Working Paper on ANNEX II No. 3 NIS2 Directive

NIS2 and REACH

Summary

The NIS2 Directive, adopted in January 2023, requires comprehensive transposition in the EU Member States by 17 October 2024. In this context, the Machinery and Equipment Manufacturers Association (VDMA) and reuschlaw are presenting a Working Paper on the assessment and specification of ANNEX II No. 3 of the NIS2 Directive.

The paper analyses the definitions in the NIS2 Directive, in particular regarding the production of chemical substances, mixtures, and articles. The focus here is on how the Directive interacts with the REACH Regulation.

The Working Paper shows that more than 22,500 companies (approx. 50%) in the manufacturing industry in Germany are affected in accordance with ANNEX II No. 3, while at the same time there is a significant overlap with other relevant sectors in accordance with ANNEX II, which reveals ambiguities, contradictions, and regulatory gaps in the NIS2 Directive.

Finally, suggested wording is presented to improve the precision and clarity of the NIS2 Directive in its national implementation. Tools such as the NIS2 Quick-Check and the VDMA NIS2 working group are presented to support companies in implementing the NIS2 Directive.

1. Definition in accordance with the NIS2 Directive and the German Act Implementing EU NIS2 and Strengthening Cybersecurity (NIS2UmsuCG)

1.1. Definition according to the NIS2 Directive

According to ANNEX II No. 3 of the NIS2 Directive[1] (Manufacture, production and distribution of chemicals), the following companies are subject to the scope of the NIS2 Directive:

German version	English version
3. Produktion, Herstellung und Handel mit chemischen Stoffen Unternehmen im Sinne des Artikels 3 Nummern 9 und 14 der Verordnung (EG) Nr. 1907/2006 des Europäischen Parlaments und des Rates (2), die Stoffe herstellen und mit Stoffen oder Gemischen handeln, und Unternehmen, die Erzeugnisse im Sinne des Artikels 3 Nummer 3 der genannten Verordnung aus Stoffen oder Gemischen produzieren.	3. Manufacture, production and distribution of chemicals Undertakings carrying out the manufacture of substances and the distribution of substances or mixtures, as referred to in Article 3, points (9) and (14), of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2) and undertakings carrying out the production of articles, as defined in Article 3, point (3), of that Regulation, from substances or mixtures.

[1] The NIS2 Directive is available at: https://eur-lex.europa.eu/legal-content/DE/TXT/HTML/?uri=CELEX:32022L2555&qid=1701438755083#ntr2-L_2022333DE.01014801-E0002.

1.2. Definition according to the German Act Implementing EU NIS2 and Strengthening Cybersecurity (NIS2UmsuCG)

In the discussion paper of the German Federal Ministry of the Interior and Homeland for economic regulations for the implementation of the NIS2 Directive in Germany[2], the wording of the NIS2 Directive in Annex 2 No. 3 "Manufacture, production and distribution of chemicals" is adopted word for word:

> *„Unternehmen im Sinne des Artikels 3 Nummern 9 und 14 der Verordnung (EG) Nr. 1907/2006 des Europäischen Parlaments und des Rates, die Stoffe herstellen und mit Stoffen oder Gemischen handeln, und Unternehmen, die Erzeugnisse im Sinne des Artikels 3 Nummer 3 der genannten Verordnung aus Stoffen oder Gemischen produzieren." [Undertakings carrying out the manufacture of substances and the distribution of substances or mixtures, as referred to in Article 3, points (9) and (14), of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2) and undertakings carrying out the production of articles, as defined in Article 3, point (3), of that Regulation, from substances or mixtures].*

2. Definition of terms in compliance with the REACH Regulation

2.1. Substances, mixtures and articles

With regard to the objects of consideration (i.e. the products), the REACH Regulation[3] differentiates between substances or mixtures on the one hand and articles on the other. The distinction between these objects of consideration is made on the basis of the composition and the respective function:

- Chemical substances, mixtures and elements are referred to as **(chemical) substances or mixtures** (see Art. 3 No. 1 REACH Regulation).

- **Articles**, on the other hand, are objects that fulfil their function primarily due to their external properties (shape, surface, design), so that the chemical composition is less relevant for this function.

- **Complex objects** (not defined in the REACH Regulation) are objects that consist of several articles. Based on the case law of the European Court of Justice *("once an article, always an article")*, an article remains an article even if, for example, it is installed or used in a complex object or combined with other articles.

