Compliance management in the area of nanomaterials in the context of the proportionality of the new obligations regarding nanoforms of substances

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COMPLIANCE MANAGEMENT IN THE AREA OF NANOMATERIALS IN THE CONTEXT OF THE PROPORTIONALITY OF THE NEW OBLIGATIONS REGARDING NANOFORMS OF SUBSTANCES

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Spis treści

List of abbreviations

CAS	–	Chemical Abstracts Service
CJEU	–	Court of Justice of the European Union
CLP	–	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
DNEL	–	Derived No Effect level
EC	–	European Community
ECHA	–	European Chemicals Agency
EINECS	–	European Inventory of Existing Commercial Chemical Substances
ELINICS	–	European List of Notified Chemical Substances
EU	–	European Union
ISO	–	International Organization for Standardization
IUPAC	–	International Union of Pure and Applied Chemistry
m	–	meter
NLP	–	No-longer polymers
nm	–	nanometer
OJ C	–	Official Journal C series
OJ L	–	Official Journal L series
PBT	–	Persistent, Bioaccumulative and Toxic substances
PEC	–	Predicted Environmental Concentration
PNEC	–	Predicted No Effect Concentration
REACH	–	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),

		establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
SAS	–	synthetic amorphous silica
SDS	–	Safety Data Sheet
SEAC	–	Committee for Socio-economic Analysis
SVHC	–	Substances of Very High Concern
TEU	–	The Treaty on European Union
TFEU	–	The Treaty on the Functioning of the European Union
UVCB	–	Unknown or Variable Composition, Complex Reaction Products or Biological Materials
vPvB	–	very Persistent and very Bioaccumulative substances

Introduction

Nanotechnology includes the design, creation and use of materials with at least one dimension in the range of 1 nm (10–9 m) – 100 nm (10–7 m)[1]. Nanomaterials enable a wide range of commercial and scientific applications due to their specific properties, which can also be tailored for specific purposes[2]. Priority applications for nanotechnology are medical applications, information technology, energy production and storage, nanotechnology–based material science, food, water and environmental research, and security[3]. At the same time, in accordance with point 28 of the European Parliament resolution "Nanosciences and nanotechnologies (2005–2009)" [4], the potential harm to health and the environment caused by newly developed nanoparticles is still not fully known and it is therefore necessary to investigate the effects of nanoparticles that do not immediately dissolve or biodegradation before using these particles in production and placing them on the market. Requiring the registration of nanoforms of substances aims to provide regulatory authorities with information on the potential health and environmental risks associated with innovative uses of nanomaterials.

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1 R. M. Brydson, C. Hammond, *Wytwarzanie i klasyfikacja nanostruktur* [in:] R. W. Kelsall, I. W. Hamley, M. Geoghegan, M. (eds.), *Nanotechnologie*, Warsaw 2012, pp. 1–56.

2 B. Enderle, *Scope of REACH* [in:] D. Drohmann, M. Townsend (eds.), *REACH. Best Practice Guide to Regulation (EC) No 1907/2006*, München 2013, p. 21.

3 Communication from the Commission – Towards a European strategy for nanotechnology, COM(2004) 0338.

4 OJ C 2006, nr 306, p. 426.

The aim of the work is to characterize the respect of the principle of proportionality in the context of the obligations regarding the registration of nanoforms of substances established by Commission Regulation (EU) 2018/1881 amending the REACH Regulation to address nanoforms of substances[5]. The following hypothesis was adopted in the work: the requirement to register nanoforms of a substance is a proportionate measure that should influence the positive perception of the law in this area by the addressees of legal norms and strengthen their conviction about the need to comply with legal obligations. The obligation to register nanoforms of substances is a proportionate measure that meets the criteria of appropriateness and indispensability.

[5] Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances, OJ L 2018, nr 308, p. 1.

Methods

The text analysis method was used in the publication. The stages of text analysis are the analysis of graphical overview, text semiotics, initial understanding, in-depth analysis and interpretation, contextual analysis and critical reflection. Review of literature involves extensively going through the literature available on the topic. Content analysis allows publications to be identified that are particularly useful for achieving the goal and the findings made in them. This helps fix the topic and helps know what body of knowledge exists on the topic and what research techniques have been previously used; a critical analysis of the methodologies used also helps choose the appropriate methods for research work. Content analysis requires assessing the quality of the researched publications, organizing research findings and identifying cognitive gaps[6]. Literature research was conducted in relation to the following subject headings: compliance management and the principle of proportionality. The following databases were selected that contain literature on the listed subject headings: the international catalogue of library resources WorldCat and the Primo search engine for resources to which the Bialystok University of Technology Library has access, as well as the Google Scholar search engine. Then, texts that directly concern the researched issue were selected. Based on the analysis of the content of publications (books and articles) in the area

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[6] R. Batko, *Czytanie tekstów* [in:] M. Kostera (ed.), *Metody badawcze w zarządzaniu humanistycznym*, Warsaw 2015, pp. 109–117; H. Dźwigoł, *Współczesne procesy badawcze w naukach o zarządzaniu. Uwarunkowania metodyczne i metodologiczne*, Warsaw 2018, pp. 51, 188, 337; S. Sadri, *An Exposition of Research Methodology in Management and Social Sciences*, "Journal of Economic Development, Environment and People" 2013, Vol. 2, pp. 5–24.

of compliance management and the principle of proportionality, the importance of respecting the principle of proportionality in the law was indicated for opinions on the value of law in the field of nanotechnology and the conviction of addressees of legal norms in this area as to respecting the obligations related to the registration procedure for nanoforms of substances. One of the parameters for evaluating the quality of law by the addressees of legal norms is the proportionality of the measures used to achieve the goals. Interinstitutional Agreement on Better Law-Making[7] in point I.3. defines this proportionality as avoiding overregulation and administrative burdens for citizens, administrations and businesses. The effect of respecting the principle of proportionality in the law should be its positive perception and strengthening the conviction of the recipients of legal norms about the need to comply with legal obligations. The research gap is understood as a divergence of scientific positions around a given issue, as well as the desire to find better ways of describing a given section of reality[8]. The method of literature research made it possible to identify a research gap – the failure to describe whether the obligation to register nanoforms of a substance is a proportionate measure to achieve the main objective of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals – REACH[9], i.e. to ensure a high level of protection of health and the environment. An adequate method to describe this phenomenon is the analysis of sources[10]. The sources used in the publication are documents: results of public consultation "Amendments of the Annexes to REACH for registration

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7 Interinstitutional Agreement of 13 April 2016 between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making, OJ L 2016, nr 123, p. 1.

8 H. Dźwigoł, *op. cit.*, pp. 51, 188, 337.

9 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 2006, nr 396, p. 1, as amended.

10 H. Dźwigoł, *op. cit.*, pp. 51, 188, 337.

of nanomaterials"[11] and sources of law. The online targeted stakeholder consultation took place between 9 October and 6 November 2017. A total of 36 responses were received[12]. The analysis of sources allowed an accurate examination to obtain knowledge about the circumstances whether the obligation to register nanoforms of substances, introduced by Commission Regulation (EU) 2018/1881 amending the REACH Regulation to address nanoforms of substances, does not violate the principle of proportionality.

[11] European Commission, website, *Amendments of the Annexes to REACH for registration of nanomaterials,* https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1141-Amendments-of-the-Annexes-to-REACH-for-registration-of-nanomaterials/feedback_en?p_id=120385 [access: 04.04.2024].

[12] *Ibidem*.

The essence of compliance management; proportionality as a principle of the compliance management system

Compliance management within an organization includes the design, implementation, maintenance, verification and reporting of compliance requirements originating in regulations and law enforcements[13]. The subject of compliance is not to violate all legal orders and prohibitions, as well as the recommended rules of good manners addressed to the enterprise[14]; these are all types of internal regulations applicable in a given enterprise, which are a frequently used mechanism, especially in large and complex international corporations[15] (in particular policies, codes of conduct and procedures, e.g. whistleblowing policy, code of ethical conduct). Compliance management in the area of nanomaterials safeguards the interests of chemical companies against the risk of non-compliance with legislation, as well as adequately counteracts the occurrence of such non-compliances; legislation in the sphere of nanomaterials is often complicated and intricate.

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13 E. Ramezani, D. Fahland, J. M. van der Verf, P. Mattheis, *Separating compliance management and business process management* [in:] F. Daniel, K. Barkaoui, S. Dustdar (eds.), *Business Process Management Workshops*, Berlin–Heidelberg 2012, pp. 459–464.

14 A. Dylus, *Compliance Management. Charakterystyka i warunki powodzenia* [in:] W. Gasparski, J. Jabłońska-Bonca (eds.), *Biznes. Prawo. Etyka*, Warsaw 2009, pp. 68–78.

15 W. Szpringer, *Regulacja a compliance na rynkach nowych technologii*, "Annales H – Oeconomia" 2016, Vol. 2, pp. 93–111.

The core of compliance management is ISO 37301. This is an international standard that provides guidance on establishing, developing, implementing, evaluating, maintaining and improving effective and responsive compliance management systems in organisations[16]. ISO 37301 supersedes ISO 19600[17]. ISO 37301 is crucial for organisations that want to ensure compliance with laws, regulations and ethical standards within their operational framework. It helps reduce the risk of non-compliance, fosters a culture based on integrity, improves corporate governance, accountability and reputation. The standard promotes ethical business practices, enhances trust among stakeholders, improves management processes and operational efficiency[18]. ISO 37301 recommends senior management commitment and legal compliance as a principle of good governance. It also recommends integrating compliance management across the organisation so that it is embedded in financial, risk, quality, environmental and health and safety management processes, as well as operational requirements and procedures. The benefits of implementing ISO 37301 are expected to include not only a reduced risk of financial penalties due to non-compliance with legislation, but also improved reputation and credibility, providing customers and other stakeholders with greater confidence and increased business opportunities[19]. ISO 37301 serves organisations of any size wishing to establish a robust compliance management system[20].

Proportionality is a principle of EU law – Art. 5 sec. 4 of the Treaty on European Union (TEU)[21] decides that: "In accordance with the principle of proportionality, the scope and form of action of the Union shall not exceed what is necessary to achieve the objectives of the Treaties." At the same time, proportionality – according to the ISO 37301 standard – is a principle

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16 ISO, website, *Compliance management systems – Requirements with guidance for use*, https://www.iso.org/standard/75080.html [access: 02.07.2024].

17 ISO, website, *New standard for compliance management makes everyone a winner,* https://www.iso.org/news/ref2656.html [access: 02.07.2024].

18 ISO, website, *Compliance management systems…*, *op. cit.*

19 ISO, website, *New standard…*, *op. cit.*

20 ISO, website, *Compliance management systems…*, *op. cit.*

21 OJ C 2016, nr 202, p. 13.

of the compliance management system[22]. The organization of a compliance management system in an enterprise and activities aimed at securing this compliance should be based on the principle of proportionality.

Proportionality – as a principle of the compliance management system – indicates that the means are measured according to the objectives, i.e. they should not go beyond what is appropriate and necessary in a given case to achieve the objective[23]. In order to conduct a comprehensive examination of the proportionality rule, it is necessary to first define the subject of the examination, i.e., on the one hand, its purpose, and, on the other hand, the means chosen to achieve this purpose[24].

Only after determining the above-mentioned object of the study one can proceed to the first step of three in the examination of proportionality, i.e. determining whether the measure is useful in achieving a given objective[25]. Inappropriate measures, i.e. those that do not support the objectives, should not be taken[26]; they mean an unnecessary waste of time, at the same time reducing the chances of success of a given compliance project, which ultimately generates senseless material losses and proves the lack of effectiveness of the system[27]. A measure is considered useful if it objectively serves the intended purpose. It should be noted that a measure does not necessarily achieve the objective in question; it is enough that by using it you can get closer to the intended goal[28].

After determining whether a given measure is appropriate to achieve a specific objective, it must be determined whether it is indispensable to achieve that objective. The chosen means must therefore be necessary to achieve a given goal. First of all, it is to determine whether there is an alternative measure, i.e. other

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22 ISO, website, *ISO 37301:2021*, https://www.iso.org/standard/75080.html [access: 15.07.2024].

23 B. Makowicz, *Wprowadzenie do zarządzania zgodnością* [in:] B. Makowicz, B. Jagura (eds.), *Systemy zarządzania zgodnością compliance w praktyce*, Warsaw 2020, pp. 44–47.

24 B. Makowicz, *Compliance w przedsiębiorstwie*, Warsaw 2011, pp. 171–183.

25 *Ibidem*.

26 B. Makowicz, *Wprowadzenie…*, *op. cit*., p. 44–47.

27 B. Makowicz, *Compliance…*, *op. cit*., p. 171–183.

28 *Ibidem*.

than the chosen one, which will result in a smaller limitation of the interest of a given person[29]. If there are less unfavorable alternatives that are equally reliable in achieving the goal, then these should be chosen[30].

The last condition for examining the proportionality of a measure to the chosen objectives is the requirement of proportionality in the strict sense[31]. This means that in many cases, commensurability, i.e. balancing various interests, should be applied when implementing a compliance management system[32]. The purpose of this condition is to examine whether, in the event of a conflict of interest, the effects of a given measure will remain in appropriate proportion to the restrictions and burdens imposed on the person who is the subject of this measure. The point here is to use a technique of balancing or harmonizing conflicting interests[33]. Any circumstances that may arise that may favor one or the other interest must be taken into account. Such premises include – on the employee's side – the burden that will be imposed on him, the possibility of making a concession, the amount of restrictions and the consequences of applying the measure, the possibility of sacrificing himself for the cause, etc. On the employer's side, important factors will include the seriousness of the irregularity committed, material losses, etc., whether the unlawful act was committed once or more often, and whether the person on whom the measure is applied is himself suspected of committing the unlawful act, whether he acts only as a witness, as well as whether there is an obligation to answer a question or submit information to the whistleblowing system, or whether it only depends on the good will of the employee and other aspects[34].

Disruption of the necessary balance between the means and the goal of the compliance management system may lead to the creation of oversized compliance structures in organizations, and in extreme cases, compliance activities may hinder business activities[35]. In cases where the compliance function

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29 *Ibidem*.

30 B. Makowicz, *Wprowadzenie…*, *op. cit*., p. 44–47.

31 B. Makowicz, *Compliance…*, *op. cit*., p. 171–183.

32 B. Makowicz, *Wprowadzenie…*, *op. cit*., p. 44–47.

33 B. Makowicz, *Compliance…*, *op. cit*., p. 171–183.

34 *Ibidem*.

35 B. Makowicz, *Wprowadzenie…*, *op. cit*., p. 44–47.

clearly exaggerates the risk of non-compliance, a certain aversion to the entire compliance management system may arise among the rest of the organization's members, which may have serious consequences for its effectiveness[36].

It is therefore important to maintain the adequacy and indispensability of the compliance management system, as well as its adjustment to existing conditions. The compliance management system should be harmonised with the characteristics and environment of the company. Respecting the above-mentioned criteria influences the favorable attitude of people covered by the company's compliance management system, their trust and the belief that this system is of high value and great importance in the company.

Proportionality is thus a principle of the compliance management system, as well as a principle of EU law. In the latter sense, it is analysed in the following chapters of the publication – in the context of proportionality of compliance obligations concerning nanoforms of substances.

[36] *Ibidem*.

Obligations regarding nanoforms of substances in Commission Regulation (EU) 2018/1881

According to Article 5 of the REACH Regulation substances on their own, in mixtures or in articles shall not be manufactured in the EU or placed on the market unless they have been registered where this is required. This rule requires that no substance be manufactured or imported before its manufacture and uses are established to be safe, based on a range of data, tests, and assessments[37].

Effective as of 01.01.2020, the REACH regulation stipulates obligations connected with the collection of additional information on the potential risk to human health and environment related to the individual nanomaterials. Commission Regulation (EU) 2018/1881 amending the REACH Regulation to address nanoforms of substances establishes the definition of the nanoform of a substance, which is based on the general definition of nanomaterial specified in Commission Recommendation 2011/696/EU on the definition of nanomaterial[38]. In accordance with Annex VI of the REACH Regulation, the nanoform of a substance is a natural or manufactured material containing particles,

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[37] L. Bergkamp, N. Herbatschek, *Information and Data Sharing Requirements* [in:] L. Bergkamp (ed.), *The European Union REACH Regulation for Chemicals. Law and Practice*, Oxford 2013, pp. 202–218; N. Herbatschek, L. Bergkamp, M. Mihova, *The REACH Programmes and Procedures* [in:] *ibidem*, pp. 82–100.

[38] Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial, OJ L 2011, nr 275, p. 38.

in an unbound state or as an aggregate or agglomerate[39], and where for 50% or more of the particles in the number size distribution have one or more external dimensions is in the size range 1–100 nm; including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm.

