APPENDIX 11

FORMS FOR USE IN CHECKING DOSSIERS FOR COMPLETENESS

Part 1 **Evaluation Form 1 -**

for use in checking that the required supporting documentation has been provided

Active substance:	
Applicant:	
Date:	

Document	Description of the document - circumstances in which required	Document provided Y/N[#]	Official use only Data Gap Y/N[#]
A	Statement of the context in which the dossier is submitted - always required	__	__
B	Task Force Information, where relevant, to include -		
	* Member ship of the task force and a contact point for the task force	__	__
	* Contact point for each member of the task force	__	__
	* List of test and study reports generated by the task force - and details of task force members rights of access to the test and study reports generated by the task force - required where relevant	__	__
C	Existing or proposed labels, and where relevant leaflets for each preparation for which a dossier is submitted - required where requested	__	__
	Existing or proposed labels relevant to the uses on the basis of which existing MRLs or import tolerances are supported or new MRLs or import tolerances are proposed - required where requested	__	__
D-1	Details of intended uses (supported by the applicant and for which data are provided or are to be provided) and the conditions of use, on food and feed crops, and on non food and feed crops, in the territory of the country to which application is made, presented using the appropriate form - always required	__	__
D-2	A list of the registered uses in the country to which application is made, an indication of whether actually used and of the extent of use, presented using the appropriate form - required for existing active substances	__	__
D-3	Details of the intented uses (supported by the applicant and for which data are provided or are to be provided) and conditions of use (GAPs) in exporting countries, for which import tolerances are required, presented using the appropriate form - required for food or feed crops which are imported in significant quantities into the territory of the country to which application is made	__	__

[#] Y = yes; N = no

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 1** **Evaluation Form 1 Supporting Documentation**

Active substance: **Applicant:** **Date:**

Document	Description of the document - circumstances in which required	Document provided Y/N	Official use only Data Gap Y/N
E-1	Listing of MRLs in the country to which application is made, presented using the appropriate form - required for existing active substances	__	__
E-2	Listing of MRLs established in exporting countries, presented using the appropriate form - required where an import tolerance is proposed	__	__
	Listing of MRLs in other OECD countries, presented using the appropriate form - required where an import tolerance is proposed	__	__
F	A copy of each statement of intentent to submit in due course , a dossier or dossiers - required for existing active substances in countries in which such a requirement exists.	__	__
G	Whether permitted in food, animal feeding stuffs, medicines or cosmetics in accordance with the legislation of the country to which application is made - required for each formulant unless a dossier is provided for the formulant	__	__
H	Safety data sheet - required for each formulant	__	__
I	Other available toxicological and environmental data on the formulant - required if requested	__	__
J	Confidential data and information, to include -		
	* A listing of the data and information for which confidentiality is requested, cross referenced to the relevant test and study reports, dossier summaries and supporting documentation - always required	__	__
	* A justification for the claim to confidentiality for each item for which confidentiality is requested - always required	__	__
	* Highlighting of information contained in relevant study reports, dossier summaries and supporting documentation - required where the information concerned is provided in those documents	__	__
	* File containing confidential data and information - optional requirement	__	__

Part 2 Evaluation Form 2 -

for use in checking that the required active substance and formulated product dossier summaries and an overall assessment, have been provided

Active substance:	
Applicant:	
Date:	

Document	Description of the document - circumstances in which required	Document provided Y/N[#]	Official use only Data Gap Y/N[#]
L (active substance)	*Tier I* reports as to the quality of individual active substance test and study reports - always required	—	—
L (Reference List)	Listing of test and study reports, test guidelines and published papers relevant to the active substance dossier:-		
	- papers and reports submitted listed by test and study type	—	—
	- papers and reports submitted listed by alphabetically by author	—	—
	- list of papers and reports not submitted, arranged alphabetically by author	—	—
	- always required		
M (active substance)	*Tier II* active substance dossier summary and overall assessment - always required	—	—
L (formulation)	*Tier I* reports as to the quality of individual test and study reports for each formulated product for which a dossier was submitted - always required		
	* First preparation	—	—
	* Second preparation	—	—
	* Third preparation	—	—
	* Fourth preparation	—	—
L (Reference List)	Listing of test and study reports, test guidelines and published papers relevant to each formulated product dossier - always required		
	* First preparation		
	- papers and reports submitted listed by Annex point	—	—
	- papers and reports submitted listed by alphabetically by author	—	—
	- list of papers and reports not submitted, arranged alphabetically by author	—	—
	* Second preparation		
	- papers and reports submitted listed by Annex point	—	—
	- papers and reports submitted listed by alphabetically by author	—	—
	- list of papers and reports not submitted, arranged alphabetically by author	—	—

