

How to develop use descriptions in applications for authorisation

June 2017

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Table of Contents

Table of Contents	3
1. Introduction	4
1.1 'Process-driven' approach	7
1.2 'Alternatives-driven' approach	7
2. Elements of use description, scope of a use and scale of an application	8
2.1 Elements of a use description	8
2.2 Scope of a use	10
2.3 Scale of an application for authorisation	11
3. How to define a 'meaningful' scope for a use	12
3.1 Developing a use with a 'meaningful' scope	12
3.2 Summary	13
3.3 Specific considerations for uses (e.g. formulation, repackaging, etc.) preceding the 'end-use of the substance'	14
4. Example of iterative 'use-scoping'	16
4.1 Relevant substance function/s, products and markets	16
4.2 Initial considerations	16
4.3 Further iteration/s	17
5. Conclusions	18

1. Introduction

Article 62(4)(c) of the REACH Regulation requires applicant(s) for an authorisation to specify for which use the authorisation is sought (so-called 'use-applied-for'), covering - where relevant - the use of the substance(s) in mixtures and/or incorporation in articles.

When considering the 'use-applied-for', it is important to appreciate that its 'description' is based on multiple elements, including the conditions of use of the Annex XIV substance, but also the 'technical function' of the Annex XIV substance and the 'products' that are placed on the market from the use of the Annex XIV substance in different supply/value chains.

These latter two elements are particularly important in relation to the suitability of alternative substances and technologies. As such, all of the information provided in an application for an authorisation contributes to the description of use, notably in relation to its 'scope' (breadth of products/processes included).

This document explains how the use(s) applied for presented in an application for authorisation should be developed and described (including the supporting justification that should be provided).

As an authorisation will be granted, or not, for a specific use, the quality of the 'use description' is fundamental to the overall credibility of an application. As outlined above, the use description is underpinned with relevant information on the conditions of use of the Annex XIV substance (exposure scenario), the remaining risks to workers and the environment, an analysis of the suitability and availability of alternatives and (where relevant) socio-economic considerations in relation to whether the benefits of the use to society outweigh the risks. As such, the use description is the basis upon which ECHA's scientific committees develop their opinions and the Commission decides on whether an authorisation should be granted (and on whether it should be subject to any conditions).

This document was initially published in 2011¹. On the basis of the experience gained from the evaluation of more than 100 applications for authorisation, the advice given has been comprehensively reviewed and revised to ensure that it reflects current understanding of best practice.

The use applied for must always be sufficiently described in terms of a **chemical safety assessment** (i.e. an *exposure scenario* detailing the operational conditions and risk management measures required for the use, an *exposure assessment* detailing the resulting exposures to relevant human populations and/or the environment and a *risk characterisation* detailing the level of remaining risk, or whether the use is adequately controlled. An application for authorisation must also be underpinned by an **analysis of alternatives**.

Both assessments are relevant to the description of the use applied for, but from a practical perspective can be useful to consider one or other of the assessment reports as the 'starting point' for the development of description of uses. The choice of whether it would be preferable to start with the chemical safety report (more precisely the exposure scenario) or the analysis of alternatives will need to be made on a case-by-case basis. However, it is possible to make some general observations of when one or the other approach could be

¹ Original document was called 'How to develop the description of uses in the context of Authorisation'

considered to be preferable.

For example, the exposure scenario from a chemical safety assessment can be used as the basis for the description of a 'use applied for' where the use is intended to allow the continued use of an Annex XIV substance to produce a single 'product' or group of 'products' with the same technical requirements. This can be considered the '**process-driven approach**' to use description and is broadly comparable with how uses are described under REACH Registration.

However, a complimentary '**alternatives-driven approach**' to use description will be more appropriate to the 'process-driven approach' when developing and describing uses applied for in applications for authorisation where a single chemical/industrial 'process' can be used to produce numerous different 'products', that have different 'substitution profiles'² dependent e.g. on the market they are used in and the requirements of downstream and end users. By using an alternatives-driven approach in these circumstances applicants reduce the potential for uncertainties in their applications that can lead to conditions or short(er) review periods.

