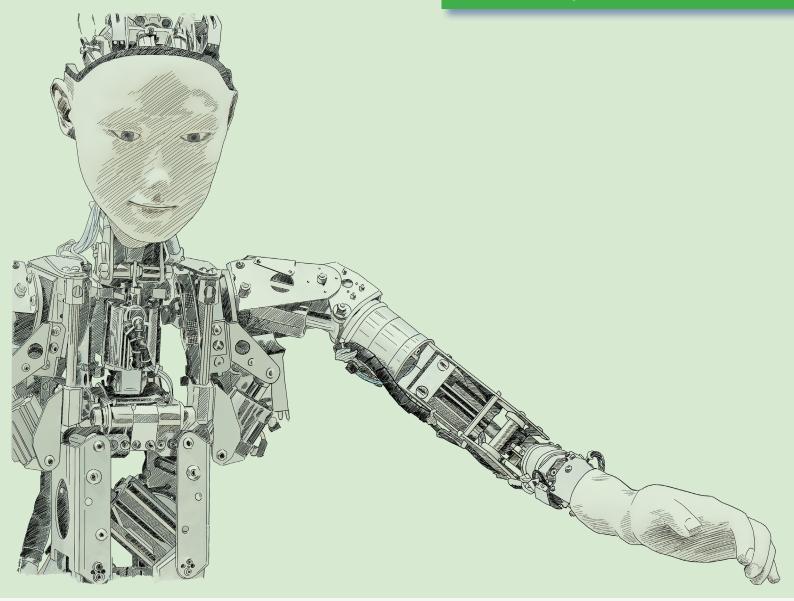
Technical report

March 2023



Challenges and opportunities with the EU Taxonomy Regulation

- with focus on chemical safety and usage in complex products

Kristina Andersson, Anna-Karin Hellström and Jenny Lundahl



A report from the Mistra SafeChem Program

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Summary

The use of Policy Lab processes has been growing in Sweden and other countries to accelerate the adaptation of regulations to emerging technologies. Policy Lab facilitates active collaboration between relevant authorities, companies, and stakeholders through interactive and iterative methods based on Design Thinking principles. This approach bridges the gap between the legislative domain responsible for developing regulatory frameworks and the innovative companies that create solutions for emerging markets using new technologies and opportunities.

In our study, we applied Policy Lab processes to the EU Taxonomy Regulation to identify challenges and opportunities related to chemical safety and usage for manufacturers of complex products. The EU Taxonomy Regulation, along with its delegated acts, represent a serious effort to establish standardized sustainability reporting within EU. However, it is still in its early stages and lacks maturity. Moreover, certain ambiguities within the regulation currently prevent a comprehensive comparison of companies due to the development of other legislations. Addressing these gaps depends on the future development of, for example, REACH. Our conclusion is that the EU Taxonomy Regulation is part of a larger "movement" that reflects the policymakers' intentions. This intention also includes increased data sharing at a significantly different level compared to current practices. In the long run, the shift will enable authorities to access the data and develop new legislations.

Our specific focus was on the objective of pollution prevention and control regarding the use and presence of hazardous substances listed in Appendix C of the EU Taxonomy Regulation. According to Appendix C, activities must not lead to the manufacture, placing on the market or use of listed substances, whether on their own, in mixture or in articles. Regarding listed substances, reference is made to existing EU legislation that regulates hazardous substances within the EU. The most challenging aspect in Appendix C is point (g), which aims to identify substances, whether alone, in mixtures, or in articles, that meet the criteria set out in Article 57 of REACH but are not yet included in the Candidate list. Our workshops, interviews, and literature review confirmed that the main challenge in meeting the criteria of Appendix C, specifically point (g) is the need to enhance transparency and traceability throughout supply chains. Overcoming these challenges requires addressing barriers, such as the lack of a harmonized regulatory framework across the value chain, the need for faster identification and restriction of hazardous substances, and the reinforcement of stronger enforcement measures. The enabling of full declaration of the hazardous properties and functions of the substances, while considering the balance between information disclosure and protecting trade secrets, would reduce the need for extensive tracking of substance of very high concern along the value chain.

To improve communication along the value chain and identify data gaps while protecting trade secrets, workshop participants have proposed the use of a user-friendly interface based on traffic light scenario. This interface would serve as a filter mechanism, allowing product manufacturers to establish specific criteria for material suppliers to respond to. The objective is to enhance communication, establish criteria, and effectively identify data gaps. While the SCIP database ensures accessibility of information on articles containing substances from the Candidate List above 0.1 w/w%, it is limited to hazardous substances on that list. This means that hazardous substances not listed in the Candidate List may not be covered by the database. The EU Commission has proposed the implementation of a digital product passport to enhance information sharing about products and their supply chain, including substances of concern.

Our study is conducted under the Mistra SafeChem program, where screening tools for hazard and exposure assessment of substances are currently being developed. These tools aim to provide screening data for direct decision-making based on the Defined Approach (DA). These screening tools have the potential to contribute to filling data gaps during the early design phases of complex products, particularly when screening for multiple material alternatives.

Definitions and abbreviations

Authorization list	List of substances included in Annex XIV of REACH	
Candidate list	List of chemicals that are identified as SVHC	
Complex product	Products made up of more than one article	
Substances of Very High Concern (SVHC)	Certain hazardous chemicals that should be replaced by less dangerous	

Foreword

Mistra SafeChem is a research program for green and sustainable chemical industry. It aims to create a sustainable chemical industry and reduce exposure to hazardous substances. The program is financed by Mistra, the Swedish Foundation for Strategic Environmental Research, and runs from 2020 to 2024.

This report is a deliverable within the Mistra SafeChem program. It describes the challenges and opportunities related to the EU Taxonomy Regulation concerning the safety and usage of chemicals in complex products. The EU Taxonomy Regulation is a new framework through which companies can classify environmentally sustainable economic activities and report externally on the share of turnover and expenditures that are sustainable. The regulation aims to enable investors and the market to identify businesses that are transitioning towards an economy aligned with the environmental objectives of the EU.

