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1 *No data, no market... really?*

2 **REACH as co-management of chemical risks**

3
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12
13 **Abstract**

14
15 This article analyzes the European regulation REACH as a co-management policy tool for
16 chemical risks. Whilst the existing literature on the topic either highlights the strong capacity
17 of authorities to force the industry to produce the data needed for decision making, or
18 criticizes the former's subordination to economic interests, this article takes a new approach
19 showing how regulators and the industry use REACH to engage in systematic compromise
20 and a pedagogical approach to chemical risks. Information and resource asymmetry make co-
21 management necessary for the implementation of the regulation, but comes at the cost of the
22 "no data, no market" principle.

23
24 **Key words:** REACH; co-management; regulation; risk; chemicals; chemicals policy

25
26 **1. Introduction**

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

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

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

37
38 REACH has been considered as the most ambitious chemical risk regulation ever proposed.
39 One of its main innovations is to reverse the burden of proof on manufacturers and importers
40 for producing the data necessary for protecting public health and the environment: “*no data,*
41 *no market*”, claims article 5 with reference to the registration procedure. This formula is
42 striking by the political force of its objectives: extensively apply the precautionary principle
43 to protect public health, by making access of chemicals to the market conditional upon a
44 strong non-market principle, namely their safe use.

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

49
50 Our methods include the content analysis of the relevant documents, publicly available on the
51 ECHA and European Commission websites (i.e., the text of the regulation, decisions made by
52 the Board of Appeal (BoA) concerning appeals against ECHA decisions, decisions made by
53 the European Court of Justice (ECJ), and various reports). Furthermore, our understanding of
54 the REACH implementation processes was significantly improved by participant observation
55 of the first author of this paper, who carried out scientific advisory activities for a national
56 health agency responsible for implementing the regulation from 2013 to date.

57
58 The paper is structured as follows: part 2 positions our work in the literature on “new modes
59 of governance” and defines the co-management regime. Part 3 describes the mechanisms of
60 co-management, present both in the text of the regulation and in the philosophy of its
61 implementation. The fourth part describes the practical modalities of co-management, through
62 networks allowing methodological coordination between regulators and regulated. The fifth
63 part concludes our study.

64

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

66

67 2.1. “No data, no market”: a formula for a hierarchical chemical policy?

68

69 The “no data, no market” formula suggests a hierarchical relationship between the regulator
70 and the regulated industries, in which authorities are masters of the regulatory process and are
71 able to oblige the industry to respect the regulation – at face value. [Jouzel and Lascoumes](#)
72 [\(2011\)](#) interpreted REACH as a major change in European chemical risk policy due to its use
73 of the precautionary principle, allowing action to be taken based on the first signs of strong
74 toxicity (e.g., carcinogenicity) and without requiring full risk assessment. By placing the
75 burden of proof on the manufacturer, REACH would thus have solved the problem of leaving
76 expertise solely in the hands of the administration, which had already caused significant
77 efficiency problems. However, the analysis of [Foss Hansen et al. \(2007\)](#) had already showed
78 that a large part of the regulation provisions require a level of evidence for decision-making
79 that is much closer to a traditional model of risk assessment than to the precautionary
80 principle.

81 To account for the central role of the industry in the production of regulatory information,
82 [Führ and Bizer \(2007\)](#) are in line with the new modes of governance ([Eberlein and Kerwer,](#)
83 [2004](#)) when they propose to consider REACH as “responsive regulation”. Responsive
84 regulation supposes that industry assumes the responsibility - in their own interest - to
85 cooperate with the authorities. Thus, REACH would manage to promote the interest of the
86 industry whilst defending the public interest, through "carrot and stick" mechanisms requiring
87 a public authority to interact with all the stakeholders concerned. However, in practice, the
88 ECHA’s interactions with the industry are largely preponderant compared to other interest
89 groups. Formal and informal interactions with the manufacturer and its consultants begin as
90 soon as a substance is considered for registration, and can continue repeatedly throughout
91 various processes: technical completeness check, compliance check, evaluation, authorization,
92 and possibly restriction. Interactions with other stakeholders are rare and essentially take
93 place at the end of these procedures, during public consultations or when the different
94 committees (Risk Assessment Committee, Socio-Economic Analysis Committee, Member
95 State Committee) formulate their opinion (as observers). Furthermore, these stakeholders
96 cannot influence the ECHA’s consideration of their feedback, while the industry has
97 numerous administrative and legal possibilities to challenge action by the agency. All the
98 applicants for the decisions delivered by the BoA therefore belong to the industry¹.

99

100 2.2. The other extreme: regulatory capture

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

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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

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

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

142

143 2.4. Co-management: a form of new governance

144

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

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

155

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

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

171

172 The co-management chemical regime has the following characteristics:

173

174 1. Pronounced asymmetry – of both information and material resources (that can be used for
175 expertise) – between the regulator and the regulated, benefitting the latter.

176 2. Great sensitivity of regulators for the economic interests of the regulated.

177 3. The regulator wants to be pedagogical instead of coercive. Binding procedures and
178 sanctions are used only as a very last resort, and not before all the options for compromise
179 have been exhausted.

180 4. The potential for coercion nevertheless exists, and the law provides regulators with
181 significant sanctioning power; this is "the shadow of the hierarchy".

182 5. Regulators and the regulated share power essentially through agreement on the concepts
183 and methods to be considered as having regulatory proof value. The regulated have significant
184 power to influence these methodological foundations, which are institutionalized by post-
185 legislative tools (guidance). These tools have no legal value, but the regulator implements
186 them in such a way that they have a strong prescriptive power.

