REACH BEYOND 2018 – RESTRICTION AND AUTHORISATION AS REGULATORY ALTERNATIVES

SUMMARY

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Project Sheet

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1 PROBLEM DEFINITION AND STUDY OBJECTIVES

Authorisation and restriction are the two key instruments established under Regulation (EC) No 1907/2006 (REACH) to manage risks from chemical substances. Their purpose is to control the nature, extent and conditions of the use of specific hazardous substances in the EU and thus ensure a high level of protection for people and the environment.

Restriction and authorisation directly and indirectly impact on the free movement of goods and patterns of use of substances (on their own or as constituents of other substances), mixtures and, to some extent, also articles. This has wide-ranging implications for European businesses.

Although the actual effects felt by companies as a result of limits on the use of a substance can to a large extent be the same, there are significant differences between the two instruments with regard to the applicable processes and, in particular, the burden of proof required.

A restriction involves formulating a universal but, if necessary, very specific ban on marketing and use for a substance or group of substances. The basis for this is a dossier elaborated either by a Member State competent authority or alternatively by the European Chemicals Agency (ECHA) on behalf of the European Commission, which proves an unacceptable level of risk from use of the substance. This enables the risks throughout the entire life cycle to be taken into consideration. In addition, either individual or all applications of the substance can be covered. A restriction can also cover the presence of a substance in articles or its presence as a constituent of another substance, its manufacture in the EU, as well as imports.

The authorisation instrument involves introducing a general ban on the use of a substance in the EU but providing the possibility to authorise continued use. This follows on from a substance being identified as a Substance of Very High Concern (SVHC)[1] and included in Annex XIV of REACH – List of Substances subject to authorisation. The authorisation instrument provides individual companies with the option to obtain an authorisation for specific uses (with a defined review period) on the basis of a well-founded application.

The evidence of the experiences to date suggests that many industry stakeholders see the burden of the application process as disproportionate to the benefits of an authorisation. In particular, formulating a sufficiently reliable estimation of the remaining risk, as well as a set of systematic arguments regarding socio-economic impacts poses a challenge for many companies based on their internally available resources and expertise.

Consequently, properly prepared restrictions are seen by industry stakeholders as a more suitable risk management measure for particularly hazardous substances.

[1] These are Substances of Very High Concern according to Article 57 of the REACH Regulation.

This has led to a desire for authorities to examine the most efficient instruments for reducing the risk from a substance as soon and as transparently as possible, using the so-called Risk Management Option Analysis – RMOA, which was introduced in the "Roadmap on Substances of Very High Concern"(SVHC-Roadmap 2020)[2]. An RMOA could, for example, conclude that there does not appear to be the need for any further regulation of the substance or that different risk management instruments outside the REACH Regulation should be considered before official steps are taken to regulate the substance.

Following on from the background to the study outlined above, the aim of this project was to elaborate specific proposals for assessing (within the framework of an RMOA) the burden/cost for the different stakeholders resulting from the two risk management options (authorisation or restriction), so that this could be taken into account in decisions on the most appropriate risk management option.

Please note that this proposal only differentiates between the two REACH instruments: authorisation and restriction. Other possible measures outside of the REACH Regulation have not been considered since they have not been analysed in detail. However, it can be assumed these could be incorporated into the proposed decision tree, using similar considerations.

2 APPROACH

In order to address the objectives of the study, the tasks that lead to a very high burden for the different stakeholders under the authorisation and restriction procedures were identified, as well as the ways in which these cost drivers are linked to the different combinations of substance properties, use conditions and market situations.

It was also necessary to research the practical implementation of RMOA to date, i. e. which authorities have been involved in their elaboration and what have been the approaches to their elaboration.

In order to examine the division of tasks and the resulting costs in the two instruments, as well as the possible cost drivers, the REACH Regulation was first examined from this specific perspective. This involved a systematic analysis of the reasons for regulation (the nature of concern) and the risk reduction approaches for which the two instruments are interchangeable or, more specifically, in which areas a preliminary decision can already be derived on the basis of the risk management situation.