Pursuant to Article 6 Section 1 of the REACH Regulation every manufacturer or importer of a substance in its own form or as component in one or more mixtures in quantities of 1 tonne or more per year, shall register them in ECHA (European Chemicals Agency). The information submitted in the registration procedure is specified in Article 10 and Annex VI of the REACH Regulation. The data may be obtained from internal sources, as well as any external sources, which may be useful from the point of view of the description of the intrinsic properties of the substance. The information on the substances should include both the data available internally and from other sources, e.g. data available to the public, which may be established based on literature research[40].

Pursuant to Article 10 of the REACH Regulation, the registrants should essentially submit the registration dossier, including: a technical dossier, and for all substances produced or imported in quantities of 10 tonnes or more per registrant, a chemical safety report[41]. Article 10 letter a and Annexes VI to XI of the REACH Regulation specify the information required in the technical dossier; the technical dossier, based on Article 10 letter a of the REACH Regulation, includes:

- the identity of the manufacturer or importer as set out in Annex VI Section 1;
- the identity of the substance as specified in Annex VI Section 2;
- information on the manufacture and uses of the substance as set out in Annex VI Section 3;
- classification and labeling of the substance in accordance with the requirements set out in Annex VI Section 4;

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[39] The term "particle" means a minute piece of matter with defined physical boundaries; the concept of "agglomerate" means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components; the term "aggregate" means a particle comprising of strongly bound or fused particles.

[40] D. Drohmann, V. J. Sobala, *Registration of Substances* [in:] D. Drohmann, M. Townsend (eds.), *op. cit.*, p. 62.

[41] S. Vaughan, *EU Chemicals Regulation. New Governance, Hybridity and REACH*, Cheltenham-Northampton 2015, p. 54.

- guidance on the safe use of substances as required in Annex VI Section 5;
- summaries of substance-related information obtained from the application of Annexes VII to XI;
- testing proposals to provide substance-specific information as set out in Annexes IX and X;
- for substances between 1 and 10 tonnes, the exposure information set out in Annex VI Section 6;
- the chemical safety report, if required under Article 14; in accordance with Article 14 Section 1 of the REACH regulation, for all substances subject to registration in quantities of 10 tonnes or more per year, a chemical safety assessment is carried out and a chemical safety report is prepared; the chemical safety report is the documentation of the chemical safety assessment, which is carried out in accordance with Article 14 and Annex I of the REACH regulation for each substance on its own, in a mixture or in an article.

The greater the tonnage, the more information on intrinsic properties of the substance shall be included pursuant to Annexes VI to XI of the REACH Regulation. The information should specify in detail how and to what extent the substance influences or may influence the environment and human health[42]. The annual tonnage thresholds of the substance, which define the information requirements for the substance, are at least: 1 tonne (Annex VII), 10 tonnes (Annex VIII), 100 tonnes (Annex IX) and 1000 tonnes (Annex X).

Commission Regulation (EU) 2018/1881 amending the REACH Regulation to address nanoforms of substances introduces obligations to submit data on the nanoforms of substances in the registration dossier, as well as in the chemical safety report. Pursuant to the change of the Annexes to the REACH Regulation on the nanoforms of substances, in case of the manufacture or import of the nanoforms of substances, standard information requirements and chemical safety report shall in detail relate to the different nanoforms. The registration dossier shall include information specific to every nanoform in relation to all applicable information requirements and the chemical safety report[43]. The changes are applicable to all new and existing registra-

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42 *Ibidem*, pp. 54, 132–133.

43 ECHA, website, *How to prepare registration dossiers covering nanoforms*, https://op.europa.eu/en/publication-detail/-/publication/44ca5169-74be-11eb-9ac9-01aa75ed71a1/language-en [access: 29.03.2024].

tions involving nanoforms[44]. The obligation to register nanoforms of substances is applicable to all nanoforms meeting the definition specified in the REACH Regulation, regardless of whether the nanoforms are manufactured intentionally or not[45]. This is applicable to the substances that are intentionally manufactured as nanomaterials, as well as substances that may include nanoforms. This may be particularly important when registering powders, in which nanoforms may occur unintentionally[46].

When registering a substance including nanoforms, the registration requirement and information requirements are determined by the total turnover of all forms of the manufactured or imported substance, including nanoforms and non-nanoforms. The dossier must include the related data covering all information requirements for all forms of the registered substance[47].

Commission Regulation (EU) 2018/1881 amending the REACH Regulation to address nanoforms of substances introduces requirements for the registration of nanoforms of substances. The revised REACH annexes addressing nanoforms introduce new provisions for:

- characterisation of nanoforms or sets of similar nanoforms covered by the registration (Annex VI), registration information requirements (Annexes III and VII–XI) and the chemical safety assessment (Annex I);
- requirements for the compilation of safety data sheets (Annex II); the safety data sheet, pursuant to Annex II Section 0.2.1, must inform the user of the hazards of the substance or mixture and contain information on the safe storage, handling and disposal of the substance or mixture;

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44 ECHA, website, *Handbook on nanoforms*, https://echa.europa.eu/documents/10162/17071/helpnet_handbook_nanoforms_en.pdf/917781e1-9a69-0916-9f76-da88890df409?t=1684810906362 [access: 29.03.2024].

45 ECHA, website, *Załącznik dotyczący nanopostaci do aktualizacji Poradnika na temat rejestracji i identyfikacji substancji,* https://echa.europa.eu/documents/10162/17250/how_to_register_nano_pl.pdf/83ca9a50-5f2b-137d-1003-977b8c3b85ff [access: 29.03.2024].

46 Labcorp, website, *Nanomaterials: How to Overcome REACH Regulatory Challenges*, https://biopharma.labcorp.com/content/dam/covance/assetLibrary/ebook/NANOMATERIALS-Regulatory-Challenges-EBKCPC004.pdf [access: 29.03.2024].

47 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

- downstream user obligations (Annex XII); downstream users are required to take into account all nanoforms of the substance that are covered by the registration when carrying out the chemical safety assessment of the substance and preparing the chemical safety report (based on Annex XII Introduction)[48].

Annexes III and VI–XI of the REACH Regulation define the detailed requirements related to data applicable to nanoforms[49]. Each registrant has an obligation to characterise each nanoform they manufacture or import[50] and submit that information in the registration dossier in accordance with Annex VI Section 2.4 of the REACH Regulation[51]. A substance may have at least one nanoform, depending on the differences in the parameters listed in items 2.4.2–2.4.5 (size distribution, shape and other morphological features, surface modification and functionalisation and surface area of particles). A change in one or more properties defined in items 2.4.2–2.4.5 entails a different nanoform[52]. To complete the safety assessment of nanoforms, first they must be properly characterised. This includes the measurements of different properties that may have an impact on their toxicity[53]. The methods of manufacture of nanomaterials may lead to the formation of multiple nanoforms with different size distribution, shape and chemical composition of the surface; these features may have an impact on the behaviour and reactivity of each nanoform. The behaviour of the nanoform may be influenced by factors like solubility, hydrophobicity or dispersibility – all of them may have an influence on the final destination of the nanoform in biological systems; the reactivity defines the impact of the nanoforms and their later toxicological

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48 European Chemicals Agency, website, *Get ready for new REACH requirements for nanomaterials*, https://echa.europa.eu/pl/-/get-ready-for-new-reach-requirements-for-nanomaterials [access: 04.04.2024].

49 Labcorp, website, *New REACH nanomaterial requirements: what you need to do*, https://www.labcorp.com/new-reach-nanomaterial-requirements-what-you-need-do [access: 29.03.2024].

50 ECHA, website, *How to prepare registration dossiers…*, *op. cit.*

51 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

52 *Ibidem*.

53 ECHA, website, *Handbook on nanoforms…*, *op. cit.*

or ecotoxicological influence. In accordance with the REACH Regulation, three features are assessed for nanoparticles: particle size – number size distribution, particle shape and chemical composition of the surface[54].

Based on Annex VI Section 2.4 of the REACH Regulation, the characterisation of the nanoforms of a substance should include the following information:

- 2.4.1 – names or other identifiers of the nanoforms or sets of similar nanoforms of the substance;
- 2.4.2 – number size distribution of particles with indication of the number fraction of constituent particles in the size range within 1 nm – 100 nm;
- 2.4.3 – description of the surface functionalisation or treatment and identification of each agent, including IUPAC name (name established by the International Union of Pure and Applied Chemistry) and CAS number (Chemical Abstracts Service) or EC number (number in EINECS – the European Inventory of Existing Commercial Chemical Substances, ELINCS – the European List of Notified Chemical Substances or on the NLP list – No-longer polymers);
- 2.4.4 – shape, aspect ratio and other morphological features: crystallinity, information on assembly structure of nanoforms, e.g. nanoshells, hollow structures, as applicable;
- 2.4.5 – surface area (surface area per volume unit, surface area per weight unit or both);
- 2.4.6 – description of analytical methods or appropriate bibliographical references for the information elements in this section; the description includes the experimental protocols applied and the appropriate interpretation of the results presented in items 2.4.2–2.4.5; this information should be sufficient for reproducing the methods.

The name of a nanoform should describe the chemical composition and, as appropriate, the key physicochemical features of the nanoform, while enabling an unambiguous identification of the nanoform[55].

The REACH Regulation includes the requirement to indicate the number size distribution of particles with the number fraction of constituent particles in the size range within 1–100 nm. The size distribution of particles shall be measured on the nanoform as manufactured[56]. The size distribution

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54 Labcorp, website, *New REACH nanomaterial requirements…*, *op. cit.*

55 ECHA, website, *How to prepare registration dossiers…*, *op. cit.*

56 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

of particles of the nanoform specific for the registered shape category should be indicated[57]. The number fraction of constituent particles with at least one external dimension in the size range within 1 nm – 100 nm shall be indicated[58]. In the dossier, the registrant should include the size distribution of external dimensions of particle of the nanoform in the form of histogram with table including the values constituting the basis of the histogram[59]; the histogram is a summary of statistical data in the form of a surface chart consisting of adjacent bars (rectangles), of which the height reflects the number of occurrences of the studied feature in the population or sample thereof, while the bases (resting on the abscissa axis) are the spans of class ranges[60]. In addition, the registrant should indicate the number fraction of constituent particles if at least one external dimension in the range within 1–100 nm is in the range from 50% to 100%[61]. In case of spherical particles, it is easy to determine the size using one sphere diameter descriptor. However, not all particles are spherical. Two commonly used approaches to the assessment of external dimensions of particles in irregular shapes are: Feret's diameter and maximum diameter of circle inscribed[62]. Feret's diameter is the distance between parallel tangents; if Feret's diameter in one dimension is <100 nm, the particle is a nanomaterial. The maximum diameter inscribed in circle is the diameter of the greatest circle that may fit into the particle profile; if <100 nm, the particle is a nanomaterial[63].

The registrant should indicate in the dossier if particles in the nanoform are subject to surface functionalisation or treatment. This information should characterise the composition of particles in entirety, including the surface treatment thereof[64]. Surface functionalisation or modification may be defined as the reaction between functional groups on the particle surface and the substance described as the surface modification substance. The particle surface may be modified by single or multiple processing, while modifications may cover

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57 ECHA, website, *How to prepare registration dossiers…*, *op. cit.*

58 *Ibidem*.

59 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

60 Encyklopedia Zarządzania, website, *Histogram*, https://mfiles.pl/pl/index.php/Histogram [access: 03.04.2024].

61 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

62 Labcorp, website, *Nanomaterials: How to Overcome…*, *op. cit.*

63 *Ibidem*.

64 ECHA, website, *How to prepare registration dossiers…*, *op. cit.*

the particle surface entirely or only partially[65]. Particles may be broadly modified by attachment of different substances (e.g. inorganic or organic substances) on their surface or by modification of surface functional groups (e.g. oxidation, reduction)[66]. Surface functionalisation or modification may be applied to control such particle properties as dispersibility in different solvents (water, organic substances, polymers etc.), reactivity (e.g. increase or complete deactivation of catalytic activity), solubility – dissolution rate (e.g. modification with calcium carbonate, silver, ZnO) etc.[67] The nanoform consisting of particles without surface processing is a different nanoform than the nanoform with particles subject to surface treatment or functionalisation[68]. The reference substance connected with each surface treatment agent shall be identified with an IUPAC name. If a name consistent with the IUPAC nomenclature cannot be obtained, a name determining the chemical character of the agent shall be still provided. In addition, the EC number and the CAS number shall be indicated, if available[69].

Solid particles may occur in varied shapes, such as spheres, cubes, tubes, wires, flakes etc. Every form, as a result of a specific manufacturing process, may consist of particles in the same shape or particles in different shapes[70]. Since the number of possible shapes of particles forming nanoforms is very high, for organisational reasons, four broad shape categories are distinguished and presented below: spheroidal (e.g. spherical, pyramidal, cubical, three-dimensional star-shaped, orthorhombic, polyhedric etc.), elongated (e.g. tubes – particles with hollow structure, rods – solid particles with non-hollow structure, wires – particles conducting electricity or semi-conducting particles etc.), flat (e.g. discs, plates etc.) and multi-form, i.e. particles with shapes belonging to different shape categories. The registrants shall present a more precise description of the shape of particles (e.g. spherical particles in regular shape for nanoforms in the category of spheroidal particles)[71].

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65 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

66 *Ibidem.*

67 *Ibidem.*

68 ECHA, website, *How to prepare registration dossiers…*, *op. cit.*

69 *Ibidem.*

70 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

71 *Ibidem.*

For nanoforms belonging to the category of elongated and flat shape, the shape ratio shall be stated. The shape ratio is a descriptor of geometrical shape defined as the ratio of the length (or the longest dimension) to the particle width. The value of the shape ratio is derived from the measurements of particle size, i.e. the measurement of length – the lateral dimension (or longest dimension) and width (or the smallest dimension perpendicular to the length) of individual particles constituting the nanoform[72].

In the dossier, the registrant should submit information on crystallinity. This information includes the identification and quantitative assessment of crystalline and amorphous structures in the submitted nanoform[73]. Nanoforms may be built of atoms set in periodical matrices (crystalline nanoforms) or atoms set at random, without long range atom or particle periodicity (amorphous nanoforms)[74]. Every nanoform of a substance has a specific amorphous, crystalline or mixed structure. It should be considered that some nanoforms may consist of particles characterised by simultaneous occurrence of different crystalline structures[75].

In case of nanoforms consisting of particles with specific organisational structure, detailed information on the structures shall be provided as well. The examples of organisational structures are structures with high shape ratio and hollow structure found in nanoparticles – nanopipes or spherical nanobulbs with the structure of concentric scales. Another example are particles forming multi-layer structures – in materials based on graphene, which are multi-layer materials, not single-layer materials. For this type of material, the information provided shall include the number of walls, scales or layers formed within the structure[76].

In the dossier, the registrant should indicate the surface area per weight unit or surface area per volume unit for the nanoform[77]. The surface area is measured as the total surface area of the substance, including both the external and the internal surfaces of the particle. The data may correspond to the total

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72 *Ibidem*.

73 ECHA, website, *How to prepare registration dossiers…*, *op. cit.*

74 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

75 *Ibidem*.

76 *Ibidem*.

77 ECHA, website, *How to prepare registration dossiers…*, *op. cit.*

surface area of the nanoform per weight unit (surface area per weight unit, in m^2/g) or the total surface area of the nanoform per volume unit (surface area per volume unit, in m^2/cm^3)[78].

In the registration dossier, information shall be provided on the uses – information on the manufacture and uses of each nanoform of the substance. The dossier shall clearly state, which uses correspond to an individual nanoform – based on Annex VI Section 3 of the REACH Regulation. If the registered substance is manufactured or imported in one or more nanoforms, the information on the manufacture and use in Annex VI Sections 3.1–3.7 of the REACH Regulation, includes separate information for each nanoform[79].

For each turnover range, the REACH Regulation defines the minimum of information that the registrant shall provide on the intrinsic properties of each substance[80]. The REACH Regulation also provides for meeting the requirements of Annexes VII–X by submitting a specific set of data on hazards for each nanoform[81]. Annexes VII–XI of the REACH Regulation include specific information requirements for nanoforms (e.g. dustiness) and modifications of existing nanoforms in the form of adaptability[82]. The data requirements irrelevant to nanoforms are underlined[83]. Thus, in addition to the introduction of standard information requirements to Annexes VII–X of REACH Regulation, in relation to nanoforms of substances, special rules are established for the adaptation of that information for nanoforms of substances.

Annex XI of the REACH Regulation (General rules for adaptation of the standard testing regime set out in Annexes VII–X) enables adapting the standard study requirements in Annexes VII–X. Pursuant to the REACH Regulation, testing is an essential tool in the determination of properties of chemicals. The legislator admits, however, that the standard end points and test methods required pursuant to Annexes VII–X of the REACH Regulation are not necessarily always scientifically validated or the most suitable methods and provides for adaptation to specific chemicals and situations in order to avoid animal tests whenever possible and only use them as a last resort. In turn, in special cases the standard end points and test methods may

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78 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

79 *Ibidem*.

80 *Ibidem*.