The choice of starting point applies equally to all applications for authorisation, irrespective of whether a particular Annex XIV substance is considered to be threshold or non-threshold or whether the Annex XV substance is present in 'products' or not. In all cases the conclusions of an analysis of alternatives are relevant to the justification provided for the length of the recommended time-limited review period. The choice of alternatives-driven or process-driven approach is depicted graphically in Figure 1.

² The term 'substitution-profile' refers to the technical and economic feasibility of a given set of alternative substances and technologies in relation to the technical requirements of a given product (or group of products) associated with the use of an Annex XIV substance. For example – 'Product X' is produced using an Annex XIV substance and is associated with alternatives A, B and C (none of which are considered to be suitable in relation to the technical requirements for Product X). 'Product Y' is produced using the same industrial process as 'Product X', but has different technical requirements when compared to Product X and is therefore associated with alternatives D, E and F. The two products have different substitution profiles as they are associated with different potential alternatives.

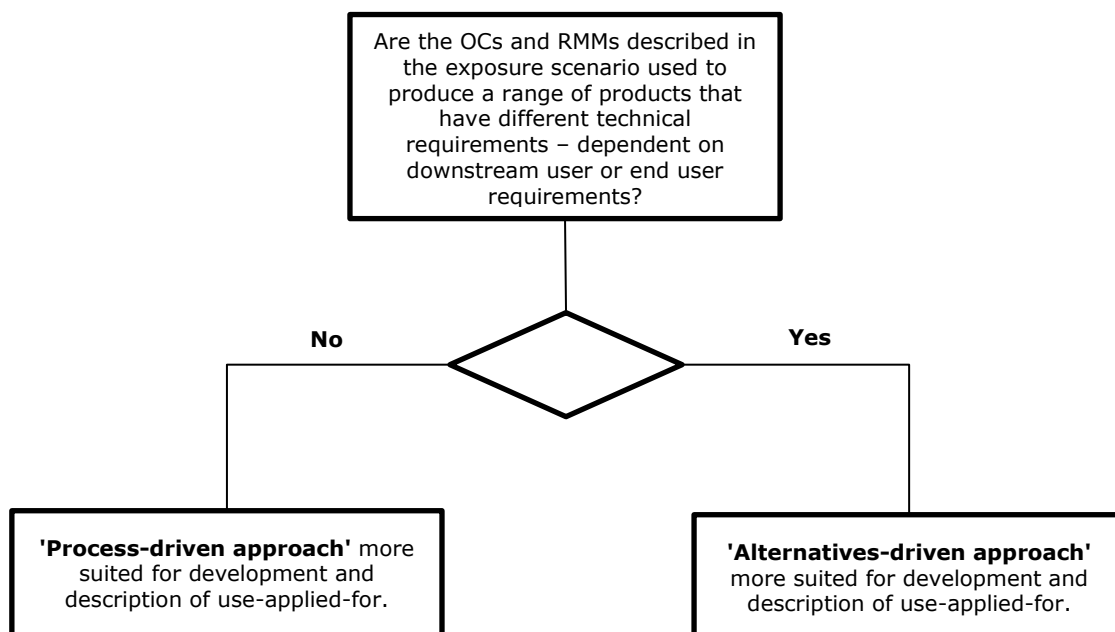


Figure 1. Decision tree for 'process-driven' or 'alternatives-driven' approach to developing and describing the use-applied-for in an application for authorisation

1.1 'Process-driven' approach

In a process-driven approach the use is principally defined based on the underlying industrial/chemical process that the Annex XIV substance is associated with. It is considered to be most applicable where there is a product/products associated with an industrial/chemical process that has a single substitution profile e.g. there is a single set of technical requirements for the product(s).

1.2 'Alternatives-driven' approach

In an alternatives-driven approach, rather than scoping and defining use(s) based on industrial process (as is typical in REACH Registration), the use(s) of an Annex XIV substance are considered primarily on the basis of the '**product(s)**' arising from the use of the Annex XIV substance and the diversity of technical/functional requirements of these products necessary for them to achieve their intended purpose (which may be different in different markets).

