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No data, no market... really?

REACH as co-management of chemical risks

Laura Maxim¹, Tristan Berger²

1. (Corresponding author) Laboratoire Interdisciplinaire Sciences Innovations Sociétés (LISIS), UMR 1326/9003 Université Gustave Eiffel, ESIEE Paris, CNRS, INRAE, 5, boulevard Descartes, Champs-sur-Marne, F-77454 Marne-la-Vallée, laura.maxim@cnrs.fr

2. Institut des Sciences Juridique et Philosophique de la Sorbonne (ISJPS), UMR 8103, CNRS, Université Paris 1 Panthéon Sorbonne, Centre de Recherche Normes Sciences et Techniques (CRNST), 37 Boulevard Port Royal, 75013 Paris, tristanberger@pm.me

Abstract

This article analyzes the European regulation REACH as a co-management policy tool for chemical risks. Whilst the existing literature on the topic either highlights the strong capacity of authorities to force the industry to produce the data needed for decision making, or criticizes the former's subordination to economic interests, this article takes a new approach showing how regulators and the industry use REACH to engage in systematic compromise and a pedagogical approach to chemical risks. Information and resource asymmetry make co-management necessary for the implementation of the regulation, but comes at the cost of the "no data, no market" principle.

Key words: REACH; co-management; regulation; risk; chemicals; chemicals policy

1. Introduction

The European regulation REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) entered into force on June 1, 2007, and covers most of the chemical substances produced, imported and used in the EU. To achieve "*a high level of protection of human health and the environment*", the regulation relies on four mechanisms:

1. *Registration*: producers/importers must submit the relevant information on the (eco)toxicological properties of their substances,
2. *Evaluation* of selected substances by the European Chemicals Agency (ECHA) and Member States Competent Authorities (MSCA),

3. Temporary *authorization* of substances “of very high concern” (SVHC), and
4. *Restriction* of hazardous substances.

REACH has been considered as the most ambitious chemical risk regulation ever proposed. One of its main innovations is to reverse the burden of proof on manufacturers and importers for producing the data necessary for protecting public health and the environment: “*no data, no market*”, claims article 5 with reference to the registration procedure. This formula is striking by the political force of its objectives: extensively apply the precautionary principle to protect public health, by making access of chemicals to the market conditional upon a strong non-market principle, namely their safe use.

This paper analyzes the effectiveness of this formula after thirteen years of implementation: does REACH keep dangerous substances out of the market when there is insufficient data on their safety? Does it keep its promise to produce a better knowledge of the risks of substances marketed in Europe? Has it improved European health protection?

Our methods include the content analysis of the relevant documents, publicly available on the ECHA and European Commission websites (i.e., the text of the regulation, decisions made by the Board of Appeal (BoA) concerning appeals against ECHA decisions, decisions made by the European Court of Justice (ECJ), and various reports). Furthermore, our understanding of the REACH implementation processes was significantly improved by participant observation of the first author of this paper, who carried out scientific advisory activities for a national health agency responsible for implementing the regulation from 2013 to date.

The paper is structured as follows: part 2 positions our work in the literature on “new modes of governance” and defines the co-management regime. Part 3 describes the mechanisms of co-management, present both in the text of the regulation and in the philosophy of its implementation. The fourth part describes the practical modalities of co-management, through networks allowing methodological coordination between regulators and regulated. The fifth part concludes our study.

2. From the precautionary principle to the co-management of chemical risks

2.1. “No data, no market”: a formula for a hierarchical chemical policy?

The “no data, no market” formula suggests a hierarchical relationship between the regulator and the regulated industries, in which authorities are masters of the regulatory process and are able to oblige the industry to respect the regulation – at face value. Jouzel and Lascoumes (2011) interpreted REACH as a major change in European chemical risk policy due to its use of the precautionary principle, allowing action to be taken based on the first signs of strong toxicity (e.g., carcinogenicity) and without requiring full risk assessment. By placing the burden of proof on the manufacturer, REACH would thus have solved the problem of leaving expertise solely in the hands of the administration, which had already caused significant efficiency problems. However, the analysis of Foss Hansen et al. (2007) had already showed that a large part of the regulation provisions require a level of evidence for decision-making that is much closer to a traditional model of risk assessment than to the precautionary principle.