We would like to thank everyone who contributed to this report.

This report reflects the situation as of March 2023. Any changes that occurred after this date have not been considered in this report.

We would like to emphasize that the views and standpoints in this report are the authors' alone. Other parties or representatives may have a different analysis and come to different conclusions.

Gothenburg, March 2023

The authors

1. Overview of the project

1.1 Project layout

To achieve the EU's climate and energy targets for 2030 and fulfil the objectives of the European Green Deal, investments must be directed towards sustainable projects and activities. The Action Plan on Financing Sustainable Growth highlights the importance of establishing a unified classification system, referred to as the "EU taxonomy", for sustainable economic activities. The EU Taxonomy Regulation is a new framework for companies to classify environmentally sustainable economic activities and report externally on their sustainable turnover and expenditures. It has a broad scope and covers numerous activities, each with corresponding rules.

The purpose of this project was to map the challenges and opportunities associated with the new EU Taxonomy Regulation, particularly on the objective of pollution prevention and control concerning the use and presence of hazardous substances. Additionally, the project aimed to explore various pathways for addressing these challenges.

The project was conducted in three steps. First a literature review was performed to examine supporting legislations. In the second step, interactive workshops and interviews were performed, based on the Policy lab process involving various stakeholders. Finally, in the last step, an analysis was performed to explore potential ways forward.

This report aims to assist companies in understanding the EU Taxonomy Regulation related to chemical safety and usage of complex products. It also explores how relevant acts and legislation can be effectively utilized to address the challenges and opportunities associated with the new EU Taxonomy Regulation.

Furthermore, this report is subject to limitations focusing only on the chemical safety and usage sections of the EU Taxonomy Regulation for large companies (500+ employees) involved in the manufacturing of complex products. It does not consider the regulation's impact on other aspects of a company's business, such as providing a service, which is regulated in other sections of the taxonomy. Additionally, the report addresses the impact of the Taxonomy on product development rather than the company as a whole.

1.2 Policy Labs

In Sweden and in other countries, so-called Policy Labs¹ have merged to accelerate the adoption of regulations in response to technology advancements through interactive and iterative methods. The concept of Policy Lab has its origins in the question "Can you work with policy and regulatory development in a better way than today?" Key features of Policy Labs include co-creation, iteration, and agility. Policy Labs are characterized using design thinking methods where new solutions are explored from a user perspective, involving relevant stakeholders to incorporate diverse viewpoints. Instead of pursuing a perfect, static solution to a problem, these methods prioritize experimentation, developing prototypes and pilots that are tested in a real environment through iterative "sprints".

¹ Fuller, A Lorchard M. 2016. "Public Policy Labs in European Union Member States." Publications Office of the European Union (June): 18.

http://blogs.ec.europa.eu/eupolicylab/files/2016/10/Mapping-policy-labs-in-EU-MS.pdf

Following several iterations, they are eventually scaled up²; ³; ⁴; ⁵. Other important characteristics of Policy Labs are:

- Interdisciplinarity: Working groups consist of experts from different disciplines to obtain a better holistic view. This helps overcoming the prevailing silo structures characteristic of public institutions.
- Co-design: Also called co-creation, it refers to the idea that public services or policies should not be designed for citizens but with them. This contributes to increased acceptance and transparency in decision-making.
- Agility: It implies a higher degree of adaptability and flexibility but should not be confused with a lack of planning. Agility is best suited for problems with inherent high uncertainty and nonlinearity.

www.sciencedirect.com/science/article/pii/S0740624X16301101

² Junginger, Sabine. 2016. Transforming Public Services by Design: Reorienting Policies, Organizations and Services around People.

³ Mergel, Ines. 2016. "Agile Innovation Management in Government: A Research Agenda." Government Information Quarterly33(3): 516–23.

⁴ Hagy, Shea, Gregory M. Morrison, and Peter Elfstrand. 2017. "Co-Creation in Living Labs." In Living Labs, Cham: Springer International Publishing, 169–78. http://link.springer.com/10.1007/978-3-319-33527-8_13 (February 13, 2017)

⁵ Keyson, David V., Gregory M. Morrison, Carolin Baedeker, and Christa Liedtke. 2017. "Living Labs to Accelerate Innovation." In Living Labs, Cham: Springer International Publishing, 55–61. http://link.springer.com/10.1007/978-3-319-33527-8_5 (February 13, 2017).

2. Overview of current policies and legislations

This report focuses on the EU Taxonomy Regulation and its relevance to the manufacturing, importing, and selling of complex products. Companies involved in these activities must consider various regulations, depending on factors such as the specific chemicals and materials used in the product, intended product use, and the target market.

Key EU legislation governing chemicals includes the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation⁶, which contains rules on registration of chemicals, bans or other restrictions on chemicals, requirements for permits for particularly hazardous substances, and rules about informing customers. Another EU regulation that may be relevant is the Classification, Labelling and Packaging (CLP) Regulation⁷, which sets out rules for the classification and labelling of substances to ensure that consumers and workers are properly informed about their hazards. In addition to EU-level regulations, companies selling complex products may also consider national regulations on substances, as well as any international regulations that may apply. Furthermore, the Ecodesign Directive⁸ may also be relevant if the complex products are intended to be marketed as environmentally sustainable.

The EU Taxonomy Regulation is a classification system that aims to assist investors and companies in understanding which economic activities that can be considered environmentally sustainable. It provides a common language and set of criteria for evaluating the environmental performance of various economic activities, including the production and use of products. The Ecodesign Directive aims to reduce the environmental impact of products throughout their lifecycle, from raw material extraction to disposal. It establishes mandatory requirements for the energy and resource efficiency of certain energy-using products and establishes a framework for the development of voluntary Ecodesign requirements for other products. If a company is selling a complex product and wants to market it as environmentally sustainable, it may need to consider how the product compares to the criteria set out in the EU Taxonomy Regulation and/or the Ecodesign Directive. Furthermore, it may be necessary to provide information on the product's environmental performance to potential customers.