As a general rule, a use should only comprise products that have similar 'substitution profile' e.g. in terms of the identity of candidate alternative substances or technologies and their technical and economic feasibility.

The adoption of an alternative-driven approach for processes that can be used to produce diverse products will facilitate the preparation of 'fit-for-purpose' applications that should be straightforward for applicants to prepare, simpler for ECHA's scientific committees to evaluate and more understandable to stakeholders and decision makers and, in the end, to improve predictability of the application for authorisation process.

2. Elements of use description, scope of a use and scale of an application

2.1 Elements of a use description

A “use” is defined in Article 3(24) of REACH as: “any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation”.

The description of a use for which an authorisation is applied for (“use-applied-for”) is comprised of:

1. a **name/title** that identifies and succinctly explains the scope of the use (including critical aspects from the elements below);
2. the **exposure scenario(s)**, documented in a Chemical Safety Report (CSR): i.e. description of the operational conditions (OCs) under which the use takes place (e.g. duration and frequency of tasks leading to exposure, process temperature, concentration of Annex XIV substance etc.) as well as a description of the risk management measures (RMMs) in place in order to limit the risks e.g. use of closed systems, automated systems, local exhaust ventilation (LEV), organisational measures, personal protective equipment (PPE), exhaust air and waste treatment etc. Refer to ECHA publications on [‘how to apply for authorisation’](#) and the [‘applicant’s checklist for preparing an application for authorisation’](#) for further advice on the preparation of exposure scenarios for an application for authorisation.
3. A description of the **substance function(s)** that the Annex XIV substance provides, documented in an Analysis of Alternatives. Examples of Annex XIV substance function include:
 - processing aid, extraction solvent, degreasing agent, corrosion inhibitor, swelling-agent, photo-sensitiser, pigment, mordant, surfactant etc.
4. A description of the **‘product/s’** resulting from the use of the Annex XIV substance and placed on the market documented in the Analysis of Alternatives. The products can be commercialised in one or more industrial/business sectors (aerospace, automotive, pharmaceutical, electronics etc.) and are not limited to products containing the Annex XIV substance (i.e. can include articles produced using the Annex XIV substance but which do not contain the Annex XIV substance themselves)³. Examples of different products associated with the use of an Annex XIV substance include:
 - a. Product(s) in the beginning of supply/value chain: For example, Cr(VI) is used to give certain properties to the surface of a ‘part’ e.g. a piston ring. The *piston ring* is the product associated with the Annex XIV substance.
 - b. Product(s) in the middle of supply/value chain: the piston ring is further assembled into a piston, which is an intermediate product. The piston is

³ The description of products is a critical element of the analysis of alternative (AoA). Applicants should define uses recognising where products and sectors have already substituted an Annex XIV substance, or where substitution of an Annex XIV substance can be achieved within different timelines.

incorporated in an engine, which is another intermediate product.

- c. Final product(s) in the supply/value chain: the engine is incorporated into a vehicle. The vehicle is the final product used by, e.g. consumers. There can be different types and models of civilian, industrial or military vehicles (motorbikes, cars, trucks, railway vehicles, ships etc.).

Different terms are commonly used to designate different types of products, which may vary across the different industrial/business sectors that they are commercialised in. For instance, products can be called:

- parts,
 - sub-components and components,
 - sub-systems and systems,
 - devices,
 - chemical substance/mixture,
 - active Pharmaceutical Ingredient (API), medicine,
 - etc.
5. A description of the **technical requirements** that products associated with the use of the Annex XIV substance must achieve, e.g. specifications or level of performance, detailed in an Analysis of Alternatives. A detailed description of the technical requirement for a product is a critical element of the description of the use applied for. It helps to identify and assess:
 - a. alternative substances which can provide the same function and/or
 - b. alternative technologies, materials that can substitute the function

Examples of technical requirements (which may be defined by internationally recognised standards e.g. EN or ISO standards or as a result of customer/industry specifications) for a product include:

- purity,
- hardness,
- resistance to corrosion,
- resistance to abrasion,
- resistance to temperature,
- etc.