[#] Y = yes; N = no

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 2** **Evaluation Form 2 Dossier Summaries and Overall Assessment**

Active substance: **Applicant:** **Date:**

Document	Description of the document - circumstances in which required	Document provided Y/N	Official use only Data Gap Y/N
	* Third preparation		
	- papers and reports submitted listed by Annex point	__	__
	- papers and reports submitted listed by alphabetically by author	__	__
	- list of papers and reports not submitted, arranged alphabetically by author	__	__
	* Fourth preparation		
	- papers and reports submitted listed by Annex point	__	__
	- papers and reports submitted listed by alphabetically by author	__	__
	- list of papers and reports not submitted, arranged alphabetically by author	__	__
M (formulation)	*Tier II* dossier summary and overall assessment for each formulated product for which a dossier was submitted - always required		
	* First preparation	__	__
	* Second preparation	__	__
	* Third preparation	__	__
	* Fourth preparation	__	__
N	An overall summary and assessment of the application - always required	__	__

Part 3 **Evaluation Form 5 -**

for use in checking that the *Tier I* quality checks for individual tests and studies are of acceptable quality [31]

Active Substance
Applicant:
Date:

Test or Study Point	Description of the requirement	Provided Y/N[#]
1.1	The data point addressed	__
1.2	A descriptive title of the type of test or study	__
2	Reference point (location) of the report in the dossier (*e.g.* volume, section and point)	__
3.1	The names of the authors	__
3.2	The title of the report	__
3.3	The owner of test or study the report	__
3.4	An indication as to whether it is a published or unpublished report	__
3.5	The report number	__
3.6	The date of the report	__
4.1	The name and address of the testing facility involved	__
4.2	The laboratory report/project number	__
5.1	The dates of commencement and completion of experimental work	__
5.1	A statement of the objectives of the test or study	__
6.1	The identity of the test substance or material (ISO common name, batch number and degree of purity)	__
6.2	An explicit reference to the relevant specification of composition of the test substance or material	__

[#] Y = yes; N = no

[31] Relevant for tests and studies for which the test methods used were not those currently specified (*e.g.* certain older studies)

Active Substance: **Applicant:** **Date:**

Test or Study Title: **Data Point:**

Test or Study Point	Description of the requirement	Provided Y/N
6.3	Where available, data relevant to the storage stability of the test substance or material	__
6.4	Where relevant and available, data as to the stability of the test substance or material in the dosing vehicle	__
6.5	Where relevant and available, data as to the homogeneity of the test substance or material in the dosing or testing vehicle	__
6.6	Where data relating to the stability or homogeneity of the test substance is not available (*e.g.* certain older studies), a justification of the scientific validity of the study	__
6.7	Where relevant, information as to the physical form of the test substance or material	__
6.8	Full details of the composition of any dosing vehicles or solvents used	__
7.1	The identity of the test method used	__
7.2	Where not a method specified, a reasoned justification for the choice of method used in terms of its scientific validity and comparability with the method currently specified	__
7.3	On request, a copy of the method - full details of methods used which are unlikely to be accessible to the regulatory authority of the country to which the dossier is submitted, should be attached to the study or test report	__
7.4	Where test guidelines provide choice as to the method to be used, a reasoned justification for the choice made	__
7.5	Where deviations from the test guidelines specified, or from other methods used, are employed, a description of and reasoned justification for the deviations	__
8.1	Where relevant, an indication as to whether, or not, the test or study has been conducted by a laboratory certified as to its competence to conduct the test or study in compliance with the principles of GLP	__
8.2	Where relevant, the certifying authority	__
8.3	Where applicable, an indication as to whether, or not, the principles of GLP have been complied with	__
8.4	Where relevant, a justification for non compliance with the principles of GLP	__

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 3** **Evaluation Form 5 *Tier I* Quality Checks**

