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Abstract

The Candidate List of the European Union regulation on the registration, evaluation, authorization, and restriction of chemicals—known as REACH— gives advanced information to industry and other stakeholders about substances that may have serious effects on human health and the environment—known as substances of very high concern (SVHCs). Both the European Chemical Agency and EEA Member States can prepare dossiers proposing substances to be considered for inclusion on the Candidate List. This study investigates what types of SVHCs are suggested by different countries, and in particular, how the national production of the substances and their toxicological properties can affect the countries' decision to submit a dossier. Moreover, I investigate what substances for which a dossier has been submitted are finally put forward for inclusion on the Candidate List and what types of comments are raised during the public consultation allowing stakeholders to provide further information on the properties of the substance. The results indicate that national economic interests have affected not only the decisions to submit a dossier but also what substances to propose for inclusion on the list, where countries submit dossiers mainly for substances where they expect little opposition from other member countries or from domestic actors.

JEL Codes: Q52, Q53, Q58.

Key Words: chemical regulation, hazardous substances, mandatory disclosure, political economy, Candidate List, REACH.

1 Introduction

Exposure to tens of thousands of chemicals constitutes a major threat to human health and the environment. In recent years, the public perception of the potential hazards associated with the use and consumption of chemicals has significantly increased. A growing body of evidence indicates that many chemicals have biological effects at doses previously considered negligible (Vandenberg et al. 2012). It is also becoming increasingly evident that long-term exposure to relatively low doses of chemicals can cause subtle harmful effects (Birnbaum 2012). Furthermore, people and ecosystems are exposed to mixtures of thousands of chemicals from a wide range of sources, which can be detrimental since low and supposedly safe levels of some chemicals can become hazardous when the substances are used in combination with others (Sarigiannis and Hansen 2012). Thus, there is a need

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to regulate chemicals to prevent the release of new chemicals with a potential to damage human health and the environment into the marketplace without safety testing, and to provide incentives for the development of products and processes that minimize the use and generation of hazardous substances.

The European regulation on the Registration, Evaluation, Authorization, and Restriction of Chemicals, i.e., the REACH regulation (Regulation [EC] No 1907/2006), addresses the production and use of chemical substances with a main objective to ensure a high level of protection of human health and the environment. REACH requires all companies manufacturing or importing chemical substances into the EU in quantities of one metric ton or more per year to provide a safety-related dataset for a large number of existing and new chemicals to the agency established to manage the technical, scientific, and administrative aspects of REACH -- the European Chemicals Agency (ECHA). REACH entered into force in 2007 and applies to countries in the European Economic Area (EEA), i.e., all European Union (EU) members plus Norway, Iceland, and Liechtenstein. An important objective of the REACH regulation is to assure that the risks posed by substances that may have serious effects on human health and the environment—known as substances of very high concern (SVHCs)—are properly controlled and progressively replaced with suitable alternative substances or technologies. This is mainly achieved through the so-called Authorization List and Candidate List of SVHCs.

Substances that are placed on the Authorization List cannot be made available in the market for use unless an authorization is granted by the European Commission (EC), and inclusion of a substance on the Candidate List is a prerequisite for inclusion on the Authorization List (ECHA 2016). The REACH Directive states that authorization should be granted only if the registrant demonstrates that (i) the risks are adequately controlled or (ii) the substance provides socio-economic advantages that outweigh the risks and no suitable alternative substances or technologies are available (Bergkamp and Herbatschek 2014). Thus, the burden of proof lies with the firms, which must apply for authorization by a deadline established under the REACH Directive and cease use of the chemical by a specified date unless authorization is granted or an application for authorization is pending.

Although substances included on the Candidate List are not banned for use, the inclusion brings obligations for producers, importers, and distributors of the substance to communicate information about its risks, use, and risk management. For example, they need to supply a safety data sheet, communicate on how it can be used safely, respond to consumer requests, and notify ECHA if the article they produce contains an SVHC in quantities above one metric ton per producer/importer per year (ECHA 2019a). When a substance is identified as an SVHC, it signals to the companies that they need to find substitutes or switch to other technologies. In addition to increasing awareness about hazardous chemicals, listing might also encourage companies not to seek authorization in order to avoid having the company name associated with controversial substances, even if the benefit-cost case for authorization is strong (see, e.g., Coria 2018).

The positive economic theory of regulation sees regulation as a form of wealth transfer where interest groups (e.g., consumers and regulated firms) compete against each other in the political arena to shape regulatory initiatives in a way that will serve their own objectives (see, e.g., Sterner and Coria 2016). In the case of SVHCs, in order to include a substance as an SVHC on the Candidate List, it first needs to be proposed. This can be done by member states and the European Commission (EC) (through ECHA). If a substance is proposed as being an SVHC, a dossier needs to be submitted and a 45-day consultation period starts, during which anyone can comment and provide further information on the properties of the substance, its uses, and available alternatives. A proposed substance is included on the Candidate List if no comments challenging the identification of a substance as an SVHC have

been received or if the Member State Committee (MSC) agrees on the identification of the substance as an SVHC after taking into account the comments submitted during the public consultation period (see, e.g., Schenten and Führ 2016). The MSC is a body of ECHA consisting of national representatives, one per Member State, usually from the national regulatory authority dealing with chemicals. The MSC, however, is not a clear-cut technical committee; although it consists of experts from national regulatory authorities, it is political in the sense that national interests are explicitly represented in committee deliberations (Klika, 2015a). Particularly since when decision makers launch a legislative initiative that affects the economic interests of certain groups, these groups have an incentive to shape the debate to have an impact on the policy options that are considered by decision makers and on the final outcome of the legislative debate (Klika, 2015b, and Klüver et al. 2015). Thus, those nominated for the MSC are wearing multiple "hats," serving as members of an EU agency committee, policy experts, and representatives of national interests at the same time (Egeberg and Trondal 2009).

It has been argued that the Candidate List and the authorization procedure are increasingly being politically exploited since the EC has set targets for the inclusion of a given number of substances on the list by the end of given years (Hanschimdt et al. 2013). These targets have been criticized because they (may) put the emphasis on the political signaling effect of the Candidate List rather than on the protection of health and the environment. Moreover, compliance with the targets might not allow performing the necessary analyses concerning uses and best risk management methods for the substances listed.[1] Nevertheless, in contrast to this argument, the evidence suggests that the process of including substances on the Candidate List has been rather slow. For example, EC (2006) estimated that about 1,500 substances are known to have SVHC properties. [2] However, only 197 substances had been included on the Candidate List by February 2019.

Political considerations might however play an important role in the process of including substances on the Candidate List since national interests are represented both when proposing substances and in the deliberation process. Thus, the aim of this paper is to investigate the political economy of the Candidate List by (i) analyzing countries' incentives for preparing SVHC dossiers, and (ii) analyzing the participation of different actors in the consultation process through which further information on the properties of the substances and their uses and alternatives is provided. Regarding incentives, the study aims to investigate whether the decision to submit a dossier is connected to the national environmental damages related to the use of the substances and/or to local production. Regarding the consultation process, the aim is to identify the identity of the parties commenting and whether the arguments provided support or oppose inclusion on the Candidate List.