[2] Roadmap for SVHC identification and implementation of REACH Risk Management measures from now to 2020, see also ECHA Website https://echa.europa.eu/de/svhc-roadmap-to-2020-implementation, the SVHC-Roadmap 2020 can be found here: http://register.consilium.europa.eu/pdf/en/13/st05/st05867.en13.pdf

A review of the already completed authorisations and restrictions was a further central part of the analysis.[3]

In addition to an extensive assessment of the reasons for regulation and the addressed risk management approaches, a more detailed assessment of two case studies was elaborated: authorisation of Chromium VI compounds and restriction on diisocyanates.

These case studies were selected for a comparative assessment on the basis of the following similarities:

- In both cases, the reason for regulation was linked to substance properties hazardous to human health and risks related to occupational safety.
- These substances are applied in downstream uses by a relatively large number of companies, a significant proportion of which are small and medium enterprises (SMEs).
- The substances fall under substance groups where one compound can to some extent be substituted for another. At the time of the decision, the possibility of substitution (via substance or technical means) was limited for both substance groups.
- From the perspective of socio-economic assessment, the articles that are manufactured using these substances are essential.

With regard to the degree of implementation and practical application of RMOAs, all available information from relevant datasets and online publications made available by ECHA and the relevant Member State authorities was first reviewed. This served, in particular, the purpose of identifying which Member States have so far carried out RMOAs and to what extent.

In-depth interviews on practical implementation and the resulting experiences were carried out with Member State authorities who have already undertaken a large number of RMOAs, namely:

- Denmark,
- France,
- the Netherlands,
- Germany,
- Sweden,

as well as those newly acquainted with this instrument (Ireland and Bulgaria). ECHA was also interviewed since the authority can carry out an RMOA on request of the European Commission. Furthermore, the foundations of RMOA are based on the methodological approaches of ECHA.

The telephone interviews with the representatives of these authorities focussed on a series of separate aspects relevant to the instrument in question, including:

- How are substances for an RMOA selected?
- Which steps and processes are applied within the framework of an RMOA?

[3] More details regarding the comparison of restriction and authorisation and about the practical cases assessed can be found in chapter 3 of the full report

- What is the typical amount of time and resources needed for the execution of an RMOA?
- Which sources of information are preferred in an RMOA?
- Is there cooperation with other Member States?
- Are there core aspects that are particularly important for the selection of the regulatory option?
- In general, which experiences and proposals for improvement are there with regard to the RMOA instrument?

The answers to the questions above were used to develop a proposal on how the RMOA could be made more systematic. The proposal covers specific decision criteria for choosing between the two regulatory instruments (authorisation and restriction), as well as considerations of the information basis for RMOA and the contributions of the market players and the role of the Candidate List (Article 59 of the REACH Regulation) since these are seen as the decisive factors in choosing between the two instruments.[4]

3 FINDINGS AND OBSERVATIONS

3.1 A comparative analysis of the authorisation and restriction procedures

With regard to the interchangeability of the two risk management options, conclusions made from analysis of the legislation are provided in the following paragraphs.

There are a number of reasons for regulating chemicals for which, for legal reasons, only a restriction can be applied. This stems from the limited scope of application of the authorisation procedure. Specifically, this relates to the following cases:

- Risk linked to the presence of a substance in articles (regardless of the content of the substance); and
- Risk arising from the presence of substances in other substances or mixtures below the thresholds set out in Article 56 of the REACH Regulation.

An analysis of the regulatory activities to date shows that the latter case is particularly relevant when it comes to substances with persistent, bioaccumulative, and toxic properties, as well as some endocrine disruptors. In this case, even very small concentrations and amounts that are released into the environment over a long timeframe and/or from a multitude of sources can lead to unacceptable risks. This is also the case when considering the risks to human health from substances for which it is not possible to define an effect threshold, such as some carcinogenic, mutagenic, or reprotoxic (CMR)

[4] More details regarding the analysis of the current status of RMOA implementation in the EU can be found in chapter 4 of the full report

substances or respiratory sensitizers. These substances can also have adverse effects in very small concentrations.

In addition, the legislator has provided the possibility of a simplified procedure according to Article 68(2) of REACH for risks from CMR substances in consumer products, which has substantially lower information requirements and therefore a significantly smaller regulatory burden emanating from the European Commission than for other restriction proposals. However, it can be argued that, in these regulatory situations, a restriction is clearly preferable.

