Setting Latest Application Dates

Practical implementation document for the Annex XIV entries approach

2 March 2017

The methogology presented in this document is tried out for the first time for the 8th Annex XIV recommendation. Depending on the comments received and experiences that will be gathered during the development of the 8th recommendation, the document might be revised.

Contents

1. Aim of the document

According to REACH Article 58(1), ECHA is required to specify the transitional arrangements for each substance recommended for inclusion in Annex XIV. In particular, this consists of a date, or dates, at least 18 months before the sunset date(s), by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s). That date is referred to as Latest Application Date (LAD).

The general approach[1] for the preparation of draft Annex XIV entries describes how ECHA determines the LADs in a particular recommendation round. How the LADs are set aims to improve the workability for processing applications (by RAC and SEAC as well as ECHA secretariat and the European Commission), while at the same time taking into account the time needed to prepare applications for authorisation (AfA).

For assigning LADs according to the general approach[1], firstly, **time slots are defined** (normally three per recommendation). This is to spread the future workload for ECHA and its committees, participants of public consultations, and the European Commission (COM). Timeslots are set as to coincide with the submission windows for applications for authorisation. The first slot is normally set at 18 months after inclusion in Annex XIV, to allow sufficient time for companies to prepare their applications.

Secondly, the recommended **substances are assigned to the slots**. This is done in a way that (i) substances/groups with a profile indicating the highest workload in terms of application-processing are allocated to different slots, and (ii) substances/groups with a profile indicating that applicants will need **more time to prepare applications** are allocated to later slots. These factors are assessed for the substances included in a recommendation round and are relative among those substances.

The aim of this document is to elaborate further on **how the time needed to prepare applications can be assessed**. The document goes through the factors, which can be used as an indication of the time needed to prepare an application for a substance in comparison to another substance. Furthermore, it describes the assessment of these factors. The purpose is the **increase of the overall transparency on how LADs are set**. The document was discussed with the Member State Committee (MSC) in autumn 2016.

The document **does not discuss** the number and length of LADs per round (currently, this is typically 18-24 months).

Setting the LADs should generally be seen in a **holistic manner**, always keeping in mind the main purpose, i.e. the comparison of a limited number of substances for the purpose of assigning them to different LAD slots in one recommendation.

2. Considering the time needed to prepare an AfA

The time required to prepare an application for authorisation depends on many different factors, e.g. the time required to decide who will apply for authorisation, whether and how

[1] The approach can be found here (see in particular Section 3): https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf (18 November 2015)

actors will share information and how applicants will organise themselves, the time required to carry out an analysis of alternatives, etc.

Most of the factors cannot be known or reasonably foreseen by ECHA at the time of recommending substances for inclusion in Annex XIV. At the same time, simplified indicators can be used for a rough assessment of potential differences per substance in terms of expected time needs.

ECHA has tried to identify factors having an impact on the time required to prepare an AfA that can be (at least preliminarily) assessed for all substances based mainly on information in registrations – these are described and further discussed in Section 2.1 below. Under Section 2.2 some factors are described which have been identified as having an impact on the time but that cannot be considered.

2.1. Factors feasible to assess (and therefore considered)

The **structure and complexity of supply chain**, including the diversity of uses and number of use sites, seem to be important factors affecting the time needed to prepare AfAs. In cases of complex supply chains and/or high number/diversity of uses and sites, more time is likely to be needed for establishing communication and the strategy within the chain(s), to cross barriers between different sectors, to obtain information from suppliers/downstream users, etc. These considerations are valid for preparation of both types: upstream AfAs (data will need to be collected from a representative set of downstream sites) and downstream AfAs (AfA for own uses – those industries may still want to share some data between the different use sites, in order to develop common elements for parts of the assessments).

For substances with no **registration requirements** potentially more time is needed, as industry may be less organised compared to substances that have registration obligations. In fact, information on the substance, its uses, and the potential for exposure may well not be (easily) available for such substances. Furthermore, it needs to be kept in mind that for such substances there might be no (or very limited) information available that would allow the assessment of the complexity of supply chain.