The fact that interest groups influence the final design of environmental policies is well documented. Fuel taxation is a good example of how politically difficult it can be to implement policies even when they are environmentally beneficial, and how policy design evolves through political processes in which various stakeholders compete. For instance, Hammar et al. (2004) investigate the political economy of fuel taxation and find that fuel taxes are particularly difficult to implement in countries

[1] For instance, the first target was to reach an inclusion of 136 substances on the Candidate List by the end of 2012. ECHA prepared inclusion dossiers for 42 substances in 2012 and 11 substances in 2011 (compared with three in 2008 and two in 2009), which allowed them to reach the target with a total of 138 substances on the Candidate List by 2012. In 2013, ECHA implemented "the roadmap for SVHC identification and implementation of REACH risk management measures from now to 2020," with the aim of presenting a credible process to ensure that the 2020 commitment be achieved (see e.g., EC 2013 and EEB 2015). The SVHC Roadmap constitutes an EU-wide commitment and outlines a methodology for working to fulfill the commitment (ECHA, 2018).

[2] Of the 1,500 substances, 900 are known to have SVHC properties and 600 are expected to become known through the generated data in the REACH regulation (EC, 2006).

with low fuel prices and high demand, and that one of the main explanations for this is that political pressure influences political decisions about taxation; high levels of fuel consumption make consumers more likely to oppose increased fuel taxes, whereas at lower levels of fuel consumption, consumers are more likely to tolerate them. Climate policy provides another good example. Kolk and Pinkse (2007) analyze the multinationals' political activities on climate change and show that instead of trying to stop policy makers from doing something to combat rising GHG emissions, many firms have taken a more cooperative approach by aiming to push policy makers in the direction of market-based solutions such as emissions trading and voluntary programs that would allow some segments of the polluting industry to gain rather than lose from the implementation of the respective policies.

The present article contributes to the literature on chemical regulation because listing of hazardous substances has become a policy instrument commonly used worldwide (see, e.g., the Consolidated List of Chemicals Subject to the Emergency Planning and Community Right to-Know Act by the United States Environmental Protection Agency, the Pesticide Action Network List of Highly Hazardous Pesticides, and the European List of Hazardous Waste). Even though the article has a primarily explorative and descriptive purpose, insights on the various key drivers of the decision to submit a dossier and on the deliberation process are crucial in order to understand what type of substances are being listed.

The article also contributes to the literature on political economy of environmental policy because lobbying is a primary avenue through which firms attempt to change economic policy (Mitra 1999). Much of the time, firms lobby against environmental protection, but there are also examples of major polluting firms lobbying for environmental regulation of their markets, and this political support can substantially increase the ability of governments to protect the environment. For instance, firms might lobby for environmental protection when they have already made some investments in cleaner production technologies and stronger environmental regulations could provide them with a competitive advantage over their rivals (Grey 2018). An example of this concerns the regulation of the use phosphates in laundry detergents, identified in the 1970s as a driver of lake eutrophication in both North America and Europe. In response to such concerns, the German firm Henkel invested in a phosphate-free detergent, and lobbied for controls. The German government implemented regulations requiring phosphates to be reduced by 50% by 1984. Henkel profited from phosphate regulation since its phosphate-free detergent proved so successful that detergents containing phosphates were phased out in Germany by 1989 (Barrett 1992).

Furthermore, the present paper provides evidence of the intensity of lobbying activities in the regulation of SVHC (measured by the input provided to the deliberation process) and insights regarding the framing used by different interest groups. Even though many scholars claim that participation of interest groups enhances the democratic legitimacy of the EU policy making, empirical evidence suggests a strong pro-business character of the policy making process as business and industry interests are considerably better represented in the consultation than the interests of the environment, trade unions, and consumers (Eising 2004). For instance, Persson (2007) investigated the public internet consultation of the policy proposal of the REACH regulation and found that participation by industry associations and businesses greatly outnumbered NGOs and representatives of diffuse interests and that chemical-producing countries were much better represented than other countries.

The paper is organized as follows. Section 2 describes major advocacies affecting chemical regulation in Europe and the process through which SVHCs are listed. Section 3 describes the RoI database and provides an overview of the information available so far. Section 4 describes the main findings of the analysis, and Section 5 concludes the paper.

2 EU Major Chemical Policy Advocacies and the Candidate List

Within the chemicals policy debate, two major advocacy coalitions are expected to shape decision making. The *business coalition* consists of industry and business; they have a strong influence on decision makers due to the dependency of governmental actors on knowledge from business actors for effective policy making. The chemicals industry, for example, has the great advantage of possessing knowledge about not only chemicals and products but also possible substitutes. This knowledge is vastly superior to that of public authorities (Pesendorfer 2006). EU member states with a large chemical sector are also expected to be important actors within the business coalition (Pesendorfer 2006).

The second advocacy coalition is the *green coalition*, the members of which share an environmentalist approach. The strongest supporters of a radical change in chemicals policy are non-governmental organizations (NGOs), which play a crucial role countervailing power of business associations and chemicals industry. Main NGOs that are active in the area of chemicals include the European Environmental Bureau, which is a federation of over 140 national environmental NGOs, the European Consumers' Organization, a federation of 40 national consumer NGOs, and a large number of individual NGOs, such as the World Wide Fund for Nature (WWF), Friends of the Earth, and Greenpeace (Selin 2007). However, NGOs have limited influence on policy making at the EU and member state levels. In fact, their influence is reduced mainly to agenda-setting and policy formulation. In decision making, they are much weaker than industry actors (Pesendorfer 2006).

Efforts to strengthen European protection standards are also often supported by the public. For instance, in the Eurobarometer from 2016, Europeans expressed great concern about being exposed to hazardous chemicals, although less than half felt well informed. In general, people in northern Europe appear to be somewhat less concerned than people in other parts of the EU. The perception of knowledge about the potential dangers of chemicals contained in different products seems to be also higher in northern Europe where respondents feel well informed about the potential dangers of chemicals contained in different products, especially in the Nordic countries, while those in southern Europe tend to feel less well informed. Furthermore, a majority of the individuals in some of the countries surveyed responded that the current level of regulation and standards in the EU is not high enough and should be increased, though this proportion varied considerably by Member State (see Figure 1).

Finally, the representatives of environmental ministries and national environmental agencies can be identified as more moderate and closer to the business coalition approach, sometimes functioning as policy brokers trying to find win-win solutions. This is true especially with regard to policy formulation and implementation that requires highly specific knowledge, making these actors largely dependent on close cooperation with industry. Furthermore, it is worth noting that northern member states including Sweden, Denmark, the Netherlands, Germany, Austria, and the UK are said to be early initiators of revisions to EU chemicals policy and regulation (see, e.g., Selin 2007). The environmental ministers of these states have also been consistent supporters of REACH. This support is partly based on a desire to export their stricter domestic chemicals standards and policies to the European level, alongside efforts to further strengthen their domestic regulations.