With regard to the overall burden, a structured analysis of the requirements for both procedures shows that the need for information and the associated substantiation does not differ significantly between authorisation and restriction. It is therefore possible that the overall burden across all stakeholders involved is the same for both procedures. However, there could be significant differences as regards the burden for individual stakeholders, with these depending on their role in the procedure (authority, industry actor).

On the one hand, this applies to the elaboration of a restriction proposal by authorities due to the required comprehensive analysis. On the other hand, there is a burden arising from the substantiation of the requirement for authorisation, i.e. the identification of an SVHC and the prioritisation, which is also carried out by authorities, and the burden associated with elaboration of applications for authorisation by companies. For both instruments, the burden for the public and private sectors is given equal consideration.

Substantial differences relate to who carries out specific tasks for the procedure and at which point in time specific types of information are required. The key reason for these differences is that the substantiation for the requirement to authorise is based on hazard, while for restriction it is based on risk.

The restriction procedure requires that the authorities (at the EU and Member State levels) carry out assessments of risk and analyse socio-economic impacts and potential alternatives. Therefore, they have to collect and collate highly detailed information within the early stages of the process, i.e. at the time of the elaboration of a restriction dossier. For the authorisation procedure, the burden of putting together an application for authorisation (collecting and processing information) falls on industry, by comparison at a later stage of the process, i.e. when the substance is already in the Annex XIV Authorisation List.

An analysis of the already completed regulatory activities clearly shows that, for the purposes of comparing the overall burden of the two regulatory alternatives, the way the substance is used is of central importance. For example:

- If suitable alternatives are already available for all or the majority of the existing uses, then the authorisation procedure can be the more efficient regulatory approach. It can be expected that, within the framework of authorisation, many users will substitute. This means that a large part of the potential applications for authorisation will no longer be necessary and the burden associated with elaborating and checking these applications will not be incurred (in the best-case scenario, no applications will be submitted).

- On the other hand, if suitable alternatives only exist for a small share of uses (such as in the case of Chromium-VI compounds or diisocyanates), restriction may be the more efficient regulatory approach. In contrast to authorisation, a restriction allows the authorities to adopt restriction conditions that differentiate between the different uses of the substance. This can take into account the substitutability but also, for example, the potential for risks to arise. This can be relevant when there is a wide range of uses and there are specific uses for which (for technical and/or socio-economic considerations) there are currently no viable possibilities to substitute. In cases of uses where substance use is already highly controlled and there is therefore a low potential for risks to arise, this can also be a reason for a different approach in comparison with other uses of the substance. Whilst a restriction can allow these uses to continue (e.g. under the condition of the implementation and further development of comprehensive substance management measures), under the authorisation procedure, it would be necessary for all relevant market players to submit applications for authorisation and these would need to be examined.
- The fact that a large proportion of stakeholders that lack expertise in REACH (e. g. SMEs) are affected by the regulation of substances, suggests the requirements regarding the elaboration of applications for authorisation of sufficient quality, and their efficient processing, are difficult to implement. This is evident from the lack of expertise on the part of these stakeholders, as well as the lack of resources needed to acquire such expertise from external consultants. In the interests of establishing a level playing field, restriction can be seen as a suitable alternative.

When choosing between the two regulatory approaches, the challenge is that, in most cases, the authorities have limited access to the relevant market and supply chain information. Also, should RMOAs sufficiently take into account aspects which relate to socio-economic implications of planned regulatory action, there would be a need to establish procedures for the collection of the necessary information basis.

3.2 Implementation of RMOA in Europe to date

An analysis carried out under this study shows that there are differences between the Member States with regard to the level of implementation of RMOAs:

1. The RMOA instrument, which is not legally binding, is being increasingly and more seriously applied by many Member States and ECHA to examine potential regulatory options for chemical substances.
2. To date, Denmark, France, the Netherlands, Germany and Sweden have carried out 80% of the RMOAs.

The table below provides, as of September 2017, an overview of the responsible Member States and summarises the type of information that has

been published in the results of RMOAs in the PACT (Public Activities Coordination Tool).

