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**About this format**

Changes related to the legal entity applying for an authorisation or related to the legal entity holding an authorisation should be notified to ECHA. An assessment will be made of the continued validity of the information submitted in the application as a result of such changes and any implications these changes may have on the RAC and SEAC opinions and/ or the authorisation decision. The notification shall address each use applied for or authorised, and must be signed by both the original applicant/authorisation holder (if still in existence) and the new legal entity.

The purpose of the provided format is to help companies describe in a structured manner the key changes to the facts submitted with the original application and their consequences due to the legal entity change. The notification and supporting material accompanying it should be submitted to ECHA via REACH-IT’s legal entity change functionality, and it will be assessed by ECHA and communicated to the European Commission.

In case of a granted authorisation, the notification will assist the Commission in evaluating whether a review according to Article 61(2) of the REACH Regulation is required.

If a decision has not yet been adopted, the notification will assist ECHA (during opinion making and after ECHA’s opinions have been sent to the Commission) in evaluating whether the opinions are still applicable to the new situation or need to be reviewed before the authorisation decision is adopted.

Please use the headings as described in the format.

# Notification of a change related to the legal entity applying for authorisation or to an authorisation holder:

Please indicate the use[[1]](#footnote-2) applied for/authorised and its corresponding submission/authorisation number:

Please indicate the Company names of the originating and of the successor legal entity[[2]](#footnote-3), as well as their roles for the substance applied for authorisation (e.g. Manufacturer / Importer / Downstream User / Only Representative):

## Description of the legal entity change

Please describe the nature of the legal entity change and identify the key impacts on the validity of the information submitted in the application for authorisation and in the authorisation application procedure as a result of the change. Make this description in a simple manner. Please specify if any interests in the business related to the application or the authorisation in question will remain with the original applicant/authorisation holder. Complement this description by a copy of your transfer of assests agreement or other agreement linked to the declared legal entity change.

## Impact of the legal entity change

Please describe any changes in the information provided in the application which result from the change affecting the applicant or the authorisation holder under the following headings, as relevant.

* + - 1. Chemical Safety Report and operational conditions and risk management measures
* Please describe any changes to the annual tonnage used, for each exposure scenario, when relevant.
* Please describe any changes to the supply chain, including changes to the links between the applicant for authorisation/authorisation holder and other actors in the supply chain (e.g., change in the identity or number of downstream users) as a result of the change.
* Please describe any changes to the number, location and type of workplaces/sites and any other change in the use of assets described in the application.
* Please describe any changes to the exposure scenarios, incuding to the exposure data and its representativeness, release estimates and the risk management measures and operational conditions (e.g., different occupational hygiene practices, different type of emissions abatement technology used in ‘new’ downstream users, changes in numbers of workers directly and indirectly exposed and population exposed, and changes in working procedures) and a justification of such changes.
	+ - 1. Analysis of alternatives
* Please describe any changes to the scope of the use applied for, such as the type of end products that you produce with the Annex XIV substance.
* Please describe any changes to the list of possible alternatives included in the analysis of alternatives and, when applicable, including the risk of additional alternatives described and compared with Annex XIV substance.
* Please describe any changes to the availability and technical feasibility of alternatives as a result of the legal entity change (e.g., access to new technologies or substances, patents, access to alternative substances or technologies).
* Please describe any changes to the economic feasibility of alternatives (cost of substitution) (e.g., resulting from changes in competitive position, changes in supply chain).
* Please describe any changes to the activities in research and development of alternatives and to the substitution plan (where applicable).
* Please indicate whether, in your view, any of the changes reported above may alter the overall conclusion on suitability and availability of alternatives, as claimed in the application or assessed by the Committes.
* Please describe any changes to the arguments provided to justify the review period (e.g., changes in availability of alternatives, access to more or less advanced progress and intelligence in the development of alternatives)
	+ - 1. Socio-economic analysis
* Please describe any changes to the use applied for and non-use scenarios resulting from the legal entity change (e.g., resulting from changes in competitive position, changes in supply chain, changed necessity for relocation).
* Please describe any changes to the socio-economic impacts of the non-use scenario and the use applied for scenario (e.g., relating to changes in employment, availability of alternatives, population at risk).
* Please indicate whether, in your view, any of the changes reported above may alter the overall conclusion on the comparsion of the socio-economic benefits and risks from the continued use, as claimed in the application or assessed by the Committes.
	+ - 1. Other
* Please describe any other relevant changes with a potential impact on the application for authorisation or on the authorisation decision.
	+ - 1. Conclusion
* Please state whether, in your view, the legal entity change alters the circumstances of the original application or authorisation decision so as to affect the content of the application for authorisation (including exposure scenarios) and/or the risk/impact to human health or the environment, the availability of alternatives, or the socio-economic impact. If so, please state to what extent this is foreseen to take place.

*[Signatures and date]*

1. If the notification concerns more than one uses, then you can either i) use a separate block per use, by creating copies of the boxes at the end of the fitst block or ii) refer to all uses in the same block (this applies when the information for all uses is the same or when differences in the impacts per use can clearly be described in a single box per section). [↑](#footnote-ref-2)
2. Please be consistent with the names indicated in REACH-IT [↑](#footnote-ref-3)