



## EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP  
AND SMES

Consumer, Environmental and Health Technologies

### REACH

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Circular Economy and Green Growth

### Sustainable Chemicals

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## ASSESSMENT OF ALTERNATIVES:

### SUITABLE ALTERNATIVE AVAILABLE IN GENERAL & REQUIREMENT FOR A SUBSTITUTION PLAN

#### Suitable Alternative available in General

Article 60(4) of the REACH Regulation stipulates, for the granting of an authorisation under the socio-economic route, two conditions: (1) that the socio-economic benefits outweigh the risk to human health or the environment resulting from that use, and (2) that there are no suitable alternatives.

Regarding the second condition, the lead chromate pigments judgment<sup>1</sup> introduced a new element in the assessment of alternatives, i.e. the question whether there are suitable alternatives available in general, which was previously not considered.

In that judgment, the Court gave its interpretation of the condition set out in Article 60(4) and (5) and Article 62(4)(f) REACH as regards suitability of alternatives and the requirement of a substitution plan. The Court established in particular that *'where (...) there remain uncertainties as regards the condition relating to the lack of availability of alternatives, it must be concluded that the applicant for authorisation has not discharged the burden of proof and, therefore, that he cannot be granted authorisation'* (par. 79). However the Court also ruled that where the information gathered and analysis made *'(...) suggest that suitable alternatives are available in general, but that those alternatives are not technically or economically feasible for the applicant for authorisation, this does not necessarily mean that authorisation under Article 60(4) of the regulation must be refused'* (par. 75). If that is the case, *'(...) and if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance, (...) authorisation may be granted if the applicant for authorisation submits, in accordance with Article 62(4)(f) of that regulation, a substitution plan within the meaning of Article 60(4)(c) of that regulation'* (par. 76).

The General Court clarified that if suitable alternatives are available *in general* but those alternatives are not technically or economically feasible *for the applicant*, and if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance, an authorisation may be granted if the applicant submits a substitution plan. In other words, if there are suitable alternatives available in general for the use applied for but the applicant has demonstrated that these alternatives are not feasible for him or his downstream users, he also has to submit a substitution plan.

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<sup>1</sup> EU General Court judgment of 7 March 2019 in Case T-837/16, *Sweden v. Commission*

The General Court provided certain key criteria to identify what is a suitable alternative, as summarised in the table and further explained in below.

**Criteria ‘suitable alternative’ [par. 72-76 lead chromates judgement]**

- Risk reduction: the alternative should be safer.
- Suitability in the EU, the alternative should:
  - (i) not be an alternative suitable *in abstracto* or in laboratory or conditions that are of exceptional nature;
  - (ii) be technically and economically feasible in the EU; and
  - (iii) be available, from the perspective of production capacities of alternative substances, or of feasibility of the alternative technology, and in light of the legal and factual requirements for placing them on the market.
- Feasibility for the applicant: *‘In the context of the socio-economic procedure, it is also necessary [...] to determine whether the alternatives established during the authorisation procedure are technically and economically feasible for the applicant.’*

A suitable alternative should be **safer**, i.e. its use should represent a lower risk to human health and/or the environment as compared to the risk of using the Annex XIV substance at stake<sup>2</sup>, also taking into account the appropriateness and effectiveness of risk management measures.

**Suitability in the European Union** means that the alternative must be **already developed and possible to be used** by the sunset date or, if the application for authorisation is submitted after the latest application date, by the date of the Commission Decision in the EU for the use applied for. An alternative would not meet these criteria if it cannot be concretely implemented yet (or at a given time before the sunset date or the date of the Commission Decision) or if it is still under research and development, although in an advanced phase. If suitable alternatives are identified as available in general, those should be assessed for their feasibility *for the applicant*: in this view, the applicant examines whether such alternatives are technically and economically feasible for him and his downstream users.

### **Substitution plan requirement**

As indicated above, if suitable alternatives are available in general, but they are not feasible for the applicant and his downstream users, an authorisation may still be granted if the applicant submits a substitution plan. The availability of a suitable alternative in general, as defined above, that is not feasible for the applicant or its downstream users, is *de facto* a trigger for the requirement to submit a substitution plan. A substitution plan is not required where there are no suitable alternatives in general.

A substitution plan “*is a commitment to take the actions needed to substitute the Annex XIV substance with a suitable alternative substance or technology within a specified timetable*”<sup>3</sup>. The key elements of the substitution plan are the **list of actions** required to transfer to the substitute and the **timing** for those actions. Justifications for the proposed actions and timing, as well as uncertainties in achieving those actions in that timing also need to be included and possible mitigation measures considered. This may also include R&D programs to make the suitable alternative available in general technically and

2 See paragraph 72 of the judgment of the General Court in case T-837/16

3 As defined in Article 62(4)(f) REACH and clarified in ECHA’s Guidance on the preparation of an application for authorisation (para 4, p. 94). The lead chromates judgment recalls, in line with the Guidance, that a substitution plan ‘includes, in particular, a timetable for proposed actions by the applicant (...) containing, in particular, information on any research and development the applicant for authorisation is undertaking or intends to undertake to support the aim of eventual replacement of substances of very high concern by suitable alternative substances or technologies’ (par. 76).

economically feasible for the applicant. In other words, the substitution plan creates an obligation to set out and implement the actions and the timetable towards substitution of the hazardous substance.