The following objects of reflection can be used as an example for categorisation in accordance with the REACH Regulation:

[2] The position paper is available at: https://www.bmi.bund.de/SharedDocs/gesetzgebungsverfahren/DE/Downloads/referentenentwuerfe/CI1/NIS-2-UmsetzungWirtschaft_DisP.pdf?__blob=publicationFile&v=2.

[3] The REACH regulation is available at: https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:02006R1907-20230806.

Object of reflection	Classification in accordance with the REACH regulation	Reasons
Adhesive (as an adhesive substance; in liquid or solid form)	Substance or mixture	Adhesives consist of one or more chemicals to permanently bond objects together. The decisive factor for this function is not so much the shape or consistency, but rather the composition of the chemicals and their adhesive properties.
Wax crayon	Mixture	A wax crayon consists of wax and colour pigments to apply colour to paper. The composition of the wax and colour pigments is more important for this function than the shape of the crayon.
Spiral drill head	Article	A drill head is an object made from a stable material that is shaped in such a way as to enable the drilling of holes in various materials. The shape of the drill head is more important in achieving this functionality than the composition of the material (metal).
Insulated wire	Article with an insulating substance or mixture	The insulated wire is produced by "applying" a molten insulating chemical substance (mixture) to the metal wire. The function of the insulated wire, on the other hand, is primarily fulfilled by its surface or shape.
Electrical cables with, or made from, insulated wires	Complex object consisting of several articles	The molten mixture is applied to the wires to obtain an insulated wire (article). Several articles (insulated wires) are joined together and united by a cable sheath to form an electric cable. The electrical cable is therefore a complex object consisting of several articles (insulated wires).

The European Chemicals Agency (ECHA) has compiled information that explains the difference between substances, mixtures and articles.[4]

3. Economic actors

By referring to the definitions of the REACH Regulation, the following economic actors fall within the scope of the NIS2 Directive:

- **Manufacturer:** A natural or legal person established in the Community who manufactures a substance in the Community.

- **Distributor:** A natural or legal person established in the Community who only stores a substance on its own or in a mixture and makes it available on the market to third parties, including retailers.

[4] See ECHA, Guidance on the requirements for substances in articles, available at: https://echa.europa.eu/-/guidance-on-requirements-for-substances-in-articles

- **Companies** that produce objects that are provided with a specific shape, surface or design during production that determines the function of the object to a greater degree than that of the chemical composition.

However, the following economic actors defined in the REACH Regulation are not included:

- **Importers:** natural or legal persons with a head office established in the Community who are responsible for imports *(author's note: of substances, mixtures or articles*).

- **Downstream user:** any natural or legal person with a head office established within the Community who uses a substance on its own or in a mixture in the course of their industrial or commercial activities without being a manufacturer or importer of such a substance or mixture.

- **Distributors** or other actors in the supply chain who place articles on the market.

4. Statistical analysis based on NACE C (manufacturing industry)

An exact number of companies cannot be determined at present. Conversely, it is also very difficult for companies to determine whether they are affected by NIS2. Alternatively, it could be possible to use the number of enterprises in the "manufacturing sector" in accordance with NACE since enterprises in this sector can, in principle, be regarded as manufacturers of articles in accordance with ANNEX II No. 3. In addition, other economic sectors may also fall within the scope of ANNEX II No. 3.

4.1. In the European Union

Eurostat provides the following statistics:

"Enterprise statistics by size class and NACE Rev.2 activity (from 2021 onwards) [sbs_sc_ovw__custom_10500298]"[5]

The dataset provides a provisional overview of the manufacturing industry in the European Union (Section C), with approximately 2.13 million companies in the manufacturing industry in total (provisional for 2022).

Of these 2.13 million European manufacturers, 77,966 companies would fall within the scope of the NIS2 Directive given that all Section C divisions would be considered manufacturers of substances, mixtures or articles. Of these 77,966 European manufacturers, more than 62,000 companies are SMEs, which means 80 percent of European manufacturers affected by the NIS2 regulation have less than 250 employees.