The time needed to identify, test and qualify alternatives depends on i) the type of products and ii) the technical requirements required for these products. Moreover, the technical requirements may vary across the different sectors where the products are further commercialised.

6. A description of the industry sector(s) where the products are commercialised, detailed in an Analysis of Alternatives. A non-exhaustive list of industry sectors includes:
- Chemical sector
 - Pharmaceutical
 - Mining
 - Textile
 - Aviation and Aerospace (civilian and military)
 - Automotive (civilian and military; road vehicles)
 - Railway vehicles (rolling stock)
 - Tooling, machining (manufacture of tools, robots)
 - Sanitary
 - Electronic
 - etc.

Where different sectors require different levels of performance this is likely to be relevant during the development of the final 'scope' of the use applied for. For instance, an electronic component associated with the use of an Annex XIV substance is further assembled into various electronic devices. The electronic devices are themselves commercialised in different industry sectors (medical, automotive, aviation, consumer). The 'same' component may be subject to different technical requirements across the different sectors in which it is used. Should these different technical requirements translate into different substitution profiles in the different sectors this could suggest that separate uses should be developed for each sector.

2.2 Scope of a use

Within both a process-driven and alternatives-driven approach to use description, the scope of a use can be defined as the discrete product or group of products associated with the use of the Annex XIV substance, together with the operational conditions (OCs) and risk management measures (RMMs) used to produce them. A use can theoretically include a number of different:

- Processes (e.g. formulation, extrusion, calendering, electroplating, spraying, dipping, brushing etc.) typically defined by sets of Worker Contributing Scenarios (WCS) and Environmental Contributing Scenarios (ECS) that describe the specific OCs and RMMs associated with each process.
- Products
- Market sectors

- Life-cycle stage(s) e.g. formulation, end-use of a substance⁴, consumer use, article service-life⁵

However, it is important that several factors should be considered as the scope of a use is developed during the preparation of an application. This is because the uncertainties associated with these factors may be critical when deciding whether the conditions for obtaining an authorisation are met, as well as for determining the duration of the review period:

- the diversity of OCs/RMMs included within a use,
- the 'substitution profile' for each of the different products associated with the use of the Annex XIV substance,
- the life-cycle stage of the use (own use, downstream use) which is intended to be covered in the application for authorisation.

Applicants should have interest in that the scope of each use-applied-for remains 'meaningful'. The notion of a meaningful scope is elaborated further in Section 3.

2.3 Scale of an application for authorisation

In addition, it is important to ensure that the scope of a use is not confused with the 'scale' of an application (e.g. the number of downstream users / sites it will cover). Considerations regarding the scope of uses should be made irrespective of the scale of an application and it should not be assumed that applications that are intended to cover many downstream user sites can be associated with uses with a wide scope, whilst applications by individual downstream users will be associated with a narrow scope.

However, it is probably accurate to assume that where an application is intended to cover many different downstream users there is a greater likelihood that there will be greater diversity of technical/functional requirements of products and certain diversity of OCs/RMMs in different downstream user's sites. This diversity could require a greater number of uses to be included within an application to ensure that they are 'meaningful'.

Further considerations on application strategy are provided in ECHA's ['how to apply for authorisation'](#) document.

⁴ 'End-use of a substance' means the use of a substance, as such or in a mixture, as a last step before the end-of-life of the substance (i.e. before the substance is consumed in a process by reaction during use (including intermediate use) or it becomes waste is included into a mixture for supply to consumers or for export or is incorporated into an article. However, mixtures containing SVHCs other than CMRs could be included in mixtures for sale to the general public; in both mixtures and articles the substance has not reached its end-of-life.

⁵ The article service-life does not constitute a 'use applied for'. However, risks arising from the uses of articles during and after their service life shall be assessed, where relevant, in an application for authorisation.