These regulations are described in more details in the following paragraphs.

2.1 The EU Taxonomy Regulation and REACH

The foundation for environmental regulations can be traced back to the United Nations Paris Climate Agreement of 2015, which involved 196 parties committed to limiting global warming to well below 2 degrees Celsius and preferably 1.5 degrees Celsius, compared to pre-industrial levels. In 2020 the European Green Deal was approved by EU, with the aim of achieving climate neutrality by 2050 ⁹.

⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restrictions 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.

⁷ 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.

⁸ Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (recast).

⁹ Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, the European Green Deal, 11.12.2019, COM (2019) 640 final.

This requires the adoption of several legislative measures aimed at meeting the objectives of the Green Deal.

The EU Taxonomy Regulation¹⁰ is an initiative undertaken by the EU to reduce greenhouse gas emission in accordance with the Paris Agreement and the Green Deal. To achieve the objectives of these agreements, significant investments, both public and private, are required. The regulation aims to guide investors towards environmentally sustainable investments by providing a harmonized legislative framework that enables comparison of different companies and prevent greenwashing. By fulfilling the requirements of the regulation, a company can demonstrate its genuine commitment to sustainability. However, it should be noted that the regulation does not force companies to become more environmentally friendly. Instead, it requires companies to report their environmental performance in a standardized manner.

There are other initiatives around the world aimed at creating a green Taxonomy, and the EU hopes that its regulation can inspire other countries outside of the EU to reach a global consensus.

The EU Taxonomy Regulation requires companies with more than 500 employees to report on how their economic activities are associated with environmentally sustainable activities, and this reporting is mandatory. The purpose of the regulation is to facilitate investors in comparing different companies and to prevent greenwashing. All companies subject to the regulation must include a description in their public report (i.e., annual reporting) of how and to what extent their economic activities are associated with the Taxonomy-aligned activities. They are required to disclose the proportion of their turnover and capital expenditures that comply with the regulation (capex and opex). Additionally, voluntary disclosers can also be made, such as project-specific disclosures. Companies were required to start reporting in the autumn of 2022 for some parts of the regulation and for other parts in 2023. Companies with less employees than 500 may voluntarily comply with the regulation by reporting in accordance with the taxonomy, which can help attract investors. It is mandatory for companies to report on how and to what extent their activities are associated with economically sustainable activities based on the technical screening criteria of the EU Taxonomy Regulation. However, companies are not obligated to meet this environmental sustainability standards, but they must report how they stand according to the EU Taxonomy Regulation. Nonetheless, the classification holds significance as investors increasingly prioritize environmentally sustainable investments and tend to choose businesses classified as such.

In order to facilitate the comparison of different companies, the regulation provides definitions for economic activities classified as environmentally sustainable (Articles 1 and 2). For a specific economic activity to be classified as environmentally sustainable, it must make a significant contribution to one of the six environmental objectives, not cause significant harm to any of the other five objectives and meet certain minimum requirements for sustainability (Articles 3 and 17).

The environmental objectives are (Article 9):

(a) climate change mitigation (the same as the goal in the Paris Agreement);

(b) climate change adaptation (the process of adjustment to actual and expected climate change and its impacts);

- (c) the sustainable use and protection of water and marine resources;
- (d) the transition to a circular economy;
- (e) pollution prevention and control;
- (f) the protection and restoration of biodiversity and ecosystems.

¹⁰ Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088

The regulation itself does not define each objective. Instead, the European Commission will issue technical screening criteria for each objective through delegated acts in different areas. Currently, technical screening criteria have been issued for the two climate-related aims: (a) climate change mitigation and (b) climate change adaptation¹¹. The remaining criteria will be introduced throughout 2023. These technical screening criteria are also intended to be regularly adapted. Furthermore, according to the regulation an economic activity must also meet some minimum safeguard, i.e., business and human rights (Articles 3 and 18).

The technical screening criteria issued by the European Commission are divided into two Annexes (Annex 1 and 2) in the delegated regulation. Annex 1 focuses on climate change mitigation, while Annex 2 pertains to climate change adaptation. Both Annexes 1 and 2 encompass an extensive list of criteria to be applied to different industry sectors. These sectors are selected due to their significant contribution to greenhouse gas emissions within the EU. Depending on its activities, a company may fall under multiple chapters and make substantial contributions to climate change mitigation and adaptation in various ways. The subsequent question to be addressed is whether the activity causes significant harm to any of the other objectives. Of interest to our study is the objective of pollution prevention and control, which is treated the same in both Annexes 1 and 2.

An activity does not harm pollution prevention and control if several criteria are fulfilled (as listed in Appendix C – generic criteria for do not significant harm to pollution prevention and control regarding use and presence of chemicals). The first criterion (a) is about chemicals listed in Annexes I and II to regulation (EU) 2019/1021 of the European Parliament and of the Council (persistent organic pollutants).¹² These chemicals are not allowed (that is the activity does not lead to the manufacture, placing on the market or use) except in the case of chemicals present as an unintentional trace contaminant. The second criterion (b) is about mercury and mercury compounds that are not allowed. The third criterion (c) is about chemicals, whether on their own, in mixture or in articles listed in Annexes I and II to regulation (EC) No 1005/2009 of the European Parliament and of the Council (chemicals that deplete the ozone layer)¹³. These chemicals are not allowed. The fourth criterion (d) is about chemicals, whether on their own, in mixture or in articles listed in Annexes II to Directive 2011/65/EU of the European Parliament and of the Council (certain hazardous chemicals in electrical and electronic equipment).¹⁴ These chemicals are not allowed with some exceptions.