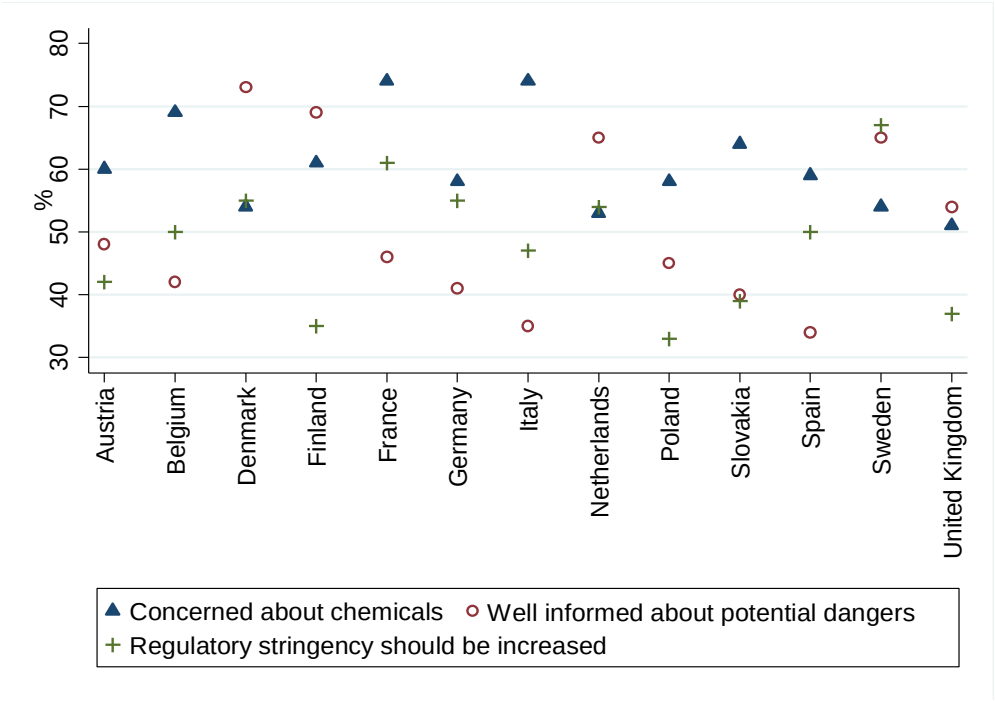

Figure 1: Attitudes to chemicals in EU countries (Special Eurobarometer 456, 2016)

EU Chemical Industry

The EU chemical industry is the world's second largest chemical producer, with €542 billion in sales in 2017, corresponding to 15.6% of total global revenues (Cefic 2018b).[3] China was the world's largest producer, with 37.2% of total global sales that year. Although the EU chemical sales have been growing continuously, the EU contribution to total world chemical sales dropped from 27.5% in 2007 to 15.6% in 2017, whereas Asia has continuously increased its share (Cefic 2018b).

The output from the EU chemical industry includes three product areas: (1) base chemicals, which in 2017 represented 58.8% of total EU chemical sales and are produced in large volumes and sold in the chemical industry itself or to other industries (including petrochemicals, polymers, and basic inorganics), (2) specialty chemicals (e.g., paints and inks, crop protection, dye, and pigments), which in 2017 represented 27.4% of total EU chemical sales, (3) consumer chemicals (e.g., soaps, detergents, and cosmetics), which in 2017 represented 14.1% of total EU chemical sales and are sold to final consumers (Cefic 2018b).

In 2017, Germany and France were the two largest chemical producers in the EU, followed by Italy and the Netherlands (Cefic 2018b). Together, these four countries generated €334.1 billion in chemical sales, which corresponds to 61.6% of the EU total. When including Belgium, Spain, and the UK, which are the fifth, sixth, and seventh largest chemical producers, the figure increases to €449.2 billion, or 82.9%. For the remaining EU member states, the share was 17.1% of total EU chemical sales.

In 2016, the chemical industry in EU28 consisted of about 28,000 companies and about 1.14 million direct employees, and the chemical industry generated 1.1% of the EU gross domestic product (GDP)

[3] EU refers to EU28.

(Cefic 2018a). Figure 2 shows the total revenues in the European chemical sector. Germany is the country with highest total revenues, with more than double the figure of France, which has the second highest number. Then come Belgium, Spain, United Kingdom, and Italy. Figure 2 also shows the number of companies in the European chemical sector by country. Germany, the country with the highest total sales, had the eighth highest number of companies. Turkey tops the list, with just over 20,000 companies, and is followed by Poland, United Kingdom, France, Spain, and Italy.

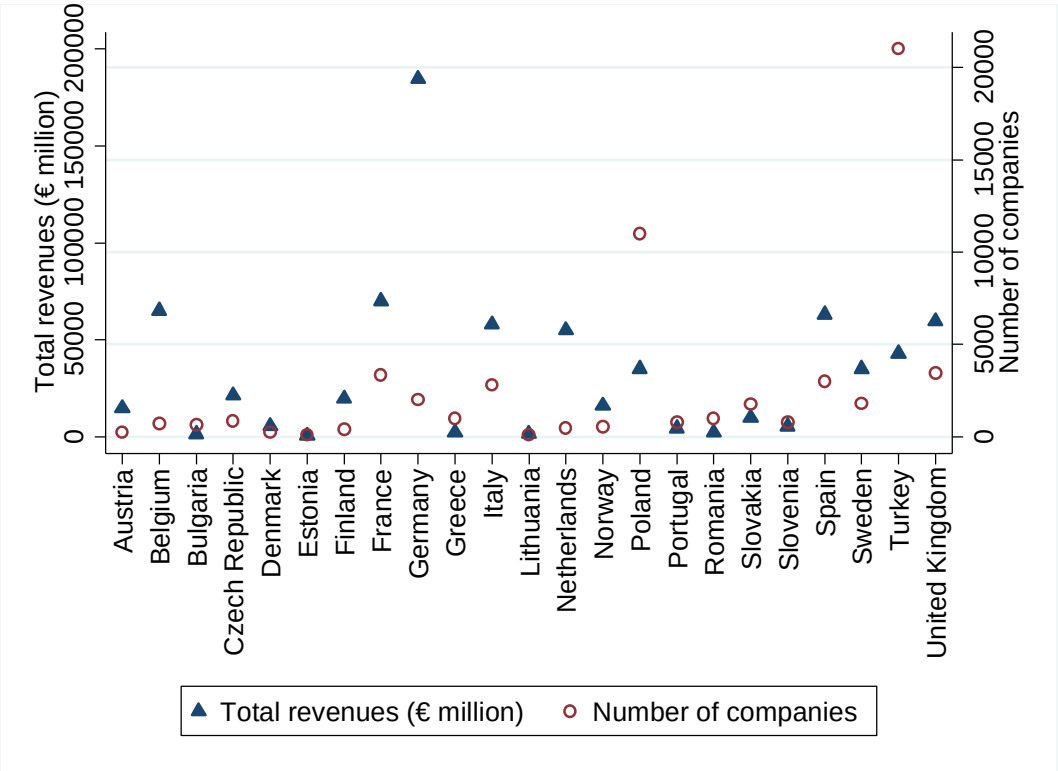

Figure 2. Total revenues and number of companies by country in the European chemical sector. Source: The European Chemical Industry Council, Cefic (2018a)

