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Advancing REACH: Dossier Evaluation

Final report

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Advancing REACH: Dossier Evaluation

Final report

by

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Abstract: Advancing REACH: Dossier Evaluation

This report is provided in the scope of the project “Advancing REACH”, funded by the research plan of the German Ministry of the Environment. The project aims to develop options to improve (the implementation of) the REACH regulation by analysing various REACH processes and related issues, including substitution, sustainable chemistry, precautionary principle, articles, cost-benefit analyses, socio-economic analyses and financing ECHA.

The study analyses, under the perspective of the aims of the REACH Regulation, how the quality of registration dossiers could be improved. Starting point are empirical data, including those provided by ECHA, indicating that a relevant part of the registration dossiers does not meet the requirements set out in REACH.

The study examines the requirements of the relevant legal mechanisms completeness check and dossier evaluation, as well as their practical implementation and, based on available data, the measurable effects of these. The report then develops "policy options" that can contribute to an improvement.

An in-depth impact assessment of the presented options is not part of the study. Nevertheless, the results suggest that the legal context requires clarification. This applies to each of the analysed problem areas.

Kurzbeschreibung: REACH Weiterentwicklung - Dossierqualität

Dieser Bericht ist Teil des Ressortforschungsplan Vorhabens „REACH-Weiterentwicklung“, das basierend auf Analysen verschiedener REACH-Prozesse sowie angrenzender Fragestellungen (Substitution, Nachhaltige Chemie, Vorsorgeprinzip, Erzeugnisse, Kosten-Nutzen Analysen, Sozio-Ökomische Analysen, Finanzierung der ECHA) Optionen für eine Verbesserung der (Umsetzung der) REACH-Verordnung entwickelte.

Die Studie analysiert unter dem Blickwinkel der Ziele der REACH-Verordnung wie sich die Qualität von Registrierungsdossiers verbessern ließe. Ausgangspunkt ist, dass empirische Daten, u.a. von der ECHA zur Verfügung gestellt, darauf hindeuten, dass ein relevanter Teil der Registrierungsdossiers die in REACH formulierten Anforderungen nicht erfüllt.

Die Studie untersucht die Anforderungen der relevanten rechtlichen Mechanismen Vollständigkeitsprüfung und Dossierbewertung sowie deren praktische Umsetzung, und anhand vorliegender Daten deren messbare Auswirkungen. Auf der Grundlage der gewonnenen Erkenntnisse entwickelt der Bericht „Policy Options“, die zu einer Verbesserung beitragen können.

Eine eingehende Folgenabschätzung der vorgestellten Optionen ist nicht Gegenstand der Studie. Dennoch legen die Ergebnisse nahe, dass der rechtliche Kontext klarstellender Maßnahmen bedarf. Dies gilt für jeden der analysierten Problembereiche.

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CARACAL	Competent Authorities for REACH and CLP
CCH	Compliance Check
CoRAP	Community Rolling Action Plan
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
Dev	Dossier Evaluation
DU	Downstream User(s)
ECHA	European Chemicals Agency
ECC	Enhanced Completeness Check
ED	Endocrine Disruptive (properties)
eMS	evaluating Member State (under SEv)
EOGRTS	Extended One-Generation Reproductive Toxicity Study
FTR	Failure To Respond
CLH	Harmonized Classification and Labelling
IUCLID	International Uniform ChemicaL Information Database
IR	Information Requirements
IRS	Integrated Regulatory Strategy
JAP	(REACH Evaluation) Joint Action Plan (by European Commission and ECHA)
MAWP	Multi-Annual Working Plan (of ECHA)
MSC	Member State Committee
MSCA	Member State Competent Authority
NEA	National Enforcement Authorities
OSOR	One Substance, One Registration
PfA	Proposals for Amendment(s)
REEG	REACH Exposure Expert Group
REF	REACH-EN-FORCE
SEv	Substance Evaluation
SONC	Statement Of Non-Compliance
SWD	(European Commission) Staff Working Document
t/a	Ton per year (annum)
TCC	Technical Completeness Check
TPE	Testing Proposal Examination
WSSD	World Summit on Sustainable Development

Summary

The current report is one of the results of the project "Advancing REACH", which is funded by the research plan of the German Ministry of the Environment. Within the project framework, various aspects of the REACH regulation and its implementation are analysed and improvement options developed, including potential changes in the regulatory text and its annexes.

The project "Advancing REACH" consists of 18 sub-projects, which discuss different aspects of (the implementation of) the regulation and related improvement options. Topics of the sub-projects are the REACH processes dossier evaluation, substance evaluation, restriction, authorisation and consultation, as well as the role of the board of appeal and the interplay of the processes. In addition, the relation between REACH and sustainable chemistry, the implementation of the precautionary principle, the enhancement of substitution and the assessment of benefits of REACH are evaluated, as well as the procedures of the socio-economic analysis, options to regulate substances in articles and the financing of the European chemicals agency's (ECHA) tasks.

To "ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation" are the objectives laid down in Art. 1(1) of the European Chemicals Regulation REACH (1907/2006). Five pillars structure the legal framework, i.e. the registration of chemical substances in a tonnage-oriented and step-wise approach stretched over a decade, evaluation of registration data and substances, supply chain communication and cooperation, the authorisation regime regarding substances of very high concern (SVHCs), and the restriction if substances may cause an unacceptable risk to human health or the environment. Yet, the registration scheme provides the data basis for all other pillars; with the final registration deadline for substances manufactured or imported in quantities between 1 and 100 tons being expired in May 2018. The "No data, no market" principle set out in Art. 5 REACH stipulates that "substances on their own, in mixtures or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions".

Recital 19 of REACH summarises that these registration provisions "require manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures. To ensure that they actually meet these obligations, as well as for transparency reasons, registration should require them to submit a dossier containing all this information to the Agency", i.e. the European Chemicals Agency (ECHA). It is the data on a substance's physico-chemical properties, toxicological and ecotoxicological effects, as well as exposure and risk information submitted by the economic actors that is needed to allow for proper risk communication along supply chains, and that inform risk management measures by authorities, e.g. the identification of SVHCs and of "unacceptable risks" (Art. 68 REACH) which may trigger a restriction process. Adequate quality of the registration data is thus central for REACH to attain its objectives. This also entails topicality, as Art. 22 REACH obliges registrants to keep their data up-to-date.

These obligations underpin the underlying regulatory approach of REACH that, at least to a large extent, is built upon "self-responsibility" of supply chain actors; captured, i.a. in Art. 1(3) REACH formulating the "principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment".

The empirical data provided i.a. by ECHA, on the other hand, indicate that a relevant fraction of registration dossiers does not meet the requirements formulated in REACH.

Aim and structure of the report

Against this normative and empirical background, the report analyses whether and how the quality of registration dossiers can be (efficiently) improved. From a procedural perspective, the first step for ECHA is to "ascertain" that submitted dossiers are complete in the sense that the registrant has provided all "elements" mentioned in Art. 20(2) REACH. Deficits in this first "duty of the Agency" (Art. 20) influence the workload and the effectiveness of the subsequent step "dossier evaluation" as foreseen in Title VI Chapter 1 of REACH. Art. 40 stipulates the testing proposal examination (TPE), i.e. ECHA has to "examine any testing proposal set out in a registration". Besides, the compliance check (CCH) rules of Art. 41(1) and (5) mandate ECHA to "examine any registration in order to verify" the conformity with the information requirements and oblige the Agency to check "no lower than 5 %" of the dossiers received for each tonnage band. This quota thus guided ECHA's compliance checking activities until 2019, which are subject to the study at hand. Commission Regulation (EU) 2020/507 of 7 April 2020 however implemented a 20% threshold for the subsequent CCH work.

In terms of self-responsibility, the two procedural measures "completeness check" and the "dossier evaluation" serve as institutional framework providing incentives towards the registration regime. Thus, both elements are to be considered in terms of "dossier quality".

Policy options strengthening the related incentives are therefore the main focus of this report. To this end, it assesses the requirements of the relevant legal mechanisms, as well as the practical implementation and, based on available empirical data, any measurable impacts of these mechanisms.

The work draws on literature research, including documents and studies in the course of the REACH REFIT-process. Besides, expert input by German authority representatives involved in the various procedures of REACH was received on the draft report. Nevertheless, the report presents the opinions of the authors.

Completeness Check

Article 20(2), first sentence, obliges ECHA to "ascertain" that "all elements" (not: data) have been provided, which are "required" in the relevant Articles (and corresponding Annexes). This obligation is not limited to the "technical dossier" as defined in Art. 10(a); rather, it includes the "chemical safety report when required under Article 14, in the format specified in Annex I" according to Art. 10(b). If the registration dossier is not complete ECHA cannot legally grant the registrant a registration number and consequently the "no data, no market"-principle applies.

Operationalisation of the Completeness Check

In the first years ECHA limited the Completeness Check to a purely technical approach allowing that dossiers without meaningful information entered the system. After a BoA decision (Case A-022-2013, 15 March 2016, "charcoal I") ECHA introduced in 2016 an "enhanced approach" which will be replaced by an even more "enhanced approach II" in October 2020. With that, ECHA scrutinizes new registrations as well as updates in a manner that provides a complete different set of incentives to comply with the regulation. The registrants are now aware that beside the (automated) technical completeness check a manual control is possible. This perception alone creates an additional incentive to comply with "all the elements required" under REACH. This obligation covers also the chemical safety report (Art. 10(b)). It can be expected that ECHA, when the strategic change is completed, is in the position to address the issue of severely incomplete dossiers adequately. It will take years, though, until a substantial

number of dossiers will be checked following the provisions of the enhanced completeness check.

Besides, deficits of the initial approach of the completeness check are still relevant. They affected the first two registration deadlines applicable to the highest tonnage bands and to substances with known CMR properties and adverse effects in the water compartment. Thus, a highly relevant part of the chemical universe was able to slip into the registration system without proper completeness ascertainment as foreseen in Art. 20(2), first Sentence. With this approach, constantly challenged in the ECHA management board (c.f. section 3.1), the ECHA Secretariat put the entire REACH registration regime at risk. The insufficient completeness check contributed to a high level of incompliant registration dossiers since the function of a gatekeeper to the system based on self-responsibility was not enacted adequately. The enhanced completeness check aims to improve the situation substantially.

The legal consequence of an incomplete dossier is simple, but striking: no registration number is assigned. This option, however, is only available for new registrations. It does not apply to registration dossiers already accepted in the years before. Here, the effect of the registration number remains valid even in cases where the incompleteness of the original dossier is unveiled in the course of the enhanced completeness check in an update procedure.

Policy Options

However, the problem of the not updated inadequate dossier remains to be solved. In a legal perspective, the application of the "no data, no market" principle by means of the withdrawal of the registration number is the appropriate administrative measure. REACH does not mention this remedy explicitly. This does not mean that it is not available to ECHA. On the contrary, based on the general administrative procedure requirement captured in the "acquis communautaire" ECHA has the power to enact this legal consequence. Preferably, the legislative bodies should add an explicit legal basis to the REACH Regulation (for a proposal see section 6.2.5.1).

Dossier Evaluation

Operationalisation of Compliance Check

Considering the unspecific CCH mandate outlined above, the Agency had to develop, and modify as appropriate, a strategic approach for CCH activities (for details, see section 5.1). Between 2012 and 2014, under the "areas of concern" approach, the majority of compliance checks addressed specific parts of dossiers, such as physico-chemical properties or missing environmental and human health information. The focus was on targeting easily identifiable data gaps (by IT algorithms) and addressing them in a standardised manner. While these targeted inspections helped identifying selected non-compliances, the scope of data requirements assessed was quite narrow and the overall approach did not sufficiently contribute to reduced rates of non-compliance or ensured dossiers containing all requested information. Likewise, it did not yield significant output for the other regulatory mechanisms, given that information obtained in dossier evaluation shall feed into substance evaluation, the authorisation and restriction procedures and other instruments outside of REACH. ECHA's compliance check approach subsequently, after having passed some additional milestones (such as the 8 super endpoint concept in 2014), evolved into an Integrated Regulatory Strategy (IRS) based on a careful mapping of the "universe of substances" and taking a more holistic view by fostering the interplay of the different REACH instruments contributing to dossier quality.

Dossier Evaluation outputs and inputs, and recent regulatory developments

With a view to ECHA's duty to check at least 5% of dossiers received for every tonnage band, the Agency reports that, between 2009 and 2019, it performed a "full compliance check" for 20.5%

of the substances registered in the highest tonnage band, as well as for 18% of substances registered in tonnage band 100 – 1.000 t/a, 4% of the next lower tonnage band (10 – 100 t/a) and 1% of the lowest band (below 10 t/a). Apparently, the number of final CCH decisions per year is levelling off at around 150, each stipulating several data requests (e.g. addressing 721 information requirements in 2019; cf. section 5.2.1 as for the details). The number of dossiers in CCH recently increased considerably: ECHA states to have carried out 301 full checks in 2019, i.e. an increase of more than 50% compared to the previous year.

As regards the CCH activities until the end of 2017, ECHA found 69% of 1 350 dossiers evaluated in the highest tonnage band, and 77% of 430 dossiers one band below respectively, non-compliant with respect to one or more data requirements. Irrespective of tonnage band, the numbers published for 2018 and 2019 indicate that in about 75% of the evaluated dossiers ECHA detected non-compliance. Comparable compliance check activities done by Member States further substantiate the general notion that non-compliance is rather widespread (cf. section 5.2.2).

After the first ten years of REACH, one should be cautious in drawing general conclusions from identified non-compliances since related findings at least to some extent are reflecting the CCH focus under the former "Area of Concern" strategic approach, in which the Agency addressed targeted endpoints. Hence, concluding that these findings show the most relevant or common violations of the data requirements is not appropriate. Indeed, a common source for non-compliance are the conditions under which registrants use alternative data (e. g. read-across to other substances) as well as insufficient justifications for data waiving or adaptations. In this respect, parts of the data requirements in the Annexes lack precision, e.g. whenever the wording "if the chemical safety assessment according to Annex I indicates the need to investigate further…" is used. Lack of or insufficient exposure data is an additional important source of non-compliance (cf. section 5.2.2).

Follow-up assessments of evaluation outcomes became an important activity. Whilst in the clear majority (about three-quarters) of assessments, registrants provided the data requested by the CCH decision within the deadline, in 13% they did so only after national authorities had been involved. Administrative actions by national enforcement authorities can therefore be considered an effective tool to motivate tardy registrants. However, employing legal remedies CCH decision addressees successfully challenged the former approach put in place by ECHA, i.e. issuing an (informal) statement of non-compliance (SONC) to Member States. The currently adapted approach is likewise under legal scrutiny (cf. section 5.2.3).

CCH activities so far led to 52 substances considered as possible candidates for a proposal for harmonised classification and labelling – note that 17 candidates out of these 52 have been identified in 2019 alone – and three potential candidates for substance evaluation. Statistical data on the effect that CCH might have had on SVHC identification and the (few) restrictions issued under REACH are not available (cf. section 5.2.3).

As for the TPE outputs, available information from ECHA reports and documentation is rather scarce. It is not clear to what extent ECHA addressed the examination priorities set out in Art. 40(1). Neither are detailed data available on the Agency's performance with respect to non-phase-in substances for which REACH stipulates a 180-day period for ECHA's examination and draft decision preparation, including related priority setting.

Registrants submitted the most testing proposals (about two-thirds) to clarify the potential hazards to human health. In very few cases, ECHA has rejected the proposal as unnecessary. One should be cautious, though, to conclude from this observation that registrants do carefully consider before they propose further animal testing. Rather, ECHA's TPE practice was subject to

a complaint lodged with the EU Ombudsman, who in September 2015 concluded that ECHA "did not take into account the fact that the avoidance of animal testing was, together with the protection of human health and the environment, one of the guiding principles of the Regulation" (cf. section 5.3.2).

Overall, the number of testing proposals is considered low. Registrants making generous use of the option to submit adaptations to standard information requirements is one possible explanation. However, for environmental endpoints, in particular, ECHA identified many cases where registrants did not submit a testing proposal but did not succeed to justify and document their adaptations adequately either. Besides, ECHA observes the overall impact of third party consultations in the TPE context as "relatively limited" (cf. section 5.3.2).

Between 2013 and 2019, TPE yielded 84 substances considered as possible candidates for a proposal for harmonised classification and labelling and two for substance evaluation.

Considering the input perspective, ECHA and Member States invest considerable resources in dossier evaluation activities. There are estimates referring to one FTE staff member at the Agency capable of performing five CCHs per year. According to other estimates, the average time to complete a CCH is 461 days; and 340 days on average for the assessment and decision-making in TPE. In addition, in the 2nd REACH Review more than 25% of ECHA's CCH resources are estimated to be allocated to decision making, including interaction with registrant, MSCAs and MSC agreement seeking (but excluding the scientific evaluation). Related interactions however have been enhanced already (cf. section 5.4.3).

In addition, registrants may appeal CCH decision before the Board of Appeals. However, the appeals rate (about 3% of all CCH decisions) is rather low, indicating ECHA does not go beyond the competences (cf. section 5.4.3).

In conclusion, shortcomings in the DEv practice of ECHA, at least until 2018 can be summarised as follows:

- The DEv administrative processes and the data generation is taking a lot of time, due to lengthy decision-making procedures (including consultations with the registrants and, in the case of TPE involving for vertebrates, the public).
- Lack of legal clarity in some information requirements hinders both registrants in achieving compliant dossiers and authorities to request missing data. Besides, obtaining adequate exposure data is a major issue.
- A lack of incentives for registrants to update their registration files despite their obligation, together with the enforcement difficulties, are the main cause of the delay to generate new information.

The REACH instruments, and the operationalisation thereof, aimed to ensure adequate dossier quality therefore require improvement in order to activate the self-responsibility of the registrants to ensure compliance effectively.

The debate on registration dossiers lacking compliance, stimulated by interventions of the European Parliament, in June 2019 led ECHA and the European Commission to launching a "REACH Evaluation Joint Action Plan" outlining 15 actions intended to ensure registrants' compliance. The proposed actions are addressing some of the mentioned shortcomings. Positive effects on dossier quality might be expected notably with respect to Action 1 aimed at raising the 5% minimum target in Article 41(5) to 20% of dossiers selected for compliance checking. Respective implementing legislation was adopted in April 2020. Furthermore, Actions 5 and 6 probably entail modifications of Annexes VI to XI of REACH intended to clarify existing

information requirements *de lege lata.* Unfortunately, the Action Plan does not provide a strategic approach with regard to shortcomings in dossiers related to descriptions of uses and exposure assessment. The REACH Exposure Expert Group (REEG) will foster a common understanding of which use and exposure data are needed to support REACH and CLP processes and may therefore provide a solid base for the identification of appropriate policy options (cf. the reflection of the Action Plan in section 6.1).

In addition, the analysis in this study identified lack of CCH transparency as a missed opportunity with respect to effective incentivising. In 2012, ECHA started to disclose in the dissemination portal of registered substances the names of the registrants, unless successfully claimed confidential. Additionally, in 2018, ECHA introduced a public database to increase transparency of the specific CCH procedures' progress. This database also provides non-confidential versions of any adopted CCH decision once available. Annex E of the decision contains a table that apparently lists the names of the addressees – which are not disclosed (blackened), though. Not actively disclosing names of registrants subject to a CCH decision, ECHA does not only miss out on untapped potentials to increase incentives for registrants. The current situation moreover bears a risk for registrants acting compliant of being accused acting in breach of law, due to the outlined uncertainties in interpreting available data.

Policy Options

As one supplement to the "REACH Evaluation Joint Action Plan", performing CCH based on random selection might send an important signal to registrants that dossiers for substances not considered a high priority can be subject to evaluation as well.