EU manufacturing industry in total (2022):	2,129,253 companies
- NIS2 - more than 50 employees:	77,966 companies
- NIS2-SME - 50-249 employees:	62,242 companies
- Percentage of SMEs in scope of NIS2:	79,83% are SMEs

[5] https://ec.europa.eu/eurostat/databrowser/product/page/sbs_sc_ovw__custom_10500298

Data extracted on 21/03/2024 09:49:22 from [ESTAT]		
Dataset:	Enterprise statistics by size class and NACE Rev.2 activity (from 2021 onwards) [sbs_sc_ovw__custom_10500298]	
Last updated:	01/03/2024 23:00	
Time frequency		Annual
Economical indicator for struct		Enterprises - number

TIME			2022							
SIZE_EMP (Labels)			Total		From 50 to 249 persons employed		250 persons employed or more		NIS2 relevant	
GEO (Labels)	NACE	NACE Label	Total		50-250		250+		50+	
European Union - 27	C	Manufacturing	2.129.253	p	62.242	p	15.724	p	77.966	
European Union - 27	C10	Manufacture of food products	271.066	p	8.879	p		c	8.879	
European Union - 27	C11	Manufacture of beverages	35.000	ep	900	ep	250	p	1.150	
European Union - 27	C12	Manufacture of tobacco products		c	31	p	39	p	70	
European Union - 27	C13	Manufacture of textiles	65.075	p	1.670	ep		c	1.670	
European Union - 27	C14	Manufacture of wearing apparel	132.152	p	1.900	ep	235	p	2.135	
European Union - 27	C15	Manufacture of leather and related products	34.000	ep	1.080	ep	169	p	1.249	
European Union - 27	C16	Manufacture of wood and of products of wood and cork, except furniture; manu	160.051	p	2.040	ep	333	p	2.373	
European Union - 27	C17	Manufacture of paper and paper products	18.559	p	1.470	p	470	ep	1.940	
European Union - 27	C18	Printing and reproduction of recorded media	101.937	p	1.300	p	166	p	1.466	
European Union - 27	C19	Manufacture of coke and refined petroleum products	848	p	82	p	75	p	157	
European Union - 27	C20	Manufacture of chemicals and chemical products	31.000	ep		c		c	0	
European Union - 27	C21	Manufacture of basic pharmaceutical products and pharmaceutical preparations	4.000	p	577	p	500	p	1.077	
European Union - 27	C22	Manufacture of rubber and plastic products	55.416	p	4.947	p	1.089	p	6.036	
European Union - 27	C23	Manufacture of other non-metallic mineral products	90.827	p	2.541	p	764	p	3.305	
European Union - 27	C24	Manufacture of basic metals	14.524	p	1.400	ep	600	p	2.000	
European Union - 27	C25	Manufacture of fabricated metal products, except machinery and equipment	403.485	p	10.154	p	1.403	p	11.557	
European Union - 27	C26	Manufacture of computer, electronic and optical products		c	2.000	p		c	2.000	
European Union - 27	C29	Manufacture of motor vehicles, trailers and semi-trailers		c	1.830	ep	1.100	p	2.930	
European Union - 27	C30	Manufacture of other transport equipment	14.821	p	831	p	330	ep	1.161	
European Union - 27	C31	Manufacture of furniture	130.000	ep	2.109	p	410	ep	2.519	
European Union - 27	C32	Other manufacturing	170.000	ep	1.702	p	400	ep	2.102	
European Union - 27	C33	Repair and installation of machinery and equipment	220.000	ep		c	400	p	400	
European Union - 27	C27	Manufacture of electrical equipment	42.100	ep	2.633	p	984	p	3.617	
European Union - 27	C28	Manufacture of machinery and equipment n.e.c.	80.000	p	7.079	p	1.900	p	8.979	

4.2. In Germany

The Federal Statistical Office of Germany provides the following statistics:

"*42271-0005: Employees and turnover of companies in the manufacturing industry: Germany, years, employee size classes, economic sectors (WZ2008 2-/3-/4-digit)*"[6]

The statistics provide an overview of the manufacturing industry in Germany (Section C), which comprised around 46,000 companies in 2022. Of these 46,000 companies, 22,646 companies would fall within the scope of the NIS2 Directive given that all Section C divisions would be considered manufacturers of substances, mixtures or articles. There is also an overlap with other sectors in Annex II, for example mechanical engineering (ANNEX II No. 5d) or vehicle construction (ANNEX II No. 5e). A corresponding statistic has been included in the table.

WZ2008 (2-digit; 2022): Manufacturing industry	**Total companies**	**NIS2 affected (>50 EE)**	**of which NIS2 50-250 EE**
WZ08 - Section C total NIS2 relevant	46,019	22,646 (49%)	17,835 (79%)
WZ08 - Section C <u>without</u> sectors already covered (C26-C30 and C33)	**31,210**	**14,353 (46%)**	**11,722 (82%)**
WZ08-10 Manufacture of food products and animal feed	5,635	2,382 (42%)	1,882 (79%)