Candidate List under the REACH regulation

The main purpose of the authorization procedure is to ensure that SVHCs are replaced with less dangerous substances or technologies whenever technically and economically feasible alternatives are available. SVHCs are chemicals classified as (i) carcinogenic, mutagenic, or toxic for reproduction, (ii) persistent, bio accumulative, and toxic chemicals (PBT); or very persistent and very bio accumulative chemicals (vPvB), (iii) substances that give "rise to an equivalent level of concern" such as endocrine-disrupting chemicals, or (iv) chemicals that meet more than one of the previous three criteria. Inclusion of an SVHC on the Candidate List, which is a prerequisite for inclusion on the Authorization List, involves several steps and actors (ECHA 2019a):

(1) The process starts when member states or ECHA (on behalf of the EC) identify a concern that a certain substance poses a risk to human health or the environment. The intention to propose a substance for identification as an SVHC is published in the Registry of Intentions (RoI) on ECHA's website before the proposal is submitted to inform industry and other stakeholders in advance of the submission.

(2) The proposal is prepared according to Annex XV to REACH and includes data and justification for identifying the substance as an SVHC, along with information on volumes in the EU market, uses, and possible alternatives to the substance.
(3) The proposal is published on ECHA's website. During a 45-day consultation period, anyone can comment and provide further information on the properties of the substance, its uses, and possible alternatives.
(4) If no comments challenging the identification as an SVHC are received, the substance is included directly on the Candidate List. If comments providing new information or challenging the basis for the identification as an SVHC are received, the proposal and the comments are referred to the MSC for consideration. If the members of the committee agree unanimously that the substance should be identified as an SVHC, the substance is added to the Candidate List. If the committee does not reach a unanimous agreement, the matter is referred to the Commission.
(5) When a substance is identified as an SVHC, it is added to the Candidate List for possible inclusion on the Authorization List.

As described earlier, inclusion of a substance on the Candidate List brings obligations for suppliers of the substance to supply information to downstream consumers about the toxicological properties of the substance. Evidence suggests that inclusion on the Candidate List provides an early warning to firms to replace SVHCs, and it has been an important driver of substitution (see, e.g., Coria 2018).

3. Registry of Intentions

In this paper I make use of the information available on the Registry of Intentions, RoI. The aim of RoI is to make all interested parties aware of the substances for which a SVHC dossier is intended to be submitted to ECHA (ECHA 2019b). The information on the RoI is updated when the substance moves between different stages of the process, such as when the dossier is submitted or if it is withdrawn. Interested parties can follow the processing of the dossier from the notification of the intention until the outcome by regularly reviewing the RoI (ECHA 2019b). Furthermore, through RoI anyone with relevant information on the identity or hazard properties of a registered substance may submit such information during the public consultation.

The first SVHCs to be proposed for inclusion on the Candidate List were proposed on June 2008. As of February 2019, the RoI database contained 216 unique substances/entries classified according to five possible statuses (see Table 1). Of the 216 dossiers submitted at that time, nine had been withdrawn, 195 substances had already been identified as SVHCs, and 12 dossiers were in the process of being identified as SVHCs. For those substances already identified as SVHCs, the length of time that elapsed from the notification of the intention until the outcome corresponded to about 260 days (with a range of 110–1,329 days). The length of time was significantly longer for the substances that had been withdrawn (i.e., 1,495 days on average). For most of these substances, the dossier was never submitted.

A total of 3,214 comments had been submitted for 195 substances, implying an average of about 16 comments per substance (with a range of 5–115 comments and a median of 12 comments per substance).

Status	# Substances	Average # Comments	Time elapsed from intention to outcome (days)
Intention	4	__	__
Submitted	7	__	__
Identification ongoing	1	18	__
Identified SVHC	195	16	260
Withdrawn	9	__	1495
Total	216	16	315

Table 1: Description of the status of substances on RoI.

In what follows, I discuss some key findings based on the analysis of the information available on RoI.

4. Key Findings

4.1 Few key countries submit the majority of the dossiers and provide most of the input to the deliberation process

Only a handful of countries (Germany, France, Sweden, the Netherlands, and Austria) account for more than 60% of the dossiers submitted, while ECHA accounts for almost 30%. Germany, France, and the Netherlands, some of the largest chemical producers in EU, account for about 40% of the dossiers submitted. Other large producers, such as Belgium and the UK, have been moderately active in submitting dossiers (about 2.7% and 1.4% of the total dossiers submitted, respectively), while large producers such as Spain, Italy, and Turkey have not been active at all. In contrast, smaller producers such as Sweden, Austria, Norway, and Denmark have submitted in total about 25% of the dossiers. This relatively large figure may be explained by strong environmental concerns (see Figure 1) or by the smaller economic importance of the chemical industry to these countries.