The three last criteria in Appendix C all have a connection to the REACH-regulation¹⁵. First (e), chemicals, whether on their own, in mixtures or in an article listed in Annex XVII to REACH-regulation are not allowed (with some exceptions, i.e., follow restrictions) because they are considered to be certain hazardous substances. As of this writing there are 71 categories with thousands of substances

¹¹ Commission Delegated Regulation (EU) 2021/2139 of 4 June 2021 supplementing Regulation (EU) 2020/852 of the Parliament and of the Council by establishing the technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to climate change mitigation or climate change adaptation and for determining whether that economic activity causes no significant harm to any other environmental objectives.

¹² Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

¹³ Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

¹⁴ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

¹⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restrictions 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.

on the list. Once a substance is published on the list, companies must comply with the requirements of the restriction. To provide industry and interested parties with sufficient advance notice of the potential restriction, the intention is made public through the Registry of Intentions and published on the ECHA website.

Second (f), chemicals, whether on their own, in mixtures or in an article, meeting the criteria in Article 57 of the REACH-regulation and identified in accordance with Article 59 of the REACHregulation are not allowed except where their use has been proven essential for the society. Article 57 is about the so-called Candidate List of Substances of Very High Concerns for Authorization.

Third (g), chemicals, whether on their own, in mixtures or in an article, meeting the criteria laid down in Art 57 of the REACH-regulation (that is substances meeting the criteria for substances of very high concern) are not allowed except where their use has been proven essential for the society.

The requisites "essential for the society" or "essential use" are not defined legally. The Commission has published a draft notice on answers to frequently asked question¹⁶. According to the Commission, in order to apply the concept of an "essential use for the society", it is necessary to determine whether the concept is applicable, i.e., whether the economic activity leads to the manufacture, placing on the market or use of those chemicals. This information should be obtained through the supply chain, according to the Commission. The Commission is also preparing a horizontal document during 2023 to define criteria for essential use to ensure that the most harmful substances are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health.

Companies that disclose against the regulation will need to assess their compliance with minimum safeguards and assess or check compliance with the technical screening criteria to avoid causing significant harm to environmental objectives. The Swedish Financial Supervisory Authority (Finansinspektionen) is responsible for verifying compliance with the regulation in Sweden.

Between 2018–2020 a Technical Expert Group has been working on recommendations related to the EU Taxonomy Regulation. Among other things the group has provided recommendations on how a company can work with an internal due diligence to show compliance with the Taxonomy.¹⁷ One suggestion is that the company identifies and assesses actual or potential adverse impacts that the business enterprise may cause or contribute to through its own activities, or which may be directly linked to its operations, products or services by its business relationships. The next step is to take measures to prevent these impacts. The company should monitor its performance and communicate its approach to addressing adverse impacts.

2.2 Sustainability Reporting in Annual Accounts Act

The EU Taxonomy Regulation is a part of a larger regulatory framework that addresses sustainability reporting in relation to a company's annual accounts. At the EU-level, two directives are of relevance for this report. As of the current writing, the Non-Financial Reporting Directive (NFRD)^{18,} is to be

¹⁶ https://ec.europa.eu/finance/docs/law/221219-draft-commission-notice-eu-taxonomy-climate.pdf.

¹⁷ EU Technical Expert Group on Sustainable Finance (March 2020) Taxonomy: Final Report of the Technical Expert Group on Sustainable Finance, page 34.

¹⁸ Directive 2014/95/EU of the European Parliament and of the Council of 22 October 2014 amending Directive 2023/34/EU as regards disclosure of non-financial and diversity information by certain large undertakings and groups.

replaced with by the Corporate Sustainability Reporting Directive (CSRD)¹⁹ in the upcoming years. Both directives are and will be implemented in the Swedish Annual Accounts Act (1995:1554).

The NFRD aims to increase transparency so that the economic, social and environmental information provided by companies in all sectors and in all Member States reaches the same high level. By achieving this, sustainability reporting from larger companies becomes more available and comparable. This allows for the analysis of sustainability risk (consequences of its operations) resulting in increased confidence among investors and consumers. The directive therefore includes provisions requiring certain companies to report specific non-financial information. Such sustainability information shall at least address issues related to the environment, social conditions, personnel, respect for human rights and anti-corruption. The companies are required to disclose their business model, policies, the outcome of the policy and the risks associated with their undertakings' activities.

CSRD means that more companies must do sustainable reporting in their annual accounts and during 2024 the reporting of disclosed information on sustainability matters will be standardized. The CSRD will also for example require management to report on the resilience of the company's business model and strategy to sustainability risks as well as report plans to ensure compatibility with the 1.5°C global warming target under the Paris Agreement.

The Swedish Annual Accounts Act (årsredovisningslagen [1995:1554]) is a frame law and the content of the legislation is filled in with good accounting practice (2 chapter 2 §). Currently, the reporting in a sustainability report is not standardized. According to 6 chapter 10 § companies e.g., with more than 250 employees must submit a sustainability report in the annual report²⁰. According to 6 chapter 12 § the sustainability report must contain sustainability information necessary for understanding the company's development, position and results and the consequences of the business, including information on issues relating to the environment, social conditions, staff, respects for human rights and counteracting against corruption. The report must include:

- 1. the company's business model,
- 2. the policy that the company applies in the issue, including the review procedures that has been implemented,
- 3. the outcome of the policy,
- 4. the significant risks that relate to the issue and are linked to the company's operations including, when applicable, the company's business relationship, products or service such as likely to have negative consequences,
- 5. how the company manages the risks, and
- 6. key performance indicators that are relevant to the business.

The report is required to be reviewed by an external part, but the review takes place at a limited level where the auditor only provides an opinion that the report has been prepared in accordance with the law.

The Swedish Annual Account Act also has a link to the EU Taxonomy Regulation. In 6 chapter 12a § the Taxonomy is mentioned as a reminder that the company also must report according to that legislation if it has more than 500 employees.

¹⁹ Directive (EU) 2022/2464 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 537/2114, Directive 2004/109/EC, Directive 2006/43/EC and Directive 2013/34/EU, as regards corporate sustainability reporting.

²⁰ When implementing the NFRD in Swedish law, Sweden chose to let the requirements cover more companies. The requirements in the NFRD only apply to companies of public interest with >500 employees.