Table 1: Overview of Member State RMOA activities

Member State	No. of RMOAs given (No. Completed)	Available information on the results of completed RMOAs
Belgium	3 (1 completed)	• Only a summary of RMOAs available • Summary comprises five sections • Section 1 (Introduction) provides some current occupational exposure limits, Section 4 provides reasons why no measures are planned for the substance
Bulgaria	1 (1completed)	• Only a summary of RMOA available
Denmark	38 (11 completed, 14 suspended, 13 in progress)	• For the majority of substances, only a summary of RMOA available • Some RMOAs are currently no longer being worked on • There are differences between summary documents for the different substances (e.g. some list uses, limits for restrictions, registration tonnages and, where relevant, follow-up activities).
Germany	33 (24 completed)	• Only a summary of RMOAs available in PACT • The document typically consists of five sections and includes a preliminary plan for further action
ECHA	10 (8 completed)	• Full RMOAs as well as summary documents available • RMOAs provide details of legal measures, hazard, tonnages, uses and risk management. • The summary document typically comprises four sections and provides a preliminary plan of action for the substance.
Finland	2 (in progress)	• RMOAs are currently in preparation.
France	30 (8 completed)	• Full RMOAs as well as summary documents available • RMOAs provide details of legal measures, hazard, tonnages, uses and risk management. • The summary document comprises a preamble and five sections. Section 5 provides a preliminary plan of action for the substance (if relevant).
Greece	1 (1 completed)	• Only a summary of RMOA available
Ireland	4 (1 completed)	• Only a summary of RMOAs available • Summary comprises four sections • No discussion in Sections 1 and 3, discussion in Sections 2 and 4 (regulatory follow-up and further action)
Italy	1 (1 completed)	• No documents in PACT
The Netherlands	16 (10 completed)	• Only a summary of RMOA available • Detailed Sections 3 and 4 (in case of no follow-up activities) with discussion of occupational health & safety legislation, REACH, CLP[5] and risk management options • No Section 5 (preliminary follow-up activities) available in the documents
Norway	2 (in progress)	• RMOAs are currently in preparation.
Austria	5 (5 completed)	• Only a summary of RMOAs available • Summary comprises four to five sections • For each substance, information on uses, tonnages, alternatives, adverse effects, existing regulation (e.g. classification and labelling, occupational exposure limits) is considered
Sweden	27 (17 completed)	• Only a summary of RMOAs available • Two RMOAs consider consumer uses (potassium hydroxide and sodium hydroxide)
Hungary	1 (1 completed)	• Only a summary of RMOA available
United Kingdom	4 (2 completed)	• Full RMOAs as well as summary documents available • Summary comprises five sections • Full RMOAs also consider regulatory measures outside the EU
Source: ECHA PACT List – https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact (accessed on 8 September 2017).		

[5] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP)

The following conclusions can be drawn from interviews with selected Member State authorities:

- The application of RMOA in the different Member States is similar with regard to the fundamental understanding of the aims and content. With regard to procedural aspects (e. g. execution of stakeholder consultation or inclusion of additional expert knowledge), there are differences in the level of detail of the research and the associated timeframe for the validation). It is, however, difficult to carry out a direct comparison on the basis of available information;
- The view of the interviewed authorities is that the burden for the elaboration of an RMOA is currently acceptable but an additional extension of the processes could lead to problems in terms of available resources;
- In some Member States, RMOA already adds to the total time it takes to complete the substance regulation process. The authorities believe that the RMOA should not substantially add to this timeframe. An extension of up to two years is seen as acceptable.

4 PROPOSALS FOR THE STRENGHTENING OF THE SELECTION DECISIONS IN THE FRAMEWORK OF RMOA

The consultation on the practical implementation of RMOA and analysis carried out for this study show that this instrument is seen by many Member States as central to the possibility of making an informed choice between the different regulatory options for substances under consideration.

In view of the many differences between the substances, regulatory drivers and real-life use conditions, the examinations and decisions to date are mostly undertaken on a case-by-case basis.

