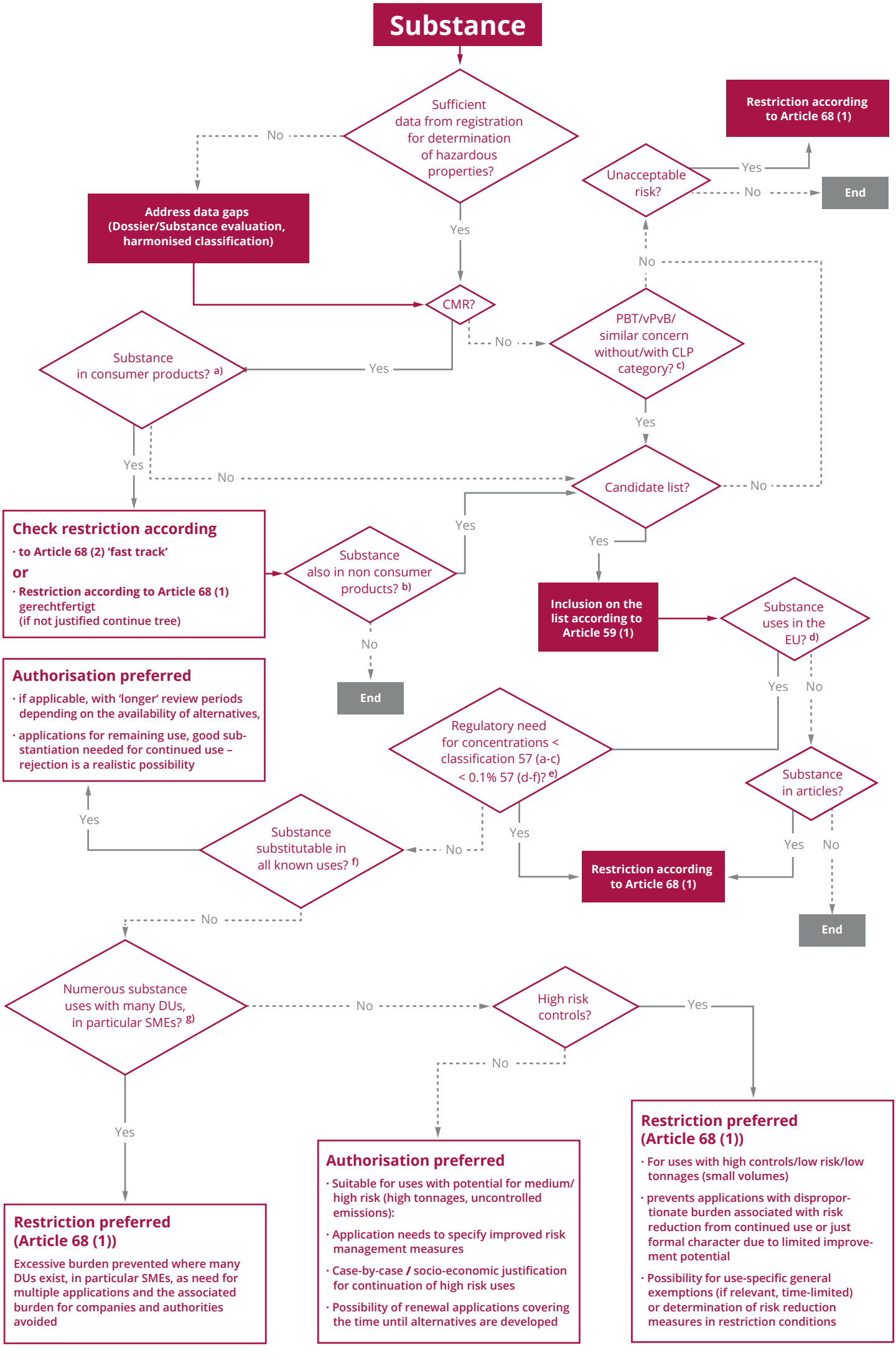
Substance
Sufficient data from registration for determination of hazardous properties?
No
Address data gaps (Dossier/Substance evaluation, harmonised classification)
Yes
CMR?
No
PBT/vPvB/ similar concern without/with CLP category? c)
Yes
Substance in consumer products? a)
Yes
No
Yes
Candidate list?
No
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.