In addition, complementing the Joint Action Plan, based on the analysis summarised above, the following policy options should be considered:

Enhancing the update requirement

Currently Art. 22(1) stipulates that a registrant is "responsible on his own initiative for updating his registration without undue delay with relevant new information" in the cases mentioned under (a) to (i). One option to enhance the update mechanism would be adding a duty for registrants to confirm electronically to ECHA that the dossier data are still valid and accurate. This confirmation serves as a nudge to analyse all additional data that are "relevant and available to the registrant" (Art. 12(1)) and reflect on the result of this endeavour in the dossier (cf. section 6.2.1). This option would underpin the concept of self-responsibility since the registrant has to confirm actively that he has reviewed the data set and concluded that no update is required or to update the dossier, respectively.

(Eco)Toxicology dashboard WikiREACH enhancing dossier update processes

New (eco)toxicological data can trigger the dossier update obligation. The question arises, however, who generates those data and how they trigger the updating mechanisms. The registrants often face no incentives to invest in new tests. On the other hand, academics, e.g. master or PhD students, conduct testing series with valuable results, which are sometimes not visible for the registrants and the authorities. The WikiREACH concept offers an approach to overcome these impediments. Considering that researchers' preferences are mostly orientated towards recognition, the WikiREACH allows them to "pin" results on a dashboard that is open to the public and at the same time – via the CAS-number of the tested substance and a "recent results" button – linked to the ECHA dissemination portal. Thus, the registrants as well as the authorities are aware of the new results. Besides, interfaces to scientific journals and databases like *ResearchGate* or *Academia* could nudge researchers uploading or registering their content to also feed the data in WikiREACH.

One structural element of the WikiREACH approach is a quality test with respect to the relevance of research data for regulatory risk management. Results published in journals will usually not be in line with the testing requirements laid down in the testing Regulation 440/2008 and might thus not be used directly. However, researchers could be provided some guidance, explaining how the impact of the study results could be enhanced in the next study design (cf. section 6.2.2 as for the details).

Increased transparency

From a transparency perspective, it should be easily visible at the ECHA portal tracking the CCH progress, which parts of a dossier ECHA has addressed in a CCH and what has been the outcome of the CCH. The CCH decisions contain a section "Information required" where the legal basis for each requested "information for the registered substance subject to the present decision" is already provided by the ECHA Secretariat. Thus, it would be a minor effort to tag the decision database with the legal basis (e.g., Annex VI, Section 2.3) allowing a structured search for the interpretation laid down in the CCH decisions. This, combined with the "Recommendations to registrants" based i.a. on CCH lessons learnt, would underpin learning processes of all actors involved in risk management, including registrants, authorities, competitors and the wide range of "third parties".

From a systematic perspective, with regard to the CCH, one could argue that the current legal scheme particularly creates incentives for the specific registrants addressed by CCH who have to comply with the final decision. By following the requirements set out in the decision, registrants can entirely "heal" their initial non-compliance. In the meantime, they were able – unlike their compliant competitors – to avoid the expenditures linked to appropriate testing and documentation in the registration dossier whilst the right to place a given substance on the market remained and remains valid. In other words, the current scheme therefore only provides weak incentives for active compliance but, at best, ensures reactive compliance. Disclosing names of companies addressed by decisions would have an additional motivational effect not only for the entity subject to a dossier evaluation but for all registrants to actively provide the data as required by law in order to avoid reputational losses. This measure could be reserved for severe cases, e.g. where there is some evidence of deliberate deception. Minor violations of data requirements, for example due to negligence, might be excluded (cf. section 6.2.3).

More streamlined testing proposal examinations

In TPE, third party consultations yielded only few data inputs relevant for the process. Moreover, only in very few cases ECHA has rejected the company's proposal as unnecessary. A "leaner" TPE is therefore another option, modifying the procedural rules as regards (third party) consultations, and modifying the entire examination mode (cf. section 6.2.4).

Zusammenfassung

Der vorliegende Bericht ist ein Teilergebnis des Ressortforschungsplan-Vorhabens „REACH-Weiterentwicklung“. Im Rahmen dieses Vorhabens wurden verschiedene Aspekte der REACH – Verordnung und ihrer Umsetzung analysiert und Verbesserungsoptionen, einschließlich einer möglichen Veränderung des Verordnungstextes und seiner Anhänge, aufgezeigt.

Das Vorhaben REACH-Weiterentwicklung besteht aus insgesamt 18 Teilprojekten, die sich mit unterschiedlichen Aspekten (der Umsetzung) der REACH Verordnung und Optionen für deren Weiterentwicklung auseinandersetzen. So werden in den jeweiligen Teilprojekten die REACH Prozesse Dossierbewertung, Stoffbewertung, Beschränkung, Zulassung und Konsultationen sowie die Rolle der Widerspruchskammer und das Zusammenspiel der Prozesse analysiert. Auch die Verbindung von REACH zur Nachhaltigen Chemie, die Umsetzung des Vorsorgeprinzips, die Förderung der Substitution und die Abschätzung des Nutzens der REACH-Verordnung werden untersucht sowie das Verfahren der sozio-ökonomischen Analyse, Optionen zur Regulierung von Stoffen in Erzeugnissen und die Finanzierung der Aufgaben der Chemikalienagentur ECHA.

Ein „hohes Schutzniveau für die menschliche Gesundheit und für die Umwelt sicherzustellen, einschließlich der Förderung alternativer Beurteilungsmethoden für von Stoffen ausgehende Gefahren, sowie den freien Verkehr von Stoffen im Binnenmarkt zu gewährleisten und gleichzeitig Wettbewerbsfähigkeit und Innovation zu verbessern" sind die in Art. 1 Abs. 1 der Europäischen Chemikalienverordnung REACH (1907/2006) festgeschriebenen Ziele. Fünf Säulen strukturieren den rechtlichen Rahmen, d.h. die nach Mengen und über den Zeitraum einer Dekade gestufte Registrierung chemischer Stoffe , die Bewertung von Registrierungsdaten und Stoffen, die Kommunikation und Kooperation in der Lieferkette, das Zulassungssystem für besonders besorgniserregende Stoffe (SVHC) und die Beschränkung, wenn Stoffe ein unannehmbares Risiko für die menschliche Gesundheit oder die Umwelt darstellen können. Jedoch bildet das Registrierungssystem die Datengrundlage für alle anderen Säulen; im Mai 2018 endete die finale Registrierungsfrist für Stoffe, die in Mengen zwischen 1 und 100 Tonnen hergestellt oder importiert werden. Nach dem Prinzip "Ohne Daten kein Markt“ aus Art. 5 REACH "dürfen Stoffe als solche, in Gemischen oder in Erzeugnissen nur dann in der Gemeinschaft hergestellt oder in Verkehr gebracht werden, wenn sie nach den einschlägigen Bestimmungen dieses Titels, soweit vorgeschrieben, registriert wurden".

Erwägungsgrund 19 der REACH-Verordnung fasst zusammen, dass diese „Registrierungsbestimmungen für Hersteller und Importeure die Verpflichtung vorsehen [sollten], Daten über die von ihnen hergestellten oder eingeführten Stoffe zu gewinnen, diese Daten zur Beurteilung der stoffspezifischen Risiken zu nutzen und geeignete Risikomanagementmaßnahmen zu entwickeln und zu empfehlen. Damit diese Verpflichtungen auch eingehalten werden sowie aus Gründen der Transparenz sollten sie im Rahmen der Registrierung bei der Agentur ein Dossier mit all diesen Informationen einreichen müssen", d.h. bei der Europäischen Chemikalienagentur (ECHA). Die Wirtschaftsakteure übermitteln Daten über die physikalisch-chemischen Eigenschaften, die toxikologischen und ökotoxikologischen Wirkungen sowie die Expositions- und Risikoinformationen der Stoffe; diese bilden zugleich die wesentliche Grundlage für die Risikokommunikation entlang der Lieferketten und für das Risikomanagement der Behörden (z.B. die Identifizierung von SVHC und von "unannehmbaren Risiken" nach Art. 68 REACH, die einen Beschränkungsprozess auslösen können). Eine angemessene Qualität der Registrierungsdaten ist daher von zentraler Bedeutung, damit REACH seine Ziele erreichen kann. Dazu gehört auch die Aktualität der Daten, zu welcher Art. 22 REACH die Registranten verpflichtet.

Dieses Pflichtenprogramm untermauert den REACH zugrunde liegenden regulatorischen Ansatz, der zumindest weitgehend auf der "Eigenverantwortung" der Akteure in der Lieferkette aufbaut. Dazu formuliert Art. 1 Abs. 3 REACH den "Grundsatz, dass Hersteller, Importeure und nachgeschaltete Anwender sicherstellen müssen, dass sie Stoffe herstellen, in Verkehr bringen und verwenden, die die menschliche Gesundheit oder die Umwelt nicht nachteilig beeinflussen".

Empirische Daten, u.a. von der ECHA zur Verfügung gestellt, deuten hingegen darauf hin, dass ein relevanter Teil der Registrierungsdossiers die in REACH formulierten Anforderungen nicht erfüllt.

Ziel und Struktur des Berichts

Vor diesem normativen und empirischen Hintergrund analysiert der Bericht, ob und wie sich die Qualität von Registrierungsdossiers (in effizienter Weise) verbessern ließe. Aus prozeduraler Sicht besteht der erste Schritt für die ECHA darin, "sich zu vergewissern", dass eingereichte Dossiers in dem Sinne vollständig sind, dass der Registrant alle in Art. 20 Abs. 2 REACH genannten "Angaben" zur Verfügung gestellt hat. Defizite in dieser ersten "Pflicht der Agentur" (Art. 20) beeinflussen die Arbeitsbelastung und die Wirksamkeit des nachfolgenden Schritts "Dossierbewertung", wie in Kapitel 1 von Titel VI REACH vorgesehen. Art. 40 schreibt die Prüfung von Vorschlägen für Versuche an Tieren (Testing Proposal Examination – TPE) vor, d.h. die ECHA „prüft alle Versuchsvorschläge“, die in einer Registrierung enthalten sind. Außerdem legitimieren die Vorgaben zur Prüfung auf Erfüllung der Anforderungen (Compliance Check – CCH) aus Art. 41 Abs. 1 und Abs. 5 die ECHA, (jedes) Registrierungsdossier zu prüfen und verpflichten die Agentur, "mindestens 5%" der für jeden Mengenbereich eingegangenen Dossiers zu prüfen. An dieser Quote orientierten sich bis 2019 die CCH-Aktivitäten der ECHA, welche Gegenstand der vorliegenden Studie sind. Verordnung (EU) 2020/507 der Kommission vom 7. April 2020 setzte jedoch den Mindestanteil auf 20% herauf, mit Wirkung für die nachfolgenden CCH-Arbeiten.

Im Sinne der Eigenverantwortung dienen die beiden Verfahrensschritte "Vollständigkeitsprüfung" und "Dossierbewertung" als institutioneller Rahmen, der Anreize für das Registrierungsregime setzt. Somit sind beide Elemente unter dem Gesichtspunkt der "Dossierqualität" zu betrachten.

Policy Options zur Stärkung der Anreize stehen daher im Mittelpunkt dieses Berichts. Zu diesem Zweck untersucht er die Anforderungen der relevanten rechtlichen Mechanismen sowie die praktische Umsetzung und alle anhand vorliegender Daten messbaren Auswirkungen dieser Mechanismen.

Die Arbeit stützt sich auf Literaturrecherchen, einschließlich Dokumenten und Studien im Rahmen des REACH REFIT-Prozesses. Zum Berichtsentwurf gingen zudem fachliche Beiträge von deutschen Behördenvertretern ein, die an den verschiedenen Verfahren von REACH beteiligt sind. Dennoch stellt der Bericht die Meinungen der Autoren dar.

Vollständigkeitsprüfung

Artikel 20 Absatz 2 Satz 1 verpflichtet die ECHA, "sich zu vergewissern", dass "alle Angaben" (nicht: Daten) vorliegen, die nach den entsprechenden Artikeln (und den entsprechenden Anhängen) in REACH "erforderlich" sind. Diese Verpflichtung beschränkt sich nicht auf das "technische Dossier", wie es in Art. 10 lit.a definiert ist; vielmehr umfasst sie auch den "Stoffsicherheitsbericht, wenn er nach Artikel 14 erforderlich ist, in dem in Anhang I festgelegten Format" (Art. 10 lit.b). Wenn das Registrierungsdossier nicht vollständig ist, kann die ECHA dem Registranten aus rechtlichen Gründen keine Registrierungsnummer zuteilen, so dass das "Ohne Daten kein Markt"-Prinzip zur Anwendung kommt.

Operationalisierung der Vollständigkeitsprüfung

In den ersten Jahren beschränkte die ECHA die Vollständigkeitsprüfung auf einen rein technischen Ansatz, so dass Dossiers auch ohne aussagekräftige Informationen in das System eingespeist werden konnten. Nach einer Entscheidung der Widerspruchskammer (Fall A-022-2013, 15. März 2016, "Charcoal I") führte die ECHA jedoch im Jahr 2016 einen verbesserten Ansatz („enhanced approach“) ein, der im Oktober 2020 durch den fortentwickelten „enhanced approach II“ ersetzt wird. Damit prüft die ECHA sowohl Neuregistrierungen als auch Aktualisierungen in einer Weise, die deutlich stärkere Anreize zur Einhaltung der Anforderungen bietet: Die Registranten sind sich nun bewusst, dass neben der technischen (automatisierten) Vollständigkeitsprüfung auch eine manuelle Kontrolle möglich ist. Allein diese Wahrnehmung schafft einen zusätzlichen Anreiz, alle erforderlichen Angaben nach REACH zu erfüllen. Diese Verpflichtung erstreckt sich auch auf den Stoffsicherheitsbericht (Art. 10 lit.b). Es kann davon ausgegangen werden, dass die ECHA mit vollendetem Strategiewechsel in der Lage sein wird, das Problem stark unvollständiger Dossiers angemessen anzugehen. Jedoch wird es Jahre dauern, bis eine beträchtliche Anzahl von Dossiers nach den Bestimmungen der erweiterten Vollständigkeitsprüfung geprüft wird.

Defizite des ursprünglichen Ansatzes der Vollständigkeitsprüfung sind zudem nach wie vor relevant. Sie betrafen die ersten beiden Registrierungsfristen, die für die höchsten Tonnagebänder sowie für Stoffe mit bekannten CMR-Eigenschaften und schädlichen Auswirkungen im Kompartiment Wasser gelten. So konnte ein hochrelevanter Teil des „Chemikalien-Universums“ in das Registrierungssystem gelangen, ohne dass eine ordnungsgemäße Vollständigkeitsprüfung gemäß Art. 20 Abs. 2 Satz 1 erfolgte. Mit diesem Ansatz, der im Verwaltungsrat der ECHA ständig in Frage gestellt wurde (vgl. Abschnitt 3.1), gefährdete das Sekretariat der ECHA das gesamte REACH-Registrierungssystem. Die ungenügende Vollständigkeitsprüfung trug zu einer hohen Anzahl inkompatibler Registrierungsdossiers bei, da die Funktion eines Torwächters des auf Eigenverantwortung basierenden Systems nicht ausreichend wahrgenommen wurde. Mit der überarbeiten Vollständigkeitsprüfung soll die Situation wesentlich verbessert werden.

Die Rechtsfolge eines unvollständigen Dossiers ist einfach, aber frappierend: Es wird keine Registrierungsnummer vergeben. Diese Option steht jedoch nur für Neuregistrierungen zur Verfügung. Sie gilt nicht für Registrierungsdossiers, die ECHA bereits in den Jahren zuvor angenommen hat. Hier bleibt die Wirkung der Registrierungsnummer selbst dann bestehen, wenn die Unvollständigkeit des ursprünglichen Dossiers im Zuge der erweiterten Vollständigkeitsprüfung in einem Aktualisierungsverfahren aufgedeckt wird.

Policy Options

Zu klären ist, wie sich mit nicht aktualisierten unvollständigen Dossiers umgehen ließe. Aus rechtlicher Sicht ist die Anwendung des Prinzips "Ohne Daten kein Markt" durch den Entzug der Registrierungsnummer die geeignete Verwaltungsmaßnahme. REACH erwähnt diese Rechtsfolge nicht ausdrücklich. Dies bedeutet nicht, dass sie der ECHA nicht zur Verfügung steht. Vielmehr ist die Agentur aufgrund des im "acquis communautaire" festgehaltenen Erfordernisses eines allgemeinen Verwaltungsverfahrens befugt, diese Rechtsfolge zu erlassen. Vorzugsweise sollten die gesetzgebenden Organe der REACH-Verordnung ein ausdrückliches rechtliches Mandat (für einen Vorschlag siehe Abschnitt 6.2.5.1).

Dossierbewertung

Operationalisierung der Prüfung auf Erfüllung der Anforderungen

In Anbetracht des oben skizzierten unspezifischen Mandats für die Prüfung auf Erfüllung der Anforderungen (CCH) hatte die Agentur einen strategischen Ansatz für die CCH-Aktivitäten zu entwickeln (Einzelheiten siehe Abschnitt 5.1). Zwischen 2012 und 2014 betraf die Mehrzahl der Prüfungen im Rahmen des sog. "Areas of Concern"-Ansatzes spezifische Teile der Dossiers, wie z.B. physikalisch-chemische Eigenschaften oder fehlende Informationen zu Wirkungen auf die Umwelt und die menschliche Gesundheit. Der Schwerpunkt lag darauf, leicht identifizierbare Datenlücken (mit Hilfe von IT-Algorithmen) gezielt und standardisiert zu schließen. Während diese gezielten Kontrollen dazu beitrugen, ausgewählte Nichterfüllungen zu identifizieren, war der Umfang der bewerteten Datenanforderungen recht eng. Zudem trug der Gesamtansatz nicht ausreichend dazu bei, die Nichterfüllungsraten zu senken und sicherzustellen, dass die Dossiers alle angeforderten Informationen enthielten. Auch ließen sich die Ergebnisse nicht in signifikanter Weise für die anderen rechtlichen Instrumente in REACH (Stoffbewertung, die Zulassungs- und Beschränkungsverfahren) und außerhalb von REACH fruchtbar machen. Vor diesem Hintergrund entwickelte ECHA den CCH-Ansatz (über einige zusätzliche Meilensteine wie das Konzept der 8 „Super-Endpunkte“ im Jahr 2014) fort zu einer Integrierten Regulierungsstrategie (IRS), die auf einer sorgfältigen Kartierung des "Chemikalien-Universums" basiert und in einer holistischen Sichtweise das Zusammenspiel der verschiedenen REACH-Instrumente fördert, die zur Qualität der Dossiers beitragen.

Outputs und Inputs der Dossierbewertung, und jüngste regulatorische Entwicklungen

Im Hinblick auf die Pflicht der ECHA, mindestens 5% der für jeden Mengenbereich eingegangenen Dossiers zu prüfen, berichtet die Agentur, dass sie zwischen 2009 und 2019 für 20,5% der im höchsten Mengenbereich (1.000 t/a oder mehr) registrierten Stoffe sowie für 18% der im Mengenbereich 100 - 1.000 t/a registrierten Stoffe, für 4% des Mengenbereichs 10 - 100 t/a und für 1% des Mengenbereichs (unter 10 t/a) einen "vollständigen“ CCH durchgeführt hat. Aktuell liegt die Zahl der (endgültigen) CCH-Entscheidungen pro Jahr bei etwa 150, wobei jede Entscheidung mehrere Datenanforderungen umfasst (z.B. insgesamt 721 Informationsanforderungen im Jahr 2019; siehe die Einzelheiten in Abschnitt 5.2.1). Die Zahl der Dossiers im CCH nahm zuletzt erheblich zu: Für 2019 gibt die ECHA an, 301 vollständige Prüfungen durchgeführt zu haben, d.h. eine Zunahme von mehr als 50% im Vergleich zum Vorjahr.