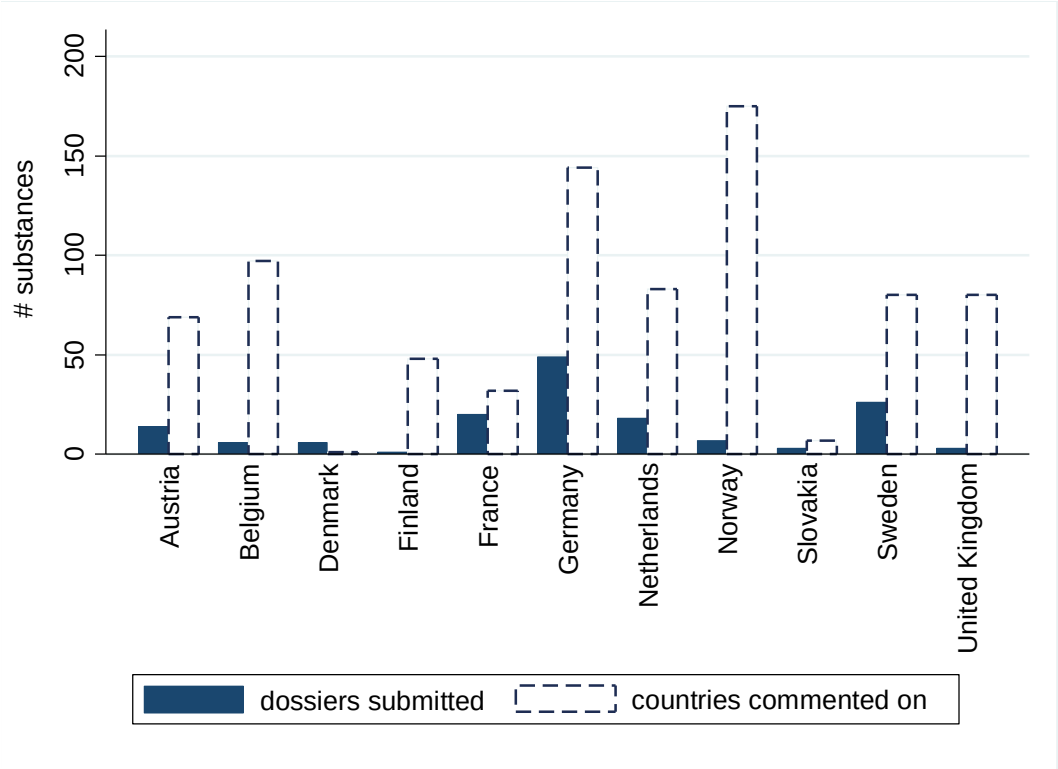

Figure 3: Dossiers and comments submitted by countries

As seen in Figure 3, some of the countries that have been active in submitting dossiers have also been active in providing comments, e.g., Germany, the Netherlands, Sweden, and Austria. Norway is the country that has provided comments for most of the substances for which dossiers have been submitted. Belgium and the United Kingdom have also provided comments for a large number of substances. Regarding Belgium, a large fraction of the comments have been provided by NGOs, which is not strange since Brussels is considered the center for European lobbying and is home to many international organizations (Biliouri 1999). As for the UK, most comments have been provided by industry and are generally against the listing of the substances, supporting the argument that UK firms seem to consider the EU environment, health, and safety regulations too burdensome (Gamble 2012)

How is the active participation by some few countries in Europe related to environmental concerns and the importance of the chemical industry in these countries? The following sections explore this issue.

4.2 A 30% of the dossiers submitted aimed to list substances that are not produced in Europe

REACH regulates chemicals commonly used in the EU in industrial processes and intentional chemical mixtures and products, which range from cleaning products and paints to clothing, furniture, and electrical appliances (e.g., Bergkamp and Herbatschek 2014). To this end, a major requirement of REACH is that manufacturers or importers of substances into the EEA in quantities of one metric ton or more per year must register the substances with ECHA. Registration is, however, not mandatory for SVHC identification, which means that countries can submit dossiers for substances that are not currently being manufactured/imported into the EEA.

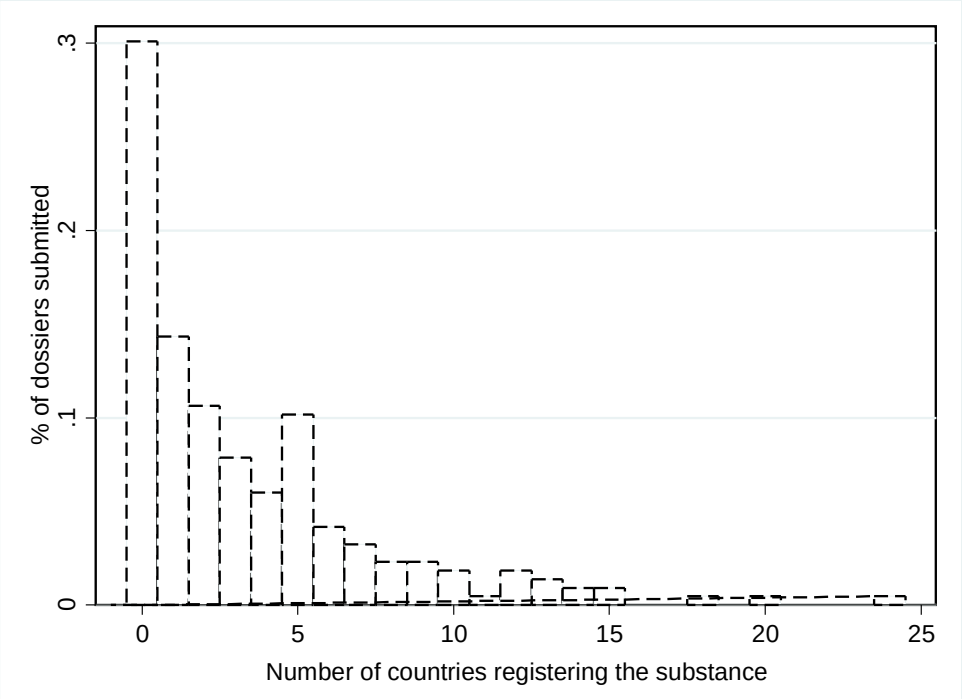

Figure 4: Dossiers submitted and registration of the substances in EEA

As shown in Figure 4, 30% of the dossiers submitted (i.e., 65 dossiers) correspond to substances currently not registered with ECHA. Why do countries submit dossiers for substances not registered in the EEA? A potential answer to this question is that European countries want to ease the political opposition from other member countries by proposing "low-hanging" fruits, e.g., chemicals known to be hazardous but whose listing will not affect the economic interests of European countries. Such incentive becomes quite apparent given the negative correlation between the frequency of the dossiers submitted and the number of countries registering the substance for which the dossier has been submitted. Indeed, about 80% of the substances for which dossiers have been submitted are produced/imported by no more than five countries.

An alternative explanation is that European countries want to prevent that such substances are produced or imported to the EEA in the future, for example, as an alternative to existing SVHCs. By doing do, European countries with stricter domestic chemicals regulations might avoid putting national companies at a competitive disadvantage or even ensure that firms that develop non-toxic chemical alternatives are properly rewarded. Interestingly enough, Germany and Sweden account for almost 50% of the dossiers of substances that are currently not being manufactured/imported into the EEA, while ECHA accounts for about 15%.

As discussed previously, the fact that some companies attempt to influence regulations in such a way to enhance their competitive advantage and also to improve the environment is well established in the literature (see, e.g., Barret 1992 and Bailey and Thomas 2017). Anecdotal evidence in the case of SVHCs is provided by the regulation of phthalates, which are esters of phthalic acid mainly used as plasticizers, i.e., substances added to plastics to increase their flexibility, transparency, durability, and longevity. Phthalates' regulation has contributed to the development of non-toxic and biodegradable bio-based plasticizers. According to the market outlook report by the European Commission (2019), the European market for bio-based plasticizers is young and in need of large investments, but rapid growth is expected from the investments that have been made so far. Bio-based plasticizer production

in the EU is to a large extent produced in Germany. Moreover, major drivers for the development of this market are the restrictions of certain phthalates through REACH. The listing of phthalates currently not being produced in the EEA might reduce the risk of regrettable substitution, as those phthalate-based plasticizers are cheaper than bio-based alternatives. Possible substitution towards hazardous phthalates not currently produced in the EEA can thus be prevented by equal treatment of all phthalates classified as SVHCs (regardless of where they are produced).

Thus, it can be argued that there are legitimate reasons behind the listing of substances that are not currently produced in the EEA, as a way to prevent the potential use of hazardous chemicals as substitutes to substances already added to the Candidate List. The case of phthalates seems to be a good example. However, considering that many German firms have currently invested in phthalate-free plasticizers it is perhaps not a coincidence that it was Germany the country proposing the listing of several phthalate-based plasticizers.

4.3 Countries often submit dossiers for substances that are not produced nationally

As described previously, environmental regulations are particularly difficult to implement in countries where interest groups are more likely to oppose them. Table 2 presents the number of dossiers submitted by countries depending on whether the country is a *country of operation* (a country is a *country of operation* when there is at least one company producing or importing the chemical in that country). As shown in Table 2, it is clear in the case of SVHCs that the national production of the substances significantly reduces the incentives to submit a dossier. Out of the 155 dossiers submitted by Member States, only a third was submitted by Member States that are a country of operation.[4] The incentive to not submit dossiers for substances produced nationally is particularly striking in the cases of Sweden, Austria, Norway, Belgium, and Denmark, and much attenuated in the case of Germany, France and the Netherlands.