81 ECHA, website, *How to prepare registration dossiers…*, *op. cit.*

82 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

83 Labcorp, website, *New REACH nanomaterial requirements…*, *op. cit.*

also be considered as insufficient[84]. Thus, the REACH Regulation provides for rules for modification of or derogation from study requirements. Such adaptation may increase or decrease the number of tests required to be completed by the registrants[85]. Based on Annex XI of the REACH Regulation, the general rules for adaptation of a standard study mode defined in Annexes VII–X are applied in relation to nanoforms without prejudice to the requirements applicable to other forms of the given substance.

Pursuant to Annex VII Section 7 of the REACH Regulation Information on the physicochemical properties of the substance:

- water solubility (7.7.) – in relation to nanoforms, a test of solubility in water and in appropriate biological and environmental media shall be included; for nanoforms, the potential disrupting impact of dispersion shall be assessed during the test;
- partition coefficient n-octanol/water (7.8.) – for nanoforms, the potential disrupting effect of dispersion in octanol and water shall be assessed during the test; in relation to nanoforms of substances, regardless of whether they are organic or inorganic substances, to which the partition coefficient n-octanol/water is not applicable, the dispersion stability shall be included as well;
- dustiness (7.14a.) – in relation to nanoforms, the test is not required, if exposure to the substance in granulate form may be excluded at all stages of existence of substances.

Pursuant to Annex VII Section 8 of the REACH Regulation Toxicologial information:

- mutagenicity (8.4.) – *in vitro* gene mutation study in bacteria (8.4.1.) – for nanoforms, *in vitro* gene mutation studies in bacteria are not required, if not applicable; in such case *in vitro* genetic mutation studies in mammalian cells shall be conducted (Annex VIII Section 8.4.3.);
- acute toxicity (8.5.) – testing by ingestion route (8.5.1.) – in relation to nanoforms, testing by ingestion route shall be replaced with testing by inhalation route (Annex VIII Section 8.5.2), unless the probability of human exposure by inhalation, including the possibility of exposure to sprays, particles or droplets in size enabling inhalation is negligible.

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[84] L. Bergkamp, N. Herbatschek, *op. cit.*, p. 213.

[85] *Ibidem*.

Based on Annex VII Section 9 of the REACH Regulation Ecotoxicological information:

- aquatic toxicity (9.1.) – short-term toxicity testing on invertebrates (9.1.1.) – for nanoforms with low solubility in the respective test media, the tests are not required; in relation to nanoforms of substances, the very fact that they are very difficult to dissolve in water shall not justify derogation from testing;
- aquatic toxicity (9.1.) – growth inhibition study on aquatic plants (9.1.2.) – for nanoforms of substances the very fact that they are very difficult to dissolve in water shall not justify derogation from testing.

The recital 21 of Commission Regulation (EU) 2018/1881 amending the REACH Regulation to address nanoforms of substances stipulates that due to feasibility and the principle of proportionality, only the entity registering substances (including any nanoforms) introduced to the market in quantities of 10 tonnes or more per year are obliged to expressly include additional information on special physicochemical properties of nanoforms if other properties of particles have a significant influence on hazards or exposure to nanoforms. Pursuant to Annex VIII Section 7 of the REACH Regulation Information on the physicochemical properties of the substance:

- further information on physicochemical properties (7.14b.) – only in relation to nanoforms, the registrant should consider further testing of the nanoforms included in the registration or it may be ordered by ECHA (pursuant to Article 41 of the REACH Regulation), if there are circumstances showing that additional special properties of particles have a significant influence on hazards created by these forms or exposure to them.

Pursuant to Annex VIII Section 8 of the REACH Regulation Toxicologial information:

- acute toxicity (8.5.) – for substances other than gases the information listed in items 8.5.1.–8.5.3., i.e. related to exposure by the ingestion route, respiratory route and skin application, in relation to the nanoforms, shall be provided for at least one route of exposure, in addition to ingestion (8.5.1.) or inhalation route (8.5.2.); the selection of the second route of exposure shall depend on the character of substances and probable route of human exposure; if only one route of exposure exists, only information on that route of exposure shall be presented;

- repeated dose toxicity (8.6.) – short–term repeated dose toxicity study (28 days) on one species, in relation to males and females, route of exposure selected according to the probable route of human exposure (8.6.1.) – for nanoforms, which are difficult to dissolve in biological media, the testing shall include toxicokinetic investigations on, among others, the recovery period and, as appropriate, lung clearance; toxicokinetic investigations are not required if equivalent toxicokinetic information on the nanoform is already available; further testing shall be proposed by the registrant or may be required by ECHA if impact is demonstrated, in relation to which the existing data is inadequate to determine the characteristics or toxicological characteristics; in such cases special toxicological examinations may be appropriate, aimed at investigating such impact (e.g. immunotoxicity, neurotoxicity, in particular for nanoforms – indirect genotoxicity);
- toxicokinetics (8.8.) – assessment of the toxicokinetic behaviour of the substance to the extent that may be derived from the available and relevant information (8.8.1.) – in relation to nanoforms, which are difficult to dissolve in biological media, the registrant may propose toxicokinetic investigation, which may also be required by ECHA, if such assessment cannot be completed based on relevant available information; the investigation shall be selected based on the type of missing information and the results of the chemical safety assessment.

Pursuant to Annex VIII Section 9 of the REACH Regulation Ecotoxicological information:

- aquatic toxicity (9.1.) – short–term toxicity testing on fish (9.1.3.) – in relation to nanoforms with low solubility in the respective test media, the tests are not required; for nanoforms of substances, the very fact that they are very difficult to dissolve in water shall not justify derogation from testing;
- aquatic toxicity (9.1.) – activated sludge respiration inhibition testing (9.1.4.) – for nanoforms of substances the very fact that they are very difficult to dissolve in water shall not justify derogation from testing;
- degradation (9.2.) – further information on degradation shall be obtained or further degradation testing shall be proposed, as described in Annex IX, if the chemical safety assessment performed in accordance with Annex I indicates that it is necessary for further examination of the degradation of the substance; for nanoforms, which are insoluble or difficult to dissolve, such testing shall include morphological transformation (e.g. irreversible

changes in particle size, shape and surface properties, loss of coating), chemical transformation (e.g. oxidation, reduction) and other forms of abiotic degradation (e.g. photolysis);
- abiotic degradation (9.2.2.) – hydrolysis as a function of pH (9.2.2.1.) – for nanoforms of substances the very fact that they are very difficult to dissolve in water shall not justify derogation from testing;
- fate and behaviour in the environment (9.3.) – screening test of adsorption/desorption (9.3.1.) – for nanoforms, if any physicochemical properties (e.g. partition coefficient n-octanol/water) are used to justify derogation from testing, appropriate justification for its representativeness for low absorption potential shall be provided.

Based on Annex IX Section 8 of the REACH Regulation Toxicological information:
- repeated dose toxicity (8.6.) – sub-chronic toxicity study (90 days), on one species of rodents, males and females, with the most appropriate route of administration, considering the most probable route of human exposure (8.6.2.) – for nanoforms, which are difficult to dissolve in biological media, the testing shall include toxicokinetic investigations on, among others, the recovery period and – as appropriate – lung clearance; toxicokinetic investigations are not required if equivalent toxicokinetic information on the nanoform is already available; the registrant shall submit application for further testing or ECHA may order it (pursuant to Article 40 or 41 of the REACH Regulation) if impact is demonstrated, in relation to which the existing data is inadequate to determine risk characteristics or toxicological characteristics; in such cases special toxicological examinations may be appropriate, aimed at investigating such impact (e.g. immunotoxicity, neurotoxicity, in particular for nanoforms – indirect genotoxicity).

Pursuant to Annex IX Section 9 of the REACH Regulation Ecotoxicological information:
- biotic degradation (9.2.1.) – simulation testing on ultimate degradation in surface water (9.2.1.2.) – for nanoforms of substances the very fact that they are very difficult to dissolve in water shall not justify derogation from testing;
- fate and behaviour in the environment (9.3.) – bioaccumulation in aquatic species (9.3.2.) – for nanoforms, if any physicochemical properties (e.g. partition coefficient n-octanol/water, solubility, dispersion stability) are used to justify derogation from testing, appropriate justification for its

representativeness for low bioaccumulation potential or low probability of direct and indirect exposure of an aquatic compartment shall be provided;

- fate and behaviour in the environment (9.3.) – further information on absorption/desorption, depending on the results of the study required based on Annex VIII, i.e. the screening test of adsorption/desorption (9.3.3.) – for nanoforms, if any physicochemical properties (e.g. partition coefficient n-octanol/water, solubility, dispersion stability) are used to justify derogation from testing, appropriate justification for its representativeness for low absorption potential shall be provided;
- effects on terrestrial organisms (9.4.) – if no data is available on toxicity for soil organisms, to assess the hazard to terrestrial organisms, the equilibrium partitioning method may be used; if the equilibrium partitioning method is applied to nanoforms, it shall be scientifically justified; the choice of the appropriate test or tests shall be made based on the results of the chemical safety assessment.

Pursuant to Annex X Section 8 of the REACH Regulation Toxicological information: repeated dose toxicity (8.6.) – the registrant may apply for the examination of the long-term repeated dose toxicity (≥ 12 months) or ECHA may order it (pursuant to Article 40 or 41 of the REACH Regulation) if the frequency and duration of human exposure indicates that a study covering a longer period of exposure is appropriate and at least one of the following conditions is met:

- during the 28- or 90-day studies, serious or concerning toxic effects are observed, whereas existing data is inadequate for the toxicological assessment or risk characterisation; or
- during the 28- or 90-day study, no effect was observed for the substance with a particle structure clearly connected with the studied substance structure; or
- the substance may have a dangerous property, which cannot be detected in a 90-day study; if the registration covers nanoforms, when determining if any of the above conditions is met, other physicochemical properties are considered, in particular the particle size, shape and other properties of the structure, surface functionalisation and the surface itself, and the molecular structure (8.6.3.).

Commission Regulation (EU) 2018/1881 amending the REACH Regulation to address nanoforms of substances also introduces the definition of a set of similar nanoforms. Pursuant to Annex VI of the REACH Regulation, the set

of similar nanoforms is a set of nanoforms, for which the characterisation was prepared in accordance with Section 2.4, which clearly defined the property boundaries listed in Sections 2.4.2–2.4.5, for the individual nanoforms in the set, enable stating that the assessment of hazards, assessment of exposure and assessment of risk may be completed jointly. The reasons shall be presented, with explanation, why changes in such boundaries have no impact on the assessment of hazard, assessment of exposure or assessment of risk of similar nanoforms within the set. A nanoform may only belong to one set of similar nanoforms.

Information shall be provided for each nanoform or set of nanoforms. In other words: detailed information shall be provided for each nanoform or set of nanoforms to meet every information requirement for the tonnage range of the registration[86]. The use of the sets of similar nanoforms ensures the enforceability of the REACH Regulation and reduces the necessity of performing unnecessary tests to assess hazards and risks[87]. Every registrant has the obligation to characterise nanoforms they manufacture or import, in accordance with Annex VI of the REACH Regulation, individually or in sets of nanoforms[88]. The registrant may identify and characterise nanoforms as sets of similar nanoforms if the parameters given in Sections 2.4.2–2.4.5 are clearly determined. In this case, variable values result from the combination of information on different nanoforms (i.e. different parameters, i.e. shape, size distribution of particles, surface modification or surface area)[89]. If the individual nanoforms are registered in a set of nanoforms, the requirements of Annexes VII–X of the REACH Regulations may be met by submitting at least one set of data on hazards including all nanoforms in the set[90]. Every set of nanoforms shall be based on specific justification, indicating that the assessments of hazards, exposure and risk of nanoforms in this set may be completed jointly; the justification shall be relevant to all applicable information requirements and it shall always be supported with supplementary data[91]. Justification shall be submitted:

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86 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

87 Labcorp, website, *Nanomaterials: How to Overcome…*, *op. cit.*

88 ECHA, website, *How to prepare registration dossiers…*, *op. cit.*

89 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

90 ECHA, website, *How to prepare registration dossiers…*, *op. cit.*

91 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

- for combining hazard assessments, i.e. the reasons why the hazard profile is the same for all nanoforms; negligible variability is permissible, provided that the assessment of hazards is based on reserved assumptions and a single conclusion on hazards may be formulated for the entire set;
- why it is possible to jointly analyse the exposure and risk for the set of nanoforms; in practice, if the same hazard profile is applicable to the entire set and a common conclusion may be formulated for the assessment of exposure, the risk analysis should be also applicable to the set of nanoforms[92].

Pursuant to Article 14 Section 1 of the REACH Regulation, for all substances subject to registration in quantities of 10 tonnes or more per year, the chemical safety assessment shall be performed and the chemical safety report shall be prepared; the chemical safety report is a chemical safety assessment dossier prepared based on Annex I of the REACH Regulation for every substance in its own form or as component in mixture or product. The chemical safety assessment is a procedure of determining the conditions for safe use or "proper control" for a substance based on the risk assessment for the substance in all relevant use scenarios[93]. The chemical safety assessment includes the following activities:

- hazard assessment – determination of intrinsic properties, e.g. physicochemical, toxicological and ecotoxicological information on the substance that may cause adverse effects;
- exposure assessment – determination of the degree, to which the exposure actually occurs (uses);
- risk characterisation – combination of information on hazards and exposure in the form of conclusion with respect to the character and scale of potential risk[94].

Based on Article 14 Section 3 of the REACH Regulation, the chemical safety assessment of the substance includes the following stages: assessment of hazards to human health, assessment of hazards resulting from physicochemical properties, assessment of environmental hazards, as well as assessment of the persistence, bioaccumulation potential and toxicity (PBT) and very high persistence and very high bioaccumulation potential (vPvB). The purpose of the assessment

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92 *Ibidem*.

93 L. Bergkamp, N. Herbatschek, *op. cit*., p. 216.

94 D. Drohmann, V. J. Sobala, *op. cit*., p. 85.

of hazards arising from the intrinsic physicochemical properties of the substance, toxicological and ecotoxicological properties is to determine their potential impact on human life and health and environment, as well as, if possible, presentation of the exposure level thresholds assumed as safe. The following exposure level thresholds, below which risks to human health and environment are concerned as controlled: DNEL and PNEC[95]. Based on Annex I Section 1.0.1. of the REACH Regulation, DNEL is the highest permissible level of human exposure to the substance. DNEL is the Derived No Effect Level, i.e. the level of exposure to the substance, below which no adverse effect is predicted; that is the exposure level, which shall not be exceeded for humans[96]. Pursuant to Annex I Section 3.0.1. of the REACH Regulation, PNEC is the concentration of the substance, below which no adverse effects of the impact of the substance on the given component of environment is predicted. PNEC is the predicted concentration that causes no changes in the environment[97].

Pursuant to Article 14 Section 4 sentence 1 of the REACH Regulation, if based on the assessment of hazard, the registrant determines that the substance meets the classification criteria as substance causing hazard in accordance with the CLP Regulation[98] or is classified in the PBT or vPvB category, the chemical safety assessment includes:

a) assessment of exposure, including the generation of one or more exposure scenarios (or determination of appropriate use and exposure categories, if appropriate) and estimation of exposure;
b) characterisation of risk.

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95 A. Krześlak, M. Palczewska-Tulińska, *Ocena bezpieczeństwa chemicznego w rozporządzeniu REACH jako element identyfikacji i kontroli ryzyka stwarzanego przez substancje chemiczne*, "Chemik" 2015, Vol. 4, p. 183.

96 M. Wasiak-Gromek, *Ocena bezpieczeństwa chemicznego oraz raport bezpieczeństwa chemicznego sporządzone według wytycznych rozporządzenia REACH* [in:] A. Tabor (ed.), *Zarządzanie chemikaliami w przedsiębiorstwie – rozporządzenie REACH*, Kraków 2010, p. 223.

97 *Ibidem*, p. 224.

98 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP), amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 2008, nr 353, p. 1, as amended.

As stipulated by Article 3 Section 37 of the REACH Regulation, the exposure scenario is the set of conditions describing the method of manufacture or use of the substance during the stages of its existence and the manufacturer's or importer's human and environmental exposure control method and the method of such control recommended to the downstream user. These conditions include:

- the so-called operating conditions, such as process duration, use frequency, substance consumption, substance concentration in the product, temperature and other process parameters that may influence the exposure;
- the applied risk management measures, such as personal protective equipment in use, type of ventilation in use, air filtering systems, sewage treatment, process encapsulation etc.[99]

If the exposure scenario includes a wide range of processes or uses, which includes at least the information on processes or uses in the form of short, general description of use, then – pursuant to Article 3 Section 38 of the REACH Regulation – it is described as the use and exposure category. For each of the generated exposure scenarios, the exposure shall be estimated in relation to all groups of people (populations) subject to exposure and all components of environment, in which exposure may occur. When estimating the human exposure to the substance, it is essential to determine the exposure level for every population, frequency and duration of exposure and every possible route of exposure individually; similarly, the exposure level shall be determined for every component of environment[100].