The analysis, assessment and interviews carried out in relation to authorisation and restriction in the frame of this project led to the conclusion that it might be possible and helpful to propose criteria that can act as a basis for structured decision making when choosing between the two options.

The types of criteria can be divided into the following:

- Criteria that relate to the legal possibilities for the scope and regulatory level of the two instruments, and
- Criteria that relate to the drivers of the overall burden of the option for the participating market players and authorities.

For these review and selection criteria, a structured decision tree was developed, which could be integrated into the relevant work processes that

takes place during the practical implementation of an RMOA. The decision tree is provided at the end of this summary.

The usability and practicability of the decision tree (and the test and selection criteria in it) in the framework of an RMOA depends on clarification of two central aspects, namely:

1. the level of relevant information on the conditions of use, market conditions, and downstream supply chains are available to the authority that wishes to carry out an RMOA, and
2. whether the Candidate List plays (or should play) a role in risk management that goes beyond its authorisation-related role as set out in legislation.

Proposals relating to the issues given above have been developed by the consultants and are set out below.

4.1 Improving the information basis for RMOA decisions

One of the key challenges to proper implementation of the authorisation and restriction procedures relates to the accessibility to information on the use of a substance.

In this regard, it is important to distinguish between data that can be found in the registration dossiers and other data.

By way of registration and the associated substance and dossier evaluation, the REACH Regulation has created sufficient instruments for the examination of substance properties. These allow the authorities to fill potential data gaps, even beyond the scope of registration as set out in the annexes to the REACH Regulation. The requirements in the content of the Chemical Safety Report mean that use information can be extracted from registration dossiers and further expanded upon on the basis of the evaluation (this primarily relates to the conditions of safe use for the identified uses). The Regulation does not provide further mechanisms for addressing other data needs that are relevant to an RMOA. This includes, amongst others, information relating to the content of the substance in articles, the use conditions for specific processes, socio-economic impacts of measures on market players, and alternatives.

Important differences between authorisation and restriction also relate to the role of market players in the two procedures. In the case of authorisation, it is the industry stakeholders that, within the framework of an application for authorisation, have to collect information in order to substantiate the continued uses of the substance (which can also be relevant along a wider supply chain). In the case of a restriction, it is the sole responsibility of the authorities to elaborate the restriction proposal. In the case of authorisation, it is in the interest of the applicant to make information available that substantiates the application for authorisation, which aims to secure not only a company's own commercial relationships but is usually also relevant to other (downstream) companies. In the case of a restriction, there is no such direct self-interest on

the part of industry players or it is limited to attempts to change the scope of a restriction proposal.

The obstacles encountered in terms of access to information result in resource constraints potentially becoming an important reason for authorities to choose (already at the stage of an RMOA) authorisation as the preferred option, even in cases where both instruments could be feasible. This means that important future cost drivers linked to applications for authorisation (specifically, the share of SMEs that use the substance but which may not be capable of submitting an application for authorisation) or the availability of alternatives for particular uses are not initially taken into consideration due to the hazard based approach associated with the substantiation of the authorisation requirement. This means that the analysis within the RMOA is restricted to the establishment of the substance properties (e. g. SVHC status).

Active participation of market players within the framework of an RMOA is a prerequisite for timely acquisition of information and, more generally, for the ability to draw informed conclusions. The following proposals serve the purpose of facilitating active provision of information by market players:

- The authorities should support the provision of information by market players within the context of an RMOA. To this end, it should, as far as possible, be made clear at which point in time and how companies can provide information to the authorities.
- Market players need to develop a willingness to provide such information, although it is not their legal obligation. Such willingness is also required for market players who may not use the substance themselves but who would be impacted indirectly by regulation of the substance. These are, for example, players whose production inputs require the use of the substance (auxiliary process substances). This can also be the case when the substance itself is not contained in the supplied products.
- Market players need to be clear on the information required
    - use-related information (e. g. emissions, concentration in products, existing risk management measures)
    - market impacts (socio-economic effects) and
    - information on alternatives.

It is particularly important to encourage market players throughout the value chains to voluntarily participate in such a process and to create structures for the implementation of these proposals (e. g. provide the resources for data collection, systematic follow-ups of RMOA activities, etc.).