3. How to define a 'meaningful' scope for a use

Users generally have extensive technical and economic knowledge of the use(s) of an Annex XIV substance, including the technical/functional requirements associated with the product(s)⁶ it is used to produce and the suitability of alternatives to achieve these technical/functional requirements. Therefore, they should be sufficiently well-informed to develop use description(s) with a 'meaningful', relevant, scope under both a 'process-driven' or 'alternatives-driven approach to use description.

3.1 Developing a use with a 'meaningful' scope

Based on the experience gained during the evaluation of more than 100 applications for authorisation (over the period from 2013 to 2017), a use with a 'meaningful' scope can be considered to be that that minimises (as far as reasonably practicable) the uncertainties in relation to the conclusions on the suitability of alternatives and the appropriateness and effectiveness of risk management measures. Uncertainties in this regard are typically introduced by including either multiple processes that have inherently different exposure potential within the same use or exposure scenario (e.g. dipping and spraying) or by including multiple 'products' with different discrete technical requirements within a single use-applied-for.

In terms of products, a product with discrete technical requirements can have a different substitution profile compared to other products produced using the same OCs and RMMs e.g. products for aerospace applications may have different potential for substitution than products for automotive applications, even if they are produced using the same industrial/chemical process. These differences can relate to the time necessary for substitution, but can also, in certain situations, relate to whether or not there are suitable alternatives for a discrete product available (perhaps based on information from the public consultation), which could compromise the justification upon which an authorisation can be granted for the whole use.

Where a use incorporates many different processes or discrete products, the use is considered to have a broad scope.

Where alternatives for certain chemical/industrial processes or products are already known to be widely used, these should be explicitly excluded from the use-applied-for. Equally, where alternatives for certain processes or products covered by the use-applied-for could be implemented sooner than for others this can affect the length of the review period for the whole use. In these circumstances applications should be 'split' into sufficient uses to ensure that products with different substitution profiles are contained in different uses.

Applications with a broad scope have tended to be submitted by upstream actors. An upstream applicant may wish to cover in its application for authorisation a large number of downstream users who use different processes to produce a large variety of products with different technical requirements for different industry sectors. However, where the scope of an application for authorisation is broad, this needs to be translated into a sufficient number of individual uses, each with a more narrow 'meaningful' scope.

In an alternatives-driven approach to use description, when the number of products

⁶ The term product is intended to have a broad meaning in this sense (see Section 2.1) and includes: parts, sub-components and components, sub-systems and systems, devices, chemical substance/mixture, Active Pharmaceutical Ingredient (API), medicine, etc.

associated with the use of the Annex XIV substance is very high (e.g. many hundreds of different products), it is obviously impractical to define uses at the level of each and every individual product. However, it is necessary for the applicants (even if challenging) to try and:

- define uses based on **categories**, derived in a meaningful manner, underpinned by reasonably foreseeable combinations of processes, products, technical requirements and market sectors,
- **exclude from the application** all categories, or processes where suitable alternatives are or could be implemented before the Sunset Date or earlier than the requested review period. This can be done e.g.
 - by providing 'negative lists' of product(s) or categories that are explicitly excluded from the scope of the use applied for;
 - by splitting a single 'broad' use into a greater number of narrower uses, associated with different substitution profiles.

3.2 Summary

To be considered meaningful, a use applied for should be developed considering either a 'process-driven' or 'an alternatives-driven' approach and should be defined in such a way that it is:

1. relevant to homogenous exposure scenarios, including OCs/RMMs, representative of all workplaces covered and their use of the Annex XIV substance,
2. relevant to a homogenous set of products defined on the basis of technical/functional requirements and substitution potential,
3. relevant to specific industry sectors (if possible and relevant), and
4. consistent with a single substitution timeline.

In practice, it is recommended to begin scoping the use(s) by analysing and categorising the substitution profiles for different industrial/chemical processes or combinations of products, technical requirements and sectors. Refer to the [applicant's checklist for preparing an application for authorisation](#).

In an alternatives-driven approach, once this analysis and categorisation has been done (resulting in one or more specific uses), applicants should then associate these with a representative exposure scenario, that is comprised of environmental, worker and, where relevant, consumer contributing scenarios.