Was die CCH-Aktivitäten bis Ende 2017 betrifft, so stellte die ECHA fest, dass 69% von 1 350 Dossiers, die im höchsten Tonnageband bewertet wurden, und 77% von 430 Dossiers, die jeweils im Mengenband 100 - 1.000 t/a lagen, in Bezug auf eine oder mehrere Datenanforderungen nicht konform waren. Unabhängig vom Mengenbereich zeigen die für 2018 und 2019 veröffentlichten Zahlen, dass die ECHA in etwa 75% der bewerteten Dossiers eine Nichterfüllung feststellte. Vergleichbare Bewertungs-Aktivitäten der Mitgliedstaaten untermauern die allgemeine Erkenntnis, dass das die Nichterfüllung der Anforderungen ein recht weit verbreitetes Phänomen ist (vgl. Abschnitt 5.2.2).

Nach den ersten zehn Jahren Dossierbewertung im Rahmen von REACH lassen sich allgemeine Schlussfolgerungen zum Ausmaß der Nichterfüllung nur äußerst zurückhaltend formulieren, da die vorliegenden Daten zumindest in gewissem Maße den früheren strategischen "Area of Concern"-Ansatz widerspiegeln, bei dem die Agentur lediglich gezielte Endpunkte adressierte. Daher wäre die Feststellung, dass diese Ergebnisse die relevantesten oder häufigsten Verstöße gegen die Datenanforderungen zeigen, unangemessen. Eine übliche Quelle für Regelverstöße sind allerdings die Bedingungen, unter denen Registranten alternative Daten verwenden (z. B. Stoffgruppen- und Analogiekonzepte) sowie unzureichende Begründungen für Datenverzicht oder -anpassungen. In dieser Hinsicht sind die Datenanforderungen in den Anhängen zum Teil nicht hinreichend präzise, z. B. immer bei Einsatz der Formulierung "wenn bei der nach

Anhang I vorgenommenen Stoffsicherheitsbeurteilung die Notwendigkeit einer Prüfung weiterer Wirkungen … erkennbar wird". Fehlende oder unzureichende Expositionsdaten sind weitere wichtige Quellen der Nichterfüllung (vgl. Abschnitt 5.2.2).

Folgemaßnahmen von Evaluationsergebnissen („Follow-up to dossier evaluation“) entwickelten sich zu einem bedeutsamen Instrument. Während bei der klaren Mehrheit (ca. drei Viertel) der durchgeführten CCH die Registranten die durch die Entscheidung angeforderten Daten fristgerecht zur Verfügung stellten, taten sie dies in 13% der Fälle erst, nachdem die nationalen Behörden eingeschaltet worden waren. Administrative Maßnahmen der nationalen Vollzugsbehörden können daher als ein wirksames Instrument zur Motivation säumiger Registranten angesehen werden. Durch den Einsatz von Rechtsmitteln fochten die Adressaten der CCH-Entscheidung jedoch erfolgreich den früheren Ansatz der ECHA an, d.h. die Abgabe einer (informellen) Erklärung der Nichterfüllung (Statement of Non-Compliance – SONC) an die Mitgliedstaaten. Der gegenwärtig angepasste Ansatz ist ebenfalls Gegenstand rechtlicher Prüfungen (vgl. Abschnitt 5.2.3).

Die bisherigen CCH-Aktivitäten führten zu 52 Stoffen, die als mögliche Kandidaten für einen Vorschlag für eine harmonisierte Einstufung und Kennzeichnung dienten – 17 davon allein im Jahr 2019 - und 3 potenzielle Kandidaten für eine Stoffbewertung. Statistische Daten über die Auswirkungen, die die CCH auf die Identifizierung von SVHC und die (wenigen) unter REACH erlassenen Beschränkungen gehabt haben könnte, sind nicht verfügbar (vgl. Abschnitt 5.2.3).

Was die Resultate der Prüfung von Versuchsvorschlägen (TPE) betrifft, so sind die verfügbaren Daten aus Berichten der ECHA eher spärlich. Es ist nicht klar, inwieweit ECHA die Prioritäten in Art. 40(1) adressiert hat. Ebenso wenig sind detaillierte Daten über die Aktivitäten hinsichtlich Nicht-Phase-in-Stoffen verfügbar, für die REACH eine 180-Tage-Frist für die Prüfung und die Vorbereitung des Entscheidungsentwurfs durch die ECHA vorsieht, einschließlich der damit verbundenen Prioritätensetzung.

Die Registranten reichten die meisten Versuchsvorschläge (etwa zwei Drittel) ein, um Gefährdungspotentiale mit Blick auf die menschliche Gesundheit zu klären. In sehr wenigen Fällen lehnte ECHA den Vorschlag als unnötig ab. Jedoch ist Zurückhaltung geboten, aus dieser Beobachtung zu schließen, dass die Registranten zumeist sorgfältig abwägen, bevor sie weitere Tierversuche vorschlagen. Vielmehr war die TPE-Praxis der ECHA Gegenstand einer Beschwerde beim EU-Ombudsmann, der im September 2015 zu dem Schluss kam, dass die ECHA nur unzureichend berücksichtige, dass die Vermeidung von Tierversuchen zusammen mit dem Schutz der menschlichen Gesundheit und der Umwelt eines der Leitprinzipien von REACH ist (vgl. Abschnitt 5.3.2).

Insgesamt wird die Zahl der Versuchsvorschläge als gering eingeschätzt. Eine mögliche Erklärung ist, dass die Registranten großzügig von der Möglichkeit Gebrauch machen, Anpassungen der Standardinformationsanforderungen einzureichen. Insbesondere für Umweltendpunkte identifizierte die ECHA jedoch viele Fälle, in denen Registranten keinen Versuchsvorschlag einreichten, es ihnen aber auch nicht gelang, ihre Anpassungen angemessen zu begründen und zu dokumentieren. Außerdem schätzt die ECHA den Mehrwert der öffentlichen Konsultationen im TPE-Kontext als "relativ begrenzt" ein (vgl. Abschnitt 5.3.2).

Die TPE-Aktivitäten zwischen 2013 und 2019 ergaben 84 Stoffe als mögliche Kandidaten für einen Vorschlag zur harmonisierten Einstufung und Kennzeichnung und zwei Stoffe, die für die Stoffbewertung in Betracht gezogen wurden.

ECHA und die Mitgliedstaaten investierten beträchtliche Ressourcen in die Dossierbewertung. Es gibt Schätzungen, wonach ein Vollzeitäquivalent-Mitarbeiter der Agentur in der Lage ist, fünf

CCHs pro Jahr durchzuführen. Andere Schätzungen gehen von einer durchschnittlichen Dauer von 461 Tagen für die Durchführung eines CCHs aus; durchschnittlich 340 Tage für die Bewertung und Entscheidungsfindung im TPE-Kontext. Darüber hinaus wendet ECHA laut dem 2. REACH Review schätzungsweise mehr als 25% der CCH-Ressourcen für die Entscheidungsfindung auf, einschließlich der Interaktion mit dem Registranten, den zuständigen Behörden der Mitgliedstaaten und dem Ausschuss der Mitgliedstaaten – jedoch ohne die wissenschaftliche Bewertung. Allerdings hat ECHA die Abläufe bereits teilweise optimiert (vgl. Abschnitt 5.4.3).

Darüber hinaus können Registranten gegen die CCH-Entscheidung bei der Widerspruchskammer Beschwerde einlegen. Die Beschwerdequote (etwa 3% aller Entscheidungen) ist jedoch eher niedrig, was darauf hindeutet, dass die ECHA in der Regel nicht über ihre Kompetenzen hinausgeht (vgl. Abschnitt 5.4.3).

Zusammenfassend lassen sich die Mängel in der Dossierbewertungspraxis der ECHA, zumindest bis 2018, wie folgt zusammenfassen:

- Die Verwaltungsprozesse und die Datengenerierung nehmen aufgrund langwieriger Entscheidungsverfahren (einschließlich Konsultationen mit den Registranten und, im Falle von TPE mit Wirbeltierbezug, der Öffentlichkeit) viel Zeit in Anspruch.
- Mangelnde rechtliche Klarheit bei einigen Informationsanforderungen behindert sowohl die Registranten, konforme Dossiers zu erstellen, als auch die Behörden bei der Anforderung fehlender Daten. Unzureichende Expositionsdaten sind ein wichtiges Thema.
- Fehlende Anreize für die Registranten, ihre Registrierungsdossiers trotz ihrer Verpflichtung zu aktualisieren, sind zusammen mit den Durchsetzungsschwierigkeiten die Hauptursache für die Verzögerung bei der Generierung neuer Informationen.

Die REACH-Instrumente und deren Operationalisierung mit dem Ziel, eine angemessene Qualität der Dossiers zu gewährleisten, sind daher zu optimieren. Dabei gilt es, die Eigenverantwortung der Registranten besser zu aktivieren, um somit die Einhaltung der Vorschriften wirksam zu gewährleisten.

Die durch Interventionen des Europäischen Parlaments angeregte Debatte über Registrierungsdossiers mit mangelnder Qualität führte im Juni 2019 dazu, dass die ECHA und die Europäische Kommission einen "REACH Evaluation Joint Action Plan" auflegten, der 15 Maßnahmen („Actions“) zur Sicherstellung der Konformität durch Registranten vorsieht. Die vorgeschlagenen Maßnahmen beheben einige der genannten Mängel. Positive Auswirkungen auf die Qualität der Dossiers könnten sich insbesondere im Hinblick auf Action 1 ergeben, die darauf abzielt, das Mindestziel von 5% gemäß Art. 41 Abs. 5 der für die Prüfung der Erfüllung der Anforderungen ausgewählten Dossiers auf 20% anzuheben. Entsprechende Durchführungsvorschriften wurden im April 2020 verabschiedet. Darüber hinaus bringen die Actions 5 und 6 voraussichtlich Änderungen der Anhänge VI bis XI von REACH mit sich, die die Informationsanforderungen de lege lata klären sollen. Leider bietet der Aktionsplan keinen strategischen Ansatz in Bezug auf Mängel in den Dossiers zu Verwendungsbeschreibungen und zur Expositionsbewertung. Es bleibt abzuwarten, ob die REACH-Expertengruppe Exposition (REEG) ein gemeinsames Verständnis darüber fördern kann, welche Verwendungs- und Expositionsdaten zur Unterstützung der Prozesse in REACH (und CLP) benötigt werden, und damit eine solide Grundlage für die Ermittlung geeigneter Policy Options bietet (vgl. die Würdigung des Aktionsplans in Abschnitt 6.1).

Darüber hinaus identifizierte die Analyse in dieser Studie mangelnde Transparenz der CCH als Optimierungspotential im Hinblick auf das Ziel, wirksame Anreize zu setzen. Im Jahr 2012

begann die ECHA damit, die Namen der Registranten in der öffentlichen Datenbank für registrierte Stoffe offenzulegen, sofern letztere diese Information nicht erfolgreich als vertraulich beanspruchen konnten. Darüber hinaus führte die ECHA im Jahr 2018 eine weitere öffentliche Datenbank ein, um die Verfahrens-Transparenz bei CCHs zu erhöhen. Diese Datenbank stellt auch nicht-vertrauliche Versionen aller angenommenen CCH-Entscheidungen bereit, sobald diese verfügbar sind. Anhang E einer solchen Entscheidung enthält eine Tabelle, in der offenbar die Namen der Adressaten aufgeführt sind - die jedoch nicht offengelegt (geschwärzt) werden. Jedoch könnten die Nutzer der Online-Datenbanken die in der Entscheidung angezeigte Registrierungsnummer mit den in der Stoff-Datenbank unter dieser Nummer gespeicherten Informationen in Beziehung setzen, z.B. die Anzahl der Registranten, die in beiden Quellen aufgeführt sind, und die in der Stoff-Datenbank angezeigten Jahre der Dossieraktualisierungen pro Registrant. Durch die Korrelation dieser Informationen ließe sich eine Vorstellung davon gewinnen, welchen Registrant ECHA in einer CCH-Entscheidung als nicht konform identifiziert hat. Dieses Vorgehen ist jedoch mit erheblichen Unsicherheiten behaftet. Zusammenfassend lässt sich sagen, dass die ECHA, indem sie die Namen der Registranten, die einer CCH-Entscheidung unterliegen, nicht aktiv offenlegt, nicht nur Potenziale ungenutzt verstreichen lässt im Hinblick auf stärkere Anreize für Registranten. Die gegenwärtige Situation birgt darüber hinaus aufgrund der skizzierten Unsicherheiten bei der Interpretation der verfügbaren Daten ein Risiko für Registranten, die sich gesetzeskonform verhalten, da sie beschuldigt werden könnten, rechtswidrig gehandelt zu haben.

Policy Options

Als Ergänzung des "Gemeinsamen Aktionsplans zur REACH-Evaluierung" könnte eine stärkere Betonung der Zufallsauswahl von Dossiers für CCH-Aktivitäten ein wichtiges Signal an die Registranten aussenden, dass auch Dossiers für Stoffe, die nicht als hochprioritär betrachtet werden, einer Bewertung unterzogen werden können.

Darüber hinaus sollten, basierend auf der oben zusammengefassten Analyse, die folgenden Optionen in Betracht gezogen werden:

Erweiterung der Aktualisierungspflicht

Derzeit bestimmt Art. 22(1) mit Blick auf die in lit.a bis lit.i genannten Fällen, dass "der Registrant dafür verantwortlich [ist], aus eigener Initiative seine Registrierung unverzüglich anhand der einschlägigen neuen Informationen zu aktualisieren". Eine Möglichkeit, den Aktualisierungsmechanismus zu verbessern, wäre eine Pflicht für Registranten hinzuzufügen, der ECHA elektronisch zu bestätigen, dass die Dossierdaten noch gültig und korrekt sind. Diese Bestätigung dient als Anstoß, alle zusätzlichen Daten, die "für den Registranten relevant sind und ihm zur Verfügung stehen" (Art. 12(1)), zu analysieren und das Ergebnis dieser Bemühung im Dossier zu reflektieren (vgl. Abschnitt 6.2.1). Diese Option würde das Prinzip der Eigenverantwortung stärken, da der Registrant aktiv zu bestätigen hätte, dass er den Datensatz überprüft hat und zu dem Schluss gekommen ist, dass keine Aktualisierung erforderlich ist oder das Dossier aktualisiert werden muss.

(Öko)toxikologisches Dashboard WikiREACH zur Verbesserung der Dossieraktualisierung

Neue (eco)toxikologische Daten können die Verpflichtung zur Aktualisierung des Dossiers auslösen. Jedoch ist fraglich, wer diese Daten erzeugt und wie sie die Aktualisierungsmechanismen auslösen. Registranten haben oft keine Anreize, in neue Tests zu investieren. Andererseits führen Forscher im akademischen Bereich, z.B. Masterstudenten oder Doktoranden, Testreihen mit wertvollen Ergebnissen durch, die für die Registranten und die Behörden manchmal nicht sichtbar sind. Das WikiREACH-Konzept bietet einen Ansatz, um diese Hemmnisse zu überwinden. In Anbetracht der Tatsache, dass die Präferenzen von Forschern

hauptsächlich auf Anerkennung ausgerichtet sind, ermöglicht es WikiREACH diesen Akteuren, ihre Ergebnisse auf einem öffentlich zugänglichen Dashboard "anzupinnen" und gleichzeitig - über die CAS-Nummer der geprüften Stoffe und eine Schaltfläche "Neueste Ergebnisse" - mit der Stoff-Datenbank der ECHA zu verlinken. Auf diese Weise sind sowohl die Registranten als auch die Behörden über neue Ergebnisse informiert. Außerdem könnten Schnittstellen zu wissenschaftlichen Zeitschriften und Datenbanken wie *ResearchGate* oder *Academia* Forscher, die ihre Inhalte hochladen oder registrieren, dazu anregen, die Daten auch in WikiREACH einzuspeisen.

Ein Strukturelement des WikiREACH-Ansatzes ist eine Qualitätsprüfung im Hinblick auf die Relevanz der Forschungsdaten für das regulatorische Risikomanagement. Ergebnisse, die in Zeitschriften veröffentlicht werden, entsprechen in der Regel nicht den in der Testverordnung 440/2008 festgelegten Testanforderungen und können daher möglicherweise nicht direkt verwendet werden. Den Forschern könnten jedoch einige Hinweise gegeben werden, wie sich die Wirkung der Studienergebnisse im nächsten Studiendesign verbessern ließen (vgl. Abschnitt 6.2.2 zu den Details).

Erhöhte Transparenz

Unter dem Gesichtspunkt der Transparenz sollte in der ECHA-Datenbank zu CCH-Verfahren leicht erkennbar sein, welche Teile eines Dossiers die Agentur in einem CCH behandelt hat und was das Ergebnis des CCH war. Die CCH-Entscheidungen enthalten einen Abschnitt "Erforderliche Informationen", in dem die rechtliche Grundlage für jede angeforderte "Information für den registrierten Stoff, der Gegenstand der vorliegenden Entscheidung ist", bereits vom ECHA-Sekretariat bereitgestellt wird. Somit wäre es ein geringer Aufwand, die Entscheidungsdatenbank mit der Rechtsgrundlage (z.B. Anhang VI, Abschnitt 6.2.3) zu versehen, um eine strukturierte Suche nach der in den Entscheidungen der CCH festgelegten Auslegung zu ermöglichen. In Verbindung mit den "Empfehlungen an die Registranten", die u.a. auf den Erfahrungen der CCH basieren, würde dies die Lernprozesse aller am Risikomanagement beteiligten Akteure, einschließlich der Registranten, Behörden, Wettbewerber und des breiten Spektrums von "Dritten", unterstützen.

Aus einer systematischen Perspektive könnte man in Bezug auf den CCH argumentieren, dass das gegenwärtige Rechtssystem insbesondere Anreize für diejenigen Registranten schafft, für die ein CCH-Verfahren eröffnet wurde und die sich an die endgültige Entscheidung halten müssen. Indem sie die in der Entscheidung festgelegten Anforderungen befolgen, können die Registranten ihre anfängliche Nichterfüllung vollständig "heilen". In der Zwischenzeit konnten sie - im Gegensatz zu ihren regelkonformen Konkurrenten - die mit den entsprechenden Tests und der Dokumentation im Registrierungsdossier verbundenen Ausgaben vermeiden, während ihr Recht, einen bestimmten Stoff in Verkehr zu bringen, bestehen blieb. Mit anderen Worten bietet die derzeitige Regelung daher nur schwache Anreize für eine aktive Einhaltung der Anforderungen, gewährleistet aber bestenfalls ein reaktives Engagement. Die Offenlegung der Namen von Unternehmen, an die sich die CCH-Entscheidungen richten, hätte eine zusätzliche Motivationswirkung nicht nur für das Unternehmen, das einer Dossierbewertung unterzogen wird, sondern für alle Registranten, die Daten aktiv und wie gesetzlich vorgeschrieben zur Verfügung zu stellen, um Reputationsverluste zu vermeiden. Eine solche Maßnahme könnte schweren Fällen vorbehalten bleiben, z.B. wenn es Anzeichen für eine vorsätzliche Täuschung gibt. Geringfügige Verstöße gegen die Datenanforderungen, z. B. aufgrund von Fahrlässigkeit, könnten ausgeschlossen werden (vgl. Abschnitt 6.2.3).