4.2 Dealing with the Candidate List within the framework of RMOA

Interviews with Member State authorities show that a high degree of importance is attached to the Candidate List. Within the framework of authorisation, this list contains substances that will be proposed for inclusion in Annex XIV of the

REACH Regulation. It is, however, the understanding of the authorities that the list also serves the following functions:

a. The list serves the purpose of identifying and covering (if possible) all Substances that have properties of very high concern. This is particularly important when no corresponding classifications under the CLP Regulation are available for these substances (such as in the case of, for example, PBT substances). The identification of a substance as a Substance of Very High Concern does not, according to some authorities statements and practical experience, necessarily result in its inclusion in Annex XIV of the REACH Regulation. Remaining on the Candidate List or use of other regulatory options are equally possible.
b. Since the inclusion of a substance on the list already triggers specific legal obligations under REACH, it is in itself seen as a risk management measure. This relates to the requirement to provide substance declarations under Article 33 of the REACH Regulation to professional and, if relevant, private recipients of articles which contain the relevant substances in concentrations of more than 0.1% weight by weight. In addition, experience of the list to date shows that the inclusion of a substance on the list itself triggers substitution activities and thus contributes to a reduction in the market presence of the substance.

In order to clarify if the inclusion of a substance on the Candidate List predetermines the subsequent regulatory course of a substance or whether there is still scope for other action, there should be discussions at the EU level about the use of this list and, if possible, harmonisation of its use.

In the view of some authorities, use of the list as a master list for substances formally designated as having hazardous properties of very high concern appears to be beneficial. In the context of an RMOA, the nature of an entry would need to be further specified as a consequence. The RMOA instrument has the ability to clarify the later regulatory options before a regulatory activity has been initially started. A substance may be included on the Candidate List for the following reasons:

- The entry has the purpose of initiating the authorisation procedure.

  ⇒ The substance will be further considered in ECHA's prioritisation activities and can be included in Annex XIV.

- The entry is initially made only to determine substance properties or in order to trigger information requirements in the supply chain and no follow-up measures are specified.

  ⇒ The substance is excluded from ECHA's prioritisation activities. Before further regulation, the RMOA process is revived and there is an opportunity for a (new) discussion of the arguments for follow-up measures.

- The entry is initially made only to determine substance properties and a follow-up measure (other than authorisation) has already been determined within the framework of RMOA.

  ⇒ The substance is excluded from ECHA's prioritisation activities and follow-up activities depending on the outcome of the RMOA are initiated.