2.2. Factors difficult to assess (and therefore not considered)

ECHA is not able to predict how sectors/supply chains will organise themselves nor what types of applications will be made (i.e. upstream vs. downstream applications). That is as the sectors/industries themselves often would not know at the time when the recommendation is developed if and how they will apply.

It is recognised that the preparation of an application is likely to be faster with an experienced[2], well-organised consortium, but ECHA cannot generically assess the readiness of a (potential) consortium.

As it is likely that the availability of information varies between sectors, ECHA cannot generally assess the level of information available. Furthermore, the availability of information should not be disadvantageous. For example, if through information received in the public consultation it appears that certain sectors seem well prepared, this should not systematically lead to giving shorter LADs to substances of such sectors, but rather all available information will be taken into account in a balanced and holistic manner.

It is recognised that small and medium-sized enterprises (SMEs) are in most cases more difficult to contact and engage in coordinating and data-sharing activities. SMEs will also typically have less capacity to work on their own AfAs, and therefore AfA preparation may

[2] E.g. sectors with previous involvement in other REACH or CLP processes.

need more time in this scenario too. On the other hand the volumes associated with their uses may be low and the scope of uses to be analysed in the AfA may be narrow.

Similarly, the geographical distribution of actors concerned by the uses of a substance, and/or the number of countries where the substance is used, may influence the time needed to get organised.

However, an assessment of specific time requirements caused by the size of the companies involved and/or their geographical setting is not possible, as this information is largely not available to ECHA (in particular information about downstream user companies)[3].

3. Assessing the factors considered

The time difference between the LAD slots appears less significant when compared to the total time needed by applicants to prepare their applications. Therefore it does not seem proportional to do a thorough assessment for allocating a substance to an LAD 3 months earlier or later. Yet a 6-month difference (e.g. the difference between 18 and 24 months after inclusion) could have more impact for the applicants. This difference justifies the comparison of the relevant factors between the substances. Still, the level of the assessment should be proportional – both to the impact of the differentiation for industry and to how accurate such an assessment can reasonably be.

Registrations are the first source of information used to assess the factors mentioned in Section 2.1 above. If available, further information (e.g. Risk Management Options Analysis, Annex XV SVHC dossier, public consultations) is used to refine the assessment. Representativeness and reliability of any such further data need to be considered.

In the following sub-sections it is described on which key information the assessment of the relevant factors is based, as well as how this information is evaluated / "scored" (see Annex for an example scoring).

3.1. Vertical Complexity (VC)

The vertical complexity of the supply chain can be roughly determined by the **number of life-cycle stages (LCS)** for the substance across all its uses given in the registrations.

Manufacture is not taken into account since it does not make a difference from the organisational point of view if the substance enters the market via manufacture or import.

The service life of articles is taken into account, as actors involved in the use of articles may well be owners of important information relevant for the analysis of alternatives and the socio-economic analysis, and have accordingly an important role in the preparation of an AfA.

The LCS that are considered are listed in Table 1.

[3] Note that these criteria could be considered as roughly reflected via the 'number of use sites' which is accounted for, if known to be above a certain limit (see Section 3.3)

Table 1 Possible LCS used to assess the vertical complexity

Code	Name
F	Formulation or re-packaging
IS	Use at industrial sites
PW	Widespread use by professional workers
C	Consumer use
SL	Service Life

The sum of LCS identified can be considered as a rough quantitative reflection of the vertical complexity of the supply chains of the substance.

If further information shows that for a certain supply chain an LCS consists of several sub-steps (e.g. subsequent formulations performed by different actors; or multiple layers of Service Life; or occurrence of a relevant recycling step), in a way that for this use the total number of layers would count higher, then this is taken into account accordingly, i.e. a higher number is considered for the vertical complexity of the substance as a whole.