To account for the central role of the industry in the production of regulatory information, Führ and Bizer (2007) are in line with the new modes of governance (Eberlein and Kerwer, 2004) when they propose to consider REACH as “responsive regulation”. Responsive regulation supposes that industry assumes the responsibility - in their own interest - to cooperate with the authorities. Thus, REACH would manage to promote the interest of the industry whilst defending the public interest, through "carrot and stick" mechanisms requiring a public authority to interact with all the stakeholders concerned. However, in practice, the ECHA’s interactions with the industry are largely preponderant compared to other interest groups. Formal and informal interactions with the manufacturer and its consultants begin as soon as a substance is considered for registration, and can continue repeatedly throughout various processes: technical completeness check, compliance check, evaluation, authorization, and possibly restriction. Interactions with other stakeholders are rare and essentially take place at the end of these procedures, during public consultations or when the different committees (Risk Assessment Committee, Socio-Economic Analysis Committee, Member State Committee) formulate their opinion (as observers). Furthermore, these stakeholders cannot influence the ECHA’s consideration of their feedback, while the industry has numerous administrative and legal possibilities to challenge action by the agency. All the applicants for the decisions delivered by the BoA therefore belong to the industry¹.

2.2. The other extreme: regulatory capture

¹ See <https://echa.europa.eu/fr/home> => About us => Who we are => Board of Appeal => Decisions

The regulatory capture theory is at the other extreme of political analyses. It predicts, for the agencies in charge of regulating environmental impacts of powerful industries, an evolution towards a situation where the agency no longer represents the public interest but rather the interest of the regulated sectors.

Initially defended by proponents of deregulation such as the economics Nobel Prize winner George Stigler, regulatory capture has recently been re-analyzed using empirical case studies (Carpenter and Moss, 2013). Its inevitability is currently widely contested, but the cultural influence of regulated industries on regulators remains clearly relevant (Kwak, 2013).

For Rodwin (2013), the fact that companies produce the information about the risks of their own products is synonymous of systematic regulatory influence and makes it impossible to ensure that risk assessments are as objective as possible. This situation is characteristic of “institutional corruption” (p. 544).

Similarly, Posner (2007) shows that companies have a rational interest in making any decision favorable for the marketing of their product. Therefore, they selectively communicate information (Seife, 2015). This interpretation implies that risk policies are deliberately favoring economic players, or even only legitimize the pursuit of commercial interests under the guise of a health protection policy.

2.3. Between the two: the “new governance”

Between the two extremes above, the “new governance” refers to a wide range of processes that “are designed to carry out public objectives using methods that differ in one way or another from classic forms of law” (Trubek and Trubek, 2005, p. 1). These include regulatory methods used as alternatives to the classical hierarchical “command and control” approaches (Vaughan, 2015).

The regulation of “existing” substances preceding REACH has been described by Foth and Hayes (2008) as a “co-operative policy” of chemical risks, where processes of argumentation and negotiation are more important than the resources of authority. Since the authorities do not have the capacity to generate the data necessary for the regulation of chemical risks by themselves, the industry is given the responsibility to produce the regulatory information and thus simultaneously obtains the means to influence the consequent decisions (Héritier and Eckert, 2003; Neyer, 2003). Héritier (2003) justifies the need for cooperative governance by

the complexity of collective action in the environmental field, which generates interdependencies between multiple actors located at different levels of decision-making, in both public and private spheres.

Among the different types of co-regulation (Senden et al., 2015), enforced self-regulation combines punitive elements with means of implementation that are specific to private actors. While the objectives are set by law and are mandatory, the means to achieve them remain at the discretion of the private sector.

2.4. Co-management: a form of new governance

Co-management lies between the two opposing visions, i.e. that of the strong hierarchical capacity of the authorities (“precautionary principle”) and that of their subordination to industrial interests (“capture”). Thus, the co-management implemented in REACH fits into the wider family of “new governance hybrids” (Hey et al., 2006), which combine traditional instruments with instruments involving the participation of diversified actors and an implementation that is highly attentive to economic constraints.

The co-management regime is made necessary by the weak position of the regulator, intrinsically associated with the limited resources that the latter can mobilize to produce or access the information necessary to implement the regulation, and reinforced by the regulator’s will to promote compromise rather than coercion.