The characterisation of risk shall be performer for every prepared exposure scenario; its purpose is to determine if the described operational conditions and risk management measures used ensure the appropriate control level[101]. Pursuant to Annex I Section 6.4 of the REACH Regulation the risk is considered as properly controlled if:

- the estimated exposure levels do not exceed the appropriate DNEL or PNEC values;
- probability of occurrence and severity of consequences of the events related to the physicochemical properties of the substance are negligible.

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99 A. Krześlak, M. Palczewska-Tulińska, *op. cit.*, p. 184.

100 *Ibidem*, pp. 184–185.

101 *Ibidem*, pp. 185–186.

Annex I of the REACH Regulation (General provisions for assessing substances and preparing chemical safety reports) provides for detailed and effective identification and characterisation of nanoforms[102]. Pursuant to Annex I Section 0.3. of the REACH Regulation chemical safety assessment is applicable to all nanoforms covered by registration; the justifications and conclusions from the assessment are applicable to these nanoforms. Pursuant to Annex I Section 0.1. of the REACH Regulation the chemical safety report determines if and which nanoforms are manufactured and imported, considering the appropriate justification for every information requirement.

Pursuant to Article 37 Section 4 of the REACH Regulation, downstream users of the substance in its own form or as component in mixture shall complete the chemical safety assessment and prepare the chemical safety report in accordance with Annex XII of the REACH Regulation, for each use failing to meet the conditions described in the exposure scenario or, if appropriate, in the use and exposure category provided in the safety data sheet or for every use advised against by the supplier. If, even despite the communication of information between the downstream user and the supplier, some conditions of use or the use itself are not covered by the safety data sheet or other information provided by the supplier, downstream users may still use the substance or mixture for that specific use provided that they prepare their own chemical safety report[103].

In accordance with Commission Regulation (EU) 2018/1881 amending the REACH Regulation to address nanoforms of substances, downstream users completing the chemical safety assessment of the substance and preparing the chemical safety report have the obligation to consider all nanoforms covered by the registration (Annex XII).

Pursuant to Annex XII of the REACH Regulation (General provisions for downstream users to assess substances and prepare chemical safety reports), risk assessment is required for all nanoforms[104]. Downstream users do not have the obligation to register new nanoforms of substances. However, the downstream user shall check if the use of the nanoform is included, e.g., in the safety data sheet delivered with it, if required. If the nanoform is not included in the document, the downstream user may submit information on new nanoforms (and their use) earlier, to enable the supplier to consider

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[102] Labcorp, website, *New REACH nanomaterial requirements…*, *op. cit.*

[103] N. Herbatschek, L. Bergkamp, M. Mihova, *op. cit.*, p. 121.

[104] Labcorp, website, *New REACH nanomaterial requirements…*, *op. cit.*

them. If the supplier refuses to include the nanoform or the downstream user refuses to disclose the nanoform and its use to the supplier, the downstream user shall prepare their own chemical safety report to present its safe use. The downstream user shall ensure the control of the risk that may be caused by the nanoform[105].

The safety data sheet (SDS) is the main source of information on the substance or mixture[106], the most important instrument communicating the information on hazards and safe use of chemicals downstream of the supply chain[107]. The obligation to provide the safety data sheet is applicable regardless of any quantitative restrictions and also applies to companies that supply substances in quantities smaller than 1 tonne per year[108]. Pursuant to Article 31 Section 1 of the REACH Regulation, the suppliers of the substance or mixture shall provide the safety data sheet to the recipients of the substance or mixture:

a) if the substance or mixture meets the hazardous classification criteria in accordance with the CLP Regulation; or
b) if the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to the criteria included in Annex XIII of the REACH Regulation; or
c) if the substance is on the candidate list of Substances of Very High Concern (SVHC) for reasons other than specified in letter a and b.

Pursuant to Article 31 Section 3 of the REACH Regulation, the suppliers shall provide the safety data sheet to the recipients, on their request, if the mixture does not meet the hazardous classification criteria in accordance with the CLP Regulation, but it includes:

a) at individual concentrations of at least 1% w/w for mixtures that do not exist in gaseous form, and at least 0.2% w/v for mixtures that exist in gaseous form, a substance hazardous to human health or environment; or
b) at individual concentrations of 0.1% w/w for mixtures that do not exist in gaseous form, at least one substance that is in carcinogenic category 2 or in toxic to reproduction category 1A, 1B and 2, in skin sensitiser category 1 or respiratory sensitiser category 1 or affects lactation

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[105] ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

[106] B. Enderle, *Information Requirements in the Supply Chain* [in:] D. Drohmann, M. Townsend (eds.), *op. cit.*, p. 302.

[107] N. Herbatschek, L. Bergkamp, M. Mihova, *op. cit.*, p. 114.

[108] *Ibidem*.

or adversely affects breast-fed children or is persistent, bioaccumulative and toxic (PBT) in accordance with the criteria defined in Annex XIII of the REACH Regulation or very persistent and very bioaccumulative (vPvB) in accordance with the criteria set in Annex XIII of the REACH Regulation or on the candidate list for reasons other than specified in letter a; or

c) a substance, for which the workplace exposure limits in the EU are defined.

There is also an obligation to include information on the nanoform in the safety data sheet in accordance with Annex II of the REACH Regulation (Requirements for compilation of safety data sheets). Annex II Section 0.1.3. of the REACH Regulation, stipulates that the safety data sheet in each appropriate section includes information on whether and what nanoforms it covers, and combines information on safety with each of these nanoforms.

Pursuant to Annex II Section 1.1. of the REACH Regulation if the safety data sheet applies to one or more nanoforms or substances that contain nanoforms, it shall be indicated – as part of identification of the substance or mixture – using the word "nanoform". Annex II Section 3.1. of the REACH Regulation stipulates that if the substance is registered and contains a nanoform, the characterisation of particles shall be provided – by presenting the composition (information on the components) – to describe the nanoform, as described in Annex VI of the REACH Regulation; if the substance is not registered, but the safety data sheet covers nanoforms, of which the particle characterisation influences the safety of the substance, this characterisation shall be indicated. In addition, in accordance with Annex II Section 3.2.3. of the REACH Regulation if the substance used in the mixture occurs as nanoform and as such it is registered or it is the subject of the chemical safety report of the downstream user, the particle characterisation shall be provided – by presenting the composition (information on the components) – that describes the nanoform as described in Annex VI of the REACH Regulation; if the substance used in a mixture occurs as nanoform, but it is neither recorded, nor subject of the chemical safety report of the downstream user, the particle characterisation shall be provided, which has an impact on the safety of the mixture.

The information on the basic psychical and chemical properties, pursuant to Annex II Section 9.1. letter m of the REACH Regulation, in relation to the nanoform, except for water solubility, shall include the dissolution rate in water or other appropriate biological or environmental media. In addition, Annex II Section 9.1. letter n of the REACH Regulation stipulates that for nanoforms of substances, for which the partition coefficient n-octanol/

water is not applied, dispersion stability in different media shall be indicated. Furthermore, pursuant to Annex II Section 9.1. letter r of the REACH Regulation, the size of particles shall be indicated (median equivalent diameter, method of calculation of the diameter – based on number, surface or volume, and the range, in which the median varies); other properties may be indicated, such as size distribution (e.g. range), shape and elongation, state of aggregation and agglomeration, surface area and dustiness; if the substance occurs as nanoform or if the supplied mixture contains the nanoform, these properties shall be indicated in this section or referenced, if already indicated in another part of the safety data sheet.

In practice and in order to reduce the chemical assessment testing (in particular animal testing) and related costs for industry, the REACH Regulation authorises the exchange of some data between the manufacturers and importers intending to register the same substance[109]. Joint submission of data by many registrants is described by Article 11 of the REACH Regulation. The REACH requires all registrant registering the same substance to submit their documents as part of the same joint submission and to collaborate in registration strategy to avoid unnecessary repetition of tests and reduce the costs[110]. The information required based on Annex VI of the REACH Regulation, including the characterisation of the nanoform, shall be submitted by each registrant individually. Information in Annexes VII–X of the REACH Regulation may be submitted jointly, in the dossier of the lead registrant, on the behalf of member registrants[111]. The purpose of the one substance – one registration rule is that one set of information shall be submitted based on Annexes VII–X of the REACH Regulation for each substance[112].

The entity registering the nanoform must decide if the information required pursuant to Annexes VII–X of the REACH Regulation, which may be specific for their nanoform, will be submitted:

- by the lead registrant as part of information submitted jointly; or
- independently, as information submitted individually ("opt–out")[113].

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[109] S. Vaughan, *op. cit.*, p. 55.

[110] ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

[111] *Ibidem*.

[112] *Ibidem*.

[113] ECHA, website, *How to prepare registration dossiers…*, *op. cit.*

Notwithstanding the general obligation to submit the joint submission, in some circumstances the registrant may opt out of the joint registration dossier in relation to some information, which otherwise should be part of joint submission[114]. The registrant may submit some (or all) data in the registration dossier individually, based on the "opt–out" mechanism, if at least one of the conditions listed in Article 11 Section 3 of the REACH Regulation is met[115]. Pursuant to Article 11 Section 3 of the REACH Regulation, the registrant may submit some or all information individually if:

a) joint submission of this information would incur disproportional costs to them; or
b) joint submission of information would lead to the disclosure of information that they consider sensitive in commercial terms and would probably cause a significant commercial damage to them; or
c) they do not agree with the lead registrant on the selection of information.

A justification shall be provided for the individual submission of all information[116]. All cases of opt–out of joint submission of data shall be explained in a statement, which shall be submitted with the dossier of the registrant[117]. This general rule is also applicable to the joint submission of data on substances containing nanoforms[118]. The justification of the opt–out may be based on Article 11 Section 3 letter c of the REACH Regulation, i.e. the registrant does not agree with the information presented jointly by the lead registrant, because it does not include their specific nanoform[119].

The REACH Regulation includes the obligation to submit information on the nanoforms of substances in the registration dossier, as part of the chemical safety assessment and in the chemical safety report, as well as in the safety data sheet. This is information about the specific properties of nanoforms that may influence the potential health and environmental risks associated with certain nanomaterials. Thus, the safety of using innovative applications of nanomaterials is strengthened.

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114 D. Francis, *REACH and Competition Law* [in:] L. Bergkamp (ed.), *op. cit.*, p. 247.

115 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

116 ECHA, website, *How to prepare registration dossiers…*, *op. cit.*

117 N. Herbatschek, L. Bergkamp, M. Mihova, *op. cit.*, p. 94.

118 ECHA, website, *Załącznik dotyczący nanopostaci…*, *op. cit.*

119 ECHA, website, *How to prepare registration dossiers…*, *op. cit.*

Characteristics of the principle of proportionality. Are the new obligations regarding nanoforms of substances consistent with the principle of proportionality?

The evaluation of the law is a factor constituting the attitude towards the law. Most often it is recognized that it is a phenomenon that can be ordered in a one-dimensional way: from strongly positive values, through zero, i.e. affectively neutral, to strongly negative values[120]. The parameter for assessing law by the recipients of legal norms is the quality of law-making[121], especially the preparation of legal acts that are clear, simple, precise, concise, efficient, effective, coherent and proportionate, i.e. excluding excessive regulation and administrative burdens for citizens, administration and enterprises. These

[120] A. Pieniążek, M. Stefaniuk, *Socjologia prawa. Zarys wykładu*, Warsaw 2014; pp. 165–220, 246–266; G. de Jong, R. Kloeze, *Institutions and the Regulation of Business – An International Firm-Level Study of Regulatory Compliance Costs*, "American Journal of Industrial and Business Management" 2013, Vol. 3, pp. 1–11; E. Malesky, M. Taussig, *The Danger of Not Listening to Firms: Government Responsiveness and the Goal of Regulatory Compliance*, "Academy of Management Journal" 2017, Vol. 60, pp. 1741–1770.

[121] A. Pieniążek, M. Stefaniuk, *op. cit.*, pp. 165–220, 246–266.

drafting principles are laid down in the Interinstitutional Agreement on Better Law-Making and in the Interinstitutional Agreement on common guidelines for the quality of drafting of Community legislation[122].

It should be examined whether the above-mentioned requirements for nanoforms of a substance comply with the principle of proportionality. As a systemic principle, the principle of proportionality clarifies the rules for the use by the EU of the powers entrusted to it on the basis of the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU)[123]. Article 5 sec. 4 TEU provides that: "In accordance with the principle of proportionality, the scope and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties." As a general principle of EU law, the principle of proportionality protects individuals against excessive interference with their rights and freedoms by both EU institutions and member state authorities[124].

The proportionality test includes the following criteria: appropriateness and indispensability. Appropriateness refers to the relationship between the means used and the intended goal. It is determined whether the action is able to lead to its achievement[125]. The criterion of appropriateness or suitability allows it to be determined whether a given measure is suitable for achieving the objective[126]. A measure should be useful to achieve a given goal[127]. Moreover, the behaviour of public authorities – regardless of what form it takes (legal act, administrative act, court decision, factual conduct, etc.) – should be limited to what is indispensable to achieve the assumed goal[128]. The review of the condition of indispensability requires an assessment of whether the assumed objective cannot be achieved equally effectively by means of other measures that

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122 Interinstitutional Agreement of 22 December 1998 on common guidelines for the quality of drafting of Community legislation. OJ C 1999, nr 73, p. 1.

123 OJ C 2016, nr 202, p. 47.

124 D. Miąsik, *Zasada proporcjonalności* [in:] J. Barcz (ed.), *Zasady ustrojowe Unii Europejskiej*, Warsaw 2010, pp. 140–156.

125 J. Maliszewska-Nienartowicz, *Zasada proporcjonalności jako podstawa oceny legalności ograniczeń swobód rynku wewnętrznego Unii Europejskiej*, Toruń 2020, p. 65.

126 A. Frąckowiak-Adamska, *Zasada proporcjonalności jako gwarancja swobód rynku wewnętrznego Wspólnoty Europejskiej*, Warsaw 2009, pp. 275, 278.

127 Ł. Polak, *The Principle of Proportionality in the Creation of Administrative Law*, "Ruch Prawniczy, Ekonomiczny i Socjologiczny" 2017, Vol. 4, pp. 57–71.

128 D. Miąsik, *op. cit.*, pp. 140–156.

will restrict the rights of individuals or member states to a lesser extent than the measure under examination[129]. The examination of indispensability in most cases boils down to the question of whether a given measure is the least restrictive alternative capable of achieving a given goal[130]. The imperative of necessity means that it is indispensable to individualize legislative interference and reduce it to the mildest level; it is the duty of the legislator to apply the smallest limitation, but at the same time be sufficient to achieve the goal, which is also related to the fact that the undertaken interference does not go beyond the actions necessary to achieve the goal[131]. Good law, adequate to a given situation, providing for commensurate means to achieve a properly chosen goal, eliminating excessive interference, excessive burdens and inconveniences, favours those who are obliged to comply with it. Only such a law, actually necessary, meeting social expectations, requiring honesty, moderation and prudence in the implementation of optimally set goals, can arouse due respect and prestige, deepening trust in its regulations and in those who create and apply them[132].

In the stakeholder consultation that preceded the introduction of Commission Regulation (EU) 2018/1881 amending the REACH Regulation to address nanoforms of substances, industry respondents questioned the proportionality of the obligation to register nanoforms of substances as well as the obligation to include nanoforms of substances in the substance registration dossier instead of registering nanomaterials as standalone substances. These are the following opinions:

- "Under the REACH Regulation the information requirements for each form of a substance are determined by the total registered tonnage. Consideration should hence be given to the information requirements dependent upon the registered tonnage, especially where several forms of a substance are covered within one REACH registration dossier. An approach

[129] *Ibidem*.

[130] A. Frąckowiak-Adamska, *op. cit*., pp. 275, 278.

[131] Ł. Polak, *op. cit*., pp. 57–71.

[132] Z. Duniewska, *The Principle of Proportionality and Administrative Law – Selected Issues*, "Studia Prawno-Ekonomiczne" 2022, Vol. CXXIII, pp. 9–26.

requiring the testing of each form for all information requirements according to the total volume of the substance will result in huge costs and in products being taken out of the market and creating high hurdles for innovation"[133];

- "The information requirements for individual nanoforms should be based on the tonnage of that nanoform, not the total tonnage for all forms, nano and larger, that may be covered in a single registration dossier. Implementing such a policy would be proportional and could significantly reduce the burden of compliance, particularly for small enterprises"[134];
- "Providing all information requirements for small volumes of nanoforms, as required for the volume of the total substance might quickly become prohibitively resource intensive and hamper innovation"[135];
- "This could lead to an unnecessarily high burden for the production of few kilos of nanomaterials of a substance registered (for the bulk form) in the highest tonnage bands"[136];

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133 European Commission, website, *Amendments of the Annexes to REACH for registration of nanomaterials. Feedback from: The European Chemical Industry Council (Cefic)*, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1141-Amendments-of-the-Annexes-to-REACH-for-registration-of-nanomaterials/F7469_en [access: 04.04.2024]; European Commission, website, *Amendments of the Annexes to REACH for registration of nanomaterials. Feedback from: Plastics Europe Deutschland e.V.*, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1141-Amendments-of-the-Annexes-to-REACH-for-registration-of-nanomaterials/F7507_en [access: 04.04.2024]; European Commission, website, *Amendments of the Annexes to REACH for registration of nanomaterials. Feedback from: VCI (German Chemical Industry Association)*, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1141-Amendments-of-the-Annexes-to-REACH-for-registration-of-nanomaterials/F7504_en [access: 04.04.2024].

