**CA-May15-Doc.4.13-Annex-Final**

**60th meeting of Representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products**

**Templates for self-declaration form and letter of confirmation of supply**

Document **CA-May15-Doc.4.13** on compliance with and enforcement of Article 95 suggests that Competent Authorities could request companies placing biocidal product on the market to clarify in writing how they comply with their obligations under Article 95 of Regulation (EU) No 528/2012. It suggests that this could be achieved by asking companies making biocidal products available on the market to fill in **self-declaration** forms, which could be made available electronically.

In terms of evidence to be provided, it is suggested that a simple **letter**[[1]](#footnote-1) should be provided as proof of compliance.

The following templates (a self-declaration form and a letter of confirmation of supply) have been developed to foster harmonisation and simplification. Please note that, while their use is encouraged, it is by no means compulsory, neither for Member States competent authorities nor for companies/persons making active substances or biocidal products available on the market.

Note also that these forms and letters have been developed in order to reduce to the minimum the administrative burden for all parties involved. As such, they are intended to cover mainstream cases, but might have to be adjusted or not suited at all for more specific cases.

The templates in Section I are self-declaration forms for companies placing biocidal products on the market.

The templates in Section II are letters of confirmation of supply to be used by product/substance suppliers included in the Article 95 list.

For administrative purposes, the submission of a self-declaration form should normally suffice as proof of compliance with Article 95 requirements. Companies should however be ready to provide upon request copies of the relevant letters of confirmation of supply.

**Section I - Self-declaration forms for companies placing biocidal products on the market**

**Self-declaration by reference to a substance supplier**

**[*Company letterhead*]**

Date \_\_\_\_\_\_\_\_\_\_\_\_\_

To Member States competent authorities for the implementation of Regulation (EU) No 528/2012

Dear Sir or Madam,

**Compliance with Article 95(2) of Regulation (EU) No 528/2012**

The undersigned, representative of [*Insert name of company*],placing on the market the biocidal product(s) [*Insert name(s) of biocidal product(s) and national registration number(s) if appropriate*], for use in product-type(s) [*Insert number of all product-types for which a use is intended*], which contains the active substance(s)[[2]](#footnote-2) [*Insert name, CAS and EC number of active substance(s)[[3]](#footnote-3)*], declares that for the above named biocidal product(s) [[4]](#footnote-4):

□ the company [*Insert name of company*] listed as substance supplier pursuant to Article 95(1) of Regulation (EU) No 528/2012, is the substance supplier.

□ the company [*Insert name of company*], which is affiliated to/distributing for [*Delete as appropriate*] [*Insert name of company*] listed as substance supplier pursuant to Article 95(1) of Regulation (EU) No 528/2012, is the substance supplier.

□ my company is listed as substance supplier pursuant to Article 95(1) of Regulation (EU) No 528/2012.

□ my company is affiliated to/distributing for company [*Insert name of company*], which is listed as substance supplier pursuant to Article 95(1) of Regulation (EU) No 528/2012.

A copy(ies) of the relevant letter(s) of confirmation of supply can be provided upon request[[5]](#footnote-5).

Signed: [*signature of representative of company responsible for the placing on the market*]

Name and capacity: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Self-declaration by reference to a product supplier**

**[*Company letterhead*]**

Date \_\_\_\_\_\_\_\_\_\_\_\_\_

To Member States competent authorities for the implementation of Regulation (EU) No 528/2012

Dear Sir or Madam,

**Compliance with Article 95(2) of Regulation (EU) No 528/2012**

The undersigned, representative of [*Insert name of company*],placing on the market the biocidal product(s) [*Insert name(s) of biocidal product(s) and national registration number(s) if appropriate*], for use in product-type(s) [*Insert number of all product-types for which a use is intended*], which contains the active substance(s)[[6]](#footnote-6) [*Insert name, CAS and EC number of active substance(s)[[7]](#footnote-7)*], declares that for the above named biocidal product(s):

□ the company [*Insert name of company*] listed as product supplier pursuant to Article 95(1) of Regulation (EU) No 528/2012, is the product supplier.