2.3 Safe and Sustainable Chemicals by Design

The European Commission adopted its Chemical Strategy for Sustainability (CSS) in 2020²¹. The strategy is a part of the EU's zero pollution ambition which is a key commitment of the European Green Deal. The new long-term vision outlined in the strategy aims to establish a toxic-free environment, where chemicals are produced and used in a way that maximizes their contribution to society, while preventing harm to the planet and to current and future generations. Safe and sustainable-by-design is defined as a pre-market approach to chemicals that focuses on providing a function (or service) while avoiding the use of volumes and chemical properties that may be harmful to human health or the environment.

The toxic-free hierarchy shall also guide management of chemicals. The hierarchy is divided into three parts:

- "Green" is safe and sustainable chemicals that should be promoted.
- "Orange" is chemicals that can harm humans etc. These are to be minimized, tracked and controlled.
- "Red" is chemicals that should not be allowed because they are too dangerous. These are to be eliminated and remediated.

The transition to chemicals and materials that are 'safe and sustainable by design' requires a common understanding of safety and sustainability considerations to be successful. Therefore, the development of a European assessment framework for 'safe and sustainable by design' chemicals and materials becomes essential. This framework can assist in the defining safety and sustainability criteria, to guarantee coherence among actors, sectors and value chains.

In July 2022, the Commission published a technical report proposing the framework²². In December 2022, the EU Commission adopted a recommendation to establish this European assessment framework for 'safe and sustainable by design' chemicals and materials²³. Recommendations are non-binding (Article 288 of the Treaty on the Functioning of the European Union), which means they have no legal consequences. Still, they may offer guidance on the interpretation or content of EU law. Recommendations allow the EU institutions to make their views known and suggest a line of action without imposing any legal obligation on those to whom they are addressed. (A recommendation is not legally binding but is more demanding than advice. Thus, it can serve as an indication for future legislation.)

A set of principles has been defined for the development of the SSbD framework:

- Define a hierarchy that puts safety first, to avoid regrettable substitutions.
- Define cut-off criteria for the design of chemicals and materials to stimulate sustainable research and innovation (R&I), based not only on data referred to in the requirements of EU legislation on chemicals, but also on data that are outside the scope of those requirements.

²¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Chemicals Strategy for Sustainability, towards a Toxic-Free Environment, COM (2020) 667 final of 14 October 2020.

²² European Commission, Joint Research Centre, Caldeira, C., Farcal, L., Garmendia Aguirre, I., et al., Safe and sustainable by design chemicals and materials: framework for the definition of criteria and evaluation procedure for chemicals and materials, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2760/487955

²³ Commission recommendation of 8.12.2022 establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials COM (2022) 8854 final.

- Focus on iteratively minimizing environmental pressures, using dynamic boundaries and cutoffs, so that the framework becomes a tool for managing improvements along the innovation process.
- Ensure optimal use of available data on adverse effects. Every (new) chemical or material should be compared to the full spectrum of structurally or functionally similar chemicals to assess the expected potential to cause negative impact on human health or the environment.
- Communicate SSbD actions taken throughout the supply chain; make all relevant and nonconfidential data available in a findable, accessible, interoperable and reusable (FAIR) format, for greater transparency and accountability and to better discharge the duty of care.
- Promote the use of a coherent framework by the various stakeholders, including industry and policy makers.

2.4 Sustainable product policy and Ecodesign

The Ecodesign Directive

The Ecodesign Directive²⁴ is an EU legislation that aims to reduce the environmental impact of energy-related products throughout their lifecycle, from raw material extraction to disposal. It sets mandatory requirements for the energy efficiency and resource efficiency of certain energy-using products (EuPs) and establishes a framework for the development of voluntary eco-design requirements for other products.

Revision and extension of the Ecodesign directive through SPI

Recently, the European Commission presented a revised Ecodesign Directive under the Sustainable Products Initiative (SPI) with the aim of turning the directive into a regulation²⁵. With this proposal, the EU Commission wants to extend the Ecodesign Directive to as wide a range of products as possible (the current Ecodesign Directive is limited to energy-related products) with the aim of achieving a circular economy and broadening the scope of requirements for products to the entire product life cycle. (However, some products will be excluded, e.g., food and pharmaceuticals.) The SPI is proposed to become a horizontal framework in the form of a regulation with delegated regulations under it. It can be product specific or include several products with similar characteristics. SPI will focus more on product design and the entire value chain than the Ecodesign Directive.

The SPI initiative proposes that the following sustainability aspects be regulated:

- durability and reliability of products
- reusability of products
- product upgradeability, repairability, maintenance and renovation
- presence of potentially harmful chemicals in products
- the product's energy and resource efficiency
- recycled content in products
- remanufacturing and recycling of products
- the products' carbon dioxide and environmental footprint
- the products' expected generation of waste material.

²⁴ Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for setting of ecodesign requirements for energy-related products.

²⁵ Proposal for a regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC, Brussels, March 30, 2022, COM (2022) 142 final.

The proposal also includes areas such as digital product passports, labelling, establishing criteria for environmentally friendly public procurement and a framework to prevent the destruction of unsold consumer products. In the proposal, there is a focus on the economic actors' obligations, market control, product conformity and notification of conformity assessment bodies.

2.5 Legislation about extended producer responsibility and recycling

A producer must already in the product development phase think about how the product can be recycled that is have a life cycle perspective regarding the product. How a product is to be recycled affects the requirements for what is to be developed. There is also legislation that requires producers to collect and recycle products such as:

- Waste from Electrical and Electronic Equipment (WEEE directive)²⁶
- RoHS Directive²⁷
- End of life vehicles directive (ELV directive)²⁸.

2.6 ISO-certification

So far in this chapter we have described different laws and regulations. But ISO 14000 can also be used as a point of reference when companies are selecting business partners from a sustainable point of view. ISO 14000 is a certification about environmental management systems that company voluntarily can apply to and builds on the concept of constant environmental improvement. However, ISO 14000 does not differentiate those companies with solid sustainability efforts from those with weaker efforts.