In so called 'service provider' situations, i.e. one set of OCs/RMMs is used to manufacture many different types of products with different technical requirements across different sectors. In this situation a different use would be needed for the different types of products, where these have different substitution profiles. However, using exposure data for the OCs and RMMs, without differentiating between the uses, will result overall risks being overestimated.

In these circumstances downstream-user applicants should consider the potential to 'apportion' a fraction of the 'process' risk to the fraction (expressed in quantities or monetised value) of products covered by the use applied for. For example, if a company

produces 90% of products (in terms of tonnage, number of products or turn-over) with stringent technical requirements (e.g. for which substitution will take an extended period of time to allow for research, testing, industrialisation and requalification) and 10% with less stringent technical requirement (for which substitution can be achieved more rapidly⁷), the remaining risk can be apportioned accordingly (i.e. 90% of the costs associated with the risks to one use and 10% of the costs associated with the risks to the second use) and compared with the associated benefits of the two uses applied for.

Several iterations might be necessary before the set of uses that will comprise an application for authorisation can be finalised.

3.3 Specific considerations for uses (e.g. formulation, repackaging, etc.) preceding the 'end-use of the substance'

When formulating an Annex XIV substance into a mixture, the presence of that substance may or may not provide an explicit function and, accordingly, may or may not require a discrete 'use-applied-for'. The same applies to other activities preceding the end use of a substance. This is elaborated further below.

In the case of formulation, for example:

1. Where a mixture is prepared by a 'formulating company' but the mixture is only 'used' at another site by a downstream user to which the mixture is supplied, formulation activities by the 'formulating company' are considered require a separate use to the downstream use. In these circumstances an AoA for the formulation use is not necessary because there is no function *per se* provided by the Annex XIV substance. However, a CSR should be developed as normal. A *'process-driven approach to use description'* is suitable.
2. Where the Annex XIV substance provides a function within the mixture itself (e.g. as a stabiliser or homogenising agent), then this should be considered as a function at the formulation stage requiring a use. A CSR, AoA (and SEA if necessary) would be required as per a normal application. *Either a process-driven or alternatives-driven approach to use description could be utilised, depending on the specifics of the case.*
3. Where an Annex XIV substance is used to produce a mixture that is subsequently used at the same site (e.g. electroplating) then this 'formulation' does not need to be applied for as separate use but can be included as a separate working contributing scenario (WCS) in the Exposure Scenario covering the use of the mixture. *Either a process-driven or alternatives-driven approach to use description could be utilised, depending on the specifics of the case.*

The same principles apply to 'uses' such as repackaging.

⁷ e.g. one use with a long review period and one use with a shorter review period.