Straffere Prüfungen von Versuchsvorschlägen

Im TPE-Kontext brachten die Konsultationen Dritter nur wenige für den Prozess relevante Dateneingaben. Darüber hinaus hat die ECHA nur in sehr wenigen Fällen den Vorschlag des Unternehmens als unnötig abgelehnt. Eine "schlankere" TPE ist daher eine weitere Option, bei der die Verfahrensregeln in Bezug auf Konsultationen (durch Dritte) und der gesamte Prüfungsmodus geändert werden könnten (vgl. Abschnitt 6.2.4).

1 Quality of dossiers – Introduction

One of the main tasks of ECHA with regard to the registration pillar in REACH is to apply those instruments aiming at adequate quality of the information provided by the registrants. The evaluation requirements laid down in Title VI Chapter 1 of REACH, however, are to be seen in the institutional framework provided by the registration regime. In a procedural perspective, the first step for ECHA is to "ascertain" that dossiers are complete in the sense that the registrant has provided all "elements" mentioned in Art. 20(2) REACH (see chapter 3). Deficits in this first "duty of the Agency" (Art. 20) influence the workload and the effectiveness of the subsequent step "dossier evaluation". Thus, both elements are to be considered in terms of "dossier quality".

Providing a normative orientation for the assessment in this report, chapter 2 describes the target state for the dossier quality. It draws from both the REACH legal objectives and requirements as well as guidelines and further official documents providing interpretation of the law.

Chapter 3 addresses the completeness check, i.e. its practical implication under the initial and the enhanced approach applied by the ECHA Secretariat. Chapter 4 explains the legal requirements and procedures in the context of dossier evaluation (DEv). Chapter 5 covers experience gained with DEv practical implementation so far and concludes with a summary of deficits, measured by the normative objectives. Finally, chapter 6 presents options to overcome these deficits.

The work draws on literature research, including documents and studies in the course of the REACH REFIT-process. Besides, expert input by German authority representatives involved in the various procedures of REACH was received on the draft report. Nevertheless, the report presents the opinions of the authors.

2 Normative context defining the target state

The regulatory process that led to the adoption of the new Regulations on Chemicals in the European Union is embedded into a global debate on chemicals safety. The "earth summit" 1992 in Rio de Janeiro (Brazil) strengthened the role of the "precautionary principle" in No. 15 of the "Rio Declaration".[1] The "Agenda 21" defined tasks for the international community, including in chapter 19 measures to achieve an "Environmentally sound management of toxic chemicals".[2] Section 19.16 stipulates that "(i)ndustry should provide data for substances produced that are needed specifically for the assessment of potential risks to human health and the environment".

In the "post Rio" process, the 2002 Johannesburg World Summit on Sustainable Development (WSSD) formulated the so-called "Johannesburg Goal": "By 2020 […] chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment".[3] An adequate quality of the data provided under the REACH registration regime is pivotal in this respect.

Explicitly referring to this goal (Recital 4) the first purpose mentioned in Art. 1(1) REACH[4] "is to ensure a high level of protection of human health and the environment, including", also with a view to reduced testing of (vertebrate) animals,[5] "the promotion of alternative methods for assessment of hazards of substances". REACH aims also at "the free circulation of substances on the internal market while enhancing competitiveness and innovation". Prominently mentioned is the normative orientation of the regulation in Art. 1(3)2: "Its provisions are underpinned by the precautionary principle". Furthermore, the "Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment" (Art. 1(3)).

Consequently, the regulation strengthens the self-responsibility of the economic actors.[6] Manufacturers and importers have the duty to, prior to the placing on the market, register their substances and thereby to provide, i.a., all physico-chemical, toxicological and ecotoxicological information that is relevant and available to them and as a minimum fulfil the standard data requirements laid down in Art. 10 and 12 (plus Annexes VI to X).[7] The registration regime established by REACH intends to overcome information deficits ("gaps in knowledge"[8]) for existing substances, which has been characterised as a state of "toxic ignorance".[9]

The registration dossier for substances in quantities above 10 t/a additionally includes a chemical safety report (CSR), documenting the substance specific risk assessment, taking into account all exposure scenarios along the life-cycle.[10] Based on the submitted substance data,

[1] United Nations Rio Declaration on Environment and Development (13 June 1992), 31 ILM 874 (1992).

[2] United Nations, Agenda 21: Programme of Action for Sustainable Development, UN Doc. A/CONF.151/26 (1992) (Agenda 21).

[3] United Nations, Plan of Implementation of the Johannesburg World Summit on Sustainable Development, UN Doc A/Conf.199/20 (2002) (Johannesburg Implementation Plan).

[4] All Articles, Recitals, Titles, Chapters and Annexes referred to in this text without further indication are those of REACH.

[5] See Recital 64.

[6] Cf. REACH recitals 16, 18, 25, 29, 56, 58 and 86; Führ and Lahl 2006.

[7] Registrants should also take into account the relevant technical guidance documents published by ECHA.

[8] COM (2001) 88 fin., p. 11 and subs. With regard to existing substances the European commission found (p. 12) "significant gaps in publicly available knowledge about these chemicals. This lack of public knowledge was identified as the major deficiency throughout the entire review process."

[9] EDF 1997.

[10] Art. 14; cf. Schmolke 2015. Under the conditions of Art. 37(4) downstream users have to prepare a CSR when the registration does not cover their application of the substance.

regulatory agencies can take further risk management measures. In addition, pursuant to Art. 22, registrants have to update submitted data "without undue delay", e.g. when new information on risk comes to their attention.

In order to "instil confidence in the general quality of registrations and to ensure that the public at large as well as all stakeholders in the chemicals industry have confidence" that registrants are meeting the obligations placed upon them (Recital 65), the legislators created three legal instruments. ECHA has to

- check the completeness of each registration in order to ascertain that all the elements legally required have been provided before assigning a registration number (completeness check, Art. 20(2) and (3));
- "examine any testing proposal set out in a registration or a downstream user report" (testing proposal examination, Art. 40) and
- "examine any registration in order to verify" the conformity with the information requirements of – at the time of writing this study – "no lower than 5% of the total received by the Agency for each tonnage band" (compliance check, Art. 41(1) and (5)). This quota guided ECHA's compliance checking activities until 2019, when regulatory changes appeared inevitable which have been adopted in April 2020.[11]

In addition, transparency mechanisms, the online publication of most registration data in particular,[12] are in place to create (indirect) incentives: transparency increases the scrutiny of civil society and thus may channel enforcement agency activities to react on non-compliant registrations.[13] As clarified by Recital 122,[14] non-compliance with the regulation "can result in damage to human health and the environment". Therefore, effective mechanisms are needed to create strong incentives for the economic actors to comply with their legal duties.

[11] Commission Regulation (EU) 2020/507 of 7 April 2020 amending REACH as regards the percentage of registration dossiers to be selected for compliance checking, OJ L 110 of 8.4.2020.

[12] For details, see Art. 119 and the related ECHA 2012, and the ECHA 2018a.

[13] Bernard et al. 2017, p. 17.

[14] The recital refers to national enforcement measures; the reasoning, however, also applies to enforcement activities of ECHA. It is further underpinned by the aims of the regulation laid down in Art. 1 and, i.a., in recitals 1 and 3.

3 Completeness Check

Article 20(2), first Sentence, obliges ECHA to "ascertain" that "all elements" (not: data) have been provided, which are "required" in the relevant Articles (and corresponding annexes). This obligation is not limited to the "technical dossier" as defined in Art. 10(a); rather, it includes the "chemical safety report when required under Article 14, in the format specified in Annex I" according to Art. 10(b). If the registration dossier is not complete ECHA cannot legally grant the registrant a registration number and consequently the "no data, no market"-principle applies.

The task assigned to ECHA is deemed as one of the cornerstones of the REACH mechanisms since the trustworthiness of the entire registration scheme with its inherent regulatory principle of "self-responsibility"[15] is put at risk.

3.1 Practical implementation

The ECHA approach, however, at the beginning was strictly limited to fully automated electronic examination; which was reflected in the term "technical completeness check" with the acronym TCC. The registrants could download a "plug-in" to IUCLID allowing to perform the TCC before submitting the dossier.[16] In a nutshell, it was sufficient that in each IUCLID field covering the standard information requirements at least some alphabetic characters or numerical symbols were to be found.

The term "Technical Completeness Check" has no basis in the legal text. On the contrary, the legal text obliges ECHA, as already mentioned, to check not only the "technical dossier" (Art. 10(a)) but also the CSR (Art. 10(b)). Although the completeness check has – unlike the CCH (see Art. 41(1)) – not the function to "verify" the quality of the data, the task assigned to the Agency is not limited to a level where the mere presence of any characters in an IUCLID field is sufficient to count as "complete". The term "ascertain" in Art. 20(2), first Sentence, underlines that meaningful information has to be provided by the registrant for each standard information requirement applicable for the respective tonnage band.[17] The completeness check thus functions as the gatekeeper of the registration process.

Obviously, the system established by ECHA was not able to deliver the appropriate level of "ascertainment".[18] Thus, the limited "technical" approach was constantly debated in the ECHA Management Board and highlighted as a severe problem in the political and scientific debate.[19] The European Parliament's ENVI Committee addressed the issue in a formal letter to ECHA's

[15] Führ and Lahl, 2006.

[16] ECHA 2010a, p. 4.

[17] See also the BoA decision in the case A-022-2013 published 15.03.2016.

[18] ClientEarth report states (Bernard et al. 2017, p. 14): "Unfortunately, ECHA largely ignored its obligation to carry out a thorough check of the completeness of the registration dossiers. ECHA interpreted its role by creating a 'check process' that could be automatically managed through software – a process called the 'Technical Completeness Check'. This approach was flawed in two ways. Firstly, it showed that ECHA holds to an overly restrictive and formal interpretation of its role. Article 20(2) REACH does say that the completeness check does not include an assessment of the quality or the adequacy of any data and justifications submitted. However, when interpreted in light of the goal of registration, it does require ECHA to control that the data provided is at least understandable and usable as it is supposed to be the basis on which the other pillars of REACH (evaluation, authorisation, and restriction) rely. Secondly, the Technical Completeness Check did not work in practice. This software only checked the presence of an alphanumerical value in the different cells of the registration dossiers. The software could not verify whether the information included had any meaning. For example, if ECHA's software had to examine a cell where a company had entered 'asdf4fnsj kfns3djfkn' it would have considered the entry valid. The system therefore almost created an incentive to cheat, reinforced by the fact that ECHA provided the registrants with a tool to check in advance whether the dossier would pass the completeness check. For those who intended to cheat the system this was very convenient. They were able to add meaningless accumulations of characters until the completeness check plug-in indicated a green light."

[19] Schaible et al. 2012, p. 11-13; Führ 2014b, p. 329/330.

Executive Director,[20] which led to another debate in the Management Board.[21] Beside the core argument that the entire registration mechanisms are endangered by this "habitual blindness" of ECHA, accepting dossiers with severe deficits was devaluating the investment of law abiding companies and encouraging free-riders to cheat the system.[22]

Nevertheless, ECHA was reluctant for many years to amend the approach. In 2016, the Board of Appeal in the "charcoal I"-case considered this practice as being a breach of ECHA's obligation:[23]

> The Board of Appeal notes, however, that the fact that the IT application used by the Agency cannot verify the presence of all the elements required under Articles 10 and 12 does not exonerate the Agency from its obligation to check the completeness of dossiers in accordance with Article 20(2).

In the following paragraphs of its reasoning, the BoA reiterates the arguments that have been introduced to the Management Board deliberations in the previous years. A few months later ECHA finally introduced an "enhanced completeness check"[24] based on deliberations and decisions of the management board:[25]

> "The updated completeness check also includes additional manual verifications by ECHA staff to ensure that when registrants waive or deviate from the information requirements, they provide justifications foreseen by REACH, and that testing proposals on vertebrate animals are accompanied by justification for why none of the adaptation possibilities under REACH could be used. The manual checks aim to establish a level playing field between registrants who follow the standard information requirements set out in REACH and those who waive or deviate from these requirements, by ensuring that the latter provide justifications with a regulatory relevance."

With the enhanced completeness check, introduced on 21 June 2016, ECHA claims "to ensure that submissions contain all the information foreseen by REACH".[26] This, in a nutshell, describes the target state as defined by Art. 20(2) REACH (see above). Until now, only limited insights in the effect of the ECC are visible. The 2017 Progress Report states[27]:

> During 2017, 4 752 registration dossiers (ca. 30% of all incoming registration dossiers) were stopped for manual verification by ECHA staff of which 1 306 initial dossiers and 3 446 update dossiers (Figure 15). In 25% of the manually verified dossiers (8% of the submitted dossiers), registrants were requested to improve the submitted information. In 95% of these cases, registrants were able to amend the dossiers as requested, and the submissions passed the completeness check at the second attempt.

[20] Letter by the chair of the European Parliament's ENVI Committee, Mathis Groote to ECHA's Executive Director from May 2012, IPOL-COM-ENVI D (2012) 26338.

[21] E.g., ECHA Management Board 27, Sept. 2012 (Bucharest) discussing a letter to the chairman of the board from a board member appointed by the Commission representing interested parties from Sept. 7, 2012 asking for a "courageous approach in implementing Art. 20(2)1 REACH (Completeness Check)".

[22] Eurometaux 2014.

[23] Case A-022-2013, 15 March 2016. Paragraph 106.

[24] The authors of this study propose to introduce a new acronym to the ECHA orbit: ECC, instead of TCC.

[25] The ECHA 2018b refers (on p. 47) to the "36th MB meeting, 16-17 December 2014, Rome - AP 11: Substance identification in registration dossiers – a strategy for improvement (including completeness check) (MB/53/2014 [not publicly available]); 38th MB meeting, 17-18 June 2015, Helsinki - AP 11: Improved substance identity check as part of the technical completeness check process (MB/26/2015 [not publicly available])."

[26] ECHA 2018b, p. 47. ECHA thus implicitly acknowledges that this has not been the case in the first nine years of its existence.

[27] ECHA 2018b, p. 47.

The need for a more comprehensive completeness check is underpinned by the fact that one out of four of the manually chec**k**ed dossiers did not meet the requirements laid down in REACH; although the manual checks were announced well in advance. A study on behalf of ECHA refers to a statement of an industry actor:[28]

> One respondent commented that they had submitted two similar dossiers within a few weeks of one another making use of the same waiver, where one had been accepted and the other rejected because it failed the manual check.

This single statement triggered a prominently placed and reiterated finding by the consultant highlighting a "lack of consistency". Based on this one case observation the report drew a general conclusion by stating "registrants were reticent about updating a dossier in case it failed on a check which could not be predicted before submission". Obviously, the previous situation with the TCC plug-in was more convenient from an industry perspective. However, a different conclusion might be drawn: in any case where manual verification unveils deficits in a dossier the other dossiers by the same registrant should be checked manually in the respective IUCLID fields as well.

3.2 Outcome of the initial approach

Under the conditions of the previous – very limited – completeness check it was possible for registrants to gain a registration number although the data provided in the dossier were not meaningful or relevant in terms of the data requirements laid down in REACH (and its Annexes). ECHA conceded the existence of the problem in the charcoal case before the BoA.[29] Consequently ECHA was not able to provide the necessary level of "ascertainment" as foreseen in Article 20(2) REACH and thus the "no data, no market" principle was violated for a relevant number of dossiers. In other words, ECHA granted registration numbers for incomplete and thus incompliant dossiers.

3.3 Outcome of the enhanced approach

The previous practice of ECHA to carry out only a "superficial completeness check"[30] after the BoA Decision in the "charcoal case"[31] was broadened into an enhanced completeness check as of 21 June 2016. Accordingly, the terminology (partly) changed to ECC instead of the – in legal terms misleading (see section 3.1) – abbreviation TCC. With this approach, ECHA began to conduct manual checks with the aim "to ascertain that all the information required by the legislation has been included."[32] With this step, ECHA formally accepted to comply with the legal text. ECHA explains the background: "The manual verification aims at establishing a level playing field between registrants who follow the standard information requirements set out in REACH,

[28] Amec Forster Weeler 2017, p. 4 and 60 f.

[29] Para 105 of the decision (Case A-022-2013, 15 March 2016) states: "In response to a written question from the Board of Appeal, the Agency conceded that the Intervener's registration dossier '*contains text that clearly does not satisfy the information requirements*' under Articles 10 and 12. The Agency further accepted at the hearing that '*not all the elements required [by Article 20(2)] were provided'* by the Intervener. The Agency also conceded that there are certain flaws in the automated system which allowed the Intervener to benefit from the '*inconsistent use*' of the '*disregarded study*' flag in the automated system for the submission of registration dossiers."

[30] Lebsanft 2018, p. 3.

[31] Case A-022-2013, 15 March 2016.

[32] ECHA 2020a.

and those who waive or deviate from these requirements, by ensuring that the latter provide justifications foreseen by the legislation."[33]

ECHA describes the focus of the manual checks as follows:[34]

- Justification for waiving of standard information requirements (physico-chemical, environmental fate and hazard information)
- Substance identification (justification for deviations from naming and identification of substances, and waiving of analytical information; identification of UVCB substances)
- Justification for waiving of chemical safety report
- Testing proposals on vertebrate animals (presence of considerations for adaptation possibilities)

ECHA sees the outcome of the improved submission tools and the related enhanced completeness check particularly in three areas:[35]

- What you get in is now much better and more structured
- Substance identification information improved by targeted measures
- Compliance with harmonised classification[36] at a very high level

The enhanced approach by its nature covers only newly uploaded registrations (including updates). In terms of "establishing a level playing field", it is necessary to scrutinise the registration dossiers stored in the REACH IT-system in a similar manner. According to ECHA those retrospective checks include:[37]

- Older dossiers may be checked retrospectively for completeness and fulfilling the one substance, one registration principle (OSOR)[38]
- Dossiers not updated are targeted for retrospective checks to ensure a level playing field
- First campaigns showed that registrants were able to fulfil information requirements, e.g. provide a missing study

In practical terms, ECHA informs registrants via REACH-IT of a retrospective check allowing them to reconsider their initial dossier. Consequently, ECHA revoked only a few registration decisions so far. It remains unclear how many retrospective completeness checks ECHA conducted.

For the latest registration deadline in 2018, ECHA reports that around 1% of the 26 081 registration dossiers received have been rejected, without providing further details on the extent to which registrants attempted to provide improved data which ECHA did not accept either.[39]

[33] ECHA 2020a.

[34] Braunschweiler 2018, p. 12.

[35] Ylä-Mononen 2018, p. 21.

[36] In accordance with Title V of the CLP Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, OJ L 353 of 31.12.2008.

[37] Braunschweiler 2018, p. 13.

[38] An Implementing Regulation from 2016 tasked ECHA to ensure joint submission OSOR.

[39] ECHA 2019c, p. 11. The figure is valid for April 2019 when ECHA published the report.

3.4 Conclusions

The deficits of the initial approach of the completeness check affected the first two registration deadlines applicable to the highest tonnage bands and to substances with known adverse effects in the water compartment. Thus, a highly relevant part of the chemical universe was able to slip into the registration system without proper completeness ascertainment as foreseen in Art. 20(2), first Sentence. With this approach, constantly challenged in the ECHA management board, the ECHA Secretariat put the entire REACH registration regime at risk. The insufficient completeness check contributed to the high level of incompliant registration dossiers (see the following chapters) since the function of a gatekeeper of a system based on self-responsibility was not enacted adequately.

The practice of the ECHA Secretariat was nothing less than an open invitation for free-riders among the registrants. It will take several years to rectify this problematic situation fully. A timeframe in which the "no data, no market" principle was undermined by the very authority who was in charge to "ascertain" that meaningful information was provided for all standard information requirements formulated in Art. 10 and 12 as well as in the other applicable provision of the regulation.