In this way, co-management responds, with a subtle combination of opportunities for coercion and laxity, to the difficulties of an extremely complex, confrontational reality with high economic stakes at European and international levels. The ECHA and the Commission essentially promote a pedagogical approach towards industry and encourage incentives to voluntary changes in reaction to regulatory pressure, rather than the strict implementation of the coercions available in REACH’s legal apparatus. This is the main difference compared to the previous regulations: REACH offers regulators an increased set of possibilities to constrain the industry (refusing a registration number, refusing an authorization, pronouncing a restriction, etc.) which define the contours of the “shadow of hierarchy” (Héritier and Eckert, 2008) and provide authorities with major advantages when negotiating with the industry. While there are possibilities of coercion in REACH, in reality they are rarely used – even when the situations would allow their implementation (as we will show later). This shows the willingness of authorities to reach compromise and pedagogically shape industry’s

behavior instead of constraining and sanctioning it. This implementation method is what we label “co-management”.

The co-management chemical regime has the following characteristics:

1. Pronounced asymmetry – of both information and material resources (that can be used for expertise) – between the regulator and the regulated, benefitting the latter.
2. Great sensitivity of regulators for the economic interests of the regulated.
3. The regulator wants to be pedagogical instead of coercive. Binding procedures and sanctions are used only as a very last resort, and not before all the options for compromise have been exhausted.
4. The potential for coercion nevertheless exists, and the law provides regulators with significant sanctioning power; this is "the shadow of the hierarchy".
5. Regulators and the regulated share power essentially through agreement on the concepts and methods to be considered as having regulatory proof value. The regulated have significant power to influence these methodological foundations, which are institutionalized by post-legislative tools (guidance). These tools have no legal value, but the regulator implements them in such a way that they have a strong prescriptive power.
6. The regulator can protect the interests of the regulated with regard to other stakeholders (e.g., competing companies producing substitutes, NGOs), while the regulated agree to play the game of regulation by providing information, which guarantees the political survival ("efficiency") of the regulator.

3. Co-managing chemical risks: grounds for negotiation and compromise in the text of the regulation and in its implementation

In the text of REACH, co-management is facilitated by tools allowing coercive action by the regulator, accompanied by a multitude of "ways out" of these constraints that are made available to the industry. Certain terms, procedures, and provisions concerning the responsibilities of each stakeholder are as many “micro-grounds” for compromise between the regulator and the industry. While the regulatory existence of coercive tools constantly poses the threat of their possible use, micro-grounds offer the industry opportunities to influence regulation and retrieve some power to force regulators to compromise.

3.1. Micro-grounds in the text

3.1.1. First micro-grounds: compulsory study abstracts, but full studies to be demanded by the regulator

The analysis of the relevance and quality of a toxicological study requires access to the full text. However, the choice that has been made in REACH is to only ask registrants for the abstracts of the studies forming the basis of their hazard and risk assessments.

When the abstract does not provide sufficient information for the authorities to carry out their substance evaluation procedure, they have to contact the registrant and ask for access to the full study. In this way, REACH promotes informal sustained coordination between the authorities and the industry willing to collaborate; otherwise, a relative deadlock occurs which the authority can only resolve by using the opportunities of coercion that REACH also offers. Without the full study, the agency either takes up the results announced in the abstract and gives up its intention to carry out an in-depth analysis of their methodological robustness, or gives a critical interpretation - if the nature of the results justifies it - thus raising the threat of a request for an additional study. While the latter solution gives industry significant additional time, it is also dissuasive in terms of the cost involved and can lead them to change their initially non-cooperative attitude.

In addition, certain information communicated by registrants is unverifiable, in particular with regard to uses and exposures: if a use “disappears” or is flagged as “uses advised against” when a substance dossier is updated by the registrant during an evaluation procedure, with the explanation that this use was suppressed on the initiative of the industry itself, this explanation will prevail for the agency (which is otherwise unable to check the internal processes of companies). Such an explanation may also prove politically comfortable, because it virtually confirms the success of REACH in inciting manufacturers to change by themselves.

3.1.2. Second micro-grounds: subjectively assessed data quality

REACH is based on the principle of “no data, no market”, which cannot be interpreted as “no good quality data, no market” or “no complete data, no market”. Certain data, whether incomplete or of poor quality (studies that are sometimes decades old can be provided by industry) are always “data” and allow access to the market.