□ the company [*Insert name of company*], which is affiliated to/distributing for [*Delete as appropriate*] [*Insert name of company*] listed as product supplier pursuant to Article 95(1) of Regulation (EU) No 528/2012, is the product supplier.

□ my company is listed as product supplier pursuant to Article 95(1) of Regulation (EU) No 528/2012.

□ my company is affiliated to/distributing for company [*Insert name of company*], which is listed as product supplier pursuant to Article 95(1) of Regulation (EU) No 528/2012.

A copy(ies) of the relevant letter(s) of confirmation of supply can be provided upon request[[8]](#footnote-8).

Signed: [*signature of representative of company responsible for the placing on the market*]

Name and capacity: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Section II - Letters of confirmation of supply to be used by companies included in the Article 95 list**

**Confirmation of supply as substance supplier**

**[*Company letterhead*]**

Date \_\_\_\_\_\_\_\_\_\_\_\_\_

To Member States competent authorities for the implementation of Regulation (EU) No 528/2012

Dear Sir or Madam,

**Compliance with Article 95(2) of Regulation (EU) No 528/2012**

The undersigned, representative of [*Insert name of company*],listed as substance supplier for the active substance(s) [*Insert name, CAS and EC number of active substance(s)*] pursuant to Article 95(1) of Regulation (EU) No 528/2012, hereby confirms that:

□ my company

□ [*Insert name of company*] affiliated to/distributing for [*Delete as appropriate*] my company

is substance supplier to [*Insert name of company*].

Signed: [*signature of representative of company listed as substance supplier*]

Name and capacity: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Confirmation of supply as product supplier**

**[*Company letterhead*]**

Date \_\_\_\_\_\_\_\_\_\_\_\_\_

To Member States competent authorities for the implementation of Regulation (EU) No 528/2012

Dear Sir or Madam,

**Compliance with Article 95(2) of Regulation (EU) No 528/2012**

The undersigned, representative of [*Insert name of company*],listed as product supplier for the active substance(s) [*Insert name, CAS and EC number of active substance(s)*] pursuant to Article 95(1) of Regulation (EU) No 528/2012, hereby confirms that:

□ my company

□ [*Insert name of company*] affiliated to/distributing for [*Delete as appropriate*] my company

is product supplier to [*Insert name of company*].

Signed: [*signature of representative of company listed as product supplier*]

Name and capacity: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Any documentary evidence linking the company as part of the supply chain to a supplier on the list could also be provided, instead of a letter from a supplier on the list. In any event, the national legislation shall be consulted as it may require more specific or different information. [↑](#footnote-ref-1)
2. All biocidal products covered by the self-declaration shall contain the same active substances [↑](#footnote-ref-2)
3. As available from ECHA’s list of active substances and suppliers available from <https://echa.europa.eu/information-on-chemicals/active-substance-suppliers> [↑](#footnote-ref-3)
4. When more than one company needs to be listed, in particular for biocidal products containing more than one active substance, duplicate paragraph as necessary and add to the end of each paragraph the name of the active substance addressed under the paragraph. [↑](#footnote-ref-4)
5. Such letters can however only be provided in the first two cases, as the other two ones, in particular the last one, may cover situation where the substance supplier is a third party, such as a toll manufacturer, not listed on Article 95. [↑](#footnote-ref-5)
6. All biocidal products covered by the self-declaration shall contain the same active substances [↑](#footnote-ref-6)
7. As available from ECHA’s list of active substances and suppliers available from <https://echa.europa.eu/information-on-chemicals/active-substance-suppliers> [↑](#footnote-ref-7)
8. Such letters can however only be provided in the first two cases, as the other two ones, in particular the last one, may cover situation where the product supplier is a third party, such as a toll manufacturer, not listed on Article 95. [↑](#footnote-ref-8)