A review of the dossiers of the substances proposed by a country of operation indicates that the majority of these dossiers are motivated by concerns of exposure-related carcinogenicity by the general population or by children's exposure to the chemicals. Such health concerns seem to overcome the focus on the protection of the industry and lead to requests to increase the stringency of the regulations. The listing of formamide (proposed by Germany) provides an example. Formamide is classified as a reprotoxic substance. The presence of formamide in children's puzzle toys at the end of the year 2010 generated a wide concern from the public. An assessment of the risk concerning formamide in puzzle mats showed that exposure of both children and adults occurs principally through inhalation, dermal contact and orally due to sucking and/or chewing on toys. Even though there is a low risk of exposure, this cannot be excluded and thus the substance was proposed in an attempt to minimize risks to consumers, particularly little children.

[4] In line with Figure 4, note that out of 104 dossiers submitted by a country that is not a country of operation, 65 dossiers correspond to substances that are not produced or imported into the EU in quantities of one metric ton or more per year by any country in the EEA.

Dossier Country	Is the dossier country a country of operation?		Total
	NO	YES	
Austria	14	0	14
Belgium	5	1	6
Denmark	6	0	6
Finland	1	0	1
France	11	9	20
Germany	27	22	49
The Netherlands	8	10	18
Norway	7	0	7
Poland	1	0	1
Slovakia	1	2	3
Spain	1	0	1
Sweden	21	5	26
United Kingdom	1	2	3
Total	104	51	155

Table 2: Countries of operation and dossiers submitted

The listing of p-(1,1-dimethylpropyl) phenol provides a similar example. The scientific evidence about the negative effects of this substance on the environment seems conclusive. Based on current data and knowledge, such substance is as endocrine disruptor for which a safe level of exposure is difficult to derive although it may exist. Moreover, its adverse effects on fish, amphibians and invertebrates are persistent as they do not cease after cease of exposure but also occur after exposure at sensitive live stages. Regarding health effects, this substance is known to cause severe skin burns and eye damage, and allergic skin reaction. Given the strong evidence of high toxicity, the listing of this substance was proposed by Germany and France, both of which are countries of operation.

4.4 CMRs are prioritized by ECHA and almost all active countries

As shown in Figure 4, most dossiers submitted so far are aimed to list CMR substances, reflecting the fact that cancer prevention is the primary objective of the evaluation of chemicals and that there is a strong societal interest in protecting human health, in particular among workers handling the substances (see Boobis et al. 2016). Indeed, in the mid-1990s, chemicals could be classified into two categories: carcinogens and non-carcinogens. It was postulated that there would be a major reduction in cancer incidence if the carcinogens could be identified and replaced with non-carcinogens. This idea sparked the use of hazard identification for carcinogenicity, a practice that has continued for nearly half a century in a largely unmodified way (see Boobis et al. 2016).

In contrast to CMRs, a very small number of dossiers submitted so far has concerned PBTs, vPvB, or endocrine-disrupting substances. A common problem with such substances is the existence of

uncertainties that can lead to a legislative standstill, which in turn can result in undesirable harm to the environment and human health. In policy making on environmental issues, there has often been a lengthy process between the first scientific early warnings about potentially serious risks to the environment and human health, and subsequent policy action to address these risks. Studies show that a great deal of damage to the environment and human health could have been avoided by ensuring quicker policy responses to early warnings. Policy makers have been more likely not to regulate something that was later found to be harmful (a so-called type 1 error) than to error on the side of caution and regulate something despite uncertainty about risks to the environment and human health (see Eckley and Selin 2004). This seems to be the case of PBTs and vPvB substances. Addressing the problems caused by PBTs and vPvB substances is a complex challenge that requires both scientific information and political will. Compiling lists of well-known substances of concern based on scientific analyses of their persistence and bioaccumulation has been a major focus of regulating persistent organic pollutant (POPs). However, there are no definitive persistence and bioaccumulation thresholds that separate POPs from non-POPs, and regulators have only been able to set certain criteria to facilitate the identification of these substances based on a combination of scientific evidence and policy judgements. It is feasible that such large uncertainties have made policy makers less likely to propose such substances to the Candidate List, delaying policy action. Furthermore, most substances for which dossiers have been withdrawn correspond to PBTs.

Similar challenges are observed with the listing of endocrine disruptors (EDCs). Despite substantial efforts by the scientific community and NGOs to evaluate the effects of EDCs, regulatory communities worldwide have been slow to incorporate the chemicals posing endocrine concerns into existing legislations (see, e.g., Munck af Rosenschöld et al. 2014), and this becomes apparent also in the listing of SVHCs. To date, 19 substances for which dossiers have been submitted have endocrine-disrupting properties that may be hazardous to human health, the environment, or both. A major challenge of identifying EDCs is that their effects depend on both the level and timing of exposure. EDCs are suspected of being capable of acting even at very low doses. Exposures are thought to have both immediate and more latent consequences, such as a heightened susceptibility to certain diseases and dysfunctions later in life. The most sensitive window of exposure to EDCs appears to be during critical periods of development (for instance, foetal development and puberty). Limited human evidence supports the idea that exposure during these periods may play a role in the increased incidence of reproductive diseases, endocrine-related cancers, behavioural and learning problems , infections, asthma, and even obesity and diabetes. However, for many of these, evidence is weak and it is very difficult to carry out meaningful experimental or epidemiological studies and prove cause and effect in humans (Lee and Jacobs 2015).