Score VC = Sum of LCS layers/sublayers

Please see Annex for an example of scoring.

3.2. Horizontal Complexity (HC)

The horizontal complexity of the supply chain and diversity of uses can be roughly determined by the **number of those use descriptors[4] that describe the market** in terms of:

- sector where the use takes place: **Sector of Use** (**SU**)
- type of product: **Product category** (**PC**)
- type of article: **Article category** (**AC**)

For reflecting the horizontal complexity and market diversity, the numbers of relevant SU, PC and AC are converted into scores.

[4] Please refer to the Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description for further guidance on use description (December 2015). https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf/ea8fa5a6-6ba1-47f4-9e47-c7216e180197

It is suggested to first assign the scores per use descriptor (SUs, PCs and ACs) separately:

# of SU/PC/AC	Score
< 5	1
5 to 10	2
> 10	3

In the next step the HC score is determined by summing up of the scores per use descriptor type.

Score HC =	Sum of scores per use descriptor type

Please see Annex for an example of scoring.

3.3. Number of industrial use sites

A complex supply chain is furthermore characterised by an overall high number of industrial use sites. As reflected above, as long as the substance is used at multiple sites, sharing of certain data and coordination may be relevant regardless of whether uses will be covered upstream or downstream.

The collection and sharing of such data is expected to be more time consuming if there are more use sites involved.

A high number of use sites could also be an indication of supply chains with many SMEs.

Based on the experience gained so far, it seems justified to account for increased complexity of supply chain when it is known that there are more than 100 industrial use sites for a substance.

Information on use sites can be indicated in registrations. However, so far this data is often not given. If no specific information is available in registrations or other relevant sources (see above), then the number of use sites can be considered as less than 100 and no extra points are added.

Score for # industrial use sites = 3 if known that more than 100 use sites

Please see Annex for an example of scoring.

3.4. Registration requirements

Certain substances are generically exempted from registration (e.g. polymers). Furthermore, for substances manufactured/imported below one tonne per year there is no

registration requirement[5].

Substances not subject to registration requirement can generally be assigned to rather later LAD slots, as explained above, regardless of the anticipated complexity of supply chain.

It is noted that if a substance is not registered even though there is a registration requirement, then this substance will be assigned to rather shorter LAD slots[6], assuming that the substance is currently not used in the EU.

3.5. Summary and assessment flow

In the table below the criteria are summarised that are used to assess the factors described above.

Table 2 Assessment criteria for factors described to estimate the time needed to prepare an AfA

Factor	Description	Assessment criteria
Vertical complexity of supply chain	Number of layers in the supply chain (length)	Number of life cycle stages
Horizontal complexity of supply chain	Number of parallel supply chains	Number of SU/PC/AC
Number of industrial use sites		Number of use sites
Registration requirement	Assess if there is no registration obligation on the substance	

Although the information in the registration(s) forms the basis for the assessment, that information needs to be critically assessed in terms of its applicability for the purpose of estimating the time to prepare an AfA. For example, if a registrant describes the uses of the substance by giving all SUs/PUs/ACs, but reliable further information indicates that the substance has rather specific uses only, then the information in the registration will be critically assessed (i.e. likely not all use descriptors will be considered in the assessment of the horizontal complexity of the supply chain).

At the same time it needs to be kept in mind that the assessment of the factors (listed in Table 2) does not aim to be an accurate or detailed analysis, but rather a rough indication of the time needed to prepare applications, for a more workable allocation of the

[5] Please refer to the Guidance on Registration for more details https://echa.europa.eu/documents/10162/13632/registration_en.pdf

[6] Unless known to be used < 1t/y, in which case a rather longer LAD is warranted (no registration obligations).

substances in the defined LAD slots.