2.7 Supervision by Swedish Financial Supervisory Authority

The implementation of the EU Taxonomy Regulation necessitated the Swedish government to introduce new legislation to determine which authority would be responsible for its supervision. Ultimately, the Swedish Financial Supervisory Authority was selected for this role.

We have interviewed employees at the Swedish Financial Supervisory Authority about the current situation and their supervision regarding the EU Taxonomy Regulation. In general, their supervision is risk-based which means that they allocate their resources where the risk is perceived as high and where the consequences can be significant. A central part of the supervisory activities is to review and analyze regulatory compliance and the ability of actors to comply with relevant rules. Another part of the supervision is supervisory dialogues with firms. The Taxonomy Regulation is a new regulatory framework, which is why the authority initially has been focusing on dialogue with undertakings to support the implementation, among other things. Since the Taxonomy Regulation is an EU regulatory framework, harmonizing supervision within the EU is also crucial. The initial focus within the EU is to examine whether firms are providing the information that the regulations stipulate and that it is reasonable and fair.

²⁶ Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).

²⁷ Directive 2011/65/EU of the European Parliament and of the Council of 4 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

²⁸ Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles

3 Results and Discussion

3.1 User experience

We conducted a series of workshops with employees involved in product development within a large company (500+ employees) and interviews with other stakeholders from the industry, non-profit organizations and authorities to gather their insights from their experiences of the EU Taxonomy Regulation. The focus of these workshops and interviews has been on chemicals, specifically understanding the meaning of the requirements in article e-g, Appendix C, in Annex 1 and 2 to the technical screening criteria.

During these sessions several challenges were identified:

- 1) The prerequisite "essential for the society" is not legally defined, leading to different interpretations of the term.
- 2) No concentration limits are specified, except for point (a) and (b)
- 3) The criterion in point (g) aims to broaden the list of substances potentially subject to Appendix C. This criterion aims to identify substances – whether on their own, in mixtures or in an article – that fulfill the criteria outlined in article 57 of REACH but that are not yet included in the Candidate list. This presents a challenge.
- 4) Challenges in transparency and traceability of hazardous substances within the supply chain. Material suppliers need to determine the extent of information they should disclose to establish trustworthiness in their claims and ensure transparency within the supply chain while at the same time protecting their own trade secrets. Similarly, manufacturers of complex products need to know how much information to request from material suppliers to back up their claims and meet their customer demands for transparency.

To overcome these challenges, especially those related to point 3) and 4), workshop participants and interviewees addressed three key regulatory barriers. First, they highlighted the absence of a harmonized regulatory framework along the value chain as a significant obstacle. Secondly, they emphasized the importance of expediting the identification and restriction of hazardous substances. Lastly, they underscored the need for implementing stronger enforcement measures, which have the potential to accelerate the phase-out of substance of very high concern and reduce the necessity for extensive tracking of hazardous chemicals along the value chain.

Enabling the full declaration of hazardous properties and functions of the substances, while considering the balance between information disclosure and protecting trade secrets would facilitate traceability of hazardous substances. To enhance the communication and transfer of data along the supply chain while protecting trade secrets, the participants proposed the implementation of a user-friendly traffic light scenario based on the signals of red, yellow, and green (similar to traffic lights where red means stop, yellow means slow down and wait, and green means go). This scenario would allow product manufacturers to establish specific criteria for material suppliers to respond to, indicating whether a substance is acceptable or restricted. Additionally, the scenario would help identify data gaps and allow rejection of incomplete data. This scenario would be embedded in the tools themselves rather than relying solely on the disclosure of material or product composition. Other formats, such as declaration forms or logbooks, could also be considered for transferring information along the supply chain.

3.2 Analysis

Our analysis consists of three parts: one part will focus on complex products, another part will address legal challenges, and the final part will serve as a bridge between the previous two parts.

3.2.1 From a complex product point of view

The supply chain of a complex product is complicated and involves many different suppliers, both horizontally and vertically (see Figure 1). The product value chain which is built up of many different materials (articles) is illustrated horizontally, and the chemical value chains are illustrated vertically. Chemicals can be used both during material manufacturing (articles) and product manufacturing. Therefore, a complex product usually requires years or even decades of research and development before it can be placed on the market. A complex product is defined as a product made up of more than one article if these articles keep a specific shape, surface or designs and do not become waste. It is the responsibility of the producer to determine whether a substance of very high concern is present in a concentration above 0.1% weight by weight of any article it produces. For importers of products made up of more than one article, they must determine for each article whether such a substance is present in a concentration above 0.1% weight by weight for each article²⁹. Furthermore, within a complex product the term "article" should be considered as an isolated object, such as a screw in an electronic equipment. It can be challenging to determine the presence of substances from the Candidate List within a complex product, which is typically comprised of numerous articles. Additionally, the Candidate List is updated twice a year with new chemicals, making it an ongoing process for producers.

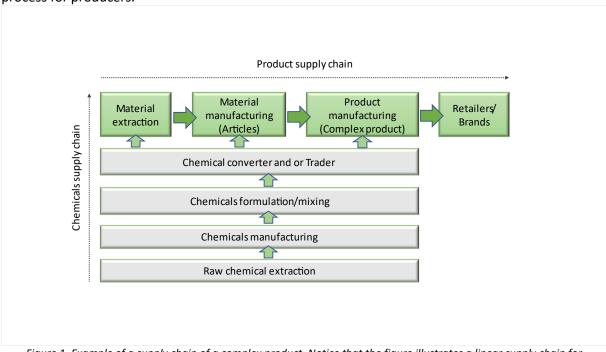


Figure 1. Example of a supply chain of a complex product. Notice that the figure illustrates a linear supply chain for simplicity.