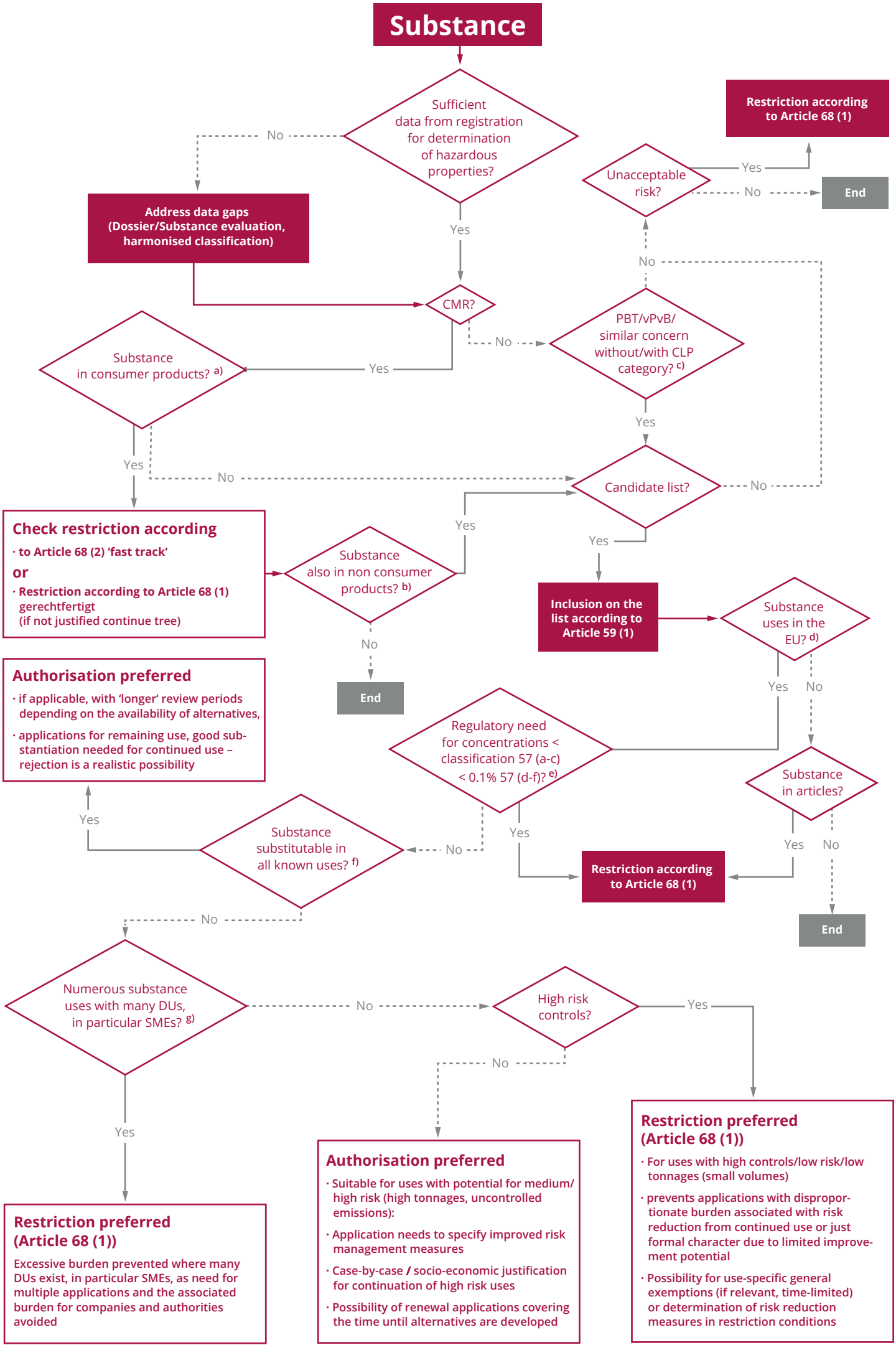
These different reasons for the inclusion of a substance on the Candidate List should also be transparently documented. This could be done either on the list itself or in the published summary of an RMOA.

4.3 Decision tree for the selection of REACH regulatory options in an RMOA

As explained above, a decision tree has been developed to support systematic decision making when choosing between either authorisation or restriction during an RMOA.

- The decision should support the authorities with the selection of either authorisation or restriction in the framework of an RMOA.
- Some of the criteria reflect the scope of each instrument set out in REACH and their boundaries (hard legal criteria).
- Other criteria relate to 'soft' aspects that reflect on past applications for authorisation and restriction proposals and that aim to minimise, to the extent possible, the total burden on market players and the authorities.
- The proposed criteria aim to support the harmonisation of the RMOA process but are not binding.
- At the individual substance level, lack of available information may preclude a conclusive assessment of some issues. In particular, information on uses and alternatives is needed early on, at the RMOA stage, and this assumes support from market players.
- Risk management measures not included under REACH are not taken into account here but can be considered by authorities.

Other important assumptions for specific review criteria are set out in the decision tree itself using reference letters and explanations (see next page).