The enhanced completeness check improved the situation substantially. The registrants are now aware that – beside the technical completeness check plugin – a manual control is possible. This perception alone creates an additional incentive to comply with "all the elements required" under REACH. This obligation covers, as already mentioned, the chemical safety report (Art. 10(b)). In a press release, as of 11 December 2019, ECHA announces that this gap in the completeness check will be closed in April 2020 together with "more explicit checks on key hazard endpoints" and missing use information:[40]

> ECHA plans to extend the completeness check to the chemical safety report. So far, the chemical safety report has remained outside the scope of the completeness check, which has focused on the other elements of the registration dossier.
>
> With experience gained in performing manual completeness checks on certain dossier elements, ECHA is now ready to tackle the content of the chemical safety reports. With this improvement, ECHA can better fulfil its obligation to ensure that all the required elements are included in the registration. (…)
>
> In parallel, ECHA will also strengthen computerised completeness checks on use information. In particular, cases where the service life description of an article is expected but has been left out of the registration dossier will be detected. Improvements are also foreseen for the endpoints related to mutagenicity, reproductive toxicity and degradation.
>
> The revised completeness check will be launched with the release of a new version of IUCLID in April 2020 and will apply to both new registrations and updates of existing ones. Registrants should, therefore, prepare for the changes as registrations submitted before may no longer pass the revised completeness check rules.

Due to the effects of the COVID-19 pandemic, ECHA later announced to postpone the completeness check of the CSR until October 2020.[41]

[40] ECHA 2019i accompanied by an Annex describing the new elements in detail.

[41] Cf. announcement by ECHA (03.07.2020).

Yet, in other words, ECHA is establishing an “enhanced approach II” aligned to the wording of the legal text (as outlined above). In particular, the exposure scenarios are taken into account.

Under these conditions, registrants cannot (any longer) expect that incomplete dossiers slip easily into the REACH IT-system.

The legal consequence of an incomplete dossier is simple, but striking: No registration number is assigned. This option, however, is only available for new registrations. It does not apply to registration dossiers already accepted in the years before. Here, the effect of the registration number remains valid even in cases where the incompleteness of the original dossier is unveiled in the course of the enhanced completeness check in an update procedure. Section 6.2.5.1 formulates policy options to address this unsatisfying situation.

4 Dossier evaluation requirements

The following sections specify the material requirements of TPE (section 4.1) and CCH (4.2) as well as the largely shared procedural requirements (4.3). Reflecting these requirements on the one hand, and the normative goals of REACH on the other, section 4.4 looks at the (lack of) incentives for registrants to ensure adequate dossier quality.

4.1 Examination of testing proposals mandate and time periods for examination

Pursuant to Art. 40(1), the Agency shall examine any testing proposal set out in a registration[42] or a downstream user CSR[43] for provision of the information specified in Annexes IX and X for a substance. Priority shall be given to registrations of substances, which have or may have PBT, vPvB, sensitising and/or CMR properties. Priority shall also be given to substances above 100 tonnes per year with uses resulting in widespread and diffuse exposure, provided they fulfil certain criteria.[44]

In the TPE framework, ECHA may also examine additional relevant information provided by the registrant, e.g. the substance identity or whether applying the category approach is appropriate.[45]

Art. 43 sets out time periods for the examination of testing proposals. Accordingly, in the case of non-phase-in substances, ECHA has to prepare a draft decision (Art. 40(3) REACH) within 180 days upon receiving a registration or downstream user report. As for phase-in substances (Art. 40(2) REACH), the draft decision is due by

a) 1 December 2012 for all registrations received by 1 December 2010 containing proposals for testing in order to fulfil the information requirements in Annexes IX and X;
b) 1 June 2016 for all registrations received by 1 June 2013 containing proposals for testing in order to fulfil the information requirements in Annex IX only;
c) 1 June 2022 for any registrations containing testing proposals received by 1 June 2018.

4.2 Compliance check mandate and time period for evaluation

Art. 41(1) mandates ECHA to "examine any registration in order to verify compliance in any of the following:"

a) of the information in the technical dossier(s) with the requirements of Art. 10, 12 and 13 and with Annexes III and VI to X;
b) of the adaptations of the standard information requirements and the related justifications with the rules set out in Annexes VII to X and XI;
c) of any required CSA and CSR with respect to the requirements of Annex I and that the proposed risk management measures are adequate;
d) of any explanation(s) for an opt-out from joint registration (Art. 11(3) or Art. 19(2)); i.e. providing an objective basis.

Until 2020, Art. 41(5) specified ECHA has to check compliance of at least 5% of the dossiers received for each tonnage band. REACH did not define a timeframe for these activities. This

[42] Cf. Art. 10(a)(ix); Art. 12(1)(d) and (e).

[43] Art. 38(2)(f).

[44] For details see Art. 40(1)2 REACH.

[45] Bergkamp (2013), p. 136.

quota thus guided ECHA's compliance checking activities until 2019, which are subject to the study at hand. Following legislative changes in April 2020,[46] ECHA's tasks are more precisely rendered, i.e. to "select, until 31 December 2023, a percentage of those dossiers no lower than 20 % of the total received by the Agency for registrations in tonnage bands of 100 tonnes or more per year. The Agency shall, until 31 December 2027, also select a percentage no lower than 20 % of the total received by the Agency for registrations in tonnage bands of less than 100 tonnes per year".

ECHA "shall give priority (…) to dossiers meeting at least one of the following criteria:

a) opt-out from joint registration (Article 11(3)) regarding information requirements specified in Art. 10(a)(iv), (vi) and/or (vii)
b) the dossier is for a substance manufactured or imported in quantities of one tonne or more per year and does not meet the requirements of Annex VII applying under either Article 12(1)(a) or (b), as the case may be; or
c) the dossier is for a substance listed in the Community rolling action plan referred to in Art. 44(2)."

However, Art. 41(5) expressly states that ECHA may also use other criteria to select dossiers for evaluation (cf. section 5.1 and subs. on the implementation).

According to Art. 41(3) ECHA hast to evaluate within 12 months and if necessary draft a decision. In these draft decisions ECHA requires the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements and specifying adequate time limits for the submission of further information.

4.3 Procedure

Decisions in dossier evaluation shall be taken in accordance with the procedure laid down in Art. 50 and 51, involving different actors (see Figure 1), whereas the examination of testing proposals involving tests for vertebrate animals entails an additional 45 days public consultation of third parties (40(2)).

After ECHA issued the draft decision to the registrant he may submit comments which ECHA needs to address. After this period, the MSCA may submit their proposals for amendments (PfAs) to ECHA´s draft decision. ECHA summarises the following steps as follows:

> "When PfAs are submitted, the Member State Committee seeks a unanimous agreement through a written procedure or in plenary meetings. For the latter, registrants can attend the open sessions. In addition, the registrant concerned is always invited to comment on the PfAs within 30 days and the Member State Committee takes those comments into account in the decision making. If the Member State Committee does not reach a unanimous agreement on the draft decision, ECHA refers the case to the Commission for decision making."[47]

Once a substance is selected for a CCH, ECHA evaluates all available dossiers (lead and member). Since January 2019, ECHA addresses all registrants (lead and member) within a draft decision if their dossier is non-compliant.[48] With this, ECHA i.a. intends to support collaboration between

[46] Commission Regulation (EU) 2020/507 of 7 April 2020.

[47] ECHA 2018b, p. 28.

[48] See ECHA 2018c; ECHA 2019d, p. 16. Before that date, ECHA's common practice was to inform only the lead-registrant, cf. Hoffstadt 2018, while Herbatschek et al. 2013, para. 4.137 construe Art. 50(1) as to obligating ECHA to inform all (co-)registrants in any case.

registrants with a view to the provision of high quality data because SIEFs legally ceased to exist after the last registration deadline in Mai 2018 has passed.

After the deadline specified in the issued decision, ECHA examines any information submitted in consequence of that decision (Art. 42).

The Agency concludes if the submitted information meets the requirements of the decision. In this case, dossier evaluation is completed. ECHA notifies the Commission and MSCAs of the information obtained and conclusions made (Art. 42(2)). In cases where the registrant failed to fulfil the requirements, ECHA used to issue a statement of non-compliance (SONC) to the concerned MSCA and NEA.

However, the Agency had to adapt its SONC practice after decisions by the Board of Appeal and the General Court found legal limitations therein.[49] Subsequently, ECHA replaced the SONC with two other documents:

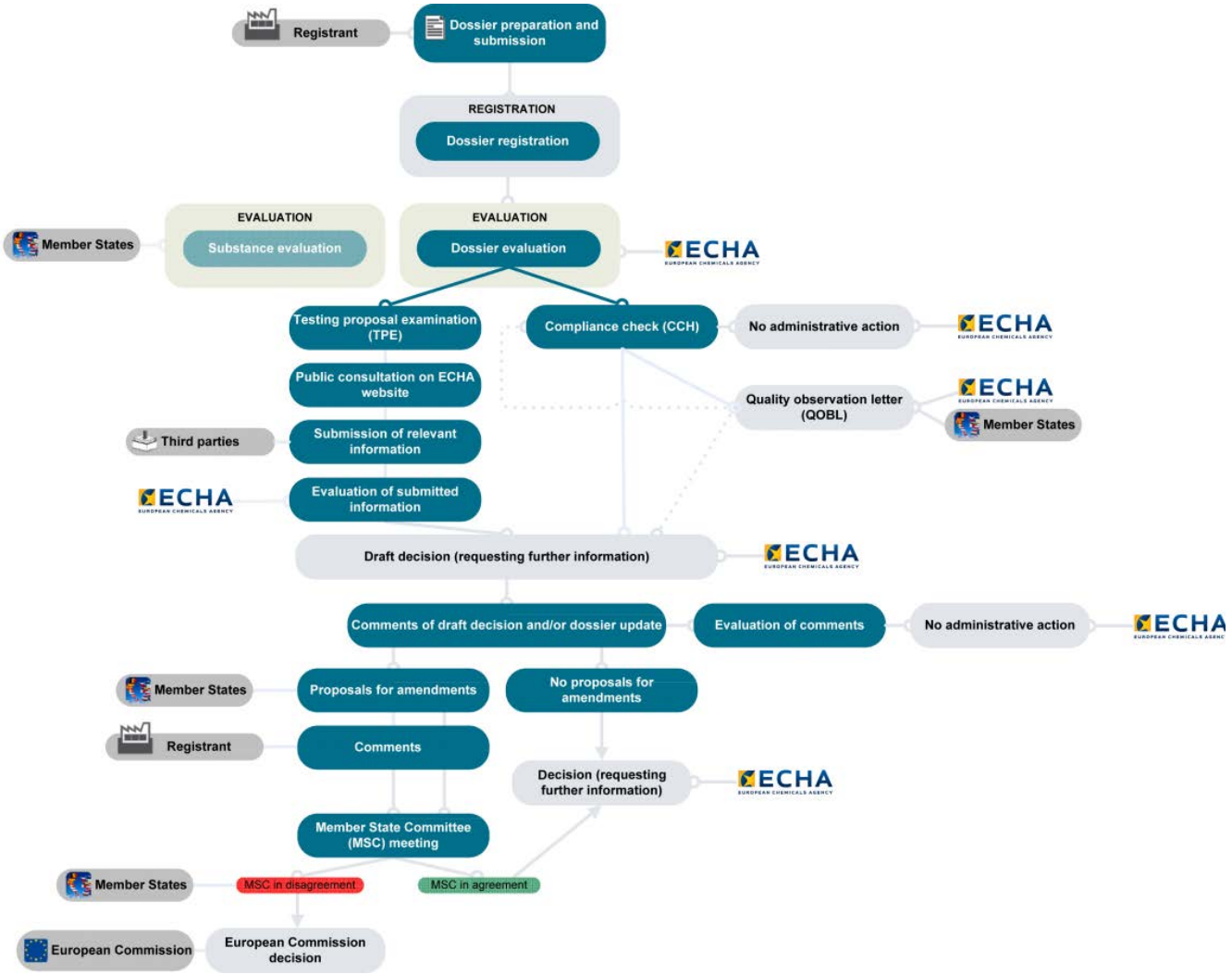
- Decision of non-compliance - If the submitted information is relevant but not sufficient and requires a new assessment, ECHA will draft a new decision according to Art. 42(1). This decision will be adopted in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation.
- FTR (Failure to respond) document - If the registrant provides no or "manifestly unreasonable" information in response to a decision, ECHA will inform the concerned MSCA/NEA.

Information obtained in the DEv context “shall be used” by ECHA and MSCA to update the CoRAP and by MSCA/European Commission for the authorisation and restriction procedures. In addition, this information can trigger regulatory risk management measures beyond REACH (e.g. harmonised classification according to CLP, occupational exposure limits). Therefore, according to Recital 68 “[i]nformation on the progress of evaluation proceedings should be made public”.[50]

[49] Cf. on the respective ruling section 5.2.3.

[50] Besides, according to Art. 41(2) the list of dossiers being checked for compliance shall be made available to MSCAs.

Figure 1: Dossier evaluation process



Source: Graphic dossier evaluation process by ECHA (27.07.2020)

4.4 Lack of incentives for dossier quality put into context

The REACH instruments have to create effective incentives for registrants to ensure adequate data quality. However, a workshop hosted by ECHA in 2014 identified several aspects contributing at that time to a lack of incentives for companies to comply with the REACH data requirements and thereby putting dossier quality at risk:

- The registration number (granting the market access) was at that point of time acquired with no assessment of compliance.
- The probability of the dossier being selected for compliance check was low (5%) and many were only partially checked.
- The consequences for non-compliance (i.e. enforcement and penalties, revocation of registration number) had so far not been fully developed or used.
- The identities of non-compliant companies were not revealed by ECHA.[51]

Meanwhile, under the enhanced completeness check, registrants must expect an initial test of their submitted dossier (see section 3.3). In addition, Commission Regulation (EU) 2020/507 superseded the 5% percent target per tonnage by 20%, applicable in a two-tiered approach for registrations in tonnage bands of 100 tonnes and more per year or below that (section 4.2), and additional measures to address shortcomings in enforcement are envisaged.[52]

Furthermore, REACH pursues transparency of submitted substance data, in order to create incentives for registrants to act compliant.[53] In 2012, ECHA started to disclose in the dissemination portal of registered substances the names of the registrants, unless successfully claimed confidential. Additionally, in 2018, ECHA introduced a public database to increase transparency of the specific CCH procedures' progress.[54] This database also provides non-confidential versions of any adopted CCH decision once available. Annex E of the decision contains a table that apparently lists the names of the addressees – which are not disclosed (blackened), though.

However, as of March 2020, users of the online databases could relate the registration number displayed in the decision with the information stored in the dissemination portal under that number, e.g. numbers of registrants listed at both sources, and years of dossier updates per registrant displayed in the dissemination portal. Correlating these pieces of information, one might get an idea about which registrant was found acting non-compliant in a CCH decision. However, this approach bears considerable uncertainties.

In conclusion, not actively disclosing names of registrants subject to a CCH decision, ECHA does not only miss out on untapped potentials to increase incentives for registrants. The current situation moreover bears a risk for registrants acting compliant of being accused acting in breach of law, due to the outlined uncertainties in interpreting available data.

[51] ECHA 2014b, p. 13 et seq.

[52] Cf. section 6.1.

[53] Cf. section 2.

[54] ECHA 2019c, infobox at p. 14: "Registrants can now consult a single table to follow the progress of a dossier for a given substance through the evaluation process. The table is part of the public activities coordination tool (PACT) on ECHA's website and replaces both the previous page hosting the non-confidential versions of adopted decisions and the list of substances potentially subject for compliance checks." For details see respective table by ECHA.

5 Dossier evaluation implementation

In its 2018 General Report on the operation of REACH, the European Commission ranks "non-compliance of registration dossiers" first in a list of issues requiring most urgent action to improve the implementation of REACH.[55] Drawing on available data on DEv activities for the years 2009 until 2018, as well as further developments in 2019 and early 2020, the following sections briefly summarise the state of play in Dossier Evaluation, considering both the outcomes generated for compliance checks (CCH, section 5.2) and testing proposal examination (TPE, section 5.3) and (resource) inputs in this respect (5.4). The first section 5.1 however appraises ECHA's strategic approach to dossier evaluation (DEv).

5.1 Operationalisation

While the TPE mandate is comparatively clear[56], i.e. ECHA has to evaluate every testing proposal, the Agency had to develop a strategic approach to CCH. This section summarizes the most important milestones of the approach, which evolved over time, while throwing a spotlight on dossier selection priorities and the transparency of the CCH process.

5.1.1 Early strategic approaches

Since 2009, ECHA has checked dossiers for compliance and soon realised that the established working procedure, so far, was not very efficient. Therefore, the Agency developed the "Area of concern"-strategy. Between 2012 and 2014, the majority of compliance checks addressed only specific parts of dossiers, so-called "areas of concern", such as physico-chemical properties or missing environmental and human health information. The focus was on targeting easily identifiable data gaps (by IT algorithms) and addressing them in a standardised manner.[57] This CCH approach aimed at inducing learning processes within the industries by generating "multiplier" effects of CCH decisions.[58] However, the unexpectedly high share of non-compliant dossiers (see section 5.2.2) indicates that such intended effects were limited, at best. Besides, there were indications that the results of the CCH and the new information received were not fed into other REACH and CLP processes.[59] Two workshops hosted by ECHA critically reviewed the CCH practice[60] and paved the way to an advanced strategic approach.

5.1.2 Advanced strategic approach and screening

In late 2014, ECHA and the MSCAs further developed the CCH approach by stronger acknowledging interlinks between the regulatory processes under REACH, CLP and beyond,[61]and by introducing the eight so-called "super endpoints" (see below). The advanced strategy reflects the strategic objective of ECHA's then Multi-annual Work Programme (MAWP) 2014-2018 to emphasise the impact of CCH on the safe use of chemicals and risk mitigation. At the same time, the new approach contributes to the implementation of the SVHC roadmap to 2020.[62] Soft measures such as targeted information campaigns for registrants are another

[55] COM (2018) 116 fin, p. 3.

[56] Yet, two Ombudsman decisions and the outcome of a BoA case drove ECHA and Member States to adapt established TPE procedures, cf. section 5.3.2 and e.g. ECHA 2016b, p. 69.

[57] ECHA 2018b, p. 12.

[58] Deloitte and VVA 2017, p. 59.

[59] Deloitte and VVA 2017, p. 59.

[60] ECHA 2014b; ECHA 2015c.

[61] Outlined in ECHA 2014a.

[62] ECHA 2013.

element, and so is the improved transparency as regards the relevant outcomes of the different steps of the CCH process.[63]

The strategic approach foresees a "common screening approach" as mechanism for integrated substance selection and priority setting. In this approach, the information available in registration dossiers, the C&L inventory as well as additional external sources are screened to identify needs for action. The screening helps identifying substances for which data gaps exist that can be tackled e.g. by CCHs and which substances should be addressed by other regulatory measures.[64] Beside a small portion of randomly selected substances[65], priority was given to dossiers of substances with a high tonnage band (i.e. above 100 t/a). In addition, significant exposure potential for workers, consumers or the environment also could trigger CCH.[66] However, low quality of exposure information is hampering this route for priority setting.[67]

Compared to early strategic approaches, the updated (screening and) CCH approach[68] aimed to allocate resources on certain "substances of potential concern". Therefore, all selected dossiers were checked for compliance in the endpoints genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation indicating a potential concern (or with an unclear hazard profile that needs to be further examined). These eight so-called "super endpoints" are addressing key information requirements needed to determine CMR, PBT and vPvB properties – with the overall goal of ensuring the availability of at least all information on higher tier chronic endpoints, to be used later e.g. as basis for identifying SVHCs. Any CCH had to address (at least) these endpoints. Non-compliances related to other than the super endpoints could be subject to CCH on a case-by-case basis, when the non-compliance is directly affecting a related super endpoint.[69] Besides this, the substance identity, to the extent relevant, is always assessed once a dossier is opened for a CCH.[70]

From a procedural perspective, ECHA aimed at an early cooperation with member states. ECHA anticipated that for example when defining screening criteria ("scenarios")[71], this might reduce the need from member states to submit proposals for amendments (PfAs, see section 4.3) to draft decisions, which adds complexity to the CCH process. However, it remains unclear if this early step will reduce PfAs because the majority of the PfAs are the result of a more detailed check during the MSCA consultation period.