²⁹ For the complex product terminology, we refer to the terminology that was used in the European Court of Justice judgment in case C-106/14, which dealt with the notification and information obligations under REACH and the interpretation of "article" under REACH. This terminology can also be found in the "Guidance on requirements for substances in articles" from the European Chemicals Agency (ECHA) (although the term "complex object" is used there instead). The judgment of the Court of Justice in case C-106/14 is available at: <u>http://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-106/14</u>. ECHA's guidance is available here: ECHA (2017), "Guidance on requirements for substances in articles" <u>Draft_for_final_tracked_ex_CARACAL_x-check (europa.eu)</u>.

3.2.2 From a legal point of view

3.2.2.1 The requisite "essential for the society"

Appendix C (listed in the technical screening criteria issued by the European Commission) uses the requisite "essential for the society" (or "essential use"). Currently, this requisite is not defined legally, leading to uncertainty regarding its interpretation. For example, if the whole complex product is essential for the society as such, do the constituent parts then also become "essential for the society? Since there is no legal definition, each company must define what it means for now, which in turn makes comparison between companies more difficult. According to the Commission, in order to apply the concept of an "essential use for the society", it is necessary to determine whether the concept is applicable, i.e., whether the economic activity leads to the manufacture, placing on the market or use of those substance. This information should be obtained through the supply chain.

3.2.2.2 The scope of the last paragraph in Appendix C

The last paragraph in Appendix C (g) stipulates those substances, whether on their own, in mixtures or in an article, meeting the criteria laid down in Art 57 of the REACH-regulation (that is substances meeting the criteria for substances of very high concern) are not allowed except where their use has been proven essential for the society. Based on the wording of the paragraph, it may imply that several substances must be checked for by the company. Moreover, the paragraph does not specify any required concentration limit values for these substances.

3.2.2.3 Transparency and traceability of hazardous substances in complex products

From a company's perspective, the development and market entry of a new product can take several years or even decades. Consequently, companies are interested in protecting their trade secrets while also upholding economic sustainability. In addition, legislation is moving towards increased requirements for companies to share information about their products. Therefore, material suppliers need to know how much information to share to establish trustworthiness in their claims and ensure transparency within the supply chain while also protecting their trade secrets. At the same time product suppliers need to know how much information to request from material suppliers to back up their claims and meet their customers demand for transparency.

To address the challenge of knowledge sharing in the supply chain, the Sustainable Product Initiative (SPI) proposes the use of a digital product passport. This passport would contain process and product-related information that can be accessed by authorities and consumers throughout the supply chain. The aim of the digital product passport is to enhance transparency and facilitate the transfer of information along the supply chain. Furthermore, the Safe and Sustainable by Design (SSbD) framework aims to guide research and development towards developing safe and sustainable products, materials and chemicals in the early design phase. This approach seeks to avoid relying on retrospective measures and controls to assess their impact on human and the environment. The focus is on designing products with optimal properties and functionality along their entire lifecycle ensuring they are not only safe and sustainable but also suitable for a climate-neutral, resource-efficient, and circular economy. The criteria for the framework have been established, but practical implementation has yet to be defined. Moreover, the Eco-design directive and EU Taxonomy Regulation may serve as push-pull link to the SSbD framework.

According to the transition pathway for the chemical industry, there are currently three barriers that prevent the progress of the twin transition (green and digital); *i*) the lack of predictability for the timelines of new legislative proposals, *ii*) inconsistencies and incoherence between EU legislation and national legislations; *iii*) the lack of harmonized legislation along the entire value chains. The

transition pathway also emphasizes the need to improve the enforceability of existing legislations ³⁰. The workshop participants and interviewees confirmed the findings that emerged from the literature review.

The BASTA system serves as a good example of addressing the identification of hazardous substances in complex products from a system perspective. Developed in Sweden, the BASTA system is a voluntary system design to address the use of hazardous substances in the construction industry. It facilitates informed decision-making by providing information on materials that are free from such substances³¹.

To identify the presence of hazardous substances and their function throughout the lifecycle of complex products while protecting trade secrets, data interfaces or other forms of substance declaration can be employed. However, effectively addressing data gaps related to the hazard properties of substances presents a more significant challenge.

3.2.2.4 Mistra SafeChem toolboxes

The vision for Mistra SafeChem is to enable and promote the expansion of a safe, sustainable and green chemical industry in Sweden. Key component of this interdisciplinary program involves the advancement of new industrial processes and the development of a toolbox comprising models and methods for assessing the risks and environmental sustainability associated with chemicals.

Safety toolbox

Within the Mistra SafeChem program, tools are being developed for hazard and exposure screening for use in a tier-based, Defined Approach (DA) approach utilizing analytical methods, in-silico tools and in-vitro assays for serious human and ecotoxicological hazards, such as mutagenesis, skin sensitization, hormone disruption and ecotoxicity. Tools predicting human barrier penetration (skin and gut) are also being developed, as well as models for prediction of the ecological and human biodegradability of chemicals. The first step in the application of the tiered approach is to assess if there is sufficient literature data available to identify the hazards associated with a substance. If there is a lack of data, in-silico tools with uncertainty considerations can be employed to provide additional insights into the potential hazards and other important biodynamic parameters controlling exposure. If necessary, a final step in-vitro tools can be utilized to further strengthen the decisionmaking process. At each step, advice is given on the interpretation of data with respect to decision making processes. Mistra SafeChem safety tools are primarily aimed at providing important screening data for either direct decision making or use in appropriate life cycle assessment. Despite this, the use of Defined approaches (DA), utilizing the tiered, DA approach is in line with the emerging hazard and safety assessment paradigms involving such new assessment methods (NAMs), including the initial tiers in the Safe and Sustainable by Design (SSbD) criteria.

Environmental sustainability toolbox

Tools to support the assessment of the environmental sustainability of chemicals are also being developed within Mistra SafeChem. These tools could also be used to screen multiple alternatives and complement the environmental sustainability assessment of the EU Taxonomy. However, further discussion of these tools is beyond the scope of this report. Nonetheless, we provide a summary of the toolbox here.