REACH uses the Klimisch score to assess the quality of toxicological studies. However, the Klimisch score is well known for its level of subjectivity of as well as its misbalanced tendency to favor standardized industry studies over academic ones (Maxim and Van der Sluijs, 2014). In addition, this preference for standardized studies does not take into account the inability of certain standardized tests to detect effects which are nevertheless of concern for REACH standards (such as endocrine disruption), or even the fact that some may be unsuitable to conclude on a sufficient level of evidence for regulatory action (e.g. identification of a substance of concern).

During the registration procedure, the regulation requires manufacturers to assess the quality of their own studies, which ignores the high degree of subjectivity of the Klimisch scores and the potential influence of conflicts of interest. Admittedly, the Member States (MS) and the ECHA can use academic literature in the evaluation and restriction procedures, but this puts the burden of human and financial resources back on the authorities, precisely when they should take advantage of the abundance of data already submitted during registration instead of having to carry out bibliographic searches and time-consuming re-evaluations of quality.

Regulators have the power to request data but have to negotiate with the industry in order to obtain sufficient amounts of quality data, and be able to somehow fulfill their regulating role. Finding a compromise through negotiation around the quantity and quality of data is characteristic of the co-management regime, where information is co-produced through round-trip communication by the two major players.

3.1.3. Third micro-grounds: proportionality in demanding information

The ECHA has the power to request additional information and further studies during the compliance check, as the MS can do during the evaluation of a substance. Both have to respect the principle of proportionality to avoid being challenged before the BoA.

According to this principle, which is regularly invoked by the registrants², the actions of EU institutions must not exceed the limits of what is "necessary" to achieve the aim sought³. Also, MSCAs must "state reasons" (art 50.4 of REACH) for requiring a new study in the evaluation procedure.

² E.g. Board of appeal, decisions n° A-008-2018, A-012-2018, A-001-2018, A-012-2017.

³ Art. 5 par. 4, Treaty on EU (JO C 326, 26.10.2012, p. 13-390).

268 According to the BoA, the competent authority can only request information if it is able to
269 demonstrate three cumulative criteria:

- 270 - there must be a potential risk for human health or the environment,
- 271 - it must be demonstrated that this risk must be clarified, and
- 272 - the information requested must enable better risk management⁴.

273 Thus the burden of proof is again reversed in this case: while companies transmit information
274 from which the authorities are supposed to identify and assess the risks, it is up to the latter to
275 demonstrate the existence of a risk, in order to request additional information. Paradoxically,
276 the MSCA has to demonstrate the lack of safety before having the information needed to
277 make that demonstration, and even to request the very information needed to prove their
278 initial claim.

279 Behind the stated objective of reversing the burden of proof, the text of the regulation and the
280 formal and informal case law created during its implementation generate an information
281 asymmetry and an imbalance of powers which make co-management necessary for the
282 authorities, enabling them to play their regulatory role as much as possible.

284 3.2. The application of regulatory constraints: seeking compromise

286 In the previous section, we showed how the text of REACH provides micro-grounds that
287 force the regulator to permanently negotiate with the manufacturer. This section analyzes how
288 the implementation of the regulation also follows a logic of compromise, even when the text
289 provides coercive measures.

291 3.2.1. Correcting non-compliant registration dossiers: the ECHA's demands for information

293 To obtain a registration number, companies must communicate safety information. The
294 majority of the registration dossiers checked by the ECHA were non-compliant with the
295 regulation: at the end of 2013, 69% of the dossiers checked by the ECHA were found to be
296 non-compliant (Luch et al., 2015; ECHA, 2014b, 2014c). Furthermore, a ClientEarth (2013)
297 report found significantly less information submitted to the ECHA database on registered
298 substances compared to published research results, which REACH's annex VI obliges the
299 industry to submit nevertheless.

⁴ BoA, decisions n° A-003-2018, A-004-2018, A-005-2018, A-008-2018, A-004-2017, A-015-2015, A-026-2015. The criteria were confirmed in a ruling of 20 September 2019, BASF Grenzach v ECHA, T-125/17..