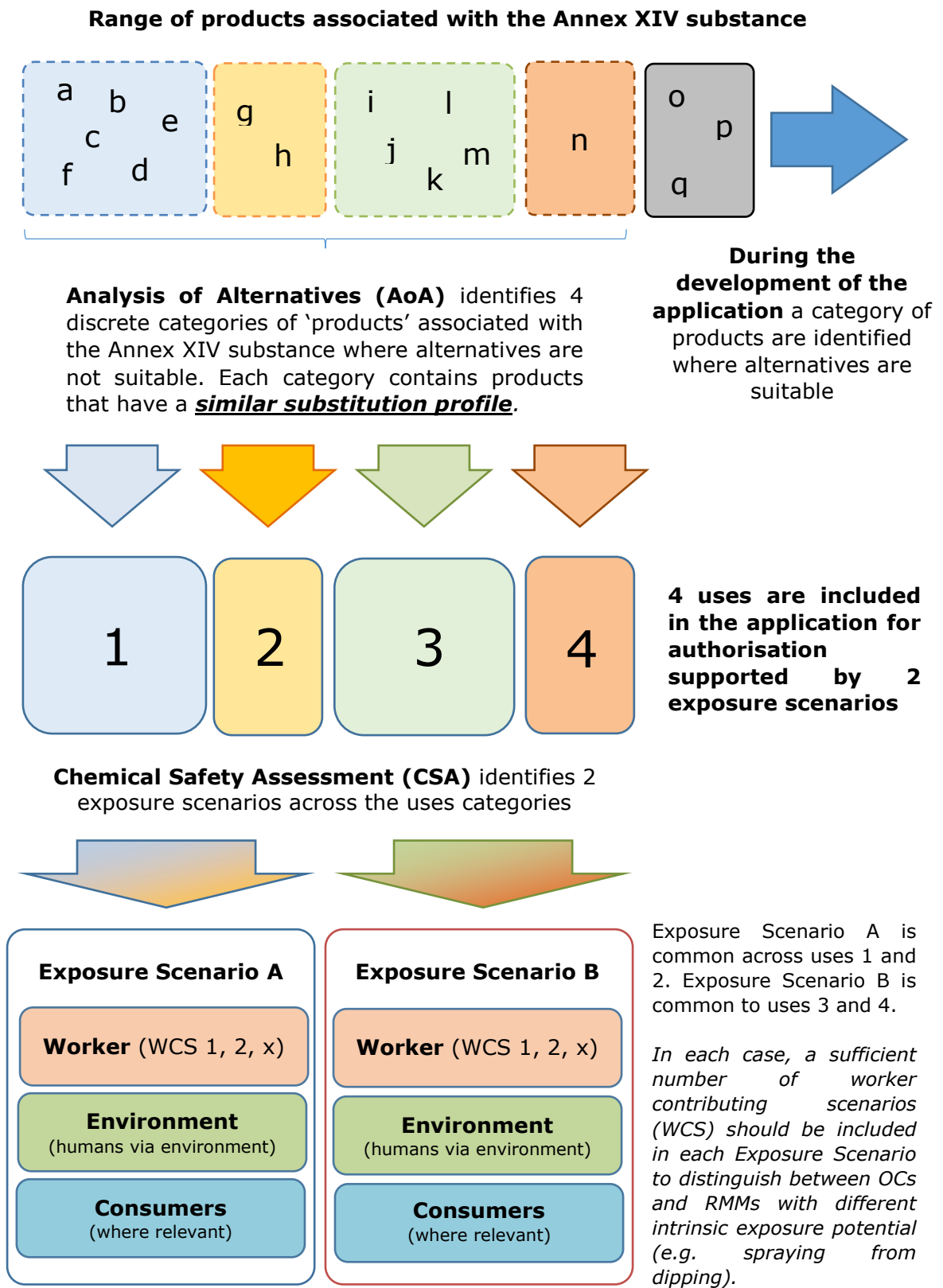


Figure 2. Overview of an example 'alternatives-driven' approach to describing uses in an application for authorisation

4. Example of iterative 'use-scoping'

The following section presents a hypothetical example of how an applicant could approach iterative 'use-scoping' during the development of an application for authorisation for a non-threshold substance using an 'alternatives-driven approach'. Whilst the example presented is hypothetical it has been informed by several applications for authorisation that were submitted to ECHA. The example is considered to be relevant irrespective of the position of the applicant in the Annex XIV supply chain i.e. whether the applicant is a downstream user or an 'upstream actor'.

4.1 Relevant substance function/s, products and markets

The example considers the use of an Annex XIV substance to produce articles used in the electrical systems of various types of military and civilian vehicles, including motorised road and off-road vehicles (e.g. cars, motorcycles, trucks and buses), railed vehicles (e.g. trains and trams), watercraft (ships and boats), aircraft and spacecraft.

The design of individual articles (size/shape) varies, dependent on the specific requirements of the electrical system. There are many hundreds of different designs currently placed on the EU market.

The Annex XIV substance provides two 'functions'. It is **(a)** used to 'condition' the surface of plastic materials prior to surface treatment as part of the production of the article, and **(b)** is applied as a coating onto metal parts during their production to enhance their resistance to environmental corrosion during the article's service-life.