134 European Commission, website, *Amendments of the Annexes to REACH for registration of nanomaterials. Feedback from: American Chemistry Council*, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1141-Amendments-of-the-Annexes-to-REACH-for-registration-of-nanomaterials/F7551_en [access: 04.04.2024].

135 European Commission, website, *Amendments of the Annexes to REACH for registration of nanomaterials. Feedback from: Nanotechnology Industries Association*, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1141-Amendments-of-the-Annexes-to-REACH-for-registration-of-nanomaterials/F7523_en [access: 04.04.2024].

136 European Commission, website, *Amendments of the Annexes to REACH for registration of nanomaterials. Feedback from: Eurometaux*, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1141-Amendments-of-the-Annexes-to-REACH-for-registration-of-nanomaterials/F7508_en [access: 04.04.2024].

- "When several nanoforms exist and especially when new nanoforms are created, this could be viewed as a very high barrier for R&D products by hindering innovation and increasing cost"[137];
- "Some nanomaterials are hazardous whilst others are not. Nanomaterial is a categorization of a substance solely by its size. However, the fact that a substance is a nanomaterial neither implies a specific risk nor does it necessarily mean that the substance has different hazard properties compared to its non-nano 'form'. Therefore, all additionally requested information should be given to increase transparency when a concern arises. Generating additional data appears disproportionate"[138].

The obligation to register nanomaterials is an appropriate measure to achieve the main objective of the REACH Regulation, which is to ensure a high level of protection of health and the environment. The introduction of these amendments to the REACH Regulation serves the purpose of obtaining data by regulatory authorities regarding the potential health and environmental risks associated with individual nanoforms of a substance. The information required to be submitted under Commission Regulation (EU) 2018/1881 amending the REACH Regulation to address nanoforms of substances relates to specific properties of nanomaterials that have a significant impact on the potential risks to health and the environment associated with certain nanomaterials. The information that registrants should provide in the registration procedure for nanoforms of a substance contributes to minimizing the potential risks to health and the environment associated with individual nanomaterials. Obtaining knowledge in this area should allow regulatory authorities to establish measures aimed at ensuring a high level of protection of health and the environment, including: authorizations for placing on the market and use of nanoforms of substances and restrictions on the production, placing on the market and use of nanoforms of substances. Article 77 Section 2 letter e of the REACH Regulation states that ECHA establishes and maintains a database containing information on all registered substances and makes this information publicly available free of charge via the Internet. The information

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[137] European Commission, website, *Amendments of the Annexes to REACH for registration of nanomaterials. Feedback from: Association of Synthetic Amorphous Silica Producers (ASASP)*, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1141-Amendments-of-the-Annexes-to-REACH-for-registration-of-nanomaterials/F7536_en [access: 04.04.2024].

[138] *Ibidem*.

obtained during the registration of nanoforms of substances is then disseminated through the ECHA database, also providing the public with access to data on nanoforms of substances.

At the same time, the requirement to register nanoforms of substances is an indispensable measure to achieve the objective of ensuring a high level of protection for health and the environment, as it cannot be achieved by other means that would be less burdensome for industry. There are no other means than the registration of nanoforms of substances to ensure that regulators and the public can benefit from data on the potential risks to health and the environment associated with certain nanomaterials; subsequently, regulators may adopt measures to ensure a high level of health and environmental protection. The notification institution provided for in Article 7 Sections 2–4 of the REACH Regulation in relation to substances contained in articles, involves the submission of a small scope of data compared to the data required during the registration of the substance. These are, in accordance with Article 7 Section 4 of the REACH Regulation, the following information: identification and contact details of the manufacturer or importer; registration number, if available; substance identification data, excluding analytical data; substance classification; a brief description of the use of the substance contained in the article and the article, as well as the tonnage range of the substance. This information does not reflect the specific properties of nanomaterials and therefore the potential risks to human health and the environment associated with certain nanomaterials. In line with the principle of proportionality, the procedure for the registration of nanoforms of substances allows for the compilation of nanoforms of substances with similar characteristics for the preparation of a registration dossier (Annex VI of the REACH Regulation), as well as a joint submission of information on substances by multiple registrants (Article 11 Section 1 of the REACH Regulation) and sharing of data on substances (Article 27 Section 3 of the REACH Regulation), significantly reducing the obligations imposed on industry.

Commission Regulation (EU) 2018/1881 amending the REACH Regulation to address nanoforms of substances does not adjust the tonnage threshold for nanomaterials, which entails the obligation to register substances, i.e. a minimum of 1 tonne per year – in accordance with Article 6 Section 1 of the REACH Regulation. The threshold of 1 tonne per year, expressed in Article 6 Section 1 of the REACH Regulation, is inappropriate as the impact of nanoparticles

may not be directly correlated with the mass produced and such a threshold may result in the complete exemption of many nanomaterials from REACH requirements[139].

Nanomaterials may have different health and environmental impacts than conventional substances, including toxic effects, and their trade volume is usually limited; this argues in favour of lowering the minimum threshold of 1 tonne per year. However, since this threshold has not been lowered, it makes sense to include nanoforms of a substance in the substance registration dossier, rather than registering nanomaterials as standalone substances. It is more likely that the total turnover of nanoforms and other forms of substances will exceed the value specified in Article 6 Section 1 of the REACH Regulation, the threshold of a minimum quantity of 1 tonne per year, which results in the obligation to register the substance, and thus the submission by manufacturers and importers of data relating to the potential risk to health and the environment associated with individual nanoforms of the substance. This obligation serves the main objective of the REACH Regulation, which is to ensure a high level of protection of health and the environment.

[139] L. Brazell, *Nanotechnology Law. Best Practices*, Alphen aan den Rijn 2012, p. 140.

Review of case law on respect for the principle of proportionality in the context of requirements relating to the production, placing on the market and use of chemicals

The case law of the Court of Justice of the European Union (CJEU) and the Board of Appeal of ECHA provides examples of decisions on the observation of the principle of proportionality in the context of the requirements for the manufacture, marketing and use of chemicals. The CJEU and the Board of Appeal of ECHA investigate if the obligations related to the manufacture, marketing and use of substances are appropriate and indispensable to fulfil the objectives of the REACH Regulation.

The assessment of substances is the proactive assessment of the registration dossier by the EU member states. The assessment of substances is used to explain any grounds for determining that the substance constitutes the risk to human health or environment and, if risk is identified, undertaking measures to mitigate that risk[140]. The assessment of substances is not applicable to a single registration dossier, but it includes all information available for the given substance (e.g. obtained from several registration dossiers and other sources)[141].

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[140] S. Vaughan, *op. cit.*, pp. 58, 149; A. P. Biwer, *Evaluation* [in:] D. Drohmann, M. Townsend (eds.), *op. cit.*, p. 412.

[141] A. P. Biwer, *op. cit.*, p. 412.

In case A-014-2015[142], following the assessment of the substance, silicon dioxide, by Holland (pursuant to Article 45 Section 1 of the REACH Regulation), ECHA adopted the decision requiring the appellants (two entities registering the synthetic amorphous silica – "SAS", who appealed the decision jointly) to present information on the physicochemical properties for every "form" of four types of SAS (except for "forms" subject to surface treatment), tests of inhalation toxicity for different "forms" of one type of SAS, information on the use of every "form" of SAS (except for forms subject to surface treatment), information on the physicochemical properties of every "form" of SAS subject to surface treatment and all available toxicological information on SAS subject to surface treatment (based on Article 46 Section 1 of the REACH Regulation). Four types of SAS included in the appealed decision are: pyrogenic (smoked) SAS, precipitated SAS, colloidal SAS and silica gel; SAS is a nanomaterial.

The Board of Appeal decided that ECHA failed to demonstrate the potential risk related to precipitated SAS, silica gel and colloidal SAS. As a consequence, all information requirements related to precipitated SAS, silica gel and colloidal SAS were voided. For the same reason, the appealed decision was voided to the extent, to which it required the presentation of information on SAS subject surface treatment. The Board of Appeal decided that the potential doubts were only determined for one type of SAS, pyrogenic SAS. Therefore, the above Board of Appeal continued the investigation of the appeal only in relation to the pyrogenic SAS.

Regarding the requirement to present information on the physicochemical properties of all "forms" of pyrogenic SAS, the appellants considered this requirement as disproportionate. The Board of Appeal noted that in accordance with the principle of proportionality, the measures used in the EU should not exceed the boundaries of suitability and necessity, which enables the achievement of the objectives, to which the given measures duly contribute. If multiple suitable measures are available, the least onerous measure shall be used and the inconveniences resulting from the use of the measure shall not be disproportionate to the purpose of use of the measure. The Board of Appeal decided that ECHA failed to indicate the use of all information on the physicochemical properties of the pyrogenic "form" of SAS to clear the doubts related to the toxicity by inhalation of the pyrogenic SAS, which – in the opinion of the Board of Appeal – was the only potential doubt demonstrated

[142] ECHA, website, *Decision of the Board of Appeal the European Chemicals Agency of 30 June 2017 in case A-014-2015*, https://echa.europa.eu/documents/10162/84c38038-4636-ec10--e9a0-6b961cac34b8 [access: 30.03.2024].

in the appealed decision. Although the main purpose of assessment of substances is to determine the potential risk, it should also clearly explain how the information requirements will be used for that purpose, in a scientifically acute and proportional manner.

Regarding the requirements to present the tests of toxicity by inhalation for four "forms" of pyrogenic SAS, the appellants considered this requirement as disproportionate. The purpose of the required tests is clearing doubts related to the potential toxicity by inhalation in case of multiple exposure to pyrogenic SAS. The Board of Appeal decided that the "forms" that require testing are clearly defined in terms of the surface area and hydroxylation degree. The Board of Appeal also noted that the required tests include only two potential toxicity factors, hydroxylation and the surface area, while testing requirements could include many other variables. The Board of Appeal also noted that in connection with the test of only one commercially available product of the group of pyrogenic SAS, described in the publication by Rezuel et al., it is not clear if the identified effects are applicable to all "forms" of pyrogenic SAS. The information on the possible toxicity by inhalation of different "forms" of pyrogenic SAS is potentially significant from the point of view of the purpose, which is to define risk management measures. The Board of Appeal decided that in the described case, the performance of tests of toxicity by inhalation for one "form" only is inappropriate, because they will not help ECHA to determine the potential toxicity factors or to explain the potential varied properties of different "forms" of the pyrogenic SAS. In connection with this information requirement, ECHA determined two physicochemical properties – the number of hydroxyl group and the surface area – as the potential causal factors of toxicity. The Board of Appeal decided that the requirement for studies analysing two potential causal factors of toxicity is a proportional requirement. Considering the justified purpose, which is to explain the effects of toxicity by inhalation of the pyrogenic SAS, and based on the evidence presented in the publication of Reuzel et al., it was legitimate and necessary to require the performance of a study of a 90-day sub-chronic toxicity by inhalation in rats, for four "forms" of the pyrogenic SAS.

In relation to the objections of the appellants, connected with the requirements to present additional information on the uses of pyrogenic SAS and proportionality of these requirements, the Board of Appeals decided that in the absence of information on the toxicity by inhalation of pyrogenic SAS, requiring the presentation of additional information related to uses was premature. In addition, although information on the use may be important from the point of view of introduction of appropriate risk management measures,

without a certain understanding of any causal factors of toxicity, the characteristics important from the point of view of identification of the "forms" and their uses for risk management purposes cannot be determined. The ECHA failed to demonstrate, why information on the uses is necessary at this stage. The Board of Appeal also decided that the appealed decision failed to explain, how the information on the uses would be used to clear the doubts, in particular in relation to the improved risk management measures.

The Board of Appeal sustained the requirement to study the toxicity by inhalation of the pyrogenic SAS included in the appealed decision. It voided the appealed decision with regard to the requirements to submit information related to: precipitated SAS, colloidal SAS and silica gel, SAS subject to surface treatment and the physicochemical properties and uses of "forms" of pyrogenic SAS.

In summary, the Board of Appeal concluded that ECHA's decision was proportionate only in so far as it required registrants to submit inhalation toxicity studies for the four pyrogenic "forms" of SAS. This decision was appropriate and necessary – it served to determine the potential toxic effect of pyrogenic SAS, taking into account the two determined physicochemical properties, i.e. hydroxylation and surface area, excluding the requirement to submit other data. This should then enable the application of risk management measures, i.e. authorizations for the placing on the market and use of substances or restrictions on the production, placing on the market and use of substances. Pursuant to Article 48 of the REACH Regulation, after completing the evaluation of a substance, the competent authority shall consider how the information obtained during that evaluation should be used for the purposes of the authorization or restriction procedure. Otherwise, ECHA's decision requiring registrants to submit additional information (related to: precipitated SAS, colloidal SAS and silica gel, SAS subject to surface treatment and the physicochemical properties and uses of "forms" of pyrogenic SAS) did not meet the requirements of appropriateness and necessity; ECHA's decision does not explain how this information will be used to fulfill the purpose of substance evaluation, i.e. determining potential risk and establishing risk management measures.

In case T-94/10 Rütgers Germany GmbH et al. vs. ECHA[143], the CJEU examined the proportionality of the decision of ECHA to place anthracene oil on the candidate list of Substances of Very High Concern (SVHC); the candidate

[143] Court of Justice of the European Union, website, *Case T-94/10 Judgment of the General Court of 7 March 2013. Rütgers Germany GmbH and Others v European Chemicals Agency (ECHA)*, https://curia.europa.eu/juris/document/document.jsf?text=&docid=134562&

list is the list of substances that are potential candidates for prohibition and thus subjection to the authorisation procedure[144]. The purpose of authorisations is to identify the most harmful chemicals on the EU market in order to prohibit using them – completely or in special circumstances, with the option for the private sector to use thus prohibited substances for the authorised uses[145]. The process of granting authorisations also imposes an effective "prohibition" on all uses of an SVHC substance, unless authorisation is granted for further specific use or uses[146].

The appellants, Rütgers Germany GmbH et al., are manufacturers and suppliers of anthracene oil in the EU. This substance is a substance with unknown or variable composition, complex reaction products or biological materials (UVCB substance), because it cannot be fully identified by its chemical composition. Well-defined substances, of which the composition is known or may be determined, and substances with variable composition, which cannot be specifically determined, are distinguished. The latter category of substances is known as UVCB substances, that is substance with unknown or variable composition,

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pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=6709293 [access: 30.03.2024]; in a uniform manner: Court of Justice of the European Union, website, *Case T-93/10 Judgment of the General Court of 7 March 2013. Bilbaína de Alquitranes, SA and Others v European Chemicals Agency (ECHA)*, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62010TJ0093 [access: 30.03.2024]; Court of Justice of the European Union, website, *Case T-95/10 Judgment of the General Court of 7 March 2013. Cindu Chemicals BV and Others v European Chemicals Agency (ECHA)*, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62010TJ0095 [access: 30.03.2024]; Court of Justice of the European Union, website, *Case T-96/10 Judgment of the General Court of 7 March 2013. Rütgers Germany GmbH and Others v European Chemicals Agency (ECHA)*, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62010TJ0096 [access: 30.03.2024]; Court of Justice of the European Union, website, *Case T-268/10 Judgment of the General Court of 25 September 2015. Polyelectrolyte Producers Group GEIE (PPG) and SNF SAS v European Chemicals Agency (ECHA)*, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62010TJ0268 [access: 30.03.2024].

144 S. Vaughan, *op. cit.*, p. 171.

145 *Ibidem*, pp. 165–166.

146 P. Fisk, O. Warwick, L. McLaughlin, R. Wildey, *Chemical Risk Assessment. A Manual for REACH*, Chichester 2014, p. 11.

complex reaction products or biological materials; these are e.g. production process residues and plant extracts[147]. The UVCB substances cannot be sufficiently identified based on their chemical composition, because:

- the number of their components is relatively high;
- their composition is to a large extent unknown;
- the variability of the composition is relatively significant or difficult to predict[148].

