should clearly state the property boundaries of the individual nanoforms in the kit and provide a rationale explaining why changes within these boundaries do not affect the hazard assessment, exposure assessment or risk assessment of similar nanoforms within the kit; a given nanoform may be from only one set of similar

nanoforms (Annex VI, introductory text). Grouping must therefore have a clear scientific justification.

This can be achieved using read-across methodologies to compare nanoforms and even nanoforms and conventional substances, if it is scientifically justified [18].

Regulation (EU) 2018/1881 also establishes the following amendments to the annexes to the REACH regulation:

– Annex I General provisions for substance evaluation and chemical safety reporting – the identification and characterization of nanoforms of substances and sets of similar nanoforms is required;

– Annex II Requirements for the compilation of safety data sheets – the new provisions related to safety data sheets complement the new requirements for the registration of nanomaterials and ensure that the same information is also reflected in safety data sheets – the amendments to this annex were introduced by Commission Regulation (EU) 2020/878 of June 18, 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) [19];

– Annexes III and VI-XI Standard information requirements for substances manufactured or imported in quantities of at least 1 ton, 10 tons, 100 tons and 1000 tons – specific data requirements applicable to nanoforms of substances are defined; nanoforms must additionally be identified and characterized as part of the substances registration, so that they can be documented individually or in a combination of similar nanoforms sets; information must be provided on production volume, uses and safe handling, as well as particle size (numerical size distribution), shape and surface properties of the nanoforms; methods of producing nanomaterials allow the multiple nanoforms production, differing in size distribution, shape and surface properties; these features can influence the behavior and reactivity of each nanoform;

– Annex XII General provisions for further users for substance evaluation and chemical safety reporting – a risk analysis is required for all nanoforms [18, 20, 21].

In accordance with the legal certainty principle, legal acts in the field of nanotechnology should be made in an obvious, accessible and at the same time strict manner, and the legal provisions should be harmoniously related to each other. Legal entities must be able to determine in advance the legal consequences of their activity, and their legal situation should be permanent and unchangeable. However, Regulation (EU) 2018/1881 contains unclear, unspecified wording; these were cited by stakeholders during the public consultation on the amendments in the REACH Annexes to include nanoforms of substances. These are the following phrases: "relevant information" (Annex VI, Stage 1); "differences in parameters in point 2.4.2-2.4.5 "(Annex VI, introductory text); "where applicable" (Annex I, subsection 5.2.2); "significant differences" (Annex VI, introductory text); "appropriate measurement unit for the evaluation and expression of the results" (Annex I, subsection 0.11 a) [22].

Public consultations on amendments to the annexes to the REACH regulation in order to include nanoforms of substances were used to obtain observations and ideas of the addressees of this legal act on its modification.

Thanks to this, the introduced amendments should be carefully polished up. Unfortunately, some important (from the perspective of legal certainty) views of the interested parties, including the above-mentioned, were not taken into account in the framework of the established amendments to the annexes to the REACH Regulation.

In addition, in Regulation (EU) 2018/1881 there are expressions of a technical nature that are unclear, imprecise or confusing and were also identified by stakeholders during the public consultation.

These are, for example, the terms "dangerous property" (Annex X, subsection 8.6.3); "nanoforms soluble in biological and environmental media" (Annex III (b)); 'indirect genotoxicity' (Annex VII, subsection 8.6.1 and Annex IX, subsection 8.6.2), 'potential confounding diffusion effect' (Annex VII, subsection 7.7); "nanoforms very difficult to dissolve " (Annex VIII, subsections 9.1.3 and 9.1.4, Annex IX, subsection 9.2.2) [22]. The quoted wording therefore requires further clarification by means of guidelines.

On the other hand, the date of entry into force and the application date of Regulation (EU) 2018/1881, i.e. according to Art. 3 respectively: on the twentieth day after publication in the EU Official Journal and from 01.01.2020, have not been coordinated with the preparation in advance of guidelines for testing nanomaterials, which would be complete and would cover the entire information requirements of the REACH Regulation (including the interpretation of the above-mentioned phrases); some of these guidelines have already been made or updated, but some are still in development. Information on the progress of work in this area is available on the EUON (European Union Observatory for Nanomaterials) internet platform – https://euon.echa.europa.eu/.

Therefore, the addressees of Regulation (EU) 2018/1881 did not have the appropriate time to prepare thoroughly for its entry into force and application. In addition, Regulation (EU) 2018/1881 sets out a definition of nanoforms of substances in Annex VI to REACH.

This definition is based on the definition of nanomaterial set out in the Commission Recommendation of 18/10/2011 on the nanomaterial definition (2011/696/EU) [23].

After the entry into force of Regulation (EU) 2018/1881, however, the Commission Recommendation of 10/06/2022 on the nanomaterial definition [24] introduced, the updated definition of nanomaterial – in relation to Recommendation 2011/696 / EU. On the basis of point 1 of the Commission Recommendation of 10/06/2022 on the nanomaterial definition, "nanomaterial" means a natural, incidental or manufactured material composed of solid particles that either exist alone or as identifiable constituent particles in aggregates or agglomerates, and in which at least 50% of such particles by number size distribution meet at least one of the following conditions: at least one

external particle size is in the range 1–100 nm; the particle has an elongated shape, such as a rod, fiber, or tube, where two outer dimensions are less than 1 nm and the other dimension is bigger than 100 nm; the particle is plate-shaped where one external dimension is less than 1 nm and the other dimensions are bigger than 100 nm. In addition, point 1 of that recommendation states that particles with two or more orthogonal external dimensions greater than 100 μm may be disregarded when determining the numerical particle size distribution; however, a material with a specific volume surface area less than 6 m^2/cm^3 shall not be considered as a nanomaterial.