The ECHA checked the compliance of dossiers submitted before 2017, 1350 (7.33%) of which concerned tonnage > 1000 t / year and 430 (3.79%) concerned tonnage of 100-1000 t / year. In the vast majority of cases (69% and 77% respectively), compliance checks confirmed one or more data gaps (ECHA, 2018a). Following the compliance check, the ECHA can conclude that additional information is necessary. In these cases, the agency prepares a draft decision, which initiates a pedagogic approach and a round of negotiations both with the registrant and with the other MS. The ECHA first initiates informal exchanges with the registrant to communicate the findings and invite them to correct the dossier. The draft decision is then sent to the registrant, who has a period of 30 days to respond. The draft decision can then be modified according to the registrant's comments. The draft decision, if amended, is then sent to the MSCAs, who can also propose modifications within 30 days.

When no modifications are proposed by any party, the ECHA takes the decision and sets a deadline for the registrant to respond. If modifications are suggested, the Agency must send a draft decision (possibly amended) to the Member States Committee (MSC), as well as all proposed modifications to all the registrants and downstream users concerned so that they can resubmit comments. The new draft is then sent to the MSC again. This time the unanimous agreement of the MSC is the condition for the adoption of the final decision by the agency. The registrant then has 3 months to appeal before the BoA.

If at least one MS disagrees, the Commission prepares a draft decision, and submits it to the REACH Committee. An essential component of the negotiation process set up by REACH is that the decision in the REACH Committee is taken on the basis of a qualified majority and therefore excludes the possibility of a veto from a MS.

When the REACH Committee is favorable to the request, the Commission adopts the draft decision. Otherwise, the project is not adopted. The Commission may still submit an amended version of the draft decision, but the Committee may again object to it. When a decision requesting information is adopted, and if the registrant does not provide the requested information within the time limit set in the decision, the ECHA can (finally) inform the national authorities.

This procedure shows that, for a simple request for information, with a view to bringing the registration dossier into conformity, the procedural provisions of the regulation imply a very long period of discussion where pedagogy and the strength of conviction can be widely deployed: the process takes sixty days if no one proposes a modification, and at least one

hundred and twenty days otherwise. In addition, for the same dossier, more information may be requested, each of which may give rise to a draft decision.

3.2.2. Provide the information requested (registration and evaluation): registrants' opportunities to contest

A registrant can seize the BoA to contest a request for information from the ECHA. Analysis of the BoA's decisions indicates that there are three possible results of such a request. Out of a total of 42 cases relating to requests for information by the ECHA:

- 16 information requests were canceled fully (14) or partially (2), and the BoA then decided in favor of the applicant;
- 12 requests for information were confirmed, i.e. the BoA decided in favor of the ECHA;
- 14 cases resulted in a withdrawal of the request by the ECHA⁵.

This shows the importance of negotiations in the procedures of the BoA and the ECHA's strong willingness to compromise, to the point of even avoiding going to the end of the procedures. Indeed, out of the 14 request withdrawals:

- only one case referred to a situation where the registrant finally agreed to communicate the information,
- for three cases⁶, the withdrawal was initiated by the applicant following negotiation with the agency under conditions which were not explicitly mentioned,
- in one case the ECHA revised its request following negotiation⁷,
- in the other nine cases, the ECHA gave up its request for information following the appeal (without negotiation).

At the end of the procedure before the BoA, when the latter confirms the agency's request for information, the registrant can still appeal to the ECJ - thus extending the deadline - or even declare that they have stopped or reduced manufacturing or importing the substance concerned - in which case no further information can be requested⁸. In the latter case, it is then up to national control bodies to determine whether this is actually the case or not, but in the spirit of the implementation of REACH, such a situation is more likely to be considered a pedagogical success. A priori the registrant has internalized the need to avoid the production

⁵ Analysis carried out on the 12th August 2020.

⁶ BoA, decisions n° A-007-, n° A-021-2015, n° A-012-2014.

⁷ BoA, decision n° A-018-2013.

⁸ Such a situation occurred 6 times in 2013 according to [ECHA, 2014a](#).

or import of a potentially dangerous substance, meaning that information concerning its dangers or risks is no longer necessary; however, this remains a hypothesis.