In practice, the assessment of the time needed to prepare Afa is performed in line with the following sequence of steps:

- Grouping substances for which applications can be made jointly - such substances will normally be allocated in the same slots and, in the following steps will be assessed as a group.
- Check registration obligations. In the absence of those, the substance would be assigned to a later LAD slot (e.g. 24 months).
- Check existing registrations. If there are no registrations, but there are still indications that the substance is used in the EU, again the substance would be assigned to a rather later LAD slot. Otherwise, it will be assigned to a rather shorter LAD slot (assuming no use in the EU).
- Scores for VC, HC and number of use sites are summed up, to assess if there are grounds to differentiate the remaining substances in terms of time needed to prepare an AfA.

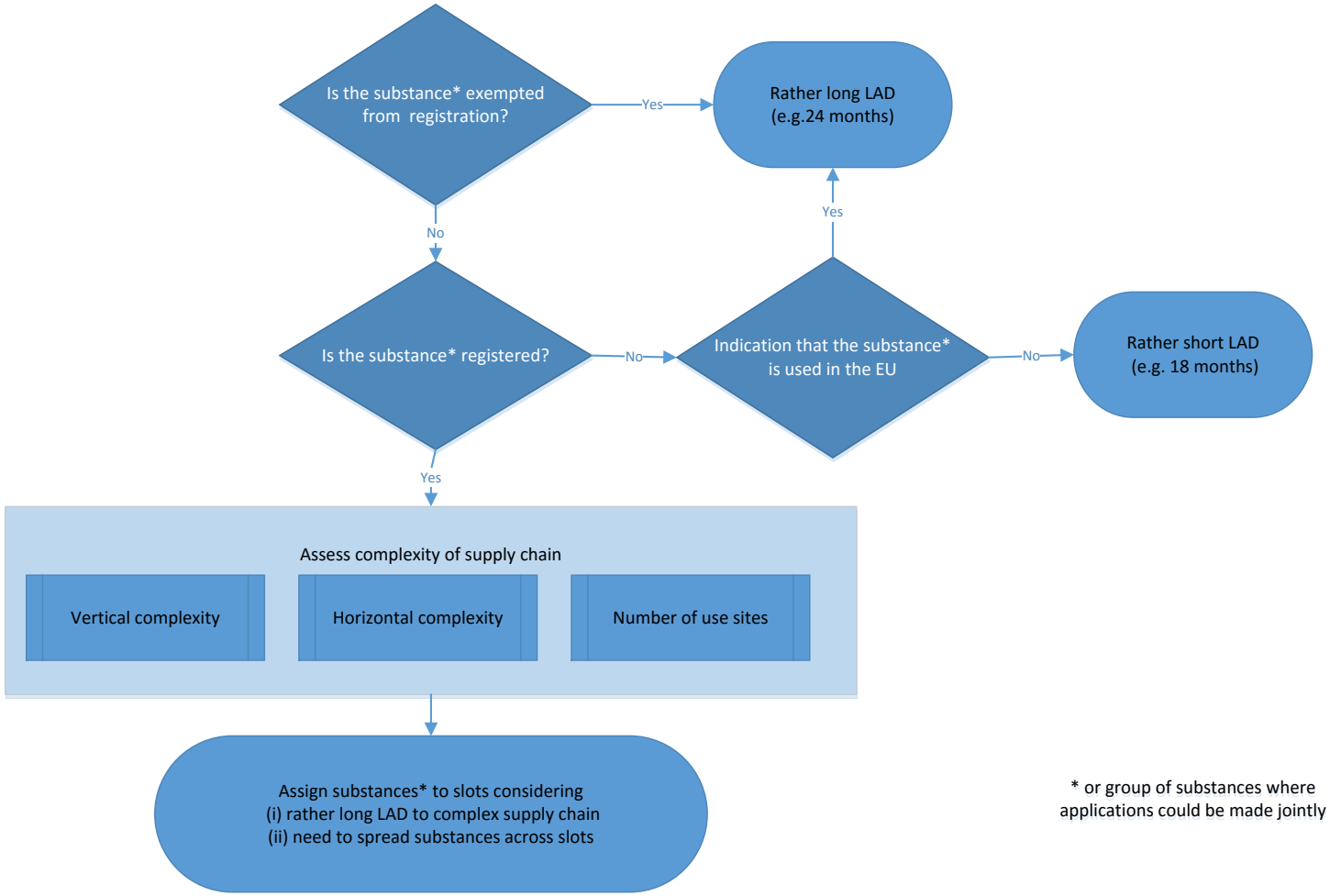
Total score = Score VC + Score HC + Score # use sites