Substance
Sufficient data from registration for determination of hazardous properties?
No
Address data gaps (Dossier/Substance evaluation, harmonised classification)
Yes
CMR?
No
PBT/vPvB/ similar concern without/with CLP category? c)
Yes
Substance in consumer products? a)
Yes
No
Yes
Candidate list?
No
Yes
Unacceptable risk?
Yes
Restriction according to Article 68 (1)
No
End
Check restriction according
· to Article 68 (2) 'fast track'
or
· Restriction according to Article 68 (1) gerechtfertigt (if not justified continue tree)
Substance also in non consumer products? b)
Yes
No
End
Inclusion on the list according to Article 59 (1)
Substance uses in the EU? d)
Yes
No
Authorisation preferred
· if applicable, with 'longer' review periods depending on the availability of alternatives,
· applications for remaining use, good substantiation needed for continued use – rejection is a realistic possibility
Regulatory need for concentrations < classification 57 (a-c) < 0.1% 57 (d-f)? e)
Yes
Substance in articles?
Yes
No
Yes
Substance substitutable in all known uses? f)
No
Restriction according to Article 68 (1)
End
No
Numerous substance uses with many DUs, in particular SMEs? g)
No
High risk controls?
Yes
Yes
No
Restriction preferred (Article 68 (1))
Excessive burden prevented where many DUs exist, in particular SMEs, as need for multiple applications and the associated burden for companies and authorities avoided
Authorisation preferred
· Suitable for uses with potential for medium/ high risk (high tonnages, uncontrolled emissions):
· Application needs to specify improved risk management measures
· Case-by-case / socio-economic justification for continuation of high risk uses
· Possibility of renewal applications covering the time until alternatives are developed
Restriction preferred (Article 68 (1))
· For uses with high controls/low risk/low tonnages (small volumes)
· prevents applications with disproportionate burden associated with risk reduction from continued use or just formal character due to limited improvement potential
· Possibility for use-specific general exemptions (if relevant, time-limited) or determination of risk reduction measures in restriction conditions

a) REACH includes reduced requirements to establish a regulation when substances have CMR properties. Therefore, the assessment to implement a regulation according the procedure laid down in article 68 (2) ´fast track` should have highest preference in such cases.

b) If there is no intention to initiate a Restriction, a check should follow if the CMR substances are to be listed on the candidate list

c) For other substances the candidate list has the function to clarify the hazardous property first. Additionally it has to be considered at the level of the RMOA, if the additional direct efforts that originate from listing are justified. If the answer to this question is no, a regulation according Article 62 (1) via a Restriction should be considered or there should be no regulation (at least for the moment). The same applies if substances do not have properties that are sufficient for candidate listing.

d) From an assessment of EU uses it can be derived if the Authorisation (strictly formally) makes sense. If the substance is not present in any use, the risk might originate from its presence in articles, instead. In this case a Restriction is the measure of choice. Since consumer risk have already been addressed such a regulation can only follow the formal procedure of article 62 (1).

e) If it is the aim to implement a regulation for substances present in mixtures below the threshold values laid down in article 56 (6), the measure to be chosen has to be a Restriction, since in such situations an Authorisation will not apply and would not cause the intended effects.

f) Is the result of an analysis that already sufficient substitution is possible or established (by other processes, technical means or substances), an Authorisation obligation can be suited to perpetuate the substitution process or to intensify it, respectively, because the final end of the substance use is defined.

The design of the authorisation entry should be flexible in such cases. When a sunset date is set there should be the possibility to define lone transition periods, e.g. in cases where the length of the substitution is defined by a revalidation of a production process on the basis of existing regulation apart from REACH. Following scenarios could be possible:

- Different periods for uses on the basis of Article 58 (1c, i and ii)
- Relatively long periods, which reflect that substitution status und, if relevant, times for revalidation of products.

The aim of this approach is that under normal conditions no market actor should have the need to apply for Authorisation as substitution has already been realised within the defined transition period. Potential applications should therefore only cover following situations:

- Substitution could not be realised in the envisaged timeframe and an elongation of the transition period is needed for single market actors (in such cases a good justification including detailed substitution plan is mandatory, refusal of an Authorisation should be a realistic option).
- A use was not in the known at the time the RMOA was prepared. For such cases a “regular” application for Authorisation should be submitted (as currently implemented).

In both situations market actors have the responsibility for the application and the main burden of the preparation of the application documents. Since the design of the Annex XIV entry is to a high degree depending on the knowledge of uses and potential alternatives, there is a high incentive for market actors to provide information early in the regulatory process.

g) With this step an excessive burden for a high number of DU, in particular SME, should be avoided. By choosing the Restriction path the burden for scientific and socio economic assessments is taken over by the authorities, which ensures the interest of the SME is adequately considered.

At the same time, this approach avoids burden for authorities, which is generated by a high number of applications that might only differ in details, content wise, for substances that are commonly used.