Annex I. Applicant information to support the process of comparative assessment

(no information is needed when the product doesn't contain a Candidate for Substitution)
(8 April 2016)

National addendum to the draft Registration Report (dRR)

Country	Netherlands
Product under evaluation	
Candidate for substitution (active substance name)	
Reasons for approval as candidate for substitution (delete as appropriate).	low ADI, ARfD or AOEL; two of PBT; significant proportion of non-active isomers; classified Carcinogen 1A or 1B; classified as toxic for reproduction 1A or 1B; endocrine disruption; other reasons for concern

Step 1. Is this application intended for a mutual recognition, derived authorisation or parallel trade permit?
If yes, no further information is needed > **stop CA.**
If no, go to step 2

Step 2. Is this product only destined for non-professional users ?
If yes, no further information is needed > **stop CA.**
If no, go to step 3

Step 3. Do you want to make use of the derogation in Article 50(3) for uses where it is necessary to acquire experience first through using that product in practice?
If yes, please state your reasons. Then > **stop CA.**
If no, go to step 4

Step 4. Is this product only destined or applied for minor use(s) according art 51 or NLKUG? (Minor Uses are defined in the list of Minor Uses).
If yes, no further information is needed > **stop CA.**
If no, go to step 5

Step 5. Does your application include a minor use?
If you apply for a minor use according art 51 or NLKUG or a minor use has been authorised (according art 51 or NLKUG) for the product, please indicate the minor uses (Minor Uses are defined in the list of Minor Uses).

If not, go to step 6

…….

……..

…….

……..

Step 6. What are the major uses of your product to be considered in a comparative assessment?
Please indicate the major uses in the tables under step 7, 8 and 9.

Step 7. Alternative authorised plant protection products with the same mode of action:
Is there an alternative authorised product with the same mode of action available for the major uses?
If yes, go to step 10. If the conclusion of step 10 is: it's no alternative, then go further to step 8.
If no, go to step 8.

Step 8. Alternative authorised plant protection products with their mode of action:
Please indicate all alternative authorised products for the major uses and their modes of action, including the product under consideration in the table below.
Please, mention the number of modes of action per crop-pest combination.

Crop	Pest	Product	Active substance	Mode of Action	RAC-code	Total number of modes of actions per crop/pest combination
Crop1	Pest1	1	AS1	MoA1	ABC	2
		2	AS2	MoA2	XYZ	
Crop1	Pest2	1	AS1	MoA1	ABC	1

Step 9. What other options (non-chemical methods) are available for the proposed uses to be assessed?
For all uses, please consider non-chemical alternatives in general or use by use, as appropriate. Indicate chemical alternatives under step 6.

Crop	Pest	Alternative	description of method

Are there 5 or more modes of action available for a use (including non-chemical methods)?

If yes, go to step 10

If no > **stop CA**

Step 10. Can the alternative products with the same mode of application and/or control methods be used without significant economic and practical disadvantages to the user ?

Please indicate significant economic and practical disadvantages (including mode of application, or difference in mitigation measures or ….) of using the alternative controls identified under step 7 and 8.

Alternative	Describe disadvantages per alternative in general or per use	Conclusion; Yes or no alternative
Methods		
Products		

Step 11. Consideration of consequences on minor uses (Art 50.1(d))

What would the consequences on the minor uses be if your product is replaced by a safer alternative product for any/some/all of those uses?

Examples of information that may be useful to consider here includes but is not limited to: the minor uses involved and the alternative products available for them; significance of the pest to the growing of those minor crops; usage data for both major and minor crops; marketing/sales/other commercial data of relevance to your product.

Step 12. Please indicate any other relevant information that will enable a comparison of risk.

Criteria low ADI/ARfD: see *Appendix I* of the Evaluation Manual, *General introduction and Generic aspects*, on how the comparative assessment will be conducted. This information can be used to provide a comparative assessment for this criteria.

Criteria low AOEL, classified Carcinogen 1A or 1B; classified as toxic for reproduction 1A or 1B; endocrine disruption; other reasons for concern: see *Appendix I* of the Evaluation Manual, *General introduction and Generic aspects* on how the comparative assessment will be conducted. This information can be used to provide a comparative assessment for this criteria.

Criteria PBT: see *Appendix I* of the Evaluation Manual, *General introduction and Generic aspects* on how the comparative assessment will be conducted. This information can be used to provide a comparative assessment for this criteria.