ANNEX

CLASSIFICATION OF CHANGES OF PRODUCTS

TITLE 1

Administrative changes of products

An administrative change of a product is a change following which any change of the existing authorisation can be expected to be only administrative within the meaning of Article 3(1)(aa) of Regulation (EU) No 528/2012.

SECTION 1

Administrative changes of products requiring prior notification before implementation

An administrative change of a product requiring prior notification before implementation is an administrative change, the knowledge of which is important for purposes of control and enforcement. Such changes include those listed in the following table, provided that the conditions therein are met:

Name of the biocidal product	
1.	Changes of the name of the biocidal product where there is no risk of confusion with the names of other biocidal products.
2.	Addition of a name for the biocidal product where there is no risk of confusion with the names of other biocidal products.
Authorisation holder	
3.	Transfer of the authorisation to a new holder established in the European Economic Area (EEA).
4.	Change in the name or address of the authorisation holder, which remains in the EEA.
Manufacturer(s) of the active substance(s)	
5.	Addition of a manufacturer of the active substance or change in the manufacturer's identity or in manufacturing location or process, where the technical equivalence between the substances from the two manufacturers, manufacturing locations and processes has been established by the Agency in accordance with Article 54 of Regulation (EU) No 528/2012, and the manufacturer or importer is listed in accordance with Article 95(2) of Regulation (EU) No 528/2012.

Biocidal product family	
6.	Authorisation as a biocidal product family of a number of authorised products falling within the specifications of a frame-formulation established in accordance with Directive 98/8/EC in accordance with the same terms and conditions.

SECTION 2

Administrative changes of products which can be notified after implementation

An administrative change of a product which can be notified after implementation is an administrative change, the knowledge of which is not important for purposes of control and enforcement. Such changes include those listed in the following table, provided that the conditions therein are met:

Authorisation holder	
1.	Change in other administrative details of the authorisation holder than the name and address.
Formulator(s) of the biocidal product	
2.	Change in the name, the administrative details or the formulating location of the biocidal product formulator, where the biocidal product composition and the formulating process remain unchanged.
3.	Deletion of a formulating location or a formulator of the biocidal product
4.	Addition of a formulator of the biocidal product, where the biocidal product composition and the formulating process remain unchanged.
Manufacturer(s) of the active substance(s)	
5.	Change in the name or the administrative details of a manufacturer of the active substance, where the manufacturing location and process remain unchanged and the manufacturer remains listed in accordance with Article 95(2) of Regulation (EU) No 528/2012
6.	Deletion of a manufacturer or a manufacturing location of the active substance
Conditions of use	

a OJ L 353, 31.12.2008, p. 1.

7.	More precise instructions for use, where only wording but not content of instructions are changed.
8.	Removal of a particular claim, such as a specific target organism or a specific use.
9.	Removal of a category of users.
10.	Addition, replacement or modification of a measuring or administration device not relevant for the risk assessment and not regarded as a risk mitigation measure.
Classification and labelling	
11.	Change to the classification and labelling, where the change is limited to what is necessary to comply with newly applicable requirements of Regulation (EC) No 1272/2008 of the European Parliament and of the Council[a].

a OJ L 353, 31.12.2008, p. 1.

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.

TITLE 3

Major changes of products

A major change of a product is a change, following which any change of the existing authorisation can be expected to be major within the meaning of Article 3(1)(ac) of Regulation (EU) No 528/2012, since the change of the product can be expected to affect the conclusion with regard to the fulfilment of the conditions of Article 19 or 25 of that Regulation.

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 :

- Annex Title 1 Section 1 point 3 words substituted by S.I. 2019/720 Sch. 2 para. 193(2)
- Annex Title 1 Section 1 point 4 words substituted by S.I. 2019/720 Sch. 2 para. 193(3)
- Annex Title 1 Section 1 point 5 words substituted by S.I. 2019/720 Sch. 2 para. 193(4)

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)