ANNEX

CLASSIFICATION OF CHANGES OF PRODUCTS

TITLE 2

Minor changes of products

A minor change of a product is a change, following which any change of the existing authorisation can be expected to be minor within the meaning of Article 3(1)(ab) of Regulation (EU) No 528/2012, since the change of the product is not expected to affect the conclusion with regard to the fulfilment of the conditions of Article 19 or 25 of that Regulation. Such changes include the changes listed in the following table, provided that the conditions therein are met:

Composition	
1.	Increase or reduction, addition, deletion or replacement of a non-active substance intentionally incorporated in the product, where: — The added or increased non active-substance is not a substance of concern. — The deletion or reduction of the non-active substance does not lead to an increase of an active substance or a substance of concern. — The physical-chemical properties and the shelf-life of the product are expected to remain the same. — The risk and efficacy profile are expected to remain the same. — A new quantitative risk assessment is not expected to be necessary
2.	Increase, reduction, addition or deletion, or replacement of a non-active substance intentionally incorporated in a biocidal product family outside the authorised range, where: — The added or increased non-active substance is not a substance of concern. — The deletion or reduction of the non-active substance does not lead to an increase of an active substance or a substance of concern. — The physical-chemical properties and the shelf-life of the products of the biocidal product family remain the same.

	— The risk and efficacy profile are expected to remain the same. — A new quantitative risk assessment is not expected to be necessary.
Conditions of use	
3.	Changed instructions for use, where the changes do not adversely affect the exposure
4.	Addition, replacement or modification of a measuring or administration device relevant for the risk assessment and regarded as a risk mitigation measure, where: — The new device accurately delivers the required dose for the biocidal product concerned in line with the approved conditions of use. — The new device is compatible with the biocidal product. — The change is not expected to adversely affect the exposure.
Shelf-life and conditions of storage	
5.	Change in the shelf-life.
6.	Change in the conditions of storage
Pack size	
7.	Change in the pack size range, where: — New range is consistent with the dose rate and instructions for use as approved in the summary of the biocidal product characteristics. — No change of user category. — The same risk-mitigation measures apply.

Changes to legislation:
There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 354/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 4(2)(d) words substituted by S.I. 2019/720 Sch. 2 para. 181(2)
- Art. 5(1) words omitted by S.I. 2019/720 Sch. 2 para. 182(2)(a)
- Art. 5(1)(b)-(d) omitted by S.I. 2019/720 Sch. 2 para. 182(2)(b)
- Art. 5(1)(e)(1) omitted by S.I. 2019/720 Sch. 2 para. 182(2)(c)(ii)
- Art. 5(1)(e)(2) omitted by S.I. 2019/720 Sch. 2 para. 182(2)(c)(ii)
- Art. 5(1)(e) words omitted by S.I. 2019/720 Sch. 2 para. 182(2)(c)(i)
- Art. 5(4) words inserted by S.I. 2019/720 Sch. 2 para. 182(3)
- Art. 5(5) omitted by S.I. 2019/720 Sch. 2 para. 182(4)
- Art. 7(2A) inserted by S.I. 2022/1291 reg. 3(2)(a)
- Art. 7(4A) inserted by S.I. 2022/1291 reg. 3(2)(c)
- Art. 7(5A) inserted by S.I. 2022/1291 reg. 3(2)(e)
- Art. 8(2A) inserted by S.I. 2022/1291 reg. 3(3)(a)
- Art. 8(4A) inserted by S.I. 2022/1291 reg. 3(3)(c)
- Art. 8(5A) inserted by S.I. 2022/1291 reg. 3(3)(e)