[6] *<u>Economic sectors (WZ2008 2-/3-/4-digit)</u>*

WZ2008 (2-digit; 2022): Manufacturing industry	Total companies	NIS2 affected (>50 EE)	of which NIS2 50-250 EE
WZ08-11 Manufacture of beverages	558	314 (56%)	260 (83%)
WZ08-12 Manufacture of tobacco products	24	18 (75%)	11 (61%)
WZ08-13 Manufacture of textiles	699	352 (50%)	321 (91%)
WZ08-14 Manufacture of wearing apparel	202	106 (52%)	85 (80%)
WZ08-15 Manufacture of leather, leather products and footwear	121	53 (44%)	39 (74%)
WZ08-16 Manufacture of wood and cork products, manufacture of articles of straw and plaiting materials (except furniture)	1,205	430 (36%)	351 (82%)
WZ08-17 Manufacture of paper, paper products, and items thereof	891	616 (69%)	482 (78%)
WZ08-18 Manufacture of printing, reproduction of sound, image and data carriers	1,140	453 (40%)	412 (91%)
WZ08-19 Manufacture of coke and refined petroleum products	67	52 (78%)	27 (52%)
WZ08-20 Manufacture of chemicals and chemical products	1,717	1,097 (64%)	820 (75%)
WZ08-21 Manufacture of pharmaceutical products	364	259 (71%)	144 (56%)
WZ08-22 Manufacture of rubber and plastic products	3,300	1,917 (58%)	1,592 (83%)
WZ08-23 Manufacture of glass and glassware, ceramics; processing of stone and earth	3,297	1,002 (30%)	862 (86%)
WZ08-24 Metal production and processing	1,015	716 (71%)	484 (68%)
WZ08-25 Manufacture of fabricated metal products	8,115	3,432 (42%)	2,985 (87%)
WZ08-26 Manufacture of data processing, electronic and optical articles	*2,010*	*1,165 (58%)*	*886 (76%)*
WZ08-27 Manufacture of electrical equipment	*2,261*	*1,358 (60%)*	*991 (73%)*
WZ08-28 Mechanical engineering	*6,254*	*3,646 (58%)*	*2,724 (75%)*
WZ08-29 Manufacture of motor vehicles, trailers and semi-trailers	*1,335*	*911 (68%)*	*544 (60%)*
WZ08-30 Other vehicle construction	*382*	*245 (64%)*	*135 (55%)*

WZ2008 (2-digit; 2022): Manufacturing industry	Total companies	NIS2 affected (>50 EE)	of which NIS2 50-250 EE
WZ08-31 Manufacture of furniture	994	441 (44%)	377 (85%)
WZ08-32 Manufacture of other goods	1,866	712 (38%)	588 (83%)
WZ08-33 Repair and installation of machinery and equipment	*2,567*	*969 (38%)*	*833 (86%)*

5. Suggested wording for the specification

The wording in the NIS2 Directive must be viewed critically in light of the definitions in the REACH Regulation as a whole. There are sufficient starting points for a justified deviation from the national formulation, which are explained in Chapter 6.

5.1. German version

Current version	Suggested wording
Unternehmen im Sinne des Artikels 3 Nummern 9 und 14 der Verordnung (EG) Nr. 1907/2006 des Europäischen Parlaments und des Rates (2), die Stoffe herstellen und mit Stoffen oder Gemischen handeln, und Unternehmen, die Erzeugnisse im Sinne des Artikels 3 Nummer 3 der genannten Verordnung aus Stoffen oder Gemischen produzieren.	Hersteller und Importeure im Sinne des Artikels 3 Nummern 9 und 11 der Verordnung (EG) Nr. 1907/2006 des Europäischen Parlaments und des Rates von chemischen Stoffen und Gemischen im Sinne des Artikels 3 Nummern 1 und 2 der genannten Verordnung.

5.2. English version

Current version	Suggested wording
Undertakings carrying out the manufacture of substances and the distribution of substances or mixtures, as referred to in Article 3, points (9) and (14), of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2) and undertakings carrying out the production of articles, as defined in Article 3, point (3), of that Regulation, from substances or mixtures.	Manufacturers and importers as referred to in Article 3, points 9 and 11 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of substances and mixtures as defined in Article 3 points 1 and 2 of aforementioned Regulation.

6. Reasons

6.1. No restriction on the relevant economic actors

The text of the Directive under ANNEX II No. 3 of the NIS2 Directive does not provide for a restriction with regard to certain aspects of the REACH Regulation. This means that a yet undetermined number of European manufacturers are covered by this point. In principle, all manufacturers of substances, mixtures and articles are subject to ANNEX II No. 3 of the NIS2 Directive, unless they are exempted from application as micro and small enterprises due to the size of their company.