Furthermore, the MSCAs and the ECHA have a limited amount of time to finalize an evaluation dossier. When the procedure takes a long time, the authorities may find themselves in a situation where they must conclude on an evaluation dossier without having obtained the elements that had generated the very need for this procedure (e.g. a particular study). As time is a major ally for registrants - which they can mobilize at will in the various legal proceedings - authorities need to negotiate in such a way that they can nevertheless accomplish their role.

When the registrant does not respond to the ECHA's request after a compliance check, the registration number is not affected. The registrant can continue to market his substance, but the national enforcement authorities - which have to make controls and apply penalties - will be informed. However, the penalties are very different from one MS to another and their level more or less dissuasive. In addition, the different MSs vary in their capacity to apply the controls and the related penalties.

In September 2018, the ECHA announced that registration numbers had been allocated for 32515 dossiers ([ECHA, 2018b](#)) out of a total of 33363 dossiers submitted before 31 May 2018. Although the 848 remaining dossiers still lacked information, mechanisms have been set up to accommodate the conditions of any company willing to cooperate. For example, among the 848 cases of incomplete dossiers, 477 were companies facing exceptional situations as defined by the ECHA in a bid to encourage the goodwill of companies that may find themselves in difficulty. The definition of these situations is precise and essentially concerns the expectation of results from analysis laboratories, changes in the structure of companies such as mergers or acquisitions, coordination difficulties between members of an SIEF, etc. In this case, these companies benefit from a further extension to submit the required information, even if approximately 1% of the dossiers are finally rejected for lack of valid interlocutors, with the opportunity nevertheless for these registrants to change their mind and to resubmit their dossier. The Danish ministry of environment criticized this situation and asked ECHA to refuse bad quality registration dossiers, describing these practices as an abandonment of the "no data, no market" principle in favor of a "no data, no regulation" practice ([Buxton, 2017](#)).

3.2.3. Capacity of the MSCAs to request and obtain information in the evaluation procedure

The MSCAs have fewer powers than the ECHA. As part of the evaluation procedure, the latter may request "further" information (art 46.1 of REACH) provided that reasons are stated, which is considered to be synonymous in practice with proof that a concern about the risk of the substance exists.

However, this possibility does not always solve the problem, because a request for an additional study can lead to a study that has ambiguous conclusions or is methodologically questionable if the method was not explained in detail in the MSCA's request. Indeed, the quality of a study can be decisively influenced by methodological decisions relating to very precise details, such as the choice of the rat strain tested ([Maxim and Van der Sluijs, 2014](#)).

When the new study is of poor quality or inconclusive, it is very difficult for an MSCA to request another study, both because of the restrictive interpretation of the proportionality principle that could be made by the registrant to contest this new request, and because of the uncertain outcome of an additional study, which could lead to the same types of difficulties.

Furthermore, as the evaluation procedure is already long (several years), requesting a second study would mean an additional extension, a timetable delay compared to that of the ECHA and MSCA public schedule, as well as an additional investment of public resources to argue the need for this new study, interact with the registrant, analyze the new results, etc.

Not being able to finalize a dossier can be perceived as an admission of failure for an agency, similar to an inability to complete its mission in the allotted time, according to a schedule that is certainly tight but consistent with the ambitions of efficiency of REACH. These constraints encourage agencies to assess at length the need for a new study request - and in some cases, may de facto end up tolerating studies with ambiguous results in relation to the initial concerns that generated them - or even closing an evaluation dossier due to the very impasse created by the uncertainty which can no longer be resolved by a new request for information.

Furthermore, no regulatory mechanism is available to request additional information for the "exposure" aspect of the risk assessment. The ECHA does not usually request this type of information in compliance checks. In practice, it cannot be formally requested by MSCAs during the evaluation procedure either, and they are encouraged to request such information informally by contacting the registrants. However, MSCAs must demonstrate a risk to request additional information, and this is an extremely difficult task when based only on information relating to the danger of the substance, and if the information concerning the exposure is of

poor quality or even absent. The authorities thus have two ways of obtaining this information: they can either finance the production of the necessary data (if they have the resources and if this data does not come from inaccessible production practices) or communicate with the registrant. The latter solution is the most economical, and encourages the authorities to adopt the negotiation-compromise approach that characterizes the co-management regime.