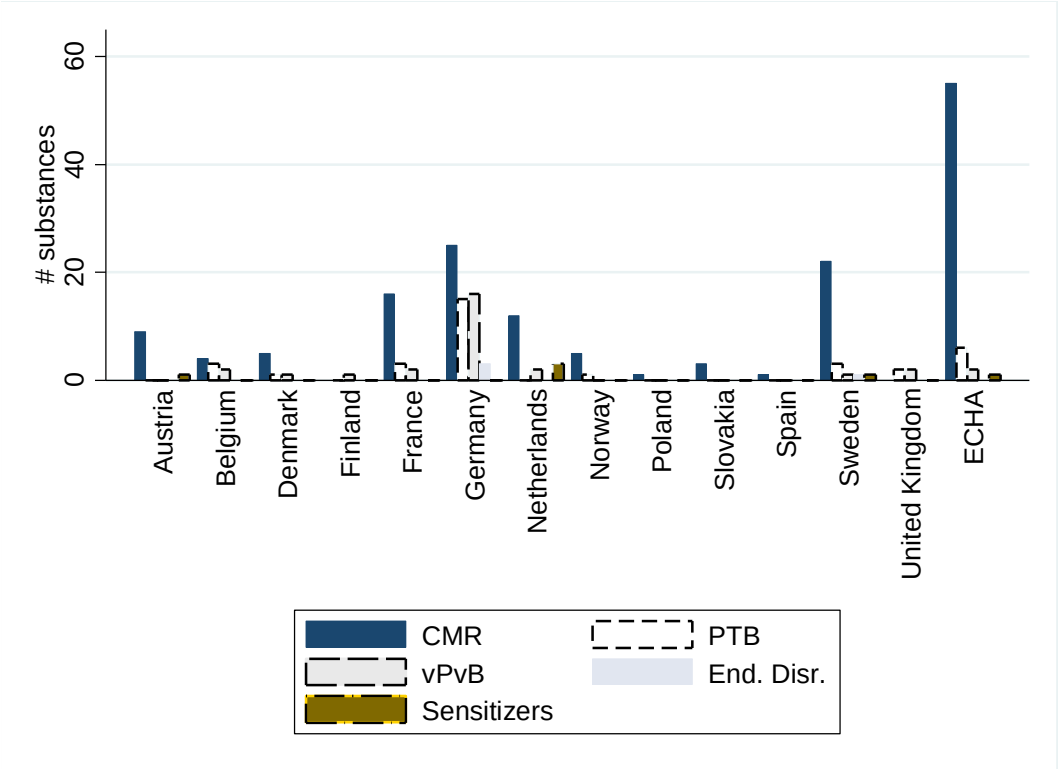

Figure 5: Dossiers submitted by country and toxicology property

4.5 Chemical industry accounts for most of the inputs to the deliberation process

Chemical firms and industry account for almost 50% of all comments; competent authorities (CAs) and national organizations (NOs) account for almost 29% of all comments; and finally, NGOs and academia account for about 21% of all comments.

The participation of chemical firms/industry varies across countries, however, with markedly higher rates among some of the largest chemical producers in the EU (i.e., Germany, France, and the UK) and in Belgium, where many international organizations are located. The participation of CAs and NOs is particularly high in Norway and Germany, while NGOs and academia participate to a largest extent in countries such as Sweden and Belgium.

About 90% of the comments provided by CAs, NOs, NGOs, and academia are supportive of the inclusion of the respective substance on the Candidate List. In contrast, only about 8.5% of the comments from firms and industry are supportive.

The high participation rates for industry are consistent with previous literature that suggests that broad participation in EU policy shaping is unlikely to bring about equal participation from different groups of actors. Moreover, EU policy making should in theory not only reflect a multitude of different actors, but also ensure representation from different member states. When considering what countries the participating actors come from, it is clear that to a very large extent they come from the member states with the largest chemical industries.

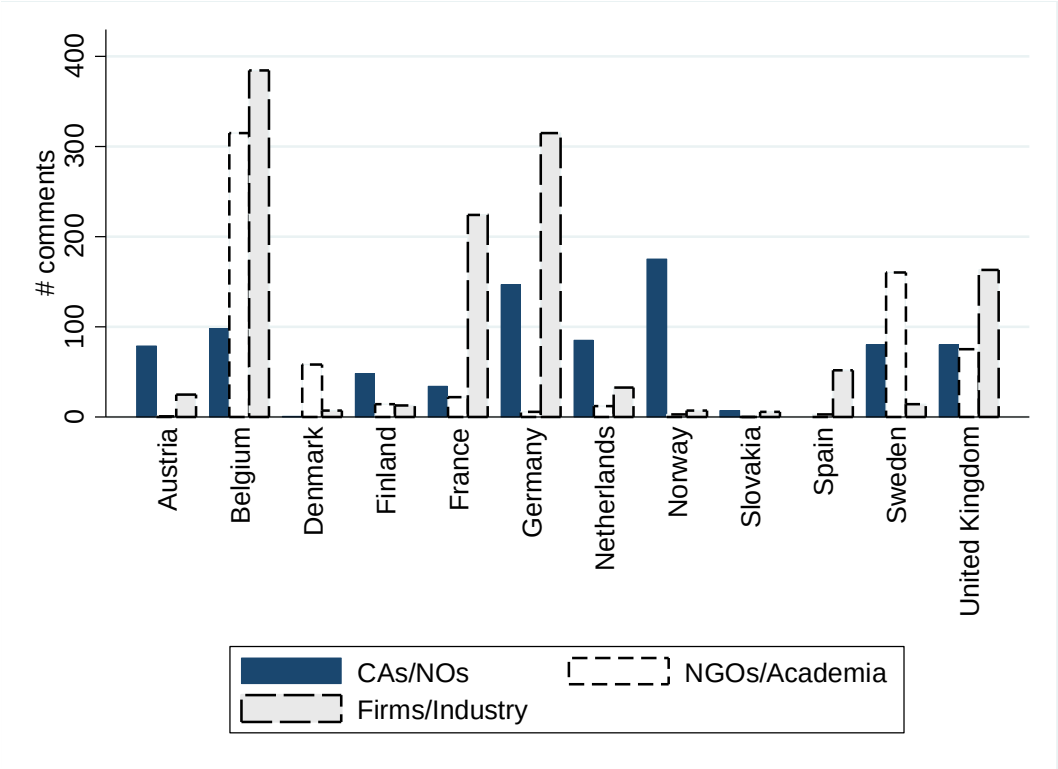

Figure 6: Comments provided by country and type of actor

Furthermore, as shown in Figure 7, there is a positive correlation between the number of comments provided by firms/industry and the number of firms registering the substance in the EEA. Such positive correlation suggests that the larger the size of the interest group that can be negatively affected by the regulation, the larger is the opposition to its implementation.