Anthracene oil is primarily used as intermediate product for the manufacture of soot, which is a colourant and activator in products made of rubber, in particular in tyres. It is also used as intermediate product for the manufacture of pure anthracene. Anthracene oil is identified, by decision of ECHA, as substance meeting – because of its persistent, bioaccumulative and toxic properties (PBT properties), as well as very persistent and very bioaccumulative properties (vPvB properties) – the criteria defined in Article 57 letter d and e of the REACH Regulation. It means the identification of anthracene oil as substance of very hight concern for its eventual introduction to Annex XIV of the REACH Regulation, which includes the List of substances subject to authorisation.

The appellants claimed that the appealed decision was contrary to the principle of proportionality, because it was not suitable for the completion of the purposes of the REACH Regulation, i.e. to ensure a high level of human health and environment protection. The appellants noted that the substances that may be used in replacement of anthracene oil also have PBT or vPvB properties. In the opinion of the appellants, ECHA could undertake different and less onerous measures, i.e. application of risk control measures based on the chemical safety assessment included in the registration dossier prepared by the appellants pursuant to Article 14 of the REACH Regulation or presentation of the dossier on restrictions on the disputed substance pursuant to Article 67 et seq. of the Regulation. The process of introduction of restrictions, pursuant to Article 68 Section 1 of the REACH Regulation, take place when there is unacceptable risk for human health or environment, resulting from the manufacture, use or marketing of a substance, which must be prevented across the EU. The restriction is applicable to substances that cause an unacceptable risk for human health or environment, which cannot

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147 L. Bergkamp, N. Herbatschek, *Key Concepts and Scope* [in:] L. Bergkamp (ed.), *op. cit.*, p. 42.

148 P. Fisk, O. Warwick, L. McLaughlin, R. Wildey, *op. cit.*, pp. 82–83.

be eliminated in an effective and immediate manner by using other provisions of the REACH Regulation (e.g. authorisation) or other EU procedures (e.g. occupational health legislation)[149]. The restriction is a legal reaction and final solution for the most harmful substances, which require urgent action[150].

The CJEU decided that based on Article 1 Section 1 of the REACH Regulation, the purpose of the regulation is to ensure a high level of human health and environment protection, including the propagation of alternative methods of assessment of hazards caused by substances, as well as free trade in substances on the internal market, while improving the competitiveness and innovation. Due to recital 16 of the REACH Regulation, the legislator set the first of these purposes as the main purpose, namely to ensure a high level of human health and environment protection. In accordance with recital 16, the REACH Regulation is based on the principle, according to which industry should manufacture, import, use or market substances, while maintaining the required responsibility and diligence to ensure that in rationally predictable conditions, no adverse consequences for human health and environment will occur. As far as the purpose of the authorisation procedure is specifically concerned, Article 55 of the REACH Regulation stipulates that its purpose is to guarantee effective functioning of the internal market, while ensuring that the risk caused by the substances of very high concern is properly controlled and that such substances are gradually replaced with suitable alternatives or technologies, if it is feasible from the economic and technical point of view.

In relation to the argumentation of the appellants, in accordance to which the appealed decision is not suitable for the completion of the purposes of the REACH Regulation, the CJEU admitted that the appealed decision consists in the identification of anthracene oil as substance of very high concern, which identification is a result of the procedure provided for in Article 59 of the REACH Regulation. Article 59 of the REACH Regulation defines the procedure of identification of the substances that may be covered with the requirement to obtain authorisation and the procedure of compilation of the candidate list of substances for eventual introduction in Annex XIV to the REACH Regulation. If the substance is identified as substance of very high concern, the interested business entities are subject to the information obligations

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[149] L. McLaren, O. de Matos, *REACH and Politics – a Review of Early Experience with the Implementation of the EU's Regulatory Regime on Chemicals* [in:] D. Drohmann, M. Townsend (eds.), *op. cit.*, p. 9.

[150] S. Vaughan, *op. cit.*, p. 181.

provided for in Article 7 Section 2 (notification of substances in products), Article 31 Section 1 letter c and Article 31 Section 3 letter b (provision of the safety data sheet of the substance or mixture) and Article 33 Section 1 and 2 of the REACH Regulation (communication of information on substances in products). According to the CJEU – in relation to the purpose of human health and environment protection – the identification of the substance as a substance of very high concern serves the purpose of providing better information to the public opinion and professionals of the risk and hazards connected with the substance and thus such identification should be considered as the measure of improving the level of such protection.

The CJEU admitted that in relation to the argumentation of the appellants, according to which the appealed decision was unsuitable in such terms, because the substances that may be used to replace the subject substance also have PBT or vPvB properties, it should be noted that the appealed decision did not entail a prohibition on marketing anthracene oil, which would oblige the interested business entities to use the alternative substances. The result in the form of prohibition on marketing of the substance is provided for only in Article 56 of the REACH Regulation, in relation to a substance included in Annex XIV of the Regulation, i.e. the list of substances subject to authorisation. Furthermore, although Article 59 Section 1 of the REACH Regulation stipulates that the substance identification procedure is used for its eventual introduction to Annex XIV of the Regulation, based on the procedure provided for in Article 58 of the REACH Regulation, the introduction of a substance to the candidate list of substances does not automatically entail the introduction thereof in Annex XIV of the mentioned Regulation. Pursuant to Article 58 Section 1 and 3 of the REACH Regulation, ECHA is obliged to recommend the introduction of priority substances in that annex, considering the opinion of the EU members states committee and determining in particular the uses or use categories exempt from the obligation to obtain authorisation. A substance may only be covered with obligation to obtain authorisation by the decision of the Commission to introduce the substance to Annex XIV of the REACH Regulation. In addition, the CJEU decided that in relation to the identification of substances of very high concern, the REACH Regulation provides for a procedure shaped so that the substances be gradually subjected to the authorisation procedure. The recital 77 of the REACH Regulation stipulates that due to the functionality and practicality both in relation to the natural and legal persons that shall prepare documents to submit application and take appropriate risk control measures and to the bodies that shall review the applications for authorisation, the authorisation procedure should only

cover a limited number of substances. Therefore, it is not excluded that as part of this gradual approach, the alternative substances mentioned by the appellants will also be covered with the identification procedure provided for in Article 59 of the REACH Regulation.

In the opinion of the CJEU, the argumentation should also be dismissed, according to which the identification of anthracene oil as substance of very high concern is not suitable for the completion of the purposes of the REACH Regulation, because the risk related to the exposure to that substance is negligible, as anthracene oil is mainly used as intermediate product for the manufacture of soot. Because anthracene oil is an intermediate product, the substance, pursuant to Article 2 Section 8 of the REACH Regulation, is not subject to the information obligations arising from the identification of the substance as substance of very high concern pursuant to Article 59 of the Regulation. An intermediate product is a substance that is manufactured, consumed or used only for chemical processing, that is synthesis, to convert it into another substance (Article 3 Section 15 of the REACH Regulation); pursuant to Article 2 Section 8 of the REACH Regulation, intermediate products are excluded from the authorisation procedure. According to the CJEU the argumentation of the appellants is irrelevant to the case, because following the argumentation, the subject substance is not used exclusively as intermediate product. By consequence, the argumentation of the appellants regarding the allegedly unsuitable character of the appealed decision should be dismissed.

The appellants also claimed that the appealed decision exceeded what was necessary to complete the assumed purposes, because the use of risk control measures or presentation – pursuant to Annex XV to the REACH Regulation – the dossier on the restrictions on the disputed substance would also ensure a high level of human health and environment protection, while being less onerous. In the context of risk control measures, the appellants referred to the obligations included in Article 14 of the REACH Regulation. Pursuant to Article 14 Section 1 of the Regulation, they should perform the chemical safety assessment and prepared the chemical safety report for the subject substance. In accordance with Article 14 Section 3 letter d of the REACH Regulation, the chemical safety assessment also includes the assessment of PBT and vPvB properties for the given substance. If such assessment led to the conclusion that the substance had PBT or vPvB properties, then pursuant to Article 14 Section 4 of the REACH Regulation, the applicants would have to complete the assessment of exposure and estimate the exposure, as well as perform the characterisation of the risk related to the identified uses. In addition, based on Article 14 Section 6 of the REACH Regulation, the appellants were obliged to determine

and use appropriate measures for proper risk control. Since the assessment was not yet available as of the identification of the disputed substance as substance of very high concern in the appealed decision, ECHA, instead of identifying the disputed substance as substance of very high concern, could decide to wait for the submission of that assessment in order to investigate the chemical safety report and the proposed risk control measures. The CJEU decided that based on the REACH Regulation, the legislator did not intend to make the identification procedure conducted pursuant to Article 59 of the Regulation – being part of the authorisation procedure for the substance – depend on the registration procedure, including the obligations listed in Article 14 of that Regulation. Although these obligations are to better inform the public opinion and professionals on the risk and hazards related to the substance, nonetheless since the registered substances – in accordance with recital 19 of the REACH Regulation – should be approved for marketing on the internal market, the purpose of the authorisation procedure, of which the part is the identification procedure provided for in Article 59 of the Regulation, is among others gradual replacement of substances of very high concern with other suitable substances or technologies, if feasible from the economic and technical point of view. In addition, in accordance with recital 69 of the REACH Regulation, substances of very high concern should be the subject of increased attention. By consequence, contrary to the claims of the appellants, the risk control measures proposed pursuant to Article 14 Section 6 of the REACH Regulation are not suitable for the completion of the purposes of the Regulation related to the treatment of substances of very high concern, thus they are not the less onerous measures in the case.

Furthermore, the CJEU decided – in relation to the argument of the appellants, according to which ECHA, before identifying anthracene oil as substance of very high concern, could have waited for the submission of the registration dossier on the disputed substance including its chemical safety assessment, because such dossier would have been a better source of information – that the identification was completed based on information included in the dossier on the disputed substance that had been unanimously approved by the EU member states committee. This committee did not find the absence of information on the validity and relevance of data. In addition, since the registration of the disputed substance should be, pursuant to Article 23 Section 1 of the REACH Regulation, absolutely completed only as of 01.12.2010, then two and a half year later, counting from the day, as of which the authorisation procedure was applicable pursuant to Article 141 Section 2 of the Regulation,

i.e. as of 01.06.2008, the alleged obligation to wait for the submission of the subject registration dossier would interfere with the effectiveness of the REACH Regulation.

In addition, in relation to the restriction measures, the appellants claimed that the dossier on the proposition of such measure, pursuant to Annex XV of the REACH Regulation, should include the available information on alternative substances, including information on the risk to human life and environment related to the manufacture and use of such alternative substances, their availability and technical and economic feasibility. In the opinion of the applicants, such proposition, which would thus be based on the parameters similar to the parameters used in the dossier to identify the substance as substance of very high concern, would have allowed to avoid negative consequences related to the mentioned identification and would have led to the same result with regards to the purposes of the REACH Regulation. The CJEU decided that the very fact that the substance is on the candidate list of substances did not prevent subjecting that substance to restrictions rather than authorisation. Based on Article 58 Section 5 and Article 69 of the REACH Regulation, the Commission or EU member state may always propose controlling the manufacture, marketing or use of the substance by restrictions rather than authorisation. Furthermore, based on Annex XVII of the REACH Regulation (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles), the restrictions set pursuant to the procedure provided for in Article 67 et seq. of the Regulation, regarding the manufacture, marketing and use of certain dangerous substances and certain dangerous mixtures and products, may vary in intensity, starting from the special conditions for the manufacture or manufacturing of the substance and ending with the complete prohibition of use of the substance. The restriction measures, even assuming that they are suitable for the completion of the objectives of the REACH Regulation, are not as such less onerous compared to the identification of the substance, which only results in information obligations. Furthermore, in relation to the claim of the appellants, according to which the information contained in the dossier on the proposition of the restriction measure pursuant to Annex XV of the REACH Regulation had demonstrated that the identification of the subject substance was not necessary, it suffices to note that the identification was completed pursuant to the procedure provided for in Article 59 of the REACH Regulation, which constituted a different procedure than the procedure provided for in Article 67 et seq. of the Regulation.

In conclusion, the CJEU found that the decision of ECHA to include anthracene oil on the candidate list of substances of very high concern (SVHC) does not violate the principle of proportionality. This measure is appropriate to achieve the objective of protecting human health and the environment, since the identification of a substance as being of very high concern serves to better inform the public about the risk and hazards associated with that substance. Moreover, this measure is necessary to meet the objective of protecting human health and the environment, as there is no other, less stringent measure that would achieve this objective. The application of risk management measures based on the chemical safety assessment included in the registration dossier is a separate measure than the substance authorization procedure, the stage of which is the inclusion of anthracene oil on the candidate list of SVHC substances. Following the registration procedure, substances are placed on the market and the consequence of the authorization procedure is the gradual replacement of SVHC substances by suitable alternative substances or technologies, provided that they are economically and technically feasible. The restriction procedure may include the establishment of conditions for the production, placing on the market or use of a substance, but also a strict measure such as a ban on the production, placing on the market or use of a substance.

In case T-226/18 Global Silicones Council et al. vs. the Commission[151], the CJEU examined the proportionality of the decision of the Commission to establish the restriction on marketing of the substance D4 and D5. The first appellant, Global Silicones Council, is a corporation that represents the companies that manufacture and sell silicone products worldwide. Other appellants, Wacker Chemie AG, Momentive Performance Materials GmbH, Shin-Etsu Silicones Europe BV and Elkem Silicones France SAS, are companies that manufacture, sell and supply silicone products, in particular the chemical substances: octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5). The Commission adopted the Regulation (EU) 2018/35 amending Annex XVII to the REACH Regulation as regards D4 and D5[152]. This Regulation

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[151] Court of Justice of the European Union, website, *Case T-226/18 Judgment of the General Court of 30 June 2021 Global Silicones Council and Others v European Commission*, https://curia.europa.eu/juris/document/document.jsf?text=&docid=243622&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=6708546 [access: 30.04.2024].

[152] Commission Regulation (EU) 2018/35 of 10 January 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards octamethylcyclotetrasiloxane ("D4") and decamethylcyclopentasiloxane ("D5"), OJ L 2018, nr 6, p. 45.

stipulates that neither D4, nor D5, shall be marketed in washable cosmetic products in the concentration equal to or greater than 0.1% by weight of any substance after 31.01.2020.

In the opinion of the appellants, considering that the alleged concerns were related to the waste stage of some cosmetic products, the appealed regulation on marketing is disproportional. According to the appellants, the risk management measure intended to clear the alleged concerns, namely the removal of waste products, would be more suitable and less onerous than the restriction on the marketing of the considered cosmetic products and would not cause inconveniences disproportional to the intended purposes. The appellants maintained that they stated, already before the adoption of the appealed regulation, that there was no unacceptable risk that could not be properly controlled; they stated that risk management measures were already in place and that the subject risk could have been identified and managed using the "standard PEC/PNEC approach". The PEC/PNEC values ratio is the most popular indicator used in the environmental risk assessment; PEC is the predicted concentration of the given substance in environment, while PNEC is the predicted concentration that causes no changes in environment. The risk is properly controlled if PEC/PNEC≤1[153].

The CJEU decided that based on recitals 1, 3 and 8 of the appealed regulation, the regulation had been adopted to prevent the environmental risk related to the use of D4 and D5 in washable cosmetic products. This purpose is in line with the objectives fulfilled by the REACH Regulation. The purpose of the REACH Regulation, pursuant to Article 1 Section 1 thereof, is to ensure a high level of human health and environmental protection, including the promotion of alternative methods of the assessment of hazards caused by the substance, as well as free trade in the substances on the internal market, while increasing the competitiveness and innovation. Considering recitals 87, 89 and 91 of the REACH Regulation, the CJEU decided that the main purpose of the legislator introducing new restrictions and amending existing restrictions, based on Article 67 et seq. of the Regulation, was the first of the three purposes, namely to ensure a high level of human health and environment protection The restriction on the marketing of washable cosmetic products containing D4 and D5 in the concentration equal to or greater than 0.1% by weight of any substance is suitable, considering that purpose. That restriction limits the use

[153] T. Komorowicz, *Ocena bezpieczeństwa chemicznego w systemie REACH*, "Czasopismo Techniczne" 2009, Vol. 1, p. 27.

of such products to the minimum. However, the intended use of these products causes the emission of D4 and D5 to aquatic environment; the Commission decided that it caused an unacceptable environmental risk.