187 6. The regulator can protect the interests of the regulated with regard to other stakeholders
188 (e.g., competing companies producing substitutes, NGOs), while the regulated agree to play
189 the game of regulation by providing information, which guarantees the political survival
190 ("efficiency") of the regulator.

191

192 **3. Co-managing chemical risks: grounds for negotiation and compromise in the text of** 193 **the regulation and in its implementation**

194

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

202

203 3.1. Micro-grounds in the text

204

205 3.1.1. First micro-grounds: compulsory study abstracts, but full studies to be demanded by the
206 regulator

207

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

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

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

230

231 3.1.2. Second micro-grounds: subjectively assessed data quality

232

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

237

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

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

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

258

259 3.1.3. Third micro-grounds: proportionality in demanding information

260

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

264 According to this principle, which is regularly invoked by the registrants², the actions of EU
265 institutions must not exceed the limits of what is "necessary" to achieve the aim sought³.

266 Also, MSCAs must "state reasons" (art 50.4 of REACH) for requiring a new study in the
267 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.

283

284 3.2. The application of regulatory constraints: seeking compromise

285

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.

290

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

292

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..

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

311

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

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

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

329

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

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

336

337 3.2.2. Provide the information requested (registration and evaluation): registrants'
338 opportunities to contest

339

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

343 - 16 information requests were canceled fully (14) or partially (2), and the BoA then decided
344 in favor of the applicant;

345 - 12 requests for information were confirmed, i.e. the BoA decided in favor of the ECHA;

346 - 14 cases resulted in a withdrawal of the request by the ECHA⁵.

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

350 - only one case referred to a situation where the registrant finally agreed to communicate the
351 information,

352 - for three cases⁶, the withdrawal was initiated by the applicant following negotiation with the
353 agency under conditions which were not explicitly mentioned,

354 - in one case the ECHA revised its request following negotiation⁷,

355 - in the other nine cases, the ECHA gave up its request for information following the appeal
356 (without negotiation).

357

358 At the end of the procedure before the BoA, when the latter confirms the agency's request for
359 information, the registrant can still appeal to the ECJ - thus extending the deadline - or even
360 declare that they have stopped or reduced manufacturing or importing the substance
361 concerned - in which case no further information can be requested⁸. In the latter case, it is
362 then up to national control bodies to determine whether this is actually the case or not, but in
363 the spirit of the implementation of REACH, such a situation is more likely to be considered a
364 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](#).

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

367

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

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

381

382 In September 2018, the ECHA announced that registration numbers had been allocated for
383 32515 dossiers ([ECHA, 2018b](#)) out of a total of 33363 dossiers submitted before 31 May
384 2018. Although the 848 remaining dossiers still lacked information, mechanisms have been
385 set up to accommodate the conditions of any company willing to cooperate. For example,
386 among the 848 cases of incomplete dossiers, 477 were companies facing exceptional
387 situations as defined by the ECHA in a bid to encourage the goodwill of companies that may
388 find themselves in difficulty. The definition of these situations is precise and essentially
389 concerns the expectation of results from analysis laboratories, changes in the structure of
390 companies such as mergers or acquisitions, coordination difficulties between members of an
391 SIEF, etc. In this case, these companies benefit from a further extension to submit the
392 required information, even if approximately 1% of the dossiers are finally rejected for lack of
393 valid interlocutors, with the opportunity nevertheless for these registrants to change their
394 mind and to resubmit their dossier. The Danish ministry of environment criticized this
395 situation and asked ECHA to refuse bad quality registration dossiers, describing these
396 practices as an abandonment of the "no data, no market" principle in favor of a "no data, no
397 regulation" practice ([Buxton, 2017](#)).

398

399 3.2.3. Capacity of the MSCAs to request and obtain information in the evaluation procedure

400

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

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

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

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

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

425

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

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

438

439 3.2.4. Penalties applied by MSs for refusal to communicate information

440

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

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

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

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

465

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

471 This is especially the case for substances manufactured or imported in quantities of 1000 t /
472 year or more. The cost of compliance with legal requirements for registration is estimated at
473 217450€ per dossier. The European Commission (2010) notes that at least fifteen MSs were
474 applying sanctions lower than this amount in 2009, knowing that the sanctions vary widely
475 from one country to another, with maximum values varying from 5000 to 55000000 euros if
476 we compare Latvia and Belgium.

477 A second element makes it possible to qualify a sanction as "dissuasive", which is the
478 probability of being sanctioned. In 2013 and 2014, only 1169 companies had been controlled
479 out of the 14713 that had submitted registration dossiers. This amounts to 4% per year, with
480 0.4% who are given financial sanctions.

481

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

483

484 As shown in the previous sections, the ECHA has many incentives to adopt a pedagogical and
485 compromissory approach. First, there are many opportunities for registrants to challenge
486 decisions made by the ECHA. The agency must respect long and complex procedures and the
487 levels of coordination are multiple, allowing a systematic interaction with the industry
488 concerned at each level. To limit the risk of challenging its actions, the ECHA prefers ex-ante
489 coordination, in particular through "expert groups". These provide the basis for political
490 coordination through compromise around methods, which are then recognized as legitimate
491 by the agency. In these groups, negotiations are carried out in the language of expertise
492 between representatives of the ECHA, the MSs, the Commission and the industry, and
493 sometimes certain NGOs. Many such groups are active, some examples being *the*
494 *Collaborative Approach* ("COLLA", gathering representatives of the ECHA, the MS and the
495 industry on a number of substances subject to manual screening for prioritization), the *Metals*
496 *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.

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

502

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

507

508 **5. Conclusion**

509

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

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

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

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

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

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

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

561

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

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

575

576 **Competing interests**

577

578 The authors declare no competing interests.

579

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