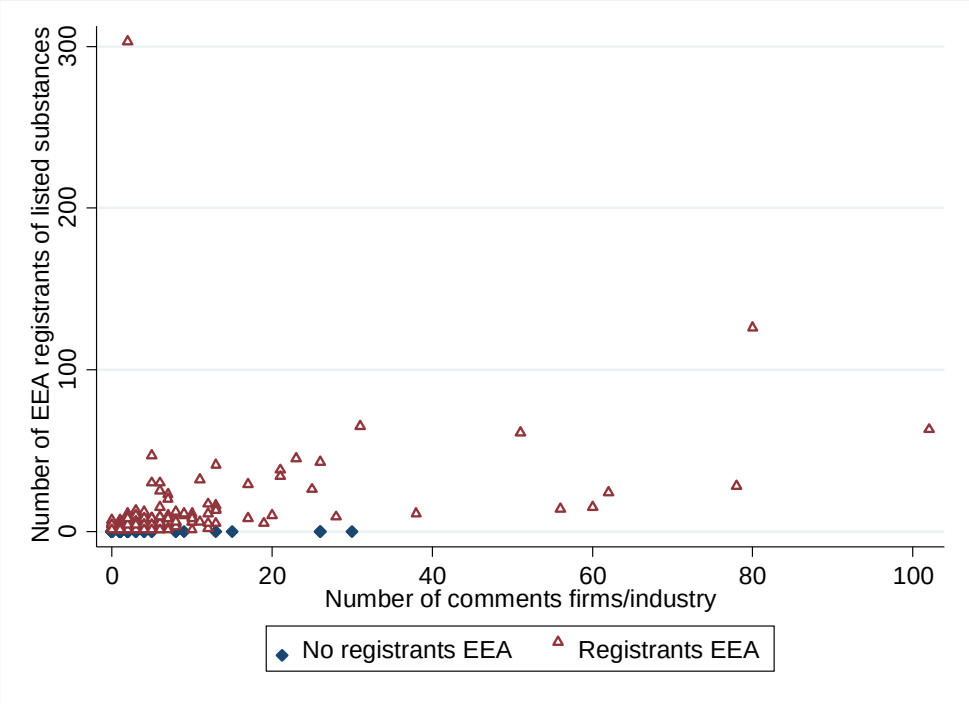

Figure 7: Number of comments provided by firms/industry vs. number of dossiers

Some of the arguments raised by firms and industry challenge the technical and scientific grounds for including the substances in question on the Candidate List (e.g., tonnage, wide-spread use, actual exposure, availability of appropriate risk management measures, substitution with equally hazardous substances, and the validity of the information on the potential risks of the substance). In contrast, the supportive comments provided by CAs/NOs and NGOs/Academia tend to emphasize the seriousness and irreversibility of the potential health effects, the consequences to society in terms of treatment costs, the difficulty of performing studies that can provide accurate estimates of the effects, and the strong signal effect to producers that the substance should eventually be stopped and substituted with less dangerous ones.

4.6 Most of the comments that support the inclusion of substance on the Candidate List come from countries that do not produce the substance

As shown in Table 3, a higher share of supportive comments comes from countries that are not countries of operation. In contrast, higher shares of the comments are non-supportive if the country is a country of operation. Moreover, in line with Figure 5, we observe that most of the comments from the largest chemical producers in EU (i.e., Germany, France, and the UK) tend to not support the inclusion of the substances on the Candidate List, especially when the substances are produced nationally.

Commenting Country	**Supporting Comments** **Is the commenting country a country of operation?**		**Non-Supporting Comments** **Is the commenting country a country of operation?**	
	NO	**YES**	**NO**	**YES**
Austria	70	7	18	10
Belgium	326	169	128	176
Denmark	57	1	8	0
Finland	52	4	11	8
France	27	13	123	118
Germany	51	63	60	296
The Netherlands	58	29	17	26
Norway	172	6	4	3
Slovakia	7	0	6	0
Spain	0	0	17	38
Sweden	211	25	14	4
United Kingdom	81	32	63	143
Total	**1,112**	**349**	**469**	**822**

Table 3: Countries of operation and type of comment

Notably, the average number of non-supporting comments is statistically smaller for those substances that are not currently produced in Europe, e.g., for such substances the average number of non-supportive comments is equal to 3.82 vs. 10.27 non-supportive comments for substances produced in Europe.

5. Conclusions

The implementation of environmental policies affects interest groups that stand to gain or lose from different types of regulatory interventions. Regulatory processes and outcomes depend on the magnitude and distribution of the costs and benefits of various regulatory interventions, the structure of the affected interest groups, the prevailing economic conditions, and the nature of political, regulatory and legal institutions within which various groups pursue their self-interest. In this paper, I analyze the incentives of countries to submit dossiers to include chemical substances on the Candidate List of substances of very high concern and to participate in the public consultation process leading to deliberations and final decisions by the Member State Committee. The Candidate List is a mandatory disclosure program that creates requirements for producers, importers, and distributors of products containing SVHCs to communicate information about risks and necessary risk management measures to the recipients of the products. Inclusion of a substance on the Candidate List also triggers a prioritization process that might lead to the inclusion of the substance on the Authorization List. A substance subject to authorization cannot be placed in the market for use on its own, in mixtures, or incorporated into an article unless the use has been specifically authorized. Since inclusion of a substance on the Candidate List is a prerequisite for the inclusion on the Authorization List, it is in the economic interest of the chemical industry that substances that they produce are not included on the Candidate List.

From the analysis of the data collected in the Registry of Intentions (RoI), it is clear that economic motives have shaped the list. National economic interests have affected not only the decisions to submit a dossier but also what substances to propose for inclusion on the list. In particular, the data reveals that thirty percent of the substances listed so far are not currently produced in the European Economic Area and that most countries submitting dossiers propose substances that are not produced nationally. This is to say, countries submit dossiers mainly for substances where they expect little opposition from other member countries or from domestic actors.

The fact that a large share of substances listed is not produced in the European Economic Area suggests that the interests of the chemical industry and the regulators can be congruent when environmental regulations confer a competitive advantage to the domestic industry at the expenses of foreign rivals. On the one hand, the disclosure mechanism embedded in the Candidate List should discourage the use of such substances in European countries with less stringent regulations, preventing thus regrettable substitutions and their negative environmental effects. On the other hand, there is a potential danger in the strategic use of environmental regulation if market power by domestic firms is enhanced as a consequence of the listing of substances not produced in the EEA, disfavoring consumers which might have to pay much higher prices. Regulators must be careful to create incentives for strategic behavior that can protect the environment, but not at the same time provide opportunities for increased market power.

The data also shows that cancer prevention is a major driver of the inclusion of substances on the Candidate List. Yet, regulation of persistent substances seems to be challenging. Anecdotal evidence of the difficulties of regulating persistent substances is provided by the fact that a majority of the substances withdrawn from the process are PBTs. Some scientists argue that persistence is in fact the single most important factor affecting chemical exposure and risk. Because of uncertainty about chemical properties, a situation could arise where accumulations have already occurred by the time evidence is gathered about a chemical's propensity for harm. As already experienced in the case of persistent ozone-depleting chemicals, the disruptive effects may not be discovered until they occur on a global scale and are affecting a vital earth system process.

The data also shows that firms provide most of the input in the public consultation process, which is intended to give interested actors such as companies, scientists, and civil society representatives the opportunity to submit evidence regarding the substance. Though meant to be democratic, this process is unlikely to bring about equal participation by different groups of actors.

As discussed in the paper, evidence suggests that the process of including substances on the Candidate List has been rather slow with only a small share of all substances known to have SVHC properties being listed so far. The political economy of the listing offers a clear explanation to the slow action since member states interested in the regulation of SVHC should naturally start by proposing substances for which there is little political opposition since submitting a dossier also comes at a cost to the country and a risk that the country fails to achieve the goal that the substance is included on the Candidate List. Thus, there is a clear trade-off between banning dangerous chemicals, on the one hand, and minimizing political opposition on the other. In other words, low-hanging fruits are picked first, but it might become more difficult over time to propose chemicals for which there is no political opposition. Thus, one can question to what extend the design of the procedures leading to the inclusion on the Candidate List can ensure that the risks posed by SVHC are timely and properly controlled, and whether alternative procedures, as listing based on expert judgments would not be a desirable alternative. Finally, though the data seems to suggest that human health – particularly cancer prevention– has been a major focus of the regulation, it is not possible to draw any conclusion on whether the listing of SVHC have resulted in the regulation of the most hazardous chemicals in the market. This, because investigating such a question would require the comparison of the hazardousness of the substances on the Candidate List vs. other all substances in the European market. Nevertheless, this is suggested as an area for further research that can make use of the chemical data available on the REACH registration dossiers.

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