4.2 Initial considerations

The applicant undertakes an Analysis of Alternatives for the functions **(a)** and **(b)**, with the following conclusions:

- The 'conditioning' use **(a)** of the Annex XIV substance can be substituted with a suitable alternative within a relatively short period of time (4 to 7 years).
- Corrosion resistance **(b)** is the key technical requirement of individual articles and applies irrespective of other considerations (such as shape/size). Corrosion resistance can be determined in articles using internationally standardised testing methods.
- The corrosion resistance **(b)** required in articles (technical performance specification) is dependent on the harshness of the environmental conditions that the vehicle is intended to operate within. Certain vehicles (or systems within vehicles) require articles that have 'typical' corrosion resistance, relative to standard testing (**termed level 1 technical performance**), whilst some vehicles (or systems within vehicles) require articles that have 'high-performance' corrosion resistance, relative to standard testing (**termed level 2 technical performance**).
- Alternatives to the use of the Annex XIV substance have been identified at laboratory scale and are likely to be suitable for use in articles that require level 1 corrosion resistance within a period of approximately 7 to 12 years (justified based on the time and activities necessary to translate the results of successful laboratory-scale

research and development into a commercial product).

- Potentially suitable alternatives for the use of the Annex XIV substance for articles that require level 2 technical requirements have not been identified, despite extensive and ongoing research efforts. Should an alternative be identified in laboratory-scale research and development it would take at least 12 years to translate these results to a commercial product on the basis of the necessary certification and testing requirements.

Based on these considerations the applicant considered, based on an alternatives-driven approach, that it should submit an application for authorisation for three uses of the Annex XIV substance in:

1. **Surface conditioning of articles** (providing justification that an authorisation will be required for at least four years).
2. Coating of articles for use in electrical systems in vehicles requiring **level 1 technical performance** (providing justification that an authorisation will be necessary for at least seven years).
3. Coating of articles for use in electrical systems in vehicles requiring **level 2 technical performance** (providing justification that an authorisation will be necessary for at least 12 years).

4.3 Further iteration/s

After undertaking additional assessment the applicant notes that different markets have different certification/type-approval requirements that will affect the duration and resources required to achieve market 'approval' for level 1 technical performance articles. Specifically, the length of time that an authorisation would be required for an article with level 1 technical performance in Market A would exceed 12 years.

Therefore, the applicant decided to further sub-divide Use 2 above, related to level 1 technical performance, resulting in an application for authorisation comprised of four uses, as follows:

1. **Surface conditioning of articles** (providing justification that an authorisation will be required for at least four years).
2. Coating of articles for use in electrical systems in vehicles requiring **level 1 technical performance** (providing justification that an authorisation will be necessary for at least seven years).
3. Coating of articles for use in electrical systems in vehicles requiring **level 1 technical performance in Market A** (providing justification that an authorisation will be necessary for at least 12 years).
4. Coating of articles for use in electrical systems in vehicles requiring **level 2 technical performance** (providing justification that an authorisation will be necessary for at least 12 years).

5. Conclusions

1. Use development and description is a fundamentally important aspect of an application for authorisation. The approach to use description is influenced by whether there are different substitution profiles for the different products associated with the Annex XIV substance.
2. Where authorisation is necessary for the continued production of a large number of different products with variable technical requirements, it is unlikely that a meaningful categorisation can be achieved in a single use or a very limited number of uses.
3. There are different, complementary, approaches to the development and description of uses and the most appropriate approach should be considered on a case-by-case basis.
4. A 'process-driven' approach to use development and description can be appropriate when the products associated with the use of an Annex XIV substance have a single substitution profile.
5. An 'alternatives-driven' approach to use development is appropriate when products are associated with a range of substitution profiles. Use of an alternatives-driven approach to use development and description should minimise the uncertainties in an application and reduce the likelihood that the resulting decision contains:
 - a. An authorisation subject to stringent conditions,
 - b. a shorter review period than sought, or
 - c. a refused authorisation (where it is concluded that the applicant has failed to demonstrate that there are no suitable alternatives and/or that benefits outweigh risks).

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