5.1.3 Integrated strategic approach

With its latest update the strategic approach of ECHA evolved into an "Integrated Regulatory Strategy" (IRS).[72] This approach is not yet fully matured; the ECHA/European Commission "Joint Action Plan" addresses some of the elements subject to IRS.[73]

[63] ECHA 2014a, p. 1.

[64] See the process overview at Integrated Regulatory Strategy by ECHA (31.10.2019).

[65] ECHA 2014a, p. 3.

[66] ECHA 2014a, p. 3.

[67] ECHA 2015b, p. 5.

[68] The screening identifies prioritised substances of which candidates for CCH are selected.

[69] ECHA 2015c, p. 8.

[70] ECHA 2018b, p. 13; ECHA 2014a, p. 3.

[71] ECHA 2015a.

[72] ECHA 2017d, p. 7; ECHA 2019e.

[73] See section 6.1.

On the one hand, starting point is the careful mapping of the "universe of substances" separating three categories, i.e. high priority for risk management, high priority for data generation, or currently of low priority,[74] while the screening moved from a single substance to a substance group approach with the aim of better avoiding regrettable substitution.[75] The focus on the "super endpoints" is also less pronounced. A set of purely quantitative[76] indicators (numbers of substances and procedures, working time spent etc.) accompanies the current CCH approach.[77] Nevertheless, also with the IRS the "super endpoints" remain the basis for ECHA's CCH work as decided in 2014.

On the other hand, in a more holistic approach the IRS fosters the interplay of the different REACH instruments contributing to dossier quality. Amendments of the information requirements[78] trigger dossier updates by the registrants. An implementing regulation could clarify the Art. 22(1) "without undue delay" requirement with respect to dossier updates,[79] whereas each update triggers the –now enhanced (section 3.3) – completeness check. Besides, any completeness check may trigger a CCH.

The interplay with the SEv is another building block of the scheme whereas different options are available and subject to analyses, mindful of the requirements[80] stipulated by the BoA.

5.2 Compliance Check Outcomes

This section summarizes the outcomes of the CCH procedures based on the reports published by ECHA or in other studies. The series of "Progress Reports" (Art. 54 REACH) as separate document ended in 2018 with the 2017 report. For 2018 and 2019, a (limited) set of data on certain CCH outputs is available at the ECHA website. Besides, the Agency announces that a "description of their impact will be included in the report on ECHA's integrated regulatory strategy, which is due to be published in April 2020".[81] The following sections are based on the latest data available.

5.2.1 Legally set targets (and dossier selection)

REACH originally does not stipulate a deadline for the 5% target (cf. section 4.2 on the legal amendments). ECHA met the 5% target set by REACH for CCH of dossiers in the highest tonnage (above 1 000 t/a) band in 2013 – subject to the Agency's interpretation of the target. CCHs applying the "Area of Concern" approach (section 5.1.1) checked only limited parts of a registration dossier, such as the partition coefficient. Some dossiers checked during the "Area of Concern" era have thus been re-opened later under the more elaborate CCH approaches.

The Agency reports that, between 2009 and 2019, it performed a "full compliance check" for 20.5% of the substances registered in the highest tonnage band, as well as for 18% of substances registered in tonnage band 100 – 1.000 t/a, 4% of the next lower tonnage band (10 – 100 t/a)

[74] ECHA 2019e, p. 12 et subs.

[75] ECHA 2019j, p. 8; cf. on the grouping approach ECHA 2017d, p. 12.

[76] Earlier versions had also used more qualitative approaches, see ECHA 2014a, p. 4.

[77] ECHA 2018d, p. 40.

[78] As for nanomaterials see Commission Regulation (EU) 2018/1881, OJ L 308 of 4.12.2018; additional amendments are foreseen by the JAP.

[79] A draft Implementing Regulation (CA/55/2019) was submitted to CARACAL on 2 July 2019.

[80] Those formulated in decisions BoA A-005-2014 and BoA A-006-2014, in particular.

[81] See ECHA 2020a.

and 1% of the lowest band (below 10 t/a).[82] ECHA additionally performed targeted compliance checks addressing specific concerns exclusively. Meanwhile, a legislative proposal aims to raise the legal target for compliance checks to 20% of each tonnage band,[83] subject to the latest update[84] of the strategic approach to enhance dossier quality.

In 2017, 100% of the dossier candidates for CCH have been selected due to priorities as defined by ECHA's manual screening (83%), by MSCA manual screening (10%), or because a dossier refers to a substance notified for CoRAP (7%).[85] There appears thus no room left for additional dossiers selected on a random basis. Performing CCH based on random selection however might send an important signal to registrants that dossiers for substances not considered a high-priority can be subject to evaluation as well.

Apparently, under the current concern-based approach of dossier selection for CCH, as defined by the IRS, the number of final decisions per year is levelling off at around 150, each stipulating several data requests (Table 1**Fehler! Verweisquelle konnte nicht gefunden werden.**). In 2018 and 2019, ECHA issued 144 CCH decisions addressing 640 information requirements,[86] respectively 150 decisions addressing 721 information requirements).[87]

The number of dossiers in CCH recently increased considerably. In its annual report of 2019[88], ECHA states to have carried out 301 full checks in 2019, which focused on relevant information to clarify long-term effects of chemicals, covering 274 unique substances. This was an increase of more than 50% compared to the previous year, where 186 full checks covering 182 substances had been completed. Additionally, ECHA performed 89 targeted compliance checks resulting in 390 checks on 3 750 dossiers covering 380 unique substances in total.

Table 1: Final compliance check decisions in 2009-2019 and number of information requests

Year	Number of adopted decisions (approx.)	Number of information requests (approx.)
2010	10	15
2011	100	180
2012	60	150
2013	150	220
2014	280	450
2015	150	260
2016	150	610
2017	140	690

[82] According to the Agency full compliance checks "cover, as a minimum: genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation", see ECHA 2020b.

[83] Cf. section 6.1.

[84] See section 5.1.35.1.3.

[85] ECHA 2018b, p 24.

[86] See ECHA 2019g.

[87] See ECHA 2020d.

[88] See ECHA 2019a.

Year	Number of adopted decisions (approx.)	Number of information requests (approx.)
2018	144	640
2019	150	721

Source: ECHA 2018b, 14; ECHA 2019g (data); ECHA 2020d (data).

Elaborating on process inputs by authorities, section 5.4 also highlights to what extent in the decision-making procedure involvement of the MSC and the Commission was required.

5.2.2 Scientific and legal assessment

For obvious reasons ECHA invests considerable resources in clarifying substance identity, either in informal exchange with registrants or in evaluation decisions (e.g., in 2017, substance identity was addressed in 36 draft decisions).[89] This applies to CCH as well as to TPE.

As regards the CCH activities until the end of 2017, ECHA found 69% of 1 350 dossiers evaluated in the highest tonnage band, and 77% of 430 dossiers one tonnage band below, respectively, non-compliant with respect to one or more data requirements.[90] Irrespective of tonnage bands, the numbers published for 2018 and 2019 indicate that in about 75% of evaluated dossiers ECHA detected non-compliance.[91]

A major assessment of more than 2 000 registration dossiers of substances in tonnages of 100 – 1 000 t/a by the German authorities UBA and BfR found the "percentage of 'non-compliance' ranged from 9 to 46% (24% on average). Hence, in at least 46% of the evaluated dossiers the information requirements under REACH are insufficiently fulfilled for at least one endpoint".[92] These and additional[93] assessments, while deviating from the CCH approach of ECHA,[94] further substantiate the general notion that non-compliance is rather widespread. In addition, one should bear in mind that demonstrating compliance during CCH with regard to specific endpoints assessed does not imply overall compliance of a given dossier, as the European Commission observes:[95]

> "ECHA targets those parts of the registration dossiers that are particularly important for the safe use of a substance. However, such limited assessment does not enable to eventually consider a dossier as compliant, and therefore the approach does not provide individual registrants with certainty about the compliance of their dossiers. It also makes statistics on the level of compliance and assessing the link between the approach and the original targets in Article 41 more difficult."

In 2018, based on 10 years' experience, ECHA reported on the endpoints related to data requirements on human health, environmental behaviour and physico-chemical properties most often found non-compliant during CCH activities (Table 2). At least to some extent these findings

[89] ECHA 2018b, p. 27.

[90] ECHA 2018b, p. 15. Similarly, ECHA's annual reports on evaluation progress before 2018 identify non-compliance between $\frac{1}{2}$ and $\frac{2}{3}$ of dossiers for at least one information requirement, cf. SWD (2018) 58 fin, PART 5/7, p. 74; SWD (2018) 58 fin, PART 1/7, p. 31.

[91] Considering 211 CCH draft decision issued in 2018 and 75 CCH concluded with no action, see ECHA 2019f and considering 296 CCH draft decision issued in 2019 and 94 CCH concluded with no action, see ECHA 2020f.

[92] The quote proceeds: "A decision on whether or not the endpoint is "compliant" could not be made for 31% (on average) of all assessed endpoint entries", see Oertel et al. 2020, p. 17, i.e. Part 3 of the project "REACH Compliance: Data availability in REACH registrations"; cf. the preceding reports Springer et al. 2015 (Part 1) and Oertel et al. 2018 (Part 2).

[93] Cf. the preceding reports Springer et al. 2015 (Part 1) and Oertel et al. 2018 (Part 2).

[94] SWD (2018) 58 fin, PART 5/7, p. 75 (footnote 184).

[95] SWD (2018) 58 fin, PART 5/7, p. 74.

are reflecting the CCH focus under the former "Area of Concern" strategic approach, in which the Agency addressed targeted endpoints. Hence, to conclude these findings show the most relevant or common violations of the data requirements is not appropriate.

Table 2: Focus of the data requirements in the CCH context

Category	Endpoint
human health-information	pre-natal developmental toxicity (first and second species), sub-chronic toxicity (90-day study), in vitro studies for gene mutation and/or cytogenicity in mammalian cells, in vitro gene mutation study in bacteria
environmental information	long-term toxicity in fish, identification in degradation products, growth inhibition in aquatic plants, bioaccumulation, effects in terrestrial organisms
physico-chemical properties	partition coefficient, water solubility, vapour pressure dissociation constant

Source (data): ECHA 2018b, 14.

A common source for non-compliance are the conditions under which registrants use alternative data (e. g. read-across to other substances) as well as insufficient justifications for data waiving or adaptations.[96] In this respect, parts of the data requirements in the Annexes lack precision, which in turn also challenges the formal compliance check of such provisions by ECHA. For example, according to Section 9.1 (column 2) of Annex IX, long-term toxicity testing with a view to aquatic organisms "shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms". The legal text does however not specify the triggers for such proposals. As for the scope of the additional data the question arises whether the registrant exclusively needs to take into account the endpoints specified in Sections 9.1.5 and 9.1.6, or whether, when the CSA e.g. flags concerns for endocrine disruptive properties, he should propose testing tailored to ED assessment. Moreover, additional data requirements[97] contain the wording "if the chemical safety assessment according to Annex I indicates the need to further investigate…", thus creating similar legal uncertainties.

Lack of or insufficient exposure data is an additional important source of non-compliance. E.g., registrants often make use of endpoint-specific waiving (Column 2 in the annexes) of exposure assessment although the latter would be required,[98] or the CSR for a classified substance does not contain an (environmental) exposure assessment.[99] Data requests addressing missing exposure data in the context of the CSR can only be directed at the registrants who usually do

[96] This was also observed by the "REACH Compliance" project, see Oertel et al. 2020 project "REACH Compliance: Data availability in REACH registrations"

[97] Annex VIII Sections 9.1.3 and 9.2, Annex IX Section 9.2 and Annex X Sections 9.2 and 9.3.4.

[98] This was also observed by the "REACH Compliance" project, see Oertel et al. 2020 project "REACH Compliance: Data availability in REACH registrations"

[99] Springer et al. 2015, p. 119 et subs.

not possess detailed information in this respect. The registrants might call upon the downstream users to provide data according to Art. 37(1) and (2), but there is no legal obligation for the downstream users to provide the corresponding data to the registrants. In addition, not all downstream users are known to the registrant and even in cases where the downstream users are identified and willing to provide data there is no safety that the obtained data is also reliable.

Another conclusion after the first 10 years of dossier evaluation concerns dossier quality issues, which cannot be sufficiently addressed in CCH, as, according to the Commission services, they "require argumentation and not just data generation", such as DNEL derivation, self-classification according to CLP, and identification of adequate risk management measures.[100] Likewise, exposure assessment is not as straight forward as, e.g., standard information requirements linked to specified OECD testing requirements. Data requests on exposure assessment under CCH may therefore lack legal certainty, in turn hampering enforcement.

ECHA provides an online inventory of recommendations for registrants how to ensure compliance in various contexts (e.g. standard information requirements, classification and labelling, adaptations, exposure assessment and risk characterisation).[101]

5.2.3 Follow-up to dossier CCH

In the last years, follow-up assessments of evaluation outcomes became an important activity.[102] According to the evaluation progress reported online, between 2013 and 2019 ECHA concluded follow-up assessments on CCH decisions for 929 substances.[103] In about 70% of the cases, registrants provided the data requested by the CCH within the deadline. However, in 13% of the cases they did so only after national authorities had been involved. Involving national enforcement authorities can therefore be considered an effective tool to motivate tardy registrants.[104]

To invite Member State competent authorities to consider enforcement actions against the registrant ECHA used to issue an (informal) statement of non-compliance (SONC). The SONC practice was subject to judicial review, both by BoA[105] and by the General Court[106]. Pursuant to the Court's judgement of 8 May 2018, when registrants submit information in response to a CCH decision, ECHA must undertake a new decision-making procedure as set out in Articles 50 and 51 REACH. The Court thus dismissed ECHA's claim that, in general, "such a system could lead to an endless procedure of new decisions which would paralyse the application of ECHA decisions".[107] In this respect the General Court states: Information that is "manifestly unreasonable as regards the [data] requirements" could constitute an abuse of process.[108] ECHA assessed the impacts on its SONC practice[109] and adjusted its practice accordingly (see already

[100] Cf. SWD (2018) 58 fin, PART 5/7, p. 76, continuing; „Complementary measures including those targeting communication in the supply chain, enforcement and concrete risk management actions (e.g. development of a restriction dossier, request for harmonised classification which would trigger RAC assessment etc.) are likely better suited to address their shortcomings".

[101] See recommendations to registrants by ECHA (23.3.2019).

[102] SWD (2018) 58 fin, PART 5/7, p. 70;

[103] For the years 2013-2018 see ECHA 2020b, for 2019 see ECHA 2020c. For a breakdown of the single year values between 2013 and 2017, refer to ECHA 2018b, p. 18.

[104] SWD (2018) 58 fin, PART 5/7, p. 71.

[105] Decision of 29 July 2015, Case A-019-2013, Solutia Europe sprl/bvba.

[106] Case T-283/15 - Esso Raffinage v ECHA, ECLI:EU:T:2018:263, appeal pending before the ECJ as Case C-471/18 P Germany v Esso Raffinage.

[107] Case T-283/15 - Esso Raffinage v ECHA, ECLI:EU:T:2018:263, para. 111.

[108] Case T-283/15 - Esso Raffinage v ECHA, ECLI:EU:T:2018:263, para. 74.

[109] Bjorn Hansen, Executive Director of ECHA, as quoted by CW at July 5th, 2018; see article on Chemical Watch (22.3.2019).

section 4.3). Since early 2019 BoA is asked to assess (parts of) the adjusted practice (Art 42(1) Decisions of non-compliance) in another appeal.[110]

In addition, the results of the dossier evaluation processes shall be used to identify additional needs for regulatory action (Art. 42(2)). According to ECHA, considering the concluded follow-up assessments between 2013 and 2018, 35 substances were considered possible candidates for a proposal for harmonised classification and labelling and one for substance evaluation.[111] In contrast, in 2019 alone 17 candidates for CLH could be identified, and two potential candidates for substance evaluation.[112] Statistical data on the effect that CCH might have had on SVHC identification and the (few) restrictions issued under REACH are not available.[113]

5.3 Testing Proposal Examination Outcomes

ECHA has to examine any testing proposal set out in a registration or a downstream user CSR (Art. 40(1), see section 4.1) within the defined time limit (section 5.3.1) and based on a scientific and legal assessment (section 5.3.2). The following sections are based on the latest data available.[114]

5.3.1 Legally set targets

REACH defines time limits for ECHA to examine testing proposals. As for phase-in substances, the first two deadlines ended in 2012, and 2016 respectively. ECHA reports to have successfully met these deadlines.[115] The last time limit ends on 1 June 2022 with respect to any registrations containing testing proposals received by 1 June 2018.

At the same time, ECHA mentions "some exceptional cases with ambiguous substance identity issues" for which the deadlines apparently might not have been met.[116] Besides, from the available information, i.e. ECHA reports and documentation in particular, it is not clear to what extent ECHA addressed the examination priorities set out in Art. 40(1).[117] Criteria when ECHA deems TPE completed are not available. For instance, the decision-making regarding 183 testing proposals for the two-generation reproductive toxicity study submitted by the 2010 deadline had been put on hold after uncertainties as to the interpretation of legal requirements became visible which triggered legal changes of REACH Annexes IX and X, replacing the mentioned study with a requirement for the extended one-generation reproductive toxicity study (EOGRTS).[118] After the legal changes, registrants were to re-submit their testing proposals.

Furthermore, the available information does not provide any details on the Agency's performance with respect to non-phase-in substances for which REACH stipulates a 180-day period for ECHA's examination and draft decision preparation, including related priority setting.

Section 5.4 reflects on the TPE decision-making procedure.

[110] Case A-001-2019, Solvay Fluor GmbH, Hannover, Germany.

[111] Cf. ECHA 2020b.

[112] ECHA 2020c.

[113] SWD (2018) 58 fin, PART 5/7, p. 76.

[114] As for the available evaluation reports and related limitations, see the introduction in section 5.2.

[115] See e.g. ECHA 2018b, p. 16.

[116] ECHA 2017c, p. 39: "Apart from some exceptional cases with ambiguous substance identity issues, ECHA has examined within the legal timeframe all testing proposals submitted for the first two registration deadlines for phase-in substances."

[117] As for the 2016 deadline, SWD (2018) 58 fin PART 7/7, p. 6 notes that "it was not possible to obtain from ECHA an overview of exactly what information had been requested for how many substances, nor of the cost of an evaluation decision".

[118] SWD (2018) 58 fin, PART 5/7, p. 30, p. 68.

5.3.2 Scientific and legal assessment

According to ECHA, registrants submitted most testing proposals to clarify the potential hazards to human health. Between 2009 and 2017, a "total of 1 588 requests were made in the testing proposal decisions, of which 964 (61%) were toxicological testing requests, 494 (31%) ecotoxicological and fate testing requests, and 130 (8%) physico-chemical testing requests".[119] The shares for 2018 are similar,[120] while 75% of the requests in 2019 are addressing human health related endpoints.[121] Available data for the reporting periods 2015, 2016 and 2017 allows a detailed overview of adopted decisions per endpoint (Table 3). In very few cases, ECHA has rejected the proposal as unnecessary. One should be cautious, though, to conclude from this observation that registrants do carefully consider before they propose further animal testing. Rather, ECHA's TPE practice was subject to a complaint lodged with the EU Ombudsman. The Ombudsman in September 2015 "concluded that ECHA's interpretation of its role was too strict and did not take into account the fact that the avoidance of animal testing was, together with the protection of human health and the environment, one of the guiding principles of the Regulation. The Ombudsman thus proposed to ECHA (i) that it requires all registrants to show that they have tried to avoid animal testing and (ii) that it provides registrants with all the information at its disposal which could allow them to avoid animal testing".[122]

[119] ECHA 2018b, p. 16.