Although the new definition of nanomaterial contains slight changes, and is still based on particle size and their numerical distribution, its establishment necessitates an update of the definition of nanoform of a substance in Regulation (EU) 2018/1881. The lack of correlation between the introduction of Regulation (EU) 2018/1881 and the nanomaterial new definition shows, contrary to the legal certainty principle, that the legal provisions in the area of nanomaterials are unstable. In addition, the definition of nanoforms of substances, introduced by Regulation (EU) 2018/1881 and included in Annex VI to the REACH Regulation, should not appear in the annexes that cover the technical issues of a given legal act, and in the normative part of the REACH Regulation, i.e. in Art. 3 containing the definitions used in this legal act. This would give the addressees a clear indication that the definition of nanoform of a substance is used throughout the legal act.

This internal systematics of the legal act is confirmed in the Interinstitutional Agreement of 22/12/1998 on common guidelines for the quality of Community legislation (points 14, 15 and 22).

It should also be mentioned that the information requirements depend on the total tonnage of the substance, in all its forms, on the market [5]. The registration of nanomaterials as nanoforms of substances (and not as separate substances), introduced by Regulation (EU) 2018/1881, highlights the possibility that the total tonnage of nanoforms and other forms of substances will exceed those expressed in Art. 6 sec. 1 of the REACH Regulation, the threshold of 1 ton per year, which implies – in accordance with the principle of legal certainty – an explicit obligation to register substances and thus submit information related to nanoforms [25]. On the other hand, the requirement to provide full information in the registration dossier for all nanoforms of substances, including those with a negligible tonnage, can be a significant administrative barrier for registrants.

This barrier is limited by the possibility of grouping nanoforms with similar characteristics into sets of similar nanoforms – in accordance with preamble 9 of the Regulation (EU) 2018/1881. Therefore, on the basis of Art. 6 sec. 1 of the REACH Regulation, each manufacturer or importer of a substance, on its own or in one or more mixtures, in the amount of 1 ton or more per year, submits registration documents to ECHA.

The 1 ton per year threshold is inappropriate as the impact of nanoparticles may not be directly correlated with the mass produced, and such a threshold value may result in the complete exclusion of many nanomaterials from REACH [26]. Due to their properties, nanomaterials tend to be much more reactive than their conventional form counterparts, thereby increasing the risk of a detrimental effect compared to the equivalent weight of the material in its normal form. This increased reactivity as well as the production costs of nanomaterials mean that they are generally produced in much smaller amounts than their conventional counterparts [27]. It is therefore desirable to lower the tonnage threshold (at least 1 ton per year) in relation to the nanoform of substances, which determines the obligation to register substances.

Regulation (EU) 2018/1881, however, does not establish a different tonnage threshold for nanoform of a substance than for conventional substances and with which the registration of substances is required. This shortcoming applies both to nanoforms of substances that have equivalents in the form of conventional substances and to nanomaterials that do not have such equivalents, which is particularly important due to the usually low volume of trade in nanomaterials.

SUMMARY

Regulation (EU) 2018/1881 clearly sets out requirements for the registration of nanoforms of substances. The introduction of these criteria is an appropriate step towards the implementation of the legal certainty principle in this area. Nevertheless, Regulation (EU) 2018/1881 contains unclear, unspecified or confusing phrases. They were recalled by stakeholders during the public consultation on amendments to the REACH Annexes to include nanoforms of the substance. However, some of the interested parties observations, significant in the context of the legal certainty principle, were not taken into account in the framework of the introduced amendments to the Annexes to the REACH Regulation. These expressions, in particular of a technical nature, therefore require further clarification using the guidelines. However, the introduction of Regulation (EU) 2018/1881 has not been correlated with the preparation of previously comprehensive guidance on the REACH information requirements for nanoforms of substances. In addition, the nanoform of a substance definition in Annex VI to REACH Regulation (EU) 2018/1881 was not coordinated with the introduction by the Commission Recommendation of 10/06/2022 on the nanomaterial definition of a new nanomaterial definition. The nanoform of a substance definition therefore needs updating, which proves the instability of legal provisions in the field of nanomaterials. Moreover, the nanoform of a substance definition should not be included in the annex, which contains only technical issues, but in the enacting terms of the REACH Regulation in Article 3 covering the definitions used in this legal act, so that the

addressees have no doubts that the nanoform of a substance definition is used in for the entire legal act.

It is also advisable to mention that Regulation (EU) 2018/1881 does not introduce for the nanoform of a substance a tonnage threshold with the registration of a substance that is different from that of conventional substances and a reduced one (at least 1 ton per year according to Art. 1 of the REACH Regulation) – despite the possible different effects of some nanomaterials on human health and the environment than their equivalents in the form of conventional substances, and the usually low level of trade in them.

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