Note

In line with the general approach[1], the **actual allocation of substances** to the different slots takes into **account also processing-workload** considerations (as mentioned above, substances/groups with a profile indicating the highest workload in terms of AfA-processing are not allocated to the same slots, in order to distribute the load for RAC, SEAC, ECHA secretariat and COM as evenly as possible between the different slots).

The assessment flow is illustrated in Figure 1.

Figure 1 Assessment flow for factors considered to estimate the time needed to prepare an AfA



4. Further advice to industry

Availability of relevant information can help ECHA to allocate substances in LAD slots in such a way that facilitates both timely preparation and workable processing of AfAs. To support this task, industry is advised to:

- Keep the registrations up-to-date and as accurate as possible, in particular with regard to the use description. Further description of the supply chain could be given in the CSR or as a separate attachment in Section 13 of IUCLID.

- Provide further relevant information (e.g. on complexity of supply chain) during the public consultation on the draft recommendation.

Timely preparation of AfAs should not be seen as mostly a matter of long LADs. Starting organisational activities early enough is essential in allowing sufficient time for the preparation of AfAs.

Annex: Example of scoring

Example substance

Assume the following use information is available:

- Relevant life cycle stages: formulation, use at industrial sites, use by professional workers and service life.
- No specific information available on the number of industrial sites where the substance is used.
- The substance seems to be formulated in diverse products. Product categories considered as relevant: PC18, PC24, PC35, PC9a and PC17.
- The following use descriptors have been considered relevant to characterise the sectors of end uses: SU1, SU8, SU9, SU2a, SU16, SU17.
- The substance ends up in diverse article types. The following use descriptors have been considered as relevant to characterise them: AC1, AC2, AC13

Scoring of example substance

1. Vertical complexicty

Score VC = Sum of LCS layers/sublayers

	Number of layers of example substance
Formulation (F):	1
Use at ind sites (IS):	1
Use by prof. workers:	1
Service Life (SL)	1
Total	4

Score VC = 4

2. Horizontal complexicty

Scoring scheme:

# of SU/PC/AC	Score
< 5	1
5 to 10	2
> 10	3

Use descriptors of example substance

Type	Use descriptors	# of use decriptors	Score
SU	SU1, SU8, SU9, SU2a, SU16, SU17	6	2
PC	PC18, PC24, PC35, PC9a, PC17	5	2
AC	AC1, AC2, AC13	3	1

Score HC = Sum of scores per use descriptor type

Score HC = 2 + 2 + 1 = 5

3. Number of industrial use sites:

No information available, therefore no additional score given for number of industrial use sites.

Score for # industrial use sites = 3

if known that more than 100 use sites

Score for # industrial use sites = 0

4. Total score

Total score = Score VC + Score HC + Score # use sites

Total score = 4 + 5 + 0

Total score = 9

Some further remarks

Assessment is done across all uses of the substance. If a substance is grouped with other substance(s), the assessment is done for the whole group.

The total score of a substance is compared with the total scores of the other substances in a particular round. Higher total scores could generally be considered as indication of a more complex supply chain compaired with substances having a smaller total score.

However, the **actual allocation of substances** to the different slots needs to take into **account also processing-workload** considerations.

As stated above, setting the LADs should generally be seen in a **holistic manner**, always keeping in mind the main purpose, i.e. the comparison of a limited number of substances for the purpose of assigning them to different LAD slots in one recommendation.