[120] ECHA 2019g.

[121] ECHA 2020d.

[122] Cf. Decision in case 1606/2013/AN on how the European Chemicals Agency applies rules concerning animal testing, decision of the EU Ombudsman (06.07.2020).

Table 3: TPE adopted decisions in 2015, 2016 and 2017 and endpoints

Endpoint	Accepted under Article 40(3)(a)			Modified under Article 40(3)(b)			Additional testing requested under Article 40(3)(c)			Rejected under Article 40(3)(d)			Original test rejected under Article 40(3)(d) and additional testing requested under Article 40(3)c			Total number of requests evaluated		
Year (20XX)	15	16	17	15	16	17	15	16	17	15	16	17	15	16	17	**15**	**16**	**17**
Human Health Endpoint																		
Mutagenicity/genotoxicity	19	5	6	1	3			4		1	4	1			2	**21**	**16**	**9**
Pre-natal development toxicity	122	71	27	1	3			12	3	1	6				8	**124**	**92**	**38**
Short-term 28-day toxicity			1															**1**
Sub-chronic 90-day toxicity	81	42	15	7	7	2		8		4	5				6	**92**	**62**	**23**
Extended one-generation study		2	1		1	3		1			1	2			3		**5**	**9**
Two-generation reproductive toxicity										1						**1**		
Environmental Endpoint																		
Biodegradation	1															**1**		
Identification of degradation products								3									**3**	
Simulation tests (water, soil, sediment)		2	3					4			2						**8**	**3**
Long-term aquatic toxicity	41	24	7					12	4	1	4	1			3	**42**	**40**	**15**
Bioaccumulation in aquatic species	4	2	1	1	1			3			3					**5**	**9**	**1**
Other aquatic toxicity								4	9								**4**	**9**

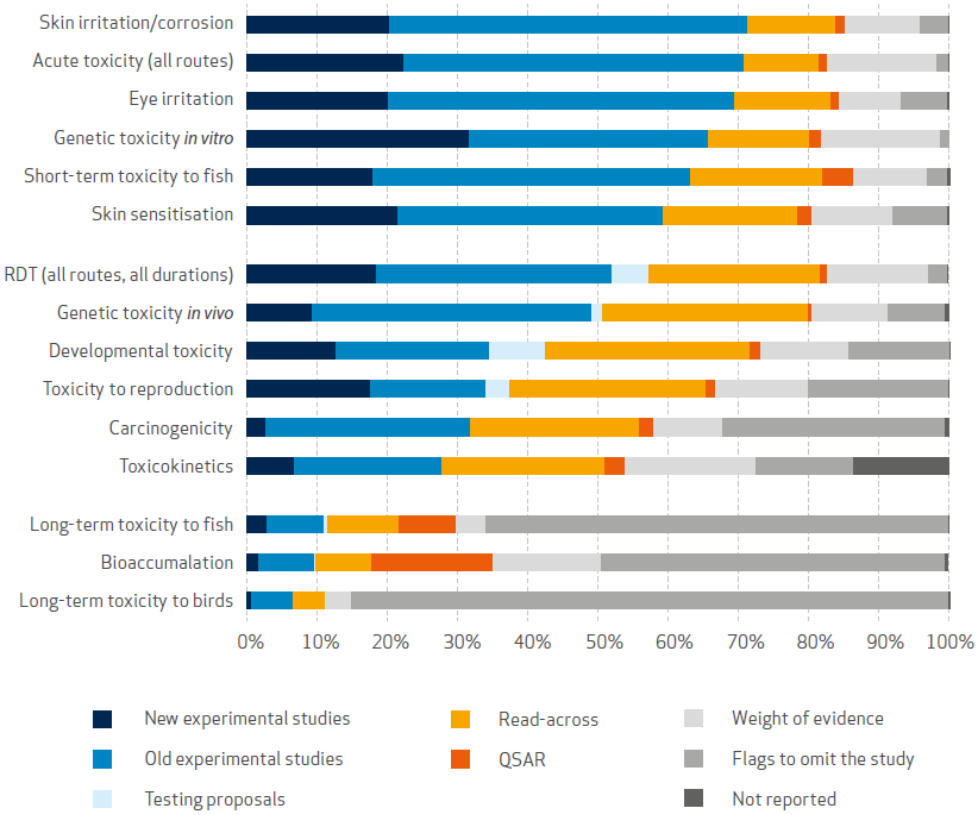
Endpoint	Accepted under Article 40(3)(a)			Modified under Article 40(3)(b)			Additional testing requested under Article 40(3)(c)			Rejected under Article 40(3)(d)			Original test rejected under Article 40(3)(d) and additional testing requested under Article 40(3)c			Total number of requests evaluated		
Long-term toxicity to sediment organisms	3	2						2			2					**3**	**6**	
Effects on terrestrial organisms	14	13	12	2				25	3	1	7				1	**17**	**45**	**16**
Psychochemical Properties																		
Physicochemical properties **(no details provided)**	28															**28**		
Viscosity		4	2														**4**	**2**
Dissociation constant			1															**1**
Total	**313**	**167**	**76**	**12**	**15**	**5**		**78**	**19**	**9**	**34**	**4**			**23**	**334**	**294**	**127**

Source (data): Evaluation Progress Reports, published by ECHA 2018b, ECHA 2017a, ECHA 2016a.

ECHA reports that between 2009 and 2017 in the TPE framework 1 087 third party consultations have yielded 826 "pieces of information".[123] Contributions originate mostly from NGOs (over 90% of comments in some cases).[124] However, ECHA observes the overall "impact" of such consultations as "relatively limited".[125] The evaluation reports contain examples of how third party contributions were used in the evaluation.

Overall, the number of testing proposal is considered low. Offering one explanation for this, the Commission Services observe registrants "extensively" submitting adaptations to standard information requirements.[126] REACH actually requests adaptations that are properly justified over animal tests. However, for environmental endpoints, in particular, ECHA identified many cases where registrants did not submit a testing proposal but did not succeed to justify and document their adaptations adequately either (see also Figure 2).[127]

Figure 2: Relative proportions of the options used by registrants to cover REACH information requirements



Source: ECHA 2017c, 31.

5.3.3 Follow-up to TPE

Observations regarding the follow-up assessments in the TPE framework are similar to such observations in the CCH context.[128] However, with 76 substances considered as possible

[123] ECHA 2018b, p. 16.

[124] SWD (2018) 58 fin, PART 1/7, p. 120.

[125] ECHA 2016b, p. 69; ECHA 2017c, p. 26.

[126] SWD (2018) 58 fin, PART 5/7, p. 73.

[127] ECHA 2017c, p. 43.

[128] Section 5.2.3.

candidates for a proposal for CLH and two for substance evaluation, the TPE procedure doubles the outcomes achieved between 2013 and 2018 under CCH.[129] In 2019, additional 8 candidates for CLH were identified.[130]

5.4 Inputs

Although ECHA is the responsible authority for DEv, both ECHA and Member States invest considerable resources in DEv activities. In this respect, extensive use of adaptations, as outlined in section 5.3.2, often lacking solid scientific justification considerably contribute to the complexity of the work by authorities[131] and related resource needs. Since available data on TPE and CCH inputs are often aggregated, the following sections provide an integrated view on staff (section 5.4.1) and time (5.4.2) resources and procedural aspects (5.4.3).

5.4.1 Staff

Dossier evaluation is a resource-intensive exercise for ECHA with estimated 59 full-time equivalent (FTE) staff members annually.[132] Other estimates refer to one FTE staff member capable of performing five CCHs in one year.[133] According to ECHA, resources assigned to CCH have been cut as the process became more automated.[134] In addition, MSCAs provide significant input into dossier evaluation whereas available data in this respect are not consistent (person-days per year dedicated to the task varies from 0.02 to 1 000 depending on the MSCA[135]). Moreover, the Commission is required to process all evaluation decisions for which the MSC could not reach unanimity.

5.4.2 Time

The average time it takes the "authorities"[136] to complete a CCH (including the initial prioritisation step) is 461 days; for the assessment and decision making for TPE they need 340 days on average.[137] For input for a final decision in CCH, or TPE respectively, ECHA estimates 25-28 person days.[138]

As for the question, how long it takes for dossier evaluation to ascertain that the "no data, no market" principle is complied with, the time needed by registrants to commission and conduct testing needs to be added. In this respect, ECHA observes that the time given to registrants to comply with a decision has increased to, on average, two or three years from the date of issue of ECHA decision. This is because, under the IRS, the majority of the information requests are more targeted for higher-tier tests.[139]

[129] ECHA 2020b. In 2019, 8 additional candidates for CLH were identified, ECHA 2020c.

[130] ECHA 2020c.

[131] ECHA and European Commission 2019, p. 2.

[132] SWD (2018) 58 fin, PART 5/7, 65.

[133] Cf. ECHA Executive Director Bjorn Hansen in a December 2018 European Parliament hearing, recording available at Multimedia Centre of the European Parliament (21.3.2019), for a summary of the discussions see also article on Chemical Watch (21.3.2019).

[134] Deloitte and VVA 2017, p. 59.

[135] SWD (2018) 58 fin, PART 1/7, p. 76.

[136] Considering the context this refers probably mostly ECHA complemented by MSCA, cf. SWD (2018) 58 fin, PART 5/7, p. 76.

[137] SWD (2018) 58 fin, PART 5/7, p. 76.

[138] See ECHA 2017b, p. 48 listing the performance indicator "Effective working time of ECHA staff used per main, final dossier evaluation output (compliance checks concluded with no draft decision, decisions on testing proposals and compliance checks)"; ECHA 2018d, p. 40.

[139] E.g. pre-natal developmental toxicity, mutagenicity or genotoxicity, reproduction toxicity and long-term aquatic toxicity, see ECHA 2018b, p. 13.

5.4.3 Procedural aspects

Based on estimates, the Commission services document allocates ECHA's resources to different activities as follows:[140]

- selection and allocation of dossiers (18% share of resources),
- scientific assessment (28%),
- drafting of the decision (20%),
- decision making, including interaction with registrant, MSCAs and MSC agreement seeking (26%),
- follow-up action141 (8%).

The procedural rules pursuant to REACH thus are setting an important frame for the resource inputs.

For 2017, ECHA reports that 65% of the registrants used their right to comment on ECHA draft decisions. In addition, registrants embrace the opportunity of having informal exchange with the Agency during their 30-day commenting period.[142]

Further, if a Member State submits a proposal for amendment (PfA) of the draft decision, ECHA, together with the MSC, needs to resolve the issue for the unanimous MSC adoption of the decision within the legal deadline of 65 days. According to a document accompanying the 2018 Commission services report on the operation of REACH, 27% of all CCH trigger PfA, and 48% of the testing proposal examinations.[143] However, for the period 2012-2015 at least 65% of the CCH draft decisions triggered PfA, with numbers rising in the years 2014 and 2015.[144] For 2018, only cumulated data for CCH and testing proposal examinations are available, according to which 21% of the final decisions were adopted with MSC involvement.[145] Despite the special case of EOGRTS related TPEs and CCHs triggering quite some Commission interference,[146] referrals for decision-making to the Commission are rather rare.

With a view to workload reductions at the meetings, the MSC attempts to resolve issues in advance and e.g. adopts 90% of dossier evaluation draft decisions by written procedure,[147] which is less time consuming, but also less transparent. In 2018, however, roughly 58% of cases were subject to written procedure.[148]

In addition, registrants may appeal CCH decision before the Board of Appeal (BoA). The BoA registered 41 appeals of CCH decisions between 2009 and 2019.[149] Compared to the overall number of 1 193 CCH decisions adopted between 2009 and the end of 2018,[150] the number of appeals is rather low (about 3%), indicating ECHA does not go beyond its competences. In

[140] SWD (2018) 58 fin, PART 5/7, p. 65.

[141] According to ECHA 2018b, p. 17, "currently, the number of follow-up evaluations carried out annually is 300 to 350 annually, with approximately 55% originating from compliance checks and 45% of testing proposal decisions".

[142] ECHA 2018, Progress Report 2017, p. 28.

[143] SWD (2018) 58 fin, PART 5/7, p. 75.

[144] See Deloitte and VVA 2017, p. 58 who provide as possible interpretation of these numbers "that the Agency and MSCAs are not well aligned on compliance".

[145] See ECHA 2019f.

[146] Cf. section 5.3.1.

[147] SWD (2018) 58 fin, PART 7/7, p. 11; SWD(2018) 58 fin, PART 5/7, p. 76.

[148] Again based on cumulative dossier evaluation data: ECHA 2019f.

[149] ECHA 2019b, p. 5.

[150] See information on progress in evaluation by ECHA (21.3.2019).

addition, the distribution of the appeals received by the BoA over time (Table 4) does not indicate a trend in the direction of rising numbers.

Table 4: Number of dossier evaluation appeal announcements per year

Year	Number of CCH appeal announcements	Number of testing proposal examination appeal announcement
2019	3	3[151]
2018	5	2
2017	3	3
2016	2	3
2015	13	1
2014	7	2
2013	2	-
2012	6	1
2011	1	-

Source (numbers): Announcement by the Board of Appeal (23.03.2019).

5.5 Conclusions

In the 2nd REACH Review, the European Commission ranks "non-compliance of registration dossiers" highest in a list of issues requiring most urgent action to improve the implementation of REACH.[152] While acknowledging ECHA's IRS as "adequate framework to identify and prioritise 'substances' that matter'", the SWD lists some shortcomings in the current practice, which also reflect the results of this chapter's analysis:[153]

- The DEv administrative processes and the data generation are taking a lot of time, due to lengthy decision-making procedures (including consultations with the registrants and, in the case of TPE involving vertebrates, the public).
- Lack of legal clarity in some information requirements hinders both registrants in achieving compliant dossiers and authorities to request missing data. Besides, obtaining adequate exposure data is a major issue.
- A lack of incentives for registrants to update their registration files despite their obligation, together with the enforcement difficulties, are the main cause of the delay to generate new information.

Hence, measured by the normative goals (section 2), the results of analysis indicate that the REACH instruments, and the operationalisation thereof, aimed to ensure adequate dossier quality require improvement in order to activate the self-responsibility of the registrants to ensure compliance effectively.

[151] One entry for 2019 refers to 14 joint cases (A-016-2019 to A-029-2019) lodged by registrants of 14 different substances derived from zinc dialkyldithiophosphate.

[152] COM (2018) 116 fin, p. 3.

[153] SWD (2018) 58 fin, PART 1/7, p. 31 et seq.

In addition, the analysis of this study identified lack of CCH transparency as a missed opportunity with respect to effective incentivising. ECHA does not publish the names of the companies addressed by CCH decisions. An easily detectable disclosure (e.g. in a separate list and in the dissemination portal highlighting the affected data entry) would be an effective motivation for all registrants to provide high quality registration data from the start, as companies have to avoid reputational losses. On the contrary, the current scheme creates the strongest incentives for the specific registrants addressed by CCH who have to comply with the final decision to remain the right to place a given substance on the market. By following the requirements set out in the decision, registrants can entirely ”heal” their initial non-compliance. In other words, the current scheme therefore only provides weak incentives for active compliance but, at best, ensures reactive compliance.

6 Policy Options

In its 2018 General Report on the operation of REACH, the European Commission requests[154] ECHA to

> "significantly increase the efficiency of the evaluation procedures by 2019 by:
> (1) identifying the main reasons for non-compliance of registration dossier and developing remedies;
> (2) where appropriate, applying the various evaluation procedures in parallel;
> (3) systematically implementing a grouping approach, where this is possible;
> (4) improving work-sharing across evaluation activities with Member States; and
> (5) improving decision-making procedures."

Reacting to the Commission's requests, in order to foster efficiency and effectiveness of DEv ECHA has changed some processes, which became applicable as of January 2019. For instance, after ECHA has issued the draft decision registrants may not anymore informally interact with the Agency.[155] Besides, in the frame of the current integrated regulatory strategy ECHA and Member States assess how to better integrate the existing REACH mechanisms beside DEv (update obligation, completeness check, SEv) in order to ensure adequate dossier quality.[156]

In addition, also reacting to the growing debate on registration dossiers lacking compliance,[157] in June 2019 ECHA and the European Commission presented a paper[158] entitled "REACH Evaluation Joint Action Plan" (JAP), outlining 15 actions intended to ensure registrants' compliance.[159] Section 6.1 reflects the proposed actions, which are addressing some of the shortcomings identified in the analysis above. Subsequently, section 6.2 presents additional policy options.

6.1 Reflection of the Joint Action Plan

Action 1 addresses "an amendment of Article 41(5) of REACH to raise the 5% minimum target in Article 41(5) to 20% of dossiers selected for compliance checking". This action to some extent will increase incentives for registrants to be compliant[160] as it indicates a much higher likelihood of non-compliances being detected, whereas for substances in the lowest tonnage bands (10 – 100 and 1 – 10 t/a) the selection for CCH is due at the end of 2027, also indicating delayed motivational effects. End of 2023 is the deadline for substances in the tonnage band 100 t/a and higher. These changes are already covered by implementing legislation adopted in April 2020.[161] The practical implementation of Action 1 has obvious implications on resources available at ECHA, but also at the Member States and the European Commission. As a reaction, ECHA re-focused its working priorities in 2019, while also increasing the available resources for dossier evaluation, and especially CCH. It is, nevertheless, necessary to regularly examine the resource situation and, if necessary, to increase resources in line with the new requirements.

[154] COM (2018) 116 fin, p. 6 (Action 2: Improve evaluation procedures).

[155] Bercaru 2018.

[156] Section 5.1.3.

[157] See e.g. this article in a German newspaper (1.11.2019).

[158] The legal status of the JAP, the publication of which did not involve prior communication with the member states, is not clear. Proposed implementing legislation however already cites the JAP (e.g. Recitals 5 and 6 of Commission Regulation 2020/507.

[159] ECHA and European Commission 2019.

[160] Section 1.

[161] Section 4.2.

Actions 2, 3 and 4 refer to the implementation of the substance categorisation approach already introduced in 2018 (priorities for risk management or data generation, low priority)[162] in a transparent manner. In addition, complementing these Actions, performing CCH based on random selection might send an important signal to registrants that dossiers for substances not considered a high priority can be subject to evaluation as well.

Action 5 asks the Commission to "assess the need, and if necessary make a proposal, to amend the Annexes VI to X of REACH to provide greater clarity to the information requirements set out therein". In addition, Action 6 refers to a Commission proposal "to amend Annex XI to ensure that adaptations to standard information requirements are properly justified". Participants at the CARACAL meeting in July 2019 already discussed a paper with a list of issues ECHA identified for possible amendments of the annexes to REACH with a view to Actions 5 and 6[163]. All options intend to clarify existing IR de lege lata, including requirements regarding ED properties of substances. Two CARACAL Sub-groups (CASG), on IR and on endocrine disrupters, have started their work. Results from these and related activities are expected to have a significant impact on the way registrants interpret certain[164] information requirements under REACH and also on the possibilities for authorities to request further data in the course of CCH.

In the same context as Actions 5 and 6, i.e. with the intention to "improve clarity of certain legal provisions",[165] Action 7 foresees that, by the "end of 2019, the Commission will assess the need of a possible implementing regulation that would efficiently put into effect the REACH evaluation decision making process". Reflecting the significance of this action is not possible, as more detailed information is not available. However, the legal text leaves little room for modifications potentially covered by the Art. 132 mandate to adopt implementing legislation.