6.2. Inconsistent differentiation of the relevant business activities due to the reference to the REACH Regulation

Due to the interpretation and explanation in ANNEX 2 No. 3 of the NIS2 Directive, there is considerable legal uncertainty regarding the scope of application of the NIS2 Directive. The REACH Regulation does not differentiate between manufacturers of articles made from substances and mixtures and manufacturers of "other" articles.

For the purposes of the REACH Regulation, machinery manufacturers and manufacturers of components for machinery are, generally speaking, manufacturers of articles or complex objects. According to the definition and regulatory system of the REACH Regulation, there are very few conceivable scenarios in which a manufacturer of an article does not simultaneously use substances or mixtures. In case of doubt, the scope of application of the NIS2 Directive is therefore opened solely by the fact that a chemical substance or a mixture (e.g. as a lubricant) is used in one of the production steps. According to this understanding, economic actors who do not explicitly carry out economic activities in the sectors listed in the Annex would also fall under the NIS2 Directive.

6.3. Contradiction to the sector category in the NIS2 Directive

Contrary to the heading "Manufacture, production and distribution of chemicals", which is relevant for ANNEX II No. 3, the explanation also includes undertakings that produce articles. This results in a contradiction to the wording of the NIS2 Directive, which leads to a significant expansion of the scope of application and thus to a considerable increase in the number of undertakings affected.

6.4. Regulatory gaps in the NIS2 Directive

The criticality of chemical substances and mixtures in relation to the NIS2 Directive has already arisen by the time these chemicals enter the market. While this time is taken into account for manufacturers, imports are not included. A company that imports chemical substances into the EU would therefore only be affected by the requirements of the NIS2 Directive if it distributes the chemical substances or manufactures products from them. However, if the company uses chemicals that have been imported by someone else as part of its industrial or commercial activity, it assumes the role of a downstream user within the meaning of Art. 3 No. 13 of the REACH Regulation and would not be affected by the NIS2 Directive.

This regulatory gap cannot be closed since distribution of chemical substances and mixtures and the manufacture of articles are to be covered. These actions presuppose that a chemical substance has already been manufactured or imported. Since manufacturers are obliged to do so anyway, the involvement of downstream market players is superfluous. In the case of imports, distribution of materials and the manufacture of articles cannot fully close the resulting gap.

7. Contacts, further information and help

7.1. NIS2 Quick-Check

The Quick Check provided by the law firm reuschlaw is a simple and free option for checking whether you are affected: The NIS2 Quick-Check uses simple questions to guide you through the requirements and exemptions in relation to whether the NIS2 Directive is applicable, and enables companies and organisations to draw up an initial assessment of their compliance with NIS2.

EN: www.nis2-check.com

DE: www.nis2-check.de

7.2. VDMA NIS2 working group

The VDMA NIS2 working group focuses on addressing the practical implementation of requirements from the NIS2 Directive. The working group is the first point of contact for the implementation of NIS2 in medium-sized industrial companies in the VDMA and, as part of the VDMA Competence Centre Industrial Security, the primary body for the security practices of medium-sized industrial companies vis-à-vis its members, authorities and standardisation organisations. Participants are member companies with up to 500 employees that fall within the scope of application in accordance with Annex 2 of NIS2. The working group is currently developing an SME-compliant implementation guidance of the Directive requirements.

vdma.org/cybersecurity

Author

The VDMA is the leading organisation of the German machinery and equipment manufacturers industry and the largest industry association in Europe. With more than 3,600 members, the majority of which are medium-sized companies, it represents more than 90% of the total turnover of Germany's largest industrial sector in terms of employment. The association is a platform of 36 trade associations and represents the entire value chain of the capital goods industry, from components to complete systems and from system suppliers to service providers.

Among other things, the VDMA and its members are committed to training young people, to research and development and to climate-neutral production and sustainability, as well as reducing subsidies in the corporate sector. The association is committed to the sustainable development of public finances, deregulation and the elimination of bureaucracy, as well as investment-friendly framework conditions.

reuschlaw is one of the leading commercial law firms in product liability law and has been advising national and international companies and public bodies since 2004. It specialises in product safety law, product liability law, data protection & cybersecurity, recall management, insurance law, compliance management and contract law. In addition to the two branches in Germany, the law firm now offers its services in a further 30 countries via its network.

Latest German version: 05.02.2024

Latest English version: 12.04.2024

VDMA: Steffen Zimmermann, steffen.zimmermann@vdma.org

reuschlaw: Stefan Hessel, stefan.hessel@reuschlaw.de