Then, the CJEU analysed, in view of the argumentation presented by the appellants, whether there was another suitable, but less onerous measure. It should be noted that during the administration procedure leading to the issue of the appealed regulation, different options were investigated to reduce the risk related to the release to environment of D4 and D5 in washable cosmetic products. Annex XV of the REACH Regulation sets out general rules for preparing dossiers to propose and justify restrictions on the production, placing on the market or use of a substance. In particular, based on the dossier prepared in accordance with the Annex XV of the REACH Regulation and ECHA document on the opinion issued on this dossier, the effectiveness of removal in existing treatment plants and measures provided for in Directive 2000/60/EC establishing the framework for community action in water policy[154], as well as the option to grant authorisation based on the REACH Regulation and the option to introduce voluntary measures by industry were analyzed. It was decided that such options were in many aspects limited. In the dossier prepared in accordance with Annex XV of the REACH Regulation, it was indicated that the sewage treatment plants were usually effective in removing D4 and D5, but the effectiveness of the removal varied according to the individual plants. In addition, the dossier stated that it was difficult to estimate the costs of the modernisation of existing treatment plants, which would depend on multiple unknown factors, and the information on the improved effectiveness of the removal of other substances suggested that these costs may be considerable. In addition, based on the dossier, in some cases the wastewater may not be treated in treatment plants. In such terms, the dossier also examined the impact of the increased share of wastewater treated in the EU, which would reduce the emission to some extent. It was stated that the measures taken based on the Directive 2000/60/EC may prove useful as a supplement of the proposed restriction. However, even if D4 and D5 were defined as priority dangerous substances based on that directive and the Commission established an environmental quality standard, then EU member states would have to adopt measures under that standard only when feasible and not disproportionately costly. Thus, the measures aimed at controlling supply, such

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[154] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, OJ L 2000, nr 327, p. 1, as amended.

as the proposed restriction, are more profitable than the national measures aimed at upgrading the water treatment stations. In addition, the latter type of measure would place the monitoring burden on the EU member states, not on industry. Considering the uncertainty related to the implementation and effectiveness of these measures, potentially alternative or supplementary in relation to the proposed restriction, as well as the fact that not all wastewater in the EU is on mandatory bases treated in treatment plants (in accordance with Council Directive 91/271/EEC concerning urban waste-water treatment[155]), it should be stated that the fact that the measures related to wastewater treatment were rejected as alternative measures, less onerous, is not contrary to the principle of proportionality. This is even more true, as the alternative proposed by the appellants would mean that the costs of minimisation of the risk related to D4 and D5 is fully covered by the taxpayer so that the appellants could continue marketing them. However, no socio-economic component was presented to justify or even require such division of the costs of the risk related to the subject substances. On the contrary, the costs related to the adopted restriction were analysed in detail as part of the administration proceedings in the dossier prepared pursuant to Annex XV of the REACH Regulation; they were considered as relatively low, compared to the benefits obtained, and it was decided that the proposed restriction is proportional. It was decided that only the subject restriction could lead to the targeted elimination of the key use, which dominates the emission to the aquatic environment. As part of the opinion of SEAC, the costs related to the adopted restriction were also analysed, compared to the benefits, and the existence of the problem of proportionality was not found; pursuant to Article 71 of the REACH Regulation, the proposed restrictions are subject to the opinion of the SEAC (Committee for Socio-economic Analysis).

In addition, the CJEU emphasised the fact that Article 68 Section 1 of the REACH Regulation provided for the change of the restrictions applicable to the manufacture, marketing and use without determining the hierarchy between these three options. However, Article 68 Section 1 of the REACH Regulation stipulates that in case of unacceptable risk for human health or environment, resulting from the manufacture, use or marketing of the substance, which shall be prevented across the EU, Annex XVII of the REACH Regulation is changed by the adoption of new restrictions or change of the restrictions on the manufacture, use or marketing of the substance in its own form

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[155] Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment, OJ L 1991, nr 135, p. 40, as amended.

or as component in mixture or in products defined in Annex XVII. Thus, the fact that the appealed regulation is applicable to the marketing of the subject products, not their use, shall not mean that it is disproportional, unless the restriction existed in the use, which would also be suitable, but less onerous than the disputed regulation. However, the appellants failed to prove in a convincing manner that it was the case.

The CJEU admitted – in relation to the argumentation of the appellants, according to which the risk related to the use of D4 and D5 in washable cosmetic products may be eliminated using the "standard PEC/PNEC approach" – that pursuant to the Annex I of the REACH Regulation, PNEC is not applicable to PBT and vPvB substances and that the assessment of hazard considering all long-term effects or estimation of the long-term exposure of environment are not credible enough for these substances. As a result the measures proposed by the applicants cannot be considered as suitable to address the risk related to D4 and D5 use in washable cosmetic products.

In addition, the CJEU decided – in relation to the argumentation of the appellants, according to which the washable cosmetic products containing D4 and D5 may be used with water in a manner that causes no risk – that the appellants failed to provide any specific description of such alleged use or method enabling imposing and controlling such specific use among the users. Thus, it is not possible to check if the measure postulated by the appellants is suitable and would be less onerous than the restriction provided for in the appealed regulation. Regardless of the circumstances, for the allegedly safe use of the considered products to reduce the emissions of D4 and D5 to the aquatic environment with the same effectiveness as the restriction provided for in the appealed restriction on the marketing, it would have to be implemented by all users of washable cosmetic products in the EU, including the consumers. Considering the difficulty of ensuring the observation of the very specific use of the cosmetic product by all consumers, it is obvious that such measure would be less suitable for the completion of the justified purpose, which is to reduce the emission of D4 and D5 to aquatic environment.

The CJEU decided – in the context of the options not to prohibit certain products, but to restrict their sale or use so that only specially trained professional users could use them – that limiting and controlling the use of washable cosmetic products containing D4 and D5 would not be as effective as restricting the marketing of these products, provided for in the appealed regulation in the reduction of the emission of D4 and D5 to aquatic environment. Such

measure would only reduce the emissions of D4 and D5 contained in washable cosmetic products, while the appealed regulation prevents the marketing of such products, thus the emissions related to the use of such products.

Furthermore, the CJEU admitted that the decision to restrict the marketing to prevent the emission of the subject substances and to reject these emissions or to prevent using public funds to eliminate the discharged substances is compliant with the principle in Article 191 Section 2 of TFEU, according to which the EU politics on environmental protection shall be based among others on the principle that environmental damage shall be eliminated first at the source and the principle that the polluter shall pay. By consequence, none of the arguments raised by the appellants demonstrated that the appealed regulation exceeded the limits of what was suitable and necessary to achieve the intended purpose.

In summary, the CJEU found the proportionality of the decision of the Commission to impose restrictions on the placing on the market of substances D4 and D5. This is an appropriate measure to achieve the objective of ensuring a high level of protection of human health and the environment, and it is also necessary because this objective cannot be achieved by other, less stringent measures. Risk management measures in the form of disposal of waste products or controlled use of substances D4 and D5 are characterized by unequal effectiveness or significant costs.

In case T-245/11 ClientEarth and The International Chemical Secretariat vs. ECHA[156], the CJEU analysed the proportionality of the decision of ECHA to refuse access to the information presented in the registration procedure of certain chemical substances. The appellants claimed that ECHA failed to investigate the option to grant partial access to information on the exact quantity marketed by each registrant, which violated on Article 4 Section 6 of the Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents[157]; pursuant to Article 4 Section 6 of this Regulation if any exceptions apply only to a part of the subject

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[156] Court of Justice of the European Union, website, *Case T-245/11 Judgment of the General Court of 23 September 2015 ClientEarth and The International Chemical Secretariat v European Chemicals Agency (ECHA)*, https://curia.europa.eu/juris/document/document.jsf?text=&docid=168464&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=6709496 [access: 30.03.2024].

[157] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 2001, nr 145, p. 43.

document of the request for disclosure, the remaining parts of the document shall be disclosed. Thus, the CJEU admitted that the wording of Article 4 Section 6 of the Regulation (EC) No 1049/2001 suggests that if exceptions apply only to a part of the subject document of the request for disclosure, the remaining parts of the document shall be disclosed. In addition, the principle of proportionality requires the derogations not to exceed the limits of what is suitable and necessary to complete the designated purpose. Article 4 Section 6 of the Regulation (EC) No 1049/2001 requires a specific and individual examination of the content of every document. Because only such examination of every document may enable the institution to assess the option to grant partial access to the applicant. The assessment of documents by category, as opposed to specific information included in the documents, proves inadequate, because the analysis required of the institution should enable a specific assessment of whether the exception is actually applicable to all information contained in the subject documents.

However, there are exceptions to the principle saying that the examination required to review the request for access to documents shall be specific and individual, in particular in case of the general presumption, according to which the disclosure of the subject document would infringe on an interest protected by the exceptions specified in Article 4 of the Regulation (EC) No. 1049/2001. Pursuant to Article 4 Section 2 of the Regulation (EC) No 1049/2001, institutions deny access to a document if the disclosure thereof would infringe on the protection of:

- business interests of a natural or legal person, including intellectual property;
- court proceedings or legal opinion;
- the purpose of control, investigation or audit,

unless the disclosure is justified by overriding public interest.

This is even more applicable, when such presumption is clearly provided for in a legal provision, namely Article 118 Section 2 letter c of the REACH Regulation; thus, pursuant to Article 118 Section 2 letter c of this Regulation, the disclosure of the exact quantity of the substance manufactured or marketed is usually considered to undermine the protection of the business interests of the person interested. To the extent, to which the appellants claimed that by consequence of the assessment of individual instances ECHA failed to consider the option to disclose information on the quantities of individual substances, it should be noted that the legal presumption specified in Article 118 Section 2 letter c of the REACH Regulation, according to which the disclosure

of the exact quantities of the substance manufactured or marketed infringes on the protection of the business interests of the interested persons, is applicable to all subjects substances and the appellants failed to present – in relation either all substances, or individual substances – the circumstances that could dismiss that legal presumption. The appellants also failed to demonstrate the existence of the overriding public interest to justify, at least in relation to a part of the substances, the disclosure of the requested information. If the legal presumption defined in this provision is applicable, the given body may decide that the disclosure would infringe on the protection of the business interests of the interested person and it does not need to complete a specific assessment of the content of every subject document of the request for disclosure. Due to this legal presumption and in the absence of specific circumstances that could call that presumption into question, ECHA does not need to demonstrate how the disclosure of the exact quantities would infringe on the business interests of the interested persons. Thus, ECHA could decide – in the absence of the obligation to examine the individual cases – that information on the exact quantities of all considered substances are covered by the exception specified in Article 4 Section 2 indent 1 of the Regulation (EC) No. 1049/2001.

The CJEU decided that the claim related to the infringement on the principle of proportionality was not justified, because ECHA did not infringe on the requirements of the principle of proportionality by not granting access to the part of the requested information after the examination of the individual instances. In view of the legal presumption defined in Article 118 Section 2 letter c of the REACH Regulation, such examination of the individual instances was not necessary. This provision does not exceed the limits of what is suitable and necessary to achieve the intended purpose, namely to protect business interests. In addition, pursuant to Article 119 Section 2 letter b of the REACH Regulation, ECHA is always obliged to publish the total turnover, for which the given substance is registered. Thus, the REACH Regulation, to some extent, enables access to information on the quantity of the substance, even if the exact quantity thereof is not disclosed.

To sum up, the CJEU ruled that ECHA's decision to refuse access to information submitted as part of the registration procedure for certain chemical substances (i.e. information about the quantity of individual substances) was proportionate. It was an appropriate and necessary measure to achieve the objective of protecting the commercial interests of the registrants. At the same time, ECHA provides (via the database) information on the total tonnage band (1–10 tonnes, 10–100 tonnes, 100–1000 tonnes or over 1000 tonnes) in which the substance is registered.

In case T-108/17, ClientEarth vs. the Commission[158], the CJEU analysed the proportionality of the decision of the Commission on authorisation of the use of secondary plasticised polyvinyl chloride (PVC) containing bis(2-ethylhexyl) phthalate (DEHP). The CJEU dismissed the appeal against the decision of the Commission, which dismissed the request to initiate the internal appeal procedure from the decision that authorised the use of secondary plasticised polyvinyl chloride (PVC) containing bis(2-ethylhexyl) phthalate (DEHP). By adopting Commission Regulation (EU) No 143/2011 amending Annex XIV of the REACH Regulation[159], the Commission included DEHP, the organic compound used mainly to soften PVC-based plastics, in Annex XIV due to the properties of the substance – toxic to reproduction. Then, three companies that provide services in waste recycling submitted, pursuant to the REACH Regulation, a joint application for authorisation to place DEHP on the market for specific applications. Pursuant to Article 60 Section 4 of the REACH Regulation, the Commission made a decision, which as a rule authorised those three companies to use secondary plasticised PCV containing DEHP. Pursuant to Article 60 Section 4 of the REACH Regulation, the Commission may grant the authorisation if it is demonstrated that the socio-economic benefits outweigh the risk for human health and environment arising from the use of the given substance and there are no suitable alternative substances or technologies. ClientEarth, an environmental protection organisation, requested the Commission to conduct the internal appeal procedure pursuant to Article 10 of the Regulation (EC) No 1367/2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies[160] regarding the decision on authorisation. The Commission dismissed that

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158 Court of Justice of the European Union, website, *Case T-108/17 Judgment of the General Court of 4 April 2019 ClientEarth v European Commission*, https://curia.europa.eu/juris/document/document.jsf?text=&docid=212665&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=7895920 [access: 30.03.2024].

159 Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH'), OJ L 2011, nr 44, p. 2.

160 Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies, OJ L 2006, 264, p. 13, as amended.

request. ClientEarth submitted a complaint aiming at the declaration of invalidity of the decision on the request to initiate the internal appeal procedure. The CJEU dismissed the complaint.

The CJEU stated the reasons, why the very fact that the given substance may be harmful to human health is not sufficient to determine that using it should remain prohibited after the introduction to Annex XIV of the REACH Regulation and despite observing the principle of precaution. This essentially takes place, because assuming the restriction measure aiming at environmental or human health protection, the Commission is obliged to ensure suitable balance between the principle of precaution and the principle of proportionality. The denial of authorisation only because the given substance may be harmful to human health would not only be contrary to the REACH Regulation as such, but also to the principle of proportionality.

Thus, the CJEU decided that on one hand based on recital 69 of the REACH Regulation, and on the other hand based on Article 60 Section 4 of the Regulation, in the absence of the demonstration that the risk for human health or environment arising from the use of the substance is properly controlled, the authorisation may be granted if it may be demonstrated that the socio-economic benefits of the use of the given substance outweigh the risk related to its use, and that no suitable alternative substances or technologies exist that are feasible from the economic and technical point of view. In the essence, for the Article 60 Section 4 of the REACH Regulation to enable granting the authorisation, when the risk resulting from the use of the given substance of very high concern is not properly controlled, but the socio-economic benefits of using the substance outweigh the risk related to its use, there are no suitable alternative substances or technologies, which are feasible from the economic or technical point of view, the EU legislator balanced human health and environment on one hand, and the interests of the applicant of authorisation and the socio-economic benefits of the use the substance on the other hand. Although in cases such as the subject case, practical balancing of the abovementioned interests may justify the application by the Commission of special supervision and short review period of the authorisation, however based on Article 60 Section 4 of the REACH Regulation, if the prerequisites in this provision are met, the Commission shall not deny the authorisation, subject to infringement on the principle of proportionality.

In summary, the CJEU found that the decision of the Commission to authorize the use of secondary plasticized polyvinyl chloride (PVC) containing bis(2-ethylhexyl) phthalate (DEHP) is proportionate, that is, appropriate and necessary. Although the risks of using a given substance is not adequately

controlled, the socio-economic benefits resulting from the use of this substance outweigh this risk, and there are no suitable alternative substances or technologies that are economically and technically feasible.

In case C-106/14, Fédération des entreprises du commerce et de la distribution (FCD) and Fédération des magasins de bricolage et de l'aménagement de la maison (FMB) vs. Ministre de l'Écologie, du Développement durable et de l'Énergie (Minister of Ecology, Sustainable Development and Energy)[161], the CJEU investigated the proportionality of the obligation to notify and inform of substances of very high concerns contained in products. The dispute between Fédération des entreprises du commerce et de la distribution (FCD) and Fédération des magasins de bricolage et de l'aménagement de la maison (FMB) and the Minister of Ecology, Sustainable Development and Energy was related to the obligation of business entities to submit information on substances contained in products pursuant to Article 7 Section 2 and Article 33 of the REACH Regulation – the interpretation of the threshold value of 0.1% w/w (weight concentration). The doubts were related to whether the obligations arising from Article 7 Section 2 and Article 33 of the REACH Regulation are applicable, if the "product" within the meaning of the Regulation consists of several components that themselves correspond to the definition of the "product" given in the Regulation, only to the combined product or to each component corresponding to the definition of the "product".

Pursuant to Article 7 Section 2 of the REACH Regulation, the manufacturer or importer of products shall inform ECHA if the substance from the candidate list of substances of very high concern is present in these products in a total quantity of more than 1 tonne per year per manufacturer or importer and in concentration higher than 0.1% w/w. Pursuant to Article 7 Section 3 of the REACH Regulation, Article 7 Section 2 of this Regulation is not applicable if the manufacturer or importer may eliminate the human or environmental exposure under normal or rationally predictable conditions for use, including the disposal. Pursuant to Article 7 Section 6 of the REACH Regulation, Article 7 Section 2 of the Regulation is not applicable to substances already registered for the given use.