Action 8 asks ECHA to, by the end of 2019, "simplify the compliance check decisions and improve the statement of reasons, to be clearer and more focused". The Agency already presented available options beside the modified approach adopted in January 2019 to address draft decisions to all registrants instead of only the lead.[166]

In Action 9, ECHA aims to, by the end of 2019, communicate with Member States to resolve "underlying differences of view" and "continue, as far as possible, [to] identify and plan discussions on more generic issues that may arise in upcoming compliance checks". Such strategic approach promises to allow for more efficient future CCH implementation, compared to former decision taking on a case-by-case basis. However, ECHA did not yet provide the full picture of all aspects it intends to address.

According to Action 10, ECHA will, by the end of 2019, "make a refined proposal to CARACAL how to better integrate substance evaluation and compliance check". The interplay of DEv and SEv is subject to discussions for quite some time now. With a view to efficient evaluation activities, it is important that the Agency assesses all available options, including a scenario where the eMS would also address any standard information request under SEv, i.e. there would be no need for having a separate CCH process at all.

In Action 11, ECHA aims to ensure, by the end of 2019, that companies submitting information in the context of other regulatory processes "will be informed of its updating obligations according

[162] See section 5.1.3.

[163] See documents on CARACAL provided by European Commission; the documents are also available on Chemical Watch (01.11.2019)

[164] See examples at section 5.2.2.

[165] ECHA and European Commission 2019, p. 5.

[166] See section 4.3.

to Article 22 of REACH. Moreover, in such cases ECHA will inform the responsible MS(s), so enforcement action is pursued as appropriate". In line with the IRS, this action refers to instruments other than CCH to ensure dossier quality (and topicality): draft implementing legislation will clarify the updating obligation, and any update will trigger a new completeness check. However, while REF-7 "Enforcement of registration obligations after the last registration deadline in cooperation with customs authorities including the verification of the strictly controlled conditions applicable to the substances registered as intermediates" covers "a check of parts of the registration dossier and of other duties related to registration, for example, whether the registrant is compliant with the duty to update a registration dossier",[167] the project is still ongoing and information on enforcement activities on Art. 22 is thus not yet available. The impact Action 11 can therefore not be assessed.

Additional actions are addressing national enforcement activities. In Action 12, as a reaction to the noticeable share of registrants not properly reacting when receiving ECHA's final decision,[168] by the end of 2019, ECHA will create an overview of enforcement activities of the Member States to ensure compliance with CCH decisions. The FORUM is already preparing a respective questionnaire to be disseminated amongst the NEA. Subsequently, by end of 2020, pursuant to Action 13, the effectiveness of these enforcement measures will be subject to assessment by the Commission. Action 14 aims to establish related reporting obligations by the Member States. The FORUM already agreed on a pilot phase for such reporting. The collection of data however is not expected to start before 2021.

Finally, in Action 15, ECHA plans to have established, by the end of 2019, "working arrangements with major industry associations, which will be transparent and inclusive, aiming at industry committing to develop action plans for proactive and continual improvement of their registration dossiers". Indeed, considering limited resources of the state sector, proactive action by companies is essential for improving the quality of dossiers. In addition to Cefic's self-commitment,[169] other associations (e.g. Eurometeaux)[170] made similar declarations. In August 2019, Cefic stated that fifty-nine companies have signed up to its voluntary action plan.[171] To achieve a considerable impact, numbers of supportive companies surely need to rise.

The JAP does not provide a strategic approach with regard to shortcomings in dossiers related to descriptions of uses and exposure assessment. Addressing such shortcomings in CCH can be hampered by legal uncertainties.[172] However, adequate exposure and use data are crucial for the development and implementation of risk management measures. The REACH Exposure Expert Group (REEG) will foster a common understanding of which use and exposure data are needed to support REACH and CLP processes[173] and may therefore provide a solid base for the identification of appropriate policy options.

It remains to be seen how the modified (manual) completeness check also considering exposure data, notably in the context of the CSR,[174] will contribute to reducing related data gaps. This could increase incentives for registrants to cover only such uses in their dossiers, for which they

[167] See ECHA (2019j).

[168] Section 5.2.3.

[169] Cefic (2019).

[170] See "Eurometaux, Echa agree REACH data cooperation framework" at article on Chemical Watch (31.03.2020).

[171] See Oziel (2019).

[172] See section 5.2.2.

[173] See Information on REACH Exposure Expert Group (21.07.2020).

[174] ECHA 2020e, p. 8.

can provide meaningful data. A follow-up evaluation of the effect of the modified completeness check should be envisaged.

6.2 Additional Policy Options

The following sections outline additional policy options addressing the shortcomings identified in the analysis (sections 4.4 and 5.5).

6.2.1 Enhancing the update requirement

A study addressing "financing options for ECHA" discusses a new update requirement.[175] One option proposed is a periodic update obligation. Along these lines, it seems worthwhile to consider a duty for registrants to confirm electronically to ECHA that the dossier data are still valid and accurate. This confirmation serves as a nudge to analyse all additional data that are "relevant and available to the registrant" (Art. 12(1)), including new results published at the WikiREACH dashboard (see section 6.2.2). This would also underpin the regulatory approach of self-responsibility stipulated by REACH.

In terms of incentives and impediments relevant for registrants, this periodic update duty should be linked with the already existing duty under Art. 22(1) in the sense that "relevant new information" should always trigger an update. In this case, the timeline for the periodic update starts again. On the other hand, the update fee, as foreseen in Art. 22(5), might hinder the proper implementation and thus the problem of suboptimal dossier quality is likely to persist. Thus, the option to implement an annual charge in the sense of an obligatory fee appears preferable.[176] It would reduce the administrative burden for ECHA and the registrants.[177] And, even more important, it does not create a negative financial incentive in the sense that under an economic perspective refraining from an update is rewarded by REACH whilst at the same time no tangible administrative sanction is to be expected by the registrants.

6.2.2 Toxicology dashboard WikiREACH enhancing dossier update processes

New toxicological data can trigger the dossier update obligation. The question arises, however, who generates those data and how they are fed into the updating mechanisms. The registrants often face no incentives to invest in new tests. On the other hand, academics, e.g. master or PhD students, conduct testing series with valuable results, but sometimes not totally in line with the testing requirements laid down in the testing Regulation 440/2008.[178] Even in cases where these requirements are met, the results are sometimes not visible for the registrants and the authorities.

An approach to overcome the aforementioned impediments offers the WikiREACH concept.[179] It draws upon the experiences gained with WikiPharma[180] and describes an institutional design for a framework providing appropriate incentives to the actors involved. Researchers' preferences are mostly orientated towards recognition. The WikiREACH concept (Figure 3) allows them to "pin" results on a dashboard that is open to the public and at the same time – via the CAS-number of the tested substance and a "recent results" button – linked to the ECHA

[175] Footitt et al. (2019), section 5.3 on p. 73.

[176] Footitt et al. (2019), section 5.2 on p. 70.

[177] Based on the assumption that a legal entity receives only one invoice per year by ECHA for all active registrations.

[178] Alcock et al. (2011).

[179] Ågerstrand et al. (2017b), p. 1466.

[180] Ågerstrand et al. (2009).

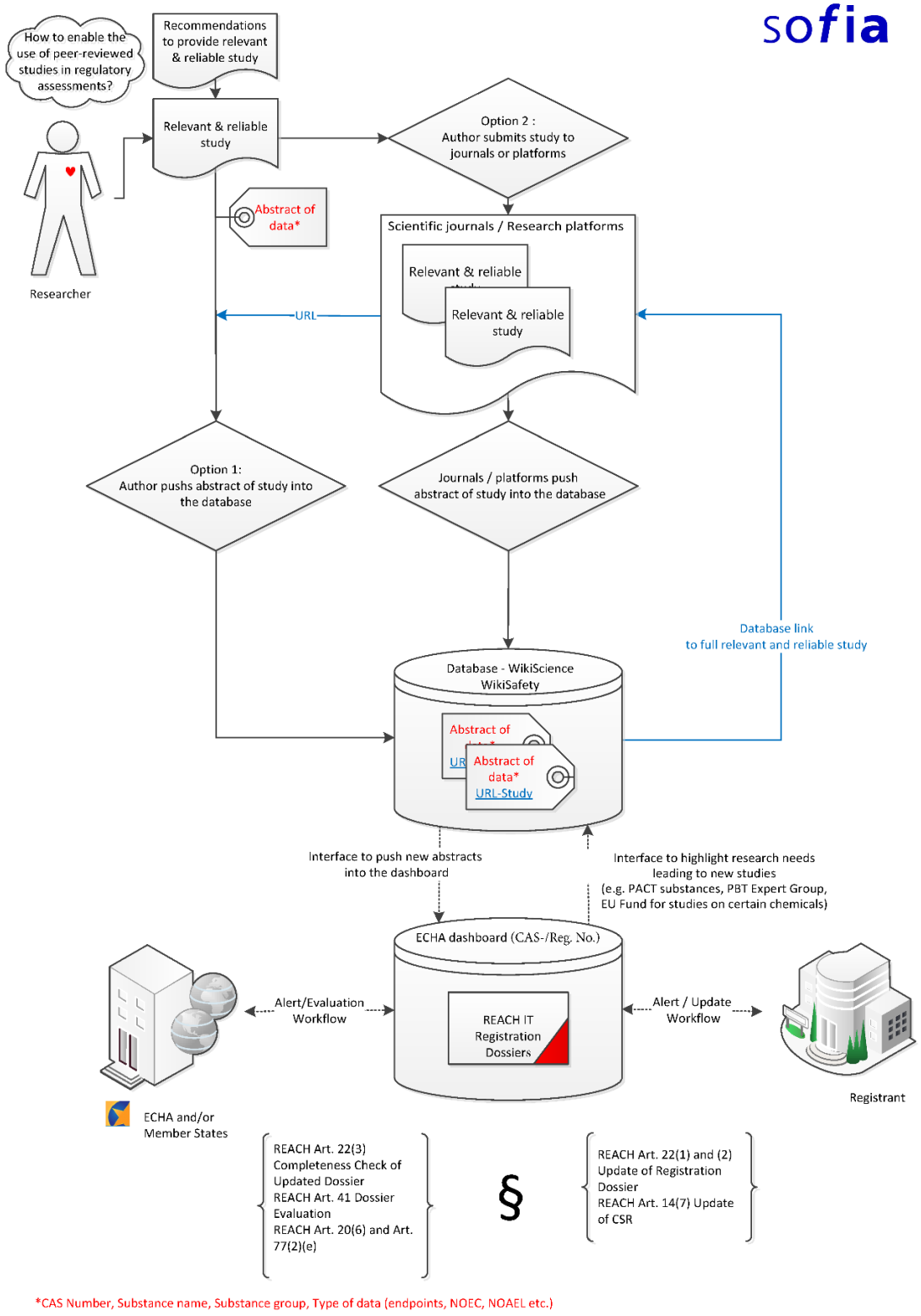
dissemination portal. Thus, the registrants as well as the authorities are aware of the new results.

Moreover, researchers regularly enter their results into a database like R*esearchGate* or *Academia*. At this occasion, according to the WikiREACH concept an additional field would ask the researcher whether the results are relevant for regulatory processes. When toxicological results are entered and the aforementioned question gets a negative reply the researchers are directed to a guidance document,[181] which explains how the impact of the study results can be enhanced in the next study design. Additionally, peer-reviewed journals are invited to create a direct link from their website to the dashboard and thus raising attention for their publication.

The WikiREACH dashboard additionally offers the option for ECHA to "pin" research needs and thus initiating studies in the academic field. This can stipulate research that is useful for regulatory purposes. This effect can be further enhanced by those organisations who administer public funds (e.g. national research organisations). They might consider including an optional requirement: funding requests for toxicological studies should indicate in how far their results are beneficial to regulatory processes, e.g. by following the testing requirements that qualify the results for regulatory processes. In this respect, the aforementioned guidance document can support the efforts. Both of the above elements would provide incentives for researcher to design their studies on toxicological effects in a manner that the findings can support regulatory processes.

[181] Ågerstrand et al. (2017a).

Figure 3: WikiREACH database with bi-directional communication between ECHA/MSCA and registrants



Source: sofia 2017.

With this institutional framework, it is likely that, on the one hand, more academic studies are designed in a manner allowing impact on regulatory processes and, on the other hand, the registrants and the authorities receive a nudge towards considering an update of the registration dossier, which is visible to the academic world and other third parties.

6.2.3 Increased transparency

A Commission SWD in the context of the 2nd REACH review encourages ECHA to consider "[f]urther improvement of the transparency and dissemination of relevant outcomes" in DEv.[182] Along these lines it appears worthwhile to consider a more systematic approach to disseminate the results of the CCH. The current dissemination portal allows for finding a CCH decision linked to the related substance with the option to filter the procedural status.[183] What is missing, however, is an option to filter the list against the data requirements formulated in the Annexes of REACH and addressed in the CCH; e.g. substance ID, the different toxicological endpoints, identification of DNEL/PNEC or exposure assessment. The CCH decisions contain a section "Information required" where the legal basis for each requested "information for the registered substance subject to the present decision" is already provided by the ECHA Secretariat.[184] Thus, it would be a minor effort to tag the decision database with the legal basis (e.g., Annex VI, Section 2.3) allowing a structured search for the interpretation laid down in the CCH decisions. This, combined with the "Recommendations to registrants" based i.a. on CCH lessons learnt, would underpin learning processes of all actors involved in risk management, including registrants, authorities, competitors and the wide range of "third parties".

From a transparency perspective, it should be easily visible at the ECHA dissemination portal which parts of a dossier ECHA has addressed in a CCH and what has been the outcome of the CCH.

With regard to the CCH, the current scheme does not create strong incentives to be compliant as non-compliance can be "healed" by providing the data specified in the decision, i.e. that would have been required by law in any case when manufacturing or importing a given substance in a given tonnage band. There are no limits as to the right to place the substance on the market as long as these data are provided after the CCH decision (section 4.4).

Disclosing names of companies addressed by decisions would have an additional motivational effect not only for the entity subject to a DEv but for all registrants to actively provide the data as required by law in order to avoid reputational losses (section 4.4). This sanction could be reserved for severe cases, e.g. where there is some evidence of deliberate deception. Minor violations of data requirements, for example due to negligence, should be excluded.

6.2.4 More streamlined testing proposal examinations

With a view to improve DEv efficiency and effectiveness, a Commission SWD suggested to review "the third party and double registrant consultation".[185] In TPE, third party consultations in fact yielded only few data inputs relevant for the process.[186] Besides, the SWD proceeds that for TPE "the Commission should assess if the presently required full examination process of all testing proposals should continue or could be replaced by a less resource intensive pre-

[182] SWD (2018) 58 fin, PART 1/7, p. 91.

[183] See information on dossier evaluation status by ECHA. In addition, it is possible to filter targeted, complete and testing proposal evaluation.

[184] See, e.g., CCH-D-2 I 14321245-67-01F (CAS-No. 29329-71-3) as of 06. March 2016.

[185] SWD (2018) 58 fin, PART 5/7, p. 83.

[186] Section 5.3.2.

notification procedure or an enquiry-type ECHA process".[187] A "leaner" TPE mode could be considered, in particular given that only in very few cases ECHA has rejected the company's proposal as unnecessary.[188] Modifying the procedural rules as regards (third party) consultations, and more so modifying the entire examination mode, would however not fall into the scope of Art. 132 and would therefore require initiating the co-decision procedure. ECHA expects submission of about 50 new testing proposals for non-phase-in substances per year.[189]

6.2.5 Completeness check

A solution that upholds for dossiers with substantial deficits the positive effect of the registration serves as an open invitation for free-riders; it also devaluates the efforts of compliant registrants and ultimately undermines the incentive system established by REACH. Under the rule of law this is a problematic situation.

6.2.5.1 Withdrawal of the registration number

From this perspective, for all dossiers not recently updated, which have been subject to the "enhanced approach II" (starting in October 2020, see section 3.4), a "fresh completeness check" should be conducted, in particular for those dossiers that already have been identified as substantially deficient.[190] The question arises what the possible outcome of that exercise might be.

In countries with an established general administrative procedure code the authorities possess the competence to correct the administrative act in such cases (e.g., the German § 48 VwVfG[191]). Therefore, the authorities have the discretion to revoke their administrative act. On the European scale, this means ECHA should have the possibility to withdraw the registration numbers if these were assigned wrongly. In cases where the registrant did not act in good faith, the withdrawal can even be enacted with retrospective effect (ex tunc); a withdrawal with effect for the future (ex nunc) is unproblematic. In any case, the affected registrant should be given the opportunity to provide ECHA with his view (audiatur et altera pars, Art. 50(1) in analogy). According to ECHA, a number of so-called "Google"-dossiers have been detected. They do not contain meaningful information; rather the IUCLID fields have been filled with more or less arbitrary results of google researches. If such – or equivalent severe – deficits are identified, the withdrawal of a registration number will be justified.

In REACH, however, there are no specific provisions empowering ECHA to amend or withdraw the administrative act granting the privileges of a registration number; neither is a general administrative procedure in place at EU level. Nevertheless, based on general (European) administrative principles it can be concluded that it is part of the "acquis communautaire" to empower an administrative body with the competence to correct an unlawful administrative

[187] SWD (2018) 58 fin, PART 5/7, p. 83; SWD(2018) 58 fin, PART 1/7, p. 93.

[188] Section 5.3.2.

[189] ECHA 2019h.

[190] ECHA has indicated that they are addressing the issue (see section 3.3). However, it is unclear how many registrations are re-opened and which substances or registrations are affected.

[191] Verwaltungsverfahrensgesetz, BGBl I 2003, 102; for an English translation of the German Administrative Procedures Act refer to Administrative Procedures Act (VwVfG) in English (05.07.2020).

decision.[192] This "acquis" is also captured in the proposal by the "Research Network on EU Administrative Law"[193]:

> (1) The public authority may rectify or withdraw an unlawful decision that is beneficial to a party. It may exercise this power ex-officio, or following a request by another party. This power may be exercised outside the time-limits for legal challenge.

Based on this rationale ECHA is already in a position to withdraw registration numbers in cases as described above.

However, an explicit legal provision stating this competence and the conditions to exercise them is preferable. This new provision should include material conditions under which a withdrawal of the registration number is possible, as well as procedural aspects.[194]

6.2.5.2 Enhanced transparency as additional incentive

The ClientEarth report summarises[195] that ECHA "has only published statistical data on the new completeness check, which does not provide any guidance on which substances have been on the market illegally, nor where and for what uses". As for the future policy options to address the delta the report formulates the following conclusions:

> To ensure the accountability of companies allowed to place substances on the market, ECHA should disseminate all the details on the completeness check, including all the substances and registrants that failed the "real" completeness check.
> In addition, ECHA should clarify what is included in the scope of their completeness check, the selection criteria and the consequences of failing the completeness check, including data on past decisions.

Under the framework of the new completeness check, the principle of "self-responsibility" should be underpinned by additional transparency mechanisms contributing to REACH as a learning system for all actors involved.

[192] In fact, the ECJ accepted this (unwritten) competence for EU bodies in several cases as a compilation of ECJ case law shows (document prepared by the legal Unit of ECHA, but not publicly available). The ECJ applies the reasoning outlined in the "Alcan" case (CJE as of 20.03.1997 - C-24/95, ECLI:EU:C:1997:163) also with regard to administrative acts of European administrative bodies.

[193] ReNEUAL 2017, section 6, III-36.

[194] For a proposal that covers these aspects see ReNEUAL 2017, section 6.

[195] Bernard et al. (2017), p. 16.

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