3.2.4. Penalties applied by MSs for refusal to communicate information

In the event of a violation of the REACH provisions, MSs should determine “*effective, proportionate and dissuasive penalties for non-compliance*”⁹. All MSs have indeed adopted a sanction regime (European Commission, 2010), but these penalties do not really play a coercive role, which shows once again the priority given to compromise between the authorities and manufacturers. At the MS level, the ECHA (2015) reported 1169 companies and 5746 substances inspected by national authorities in 2013 and 2014. Overall, 13% of companies were in non-compliance with their registration obligations, and 2% of these companies had not registered any of the substances that required registration. Importers were more often in non-compliance than producers. States imposed financial penalties in 10% of the cases and initiated criminal proceedings in 7% of the cases. However, in most cases (69%) the authorities decided to only give advice to the companies concerned or simply asked them to comply with their obligations (23% of cases). In 41% of the cases, a long-term monitoring procedure for the actions implemented by the companies had been decided.

In most cases, when a dossier is non-compliant, the authorities only give verbal or written advice (ECHA, 2014b ; 2014c). The approach therefore remains pedagogic and accommodating. Even if they have the power of coercion, the authorities consciously decide not to use it to preserve the logic of compromise, which we have identified as one of the main characteristics of the co-management regime.

Over the 2012-2017 period, 207 Statements of Non-Compliance (SONC) were issued (114 for reasons of compliance check and 93 for test proposals), all of which were notified to the MSs. In 2017, 76 SONCs (about 40%) were still unresolved. In order to promote a cooperative approach between MSs and non-compliant manufacturers, the ECHA did not publish SONCs precisely so as to avoid putting registrants in the public eye and rather encourage them to find solutions to their non-compliance.

⁹ § 122 of the preamble and art. 126 of REACH

Even if the sanctions were implemented, would they be dissuasive? Jurisprudence specifies that the dissuasive measures aim to repress unlawful behavior and prevent its recurrence¹⁰. For chemicals, the penalties for non-compliant cases are, in some cases, lower than the cost of compliance – meaning that it is more profitable in the short term for a company to take the risk of being sanctioned than to be compliant (European Commission, 2010).

This is especially the case for substances manufactured or imported in quantities of 1000 t / year or more. The cost of compliance with legal requirements for registration is estimated at 217450€ per dossier. The European Commission (2010) notes that at least fifteen MSs were applying sanctions lower than this amount in 2009, knowing that the sanctions vary widely from one country to another, with maximum values varying from 5000 to 55000000 euros if we compare Latvia and Belgium.

A second element makes it possible to qualify a sanction as "dissuasive", which is the probability of being sanctioned. In 2013 and 2014, only 1169 companies had been controlled out of the 14713 that had submitted registration dossiers. This amounts to 4% per year, with 0.4% who are given financial sanctions.

4. The practical modalities of co-management: arenas of methodological coordination

As shown in the previous sections, the ECHA has many incentives to adopt a pedagogical and compromissory approach. First, there are many opportunities for registrants to challenge decisions made by the ECHA. The agency must respect long and complex procedures and the levels of coordination are multiple, allowing a systematic interaction with the industry concerned at each level. To limit the risk of challenging its actions, the ECHA prefers ex-ante coordination, in particular through "expert groups". These provide the basis for political coordination through compromise around methods, which are then recognized as legitimate by the agency. In these groups, negotiations are carried out in the language of expertise between representatives of the ECHA, the MSs, the Commission and the industry, and sometimes certain NGOs. Many such groups are active, some examples being the *Collaborative Approach* ("COLLA", gathering representatives of the ECHA, the MS and the industry on a number of substances subject to manual screening for prioritization), the *Metals and Inorganics Sectoral Approach* ("MISA", a cooperative platform between the ECHA and

¹⁰ Court of First Instance (Second Chamber), 12.12.2007, case n° T-101/05 and T-111/05, § 43 ; 9.09.2011, case n° T-25/06, § 234.

the metals industry that drafts methods), the *Exchange Network on Exposure Scenarios* (“ENES”, linking the ECHA, the MSs and industry representatives such as Cefic, Concawe, Eurometaux, Fecc and DUCC to share knowledge and methods to build exposure scenarios), the *Petroleum and Coal stream Substances* (“Petco”, linking the ECHA, the Commission and the industry, for carbon and oil derivatives).