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[161] Court of Justice of the European Union, website, *Case C-106/14 Judgment of the Court of 10 September 2015 Fédération des entreprises du commerce et de la distribution (FCD) and Fédération des magasins de bricolage et de l'aménagement de la maison (FMB) v Ministre de l'écologie, du développement durable et de l'énergie*, https://curia.europa.eu/juris/document/document.jsf?text=&docid=167286&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=7896426 [access: 30.03.2024].

The CJEU decided that based on the information quoted, the obligation of the manufacturer, provided for in Article 7 Section 2 of the REACH Regulation, to notify requires meeting the following four cumulative prerequisites:

- the use of the substance of very high concern has not been subject of registration yet;
- human and environmental exposure to the substance cannot be excluded;
- the total quantity of the given substance exceeds 1 tonne per year per manufacturer or importer;
- the concentration of the substance exceeds 0.1% w/w in the given product.

In relation to Article 33 of the REACH Regulation, it establishes the obligation to submit information on substances contained in products. Pursuant to Article 33 Section 1 of the REACH Regulation, the supplier of the product containing the substance of very high concern in the concentration of more than 0.1% w/w shall provide the product recipient with sufficient information, available to them, enabling the safe use of the product, at least the name of the substance. Article 33 Section 2 of the REACH Regulation imposes the obligation to submit analogical information on request of the consumer for every supplier of the product meeting the same requirements.

The doubts were related to whether, in the case of the product consisting of multiple products within the meaning of Article 3 Section 3 of the REACH Regulation, Article 7 Section 2 and Article 33 of the Regulation, should be interpreted so that the concentration threshold of the substance of very high concern at the level of 0.1% w/w, governed by these provisions, shall be referred to the total weight of the product. Based on Article 3 Section 3 of the REACH Regulation, the product is an item that during the manufacture obtains a specific shape, surface structure or outside appearance, which determines its function to an extent greater than its chemical composition. The CJEU admitted that in cases subject to the scope of Article 7 Section 2 of the REACH Regulation, the manufacturers shall submit information on the presence of substances of very high concern in products they manufacture or assemble to ECHA. Then, if the product is used at further stage by a downstream manufacturer as component for the manufacture of a complex product, the downstream manufacturer, in turn, is no longer obliged to submit to information on the presence of the given substance in the product to ECHA. Such notification would duplicate the action taken by the manufacturer of the product. Such excessive and redundant obligation would be difficult to reconcile with the principle of proportionality. Thus, Article 7 Section 2 of the REACH

Regulation shall be interpreted so that to apply this provision, the manufacturer is obliged to determine if the substance of very high concern identified pursuant to Article 59 Section 1 of the Regulation is present in the concentration of above 0.1% w/w of the manufactured product and the importer of the product consisting of multiple component products is obliged to determine for each component product if such substance is present in the concentration of above 0.1% w/w of the component product.

In the context of the compliance of such system with the principle of proportionality, the CJEU also decided that the obligation to submit information is based on the notification obligation provided for in Article 7 Section 2 of the REACH Regulation, which is supplemented by the arrangement for all entities in the supply chain up to the final consumer of the communication of essential information on the presence of substances of very high concern. Nonetheless, the extent of its applicability is limited by Article 33 of the REACH Regulation, which stipulates that sufficient information, available to the supplier, enabling the safe use of the given product, should include at least the name of the subject substance. This requirement, due to its minimal range, cannot be considered to impose an excessive burden. Thus, Article 33 of the REACH Regulation shall be interpreted so that to apply this provision to the supplier of the product, in which one or more component products contains a substance of very high concern identified pursuant to Article 59 Section 1 of the Regulation, at the concentration of above 0/1% w/w for each component product, the recipient and – on request – the consumer shall be informed of the presence of the substance by providing at least the name of the substance.

In summary, the CJEU found the proportionality of obligations to notify and inform about substances of very high concern (SVHC) contained in products; where a "product" consists of multiple components which themselves meet the definition of a "product" in the REACH Regulation, the obligation to inform applies to each of the components meeting the definition of a "product". The obligation to provide information in the supply chain on the presence of SVHC substances in products, which is based on the prior obligation to notify substances contained in products, is limited to information that enables the safe use of the product in question, i.e. at least the name of the substance. Therefore, the minimum scope of this obligation proves its appropriateness and necessity, i.e. compliance with the principle of proportionality.

In case C-558/07, SPCM SA et al. vs. Secretary of State for the Environment, Food and Rural Affairs[162], the CJEU assessed the proportionality of the registration conditions for monomers. SPCM SA is a manufacturer of water-soluble polymers for industrial use in wastewater treatment, C.H. Erbslöh KG is a distributor and wholesaler of chemical products for special purposes and use in industry, including preparations and polymers, Lake Chemicals and Minerals Ltd is an importer of chemical products, including polymers and preparations, while Hercules Inc. is a supplier of polymer-based products that are soluble in water and organic substances.

Pursuant to Article 2 Section 9 of the REACH Regulation, the provisions on the registration of substances are not applicable to polymers. However, Article 6 Section 3 of the REACH Regulation stipulates that every manufacturer or importer of polymers shall submit to ECHA the registration documents for one or more monomers and other substances, which have not been registered earlier by another participant, constituting the upstream link of the supply chain, if the following conditions are met jointly:

a) this polymer contains at least 2% w/w of such monomers or other substances in the form of units of monomer and chemically bonded substances;
b) the total quantity of such monomers or other substances is 1 tonne or more per year.

Pursuant to Article 3 Section 5 of the REACH Regulation, polymer is a substance consisting of particles constituting a sequence of one or more types of monomer unit; such particles shall be characterised by the statistic distribution of particle weight in a certain range, while the differences in the particle weight should result above all from differences in the quantity of monomer units in a particle; the polymer contains:

a) particles constituting the simple weight majority, which contain at least three units of monomer in covalent bonding with at least one more monomer unit or other strong reagent;
b) particles not constituting the simple weight majority among particles with the same particle weight.

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[162] Court of Justice of the European Union, website, *Case C-558/07 Judgment of the Court of 7 July 2009. The Queen, on the application of S.P.C.M. SA, C.H. Erbslöh KG, Lake Chemicals and Minerals Ltd and Hercules Inc. v Secretary of State for the Environment, Food and Rural Affairs*, https://curia.europa.eu/juris/document/document.jsf?text=&docid=77548&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=7896717 [access: 30.03.2024].

In addition, in the context of this definition, the "monomer unit" is the reacted form of monomer in the polymer.

Based on Article 3 Section 6 of the REACH Regulation, the monomer is a substance, which can form covalent bondings with a series of other similar or dissimilar particles in a polymer-forming reaction, in appropriate conditions used in the given process.

The appellants claimed that the reacted monomers lose their intrinsic chemical characteristics and that polymers are essentially stable and safe. Thus, in the opinion of the applicants, if the term "monomers" in Article 6 Section 3 of the REACH Regulation were interpreted to mean or include reacted monomers, then the exemption of polymers from the registration would make no sense, since the registration of monomers is required. Such interpretation would be also contrary to the purposes of the Regulation, as well as disproportionate.

The CJEU investigated whether the obligation to register monomers meeting the cumulative conditions provided for in Article 6 Section 3 of the REACH Regulation is disproportionate as measure to achieve the purposes of this Regulation. The purposes of the REACH Regulation, defined in Article 1 Section 1 thereof, consist in ensuring a high level of human health and environmental protection, as well as free trade in the substances on the internal market, while supporting the competitiveness and innovation. However, in view of recital 16 of the REACH Regulation, it should be noted that the given purpose of the registration obligation in Article 6 Section 3, set by the legislator, is the first of three indicated purposes, i.e. to ensure the high level of human health and environmental protection. The measure to achieve this purpose, arising from recital 19 of the REACH Regulation, is the registration obligation imposed on the manufacturers and importers, including the obligation to provide data on the manufactured or imported substances, use of such data to assess the risk related to these substances, and to prepare and recommend appropriate risk management measures. As far as the purpose of health and environmental protection is concerned, it should be stated that registering substances serves the purpose of informing the public and professionals on the possible risk and that registration should be considered as the measure of improving the level of such protection. In this regard, it should be noted that although polymers are exempt from the registration obligation for practical reasons related to their great numbers, the situation may change pursuant to Article 138 Section 2 of the REACH Regulation, as soon as a feasible and profitable method for selection of polymers subject to registration is established. Thus, the obligation of registering monomers, less numerous than polymers, enables knowing the risk related not only to these substances,

but also to monomers in the form of residues of the polymerisation process or after the eventual decomposition of polymers. If polymers are manufactured in EU, the interest in the registration of monomers is obvious, because in the EU monomers are used in non-reacted form, so it is essential that registration information in this area is available to control the potential risk. In addition, if polymers are imported to the EU, the registration obligation for monomers in reacted form serves, on the same terms, the purpose of health and environmental protection, because it enables obtaining more specific information on polymers. Furthermore, this type of obligation to register monomers is compliant with the principle of precaution included in Article 1 Section 3 of the REACH Regulation; this provision stipulates that the REACH Regulation is based on the principle of precaution, in accordance with which the manufacturers, importers and downstream users are responsible for guaranteeing that the substances they manufacture, market or use do not have an adverse impact on human health or environment. The registration obligation imposed on the importers leads to a more sustainable division of registration costs between the EU manufacturers and importers. This equal treatment prevents the disruption of competition, thus ensuring loyal competition within the EU. Protecting EU manufacturers from adverse consequences in terms of competitiveness, which may result from different conditions created for importers, is the legally acceptable purpose of the legislator. Hence, the registration obligation for the monomers in reacted form contained in polymers is suitable for completing the purposes of the REACH Regulation.

The CJEU also analysed whether such obligation does not exceed what is necessary to complete these purposes. To ensure real competition in the EU, the importers of monomers shall be subject to the same obligations as EU manufacturers or similar obligations, leading to the equalisation of costs. Any other provision aiming at compensating for the absence of registration costs on the side of the importers would not have been less stringent for them. Similarly, any limitation of the registration obligation to monomers manufactured in the EU only would be contrary with the purpose of ensuring competitiveness and innovation, because the import of monomers at lower prices, exclusive of the registration costs, would discourage EU manufacturers to initiate or continue research on these monomers. Hence, the obligation to register monomers in reacted form, being a component of polymers, does not exceed what is necessary to complete the purposes of the REACH Regulation.

The appellants, however, challenged the proportionality of the above registration obligation and claimed that the importers encounter serious practical difficulties, resulting in particular form the fact that they do not know

the composition of the imported polymers and the costs of the registration procedure are significantly disproportionate to the generated turnover and quantities of the subject substances. In this regard, it should be above all noted that Article 8 Section 1 of the REACH Regulation provides for the option to determine an exclusive representative for the person that manufactures the substance in its own form or as component in mixture or that manufactures a product imported to the EU; such representative shall fulfil all obligations applicable to the importers, which are duly informed and thus considered as downstream users. Thus, the registration obligations are borne by the representative, who is designated by the manufacturer without a registered office in the EU and who is trusted by the latter. Furthermore, in relation to the costs caused by the registration procedure, it should be noted that the procedure is the same regardless of whether the products are manufactured in the EU or outside, and that, by consequences, the manufacturers without the registered office in the EU and the importers do not incur burdens greater than EU manufacturers.

In addition, the REACH Regulation provides for a division of the information submission obligation to reduce the costs related to substances between the persons submitting the same substance. And so, recital 33 of this Regulation stipulates that joint submission of information of substances and sharing this information should be provided for to increase the effectiveness of the registration system, reduce its costs and decrease the number of tests performed on vertebrate animals. The completion of this purpose shall be ensured pursuant to Article 27 Section 3 of the REACH Regulation, which provides for the division of the information sharing obligation between the registrants to reduce the costs. Pursuant to Article 27 Section 3 of the REACH Regulation, the previous registrant and potential registrants shall make every effort to guarantee that the information sharing costs are set in a just, transparent and non-discriminatory manner; the registrants are only required to participate in the costs of such information that they are required to submit to meet the registration requirements.

Thus, the CJEU decided that considering the limited number of potential monomers, the twelve-year validity period of previous registration of the substance provided for in Article 27 of the REACH Regulation, as well as the option to divide between registrants the obligation to provide information to reduce the costs, the financial burdens resulting from the obligation to register monomers in the reacted form in polymer are obviously not disproportional under the conditions of free trade of products on the internal marker open to loyal competition. Article 27 Section 1 of the REACH Regulation stipulates that if the substance was registered not earlier than within the last 12 years,

the potential registrant shall request information on tests on vertebrate animals and may request information not related to tests on vertebrate animals from the previous registrants, regarding the information required to complete the registration.

Based on the above considerations, Article 6 Section 3 of the REACH Regulation is not void due to non-compliance with the principle of proportionality.

In conclusion, the CJEU found the proportionality of the conditions for the registration of monomers. Registration is an appropriate measure to achieve the objective of guaranteeing a high level of protection of human health and the environment by obliging registrants (producers and importers) to submit data on substances, to use this data to assess the risks associated with these substances, to apply risk management measures, as well as to inform the public about potential risks. Registration is also a necessary measure because there is no other, less restrictive measure to achieve this objective. The following elements significantly reduce the costs of the monomer registration procedure: the obligation to provide existing data in the case of substances registered within the last 12 years and the sharing of the costs of providing information.

Conclusions

Based on the analysis of the collected materials, a conclusion was formulated, confirming the hypothesis adopted in the work, that the requirement to register nanoforms of a substance is a proportionate measure that should influence the positive perception of the law in this area by the addressees of legal norms and strengthen their conviction about the need to comply with legal obligations. The obligation to register nanoforms of substances is an appropriate measure that serves the main objective of the REACH Regulation, i.e. ensuring a high level of protection of health and the environment. The obligation to register nanoforms of substances is also an indispensable measure; the objective of ensuring a high level of protection of health and the environment cannot be achieved by other means that would be less burdensome for industry, in particular through notification of substances contained in articles. In addition, the registration procedure for nanoforms of substances allows for the collating of nanoforms of substances with similar characteristics, the joint submission of information on substances by multiple registrants and the sharing of data on substances, significantly reducing the burden on industry.

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Summary

In the stakeholder consultation that preceded the introduction of Commission Regulation (EU) 2018/1881 amending the REACH Regulation to address nanoforms of substances, industry respondents questioned the proportionality of the obligation to register nanoforms of substances as well as the obligation to include nanoforms of substances in the substance registration dossier instead of registering nanomaterials as standalone substances. Respecting the principle of proportionality of the requirements relating to the registration of nanoforms of substances should contribute to a positive perception of the law in this area by the addressees of legal norms and strengthen their conviction about the need to meet these requirements. The obligation to register nanoforms of substances serves the main objective of the REACH Regulation, i.e. ensuring a high level of protection of health and the environment. Whether the obligation to register nanoforms of a substance is a proportionate measure has not been sufficiently explored in the scientific literature. The aim of the work is to characterize the respect of the principle of proportionality in the context of the obligations regarding the registration of nanoforms of substances, introduced by Commission Regulation (EU) 2018/1881 amending the REACH Regulation to address nanoforms of substances. The work uses the method of analysing the content of publications (books and articles) in the area of compliance management and the principle of proportionality, as well as the method of analysing sources, such as documents (results of public consultation "Amendments of the Annexes to REACH for registration of nanomaterials") and sources of law.

Streszczenie

Podczas konsultacji z zainteresowanymi stronami, które poprzedziły wprowadzenie rozporządzenia Komisji (UE) 2018/1881 zmieniającego rozporządzenie REACH w celu uwzględnienia nanopostaci substancji, respondenci reprezentujący przemysł zakwestionowali proporcjonalność obowiązku rejestracji nanopostaci substancji, a także obowiązku jej uwzględniania w dokumentacji rejestracyjnej substancji zamiast rejestrowania nanomateriałów jako samodzielnych substancji. Przestrzeganie zasady proporcjonalności wymagań związanych z rejestracją nanopostaci substancji powinno przyczynić się do pozytywnego postrzegania prawa w tym zakresie przez adresatów norm prawnych i umocnić ich przekonanie o konieczności spełniania tych wymagań. Obowiązek rejestracji nanopostaci substancji służy głównemu celowi rozporządzenia REACH, jakim jest zapewnienie wysokiego poziomu ochrony zdrowia i środowiska. W literaturze naukowej nie zbadano dostatecznie, czy obowiązek rejestracji nanopostaci substancji jest środkiem proporcjonalnym. Celem pracy jest scharakteryzowanie przestrzegania zasady proporcjonalności w kontekście obowiązków dotyczących rejestracji nanopostaci substancji, wprowadzonych rozporządzeniem Komisji (UE) 2018/1881 zmieniającym rozporządzenie REACH w celu uwzględnienia nanopostaci substancji. W pracy wykorzystano metodę analizy treści publikacji (książek i artykułów) z obszaru zarządzania zgodnością i zasady proporcjonalności, a także metodę analizy źródeł – dokumentów (wyniki konsultacji społecznych „Zmiany załączników do rozporządzenia REACH w zakresie rejestracji nanomateriałów") i źródeł prawa.

Politechnika
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