³⁰ EU commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs "Transition pathway for the chemical industry", (2023), doi: 10.2873/873037

³¹ BASTA bedömningssystem; retrieved 230528; <u>Startpage (byggvarubedomningen.com)</u>

Substituting hazardous chemicals in industrial processes and consumer products requires not only selecting alternatives that are less hazardous but also ensuring that the substitution does not lead to unacceptable trade-offs elsewhere in the chemical or product life cycle. Similarly, in process design and optimization, considering the entire life cycle is crucial, to prevent burden shifting from one health and environmental related potential impact to another. To address these challenges, robust methods and tools are needed. Life cycle-based tools need to incorporate hazardous properties of chemicals and materials, as well as the risks for exposure along the entire life cycles. As part of the Mistra SafeChem research program, a life cycle-based assessment toolbox is being developed to support the assessment of the environmental sustainability of chemicals. This toolbox is based on available models already applied in life cycle assessment for evaluating chemical toxicity and ecotoxicity, while also incorporating the advancements in digitalization methods

3.2.2.5 Sustainable reporting and supervision

Sustainable reporting encompasses a fast growing "family" made up of various legislations and is experiencing rapid growth. One distinguishing factor within this family is the level of supervision. Under the Swedish Annual Account Act, sustainable reporting requires external review. However, this review takes place at a limited level where the auditor only provides an opinion that the report has been prepared in accordance with the law. However, the EU Taxonomy Regulation stipulates supervision by an agency. Presently, the specific approach to supervision remains unclear and is the responsibility of the agency. The Swedish Financial Supervisory Authority and the Swedish Environmental Protection Agency have both expressed their concern about how the supervision should be carried out. The EU Taxonomy Regulation, along with its technical criteria, is a relatively young legislation and many aspects are still unclear.

4. Conclusions

The EU Taxonomy Regulation and its delegated acts represent a serious effort to establish standardized sustainability reporting within the EU. However, the regulation is in its early stages and lacks maturity. Moreover, certain ambiguities in the regulation currently prevent a comprehensive comparison of companies due to the development of other legislations. Addressing these gaps depends on the future development of other legislations, such as REACH. Sustainable reporting, as a legal field, also involves numerous activities. Our conclusion is that the EU Taxonomy Regulation is a part of a larger "movement" that reflects the policymakers' intentions. This intention also includes increased data sharing at a significantly different level compared to the current practices. In the long run, the shift will enable authorities to access data and develop new legislations.

The EU Taxonomy Regulation also aims to foster collaboration between different areas of expertise and break down silos. Experts from finance know very little about chemistry and vice versa. Hence, it is essential to establish a common language and understanding of the challenges posed by the EU Taxonomy Regulation. This involves finding new ways to collaborate and share information within the supply chain.

Our workshops, interviews, and literature review have confirmed that the main challenge in meeting the criteria of Appendix C, specifically point (g), is the need to enhance transparency and traceability throughout supply chains. Appendix C, point (g) aims to identify substances, whether alone, in mixtures, or in articles, that meet the criteria of Article 57 of REACH but are not yet included in the Candidate list. These substances can be sourced from various places and is described in the Commission's notice on the interpretation and implementation of certain legal provisions³². However, despite these sources, data gaps may still exist. Additionally, substances listed in the Candidate list according to REACH, for example, are not currently prohibited to use, but companies need to inform their customers if a product contains more than 0.1 w/w% of a listed substance.

The supply chain of complex products is often global and involves numerous suppliers in an asymmetric structure. The SCIP database, mandated by the Waste Framework Directive (WFD), ensures that information on articles containing substances from the Candidate List above 0.1 w/w% is accessible throughout the product and material lifecycle. However, the SCIP database only covers substances on the Candidate list. To address transparency barriers in the value chain of complex products, the product passport proposed by the EU Commission would facilitate the communication and data transfer along the supply chains.

Furthermore, a harmonized regulatory framework throughout the value chain would facilitate the linguistic and content requirements of supply chains. However, it is also essential to expedite the identification and restriction of hazardous substances and establish stronger enforcement measures to accelerate the phase-out of substances of very high concern. This would reduce the need for extensive tracking of substance of very high concern along the value chain.

The BASTA system serves as a good example of how to address the identification of hazardous substances in complex products from a system perspective. The BASTA system, a voluntary system developed in Sweden, addresses the use of hazardous substances in the construction industry and facilitates informed decision making by promoting the selection of materials free from hazardous substances.

³² https://ec.europa.eu/finance/docs/law/221219-draft-commission-notice-eu-taxonomy-climate.pdf

Although many industries that manufacture and supply complex products use restricted substances lists (RSL) in their dialogue with suppliers, there is still a need to develop tools to identify data gaps. Enabling the full declaration of hazardous properties and functions of substances, while considering the balance between information disclosure and protecting trade secrets, can facilitate the traceability of hazardous substances. To enhance communication and data transfer along the supply chain while protecting trade secrets, the workshop participants proposed the implementation of a user-friendly interface based on a traffic-light scenario, similar to traffic light (red means stop, yellow means slow down and wait, and green means go). This scenario would allow product manufacturers to establish specific criteria for material suppliers to respond to, indicating whether a substance is acceptable or restricted. Additionally, the scenario would help identify data gaps and allow rejection for incomplete data. This scenario would enable 100% full declaration of substances while considering trade secrets. Transparency should be embedded in the tools itself rather than relying solely on the disclosure of material or product composition. This could also be achieved through other formats such as declaration forms or logbook.

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About Mistra SafeChem

Mistra SafeChem is a research programme with the vision to enable and promote the expansion of a safe, sustainable, and green chemical industry.

The programme is developed with the twelve principles of green chemistry as a fundament.

The research combines the potential of innovative manufacturing processes, tools for hazard and risk screening, and life cycle assessment with ambitions and opportunities for the development and growth of a safe and sustainable chemical industry.

More information: News from the programme, publications, and persons to contact you find at the website <u>mistrasafechem.se</u>

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