DOCUMENTS TO BE SUBMITTED PER APPLICATION

- **First authorisations (NA-APP)**

Documents to be submitted	FR or EN
Draft SPC (xml format)	EN
Draft RCP (xml format)	FR
Completed technical IUCLID dossier. In section 13: - PAR in ECHA format: http://echa.europa.eu/fr/support/guidance-on-reach-and-clp-implementation/formats - LoA and/or data on active substances - Product MSDS in French - MSDS of each ingredient - Label / draft label in French (and instructions for use in French, if appropriate) - 'Permission to refer' decision granted by ECHA – if necessary - ECHA decision concerning technical equivalence – if necessary	FR or EN
Table of intended uses in Word format	FR or EN
Detailed composition form in Excel or Word format	FR or EN
List of all trade names included in each meta-SPC of the product family – only for family	FR
Supporting document (see ECHA website): "Statement for national authorisation application"	FR or EN

- **Mutual recognition in sequence (NA-MRS)**

Documents to be submitted	FR or EN
Draft RCP (xml format)	FR
Translation of the national authorisation of RMS (authorisation + RCP)	FR
Letter of access for active substances	FR or EN
LoA for product data if the holder is different between RMS and CMS	FR or EN
Label / draft label (and instructions for use in French, if appropriate)	FR
Product MSDS	FR
List of all trade names included in each meta-SPC of the product family – only for family	FR

- **Mutual recognition in parallel (NA-MRP)**

Documents to be submitted	FR or EN
Draft SPC (xml format)	EN
Letter of access for active substances	FR ou EN
LoA for product data if the holder is different between RMS and CMS	FR or EN
MSDS of each ingredient	FR or EN
List of all trade names included in each meta-SPC of the product family – only for family	FR

- **Major changes (NA-MAC)**

Documents to be submitted	FR or EN
Draft SPC (xml format)	EN
Draft RCP (xml format)	FR
Completed IUCLID dossier including expected changes. In section 13: - LoA and/or data on active substances - Product MSDS in French - Label / draft label in French (and instructions for use in French, if appropriate) - Supporting documents to demonstrate that the proposed changes would not adversely affect the conclusions previously reached – if necessary - Opinion issued by ECHA regarding the classification of the application – if necessary - ECHA decision concerning technical equivalence – if necessary - Written confirmation from the evaluating RMS stating their agreement to evaluate the application - if necessary	FR or EN
Supporting document (see ECHA website): "supporting document for the application for a major change of a product authorization"	FR or EN
Detailed composition form in Word format	FR or EN

- **Minor changes (NA-MIC)**

Documents à soumettre	FR or EN
Draft SPC (xml format)	EN
Draft RCP (xml format)	FR
Completed IUCLID dossier including expected changes. In section 13: - LoA and/or data on active substances - Product MSDS in French - Label / draft label in French (and instructions for use in French, if appropriate) - Supporting documents to demonstrate that the proposed changes would not adversely affect the conclusions previously reached – if necessary - Opinion issued by ECHA regarding the classification of the application – if necessary - ECHA decision concerning technical equivalence – if necessary - Written confirmation from the evaluating RMS stating their agreement to evaluate the application - if necessary	FR or EN
Supporting document (see ECHA website) "Application for a minor change of a national/simplified authorisation"	FR or EN
Detailed composition form in Excel or Word format	FR or EN

- **Administrative changes (NA-ADC)**

Documents à soumettre	FR or EN
Draft RCP (xml format)	FR
Supporting document (see ECHA website) "Notification for an administrative change of a national/simplified authorisation"	FR or EN
Opinion issued by ECHA regarding the classification of the application – if necessary	EN
Cross-certificate of acceptance of the product transfer – in case of transfer of the authorisation	FR
Extract from the Commercial Register or any other official document showing the change in holder name – in case of change in the name or address of the authorisation holder	FR
LoA updated for AS and/or reference product – in case of transfer of the authorisation , or change in the name or address of the authorisation holder	FR or EN
New LoA for active substance – in case of addition or modification of AS manufacturer	FR or EN

- **Same products (NA-BBP or BBS)**

Documents to be submitted	FR or EN
Draft SPC (xml format) **– for BBP**	EN
Draft RCP (xml format) **– for BBS**	FR
Supporting document (see ECHA website): "supporting document for the application for national authorisation of the same biocidal product"	FR or EN
Letter of access for active substances	FR or EN
Certificate from applicant which confirms that the product is identical to the reference product excepted for possible administrative changes	FR
List of all trade names included in each meta-SPC of the product family – only for family	FR
Letter of access for the original reference product if holders are different – if necessary	FR or EN
Letter of access for the related product, if holders are different – in case of same on same for example	FR or EN
'Permission to refer' decision granted by ECHA – if necessary	FR or EN
ECHA decision concerning technical equivalence – if necessary	FR or EN

- **Transfer (NA-TRS) –** only if the product is already authorised

Documents to be submitted	FR or EN
Draft RCP (xml format)	FR
Supporting document (see ECHA website) "Notification for an administrative change of a national/simplified authorisation"	FR or EN
Cross-certificate of acceptance of the product transfer – in case of transfer of the authorisation	FR
LoA updated for AS and/or reference product – in case of transfer of the authorisation , or change in the name or address of the authorisation holder	FR or EN
Opinion issued by ECHA regarding the classification of the application – if necessary	EN

- **Simplified authorisation (SA-APP)**

Documents to be submitted	FR or EN
Draft SPC (xml format)	EN
Draft RCP (xml format)	FR
Completed IUCLID dossier. In section 13: - LoA and/or data on active substances - Product MSDS in French - MSDS of each ingredient - Label / draft label in French (and instructions for use in French, if appropriate) - 'Permission to refer' decision granted by ECHA – if necessary - Written confirmation from the evaluating RMS stating their agreement to evaluate the application	FR or EN
Table of intended uses in Word format	FR or EN
Detailed composition form in Excel or Word format	FR or EN

- **Notification of simplified authorisation (SN-NOT)**

Following article 27 of BPR, the reference product has to be authorised in the first Member State.

Documents to be submitted	FR or EN
Draft RCP (xml format)	FR
Draft label	FR

- **Research and development (ET-NOT): Notification and Authorisation**

Documents to be submitted	FR or EN
Completed IUCLID dossier (with information described in article 53.2 of BPR)	FR or EN

- **AS approbation (AS-APP)**

Documents to be submitted	FR or EN
Completed IUCLID dossier. In section 13: - Draft assessment report in ECHA format (draft AR) : http://echa.europa.eu/fr/support/guidance-on-reach-and-clp-implementation/formats - Letter of access – if necessary - Justification concerning exclusion criteria – if necessary - Permission to refer' decision granted by ECHA – if necessary	FR or EN
Written confirmation from the evaluating RMS stating their agreement to evaluate the application	FR
Supporting document (see ECHA website): « Approval for active substance »	FR or EN