In the co-management regime, authorities and regulated industries share power through technical language, concepts and methods to be considered as having value of proof to implement the regulation. Even if these methods have no a priori legal value, they constitute means that regulators can then use to have a strong prescriptive power (Vaughan, 2015).

5. Conclusion

The questions we planned to answer were: with a “no data, no market” principle put forward, does REACH keep dangerous substances out of the market when data on their safety is not sufficient? Does REACH keep its promise to produce a better knowledge of chemical risks in Europe than its regulatory predecessors? Does it provide better health protection for Europeans?

The answer to the first question is “no”. In certain cases, it seems difficult for the ECHA to obtain missing data from registration dossiers, and the MSCAs have difficulties to obtain the data needed during evaluation procedures. Nevertheless, incomplete and low quality data do not impact registration numbers, and substances can still be marketed.

Despite the huge quantity of data now available, it is hard to say if REACH really provides a better knowledge of chemical risks in Europe. Many registration dossiers are not complete, and the quality of all the available data is uncertain. The co-management regime gives the industry the responsibility of assessing data quality during registration. Regulators can assess data quality during the evaluation, authorisation and restriction processes. However, regulators implement these three procedures through continuous interaction with the industry, and the quality of the data used through is continuously negotiated to find a compromise with the industry’s interests, in particular for substance registration and authorization.

Broadly speaking, it is hard to say if REACH protects the health of Europeans better than its regulatory predecessors. The European Commission has constantly put forward the idea that REACH is a strong expression of the precautionary principle. The very adoption of the regulation, after five years of conflicting negotiations, has been considered a victory for the

objectives of protecting public health. However, the interpretation given to the text of the regulation throughout its implementation strongly questions this discourse. The incomplete information submitted in the registration dossiers does not give rise to actions to protect public health but rather to endless loops of negotiation and compromise with manufacturers. Few evaluation dossiers for potentially risky substances are finalized, years after their initiation, and are not always finalized as regulators would have wanted. All this might contribute to persisting potential risks to public health. In addition, the authorization procedure systematically allows substances recognized as dangerous (SVHC) to continue to be marketed (all but one request for authorization have been granted). Finally, restrictions often concern marginal uses of dangerous substances and in some cases only replace one risk by another (such as the restriction of Bisphenol-A in cash receipts, much of which was quickly replaced by Bisphenol-S). While REACH undoubtedly offers coercive tools (possibility of refusing a registration number, of restricting the use of a substance or of refusing an authorization), these constraints are rarely used.

However, the text of REACH contained an important potential of hierarchical policy based on coercion and strict respect of legal provisions. Why was it interpreted in such a way during its implementation that, thirteen years after its entry into force, its efficacy in reducing chemical impacts on Europeans' health remains uncertain? The response we propose in this paper is that strong information asymmetry and the low human and financial resources of public authorities weakened by continuous deregulatory policies led regulators to promote a co-management regime in order to obtain (or at least demonstrate) efficacy in dealing with chemical risks.

While it allows access to information that is difficult or even impossible to obtain with public resources, co-management - masked by the argument of the legitimate reversal of the burden of proof – demonstrates the regulators' willingness to force self-regulation. The production of information processes in the private sector has a more pedagogical function than direct usefulness for coercively reducing risks: the authorities hope that producing risk data would lead companies to learn about their risks, to understand their origins, to ask about the need to produce / import one substance rather than another, to come into closer contact with their downstream users, or even give up a risky activity.

While co-management certainly does not respond to the initial condition of "no data, no market", it nevertheless adapts to the constraints of a very complex reality, characterized by an imbalance of resources that disadvantage the regulators and had led to the obvious

ineffectiveness of the regulations preceding REACH. Unable to produce the information that is necessary for them to exercise their role, regulators use the regulatory text to project “the shadow of the hierarchy”, thus accumulating resources of authority that they most often use simply to strengthen their negotiating position with the industry. While it does not provide the level of public health protection expected and announced at the adoption of REACH, co-management responds pragmatically to the heavy constraints of governing chemical risks in a wider context of the weakened powers of States in their relationship with the private sector, namely information asymmetry, the high costs of producing information, the significant resources necessary for its processing and use, a persistent uncertainty regardless of the quantity of data available, and very high socioeconomic stakes.

Competing interests

The authors declare no competing interests.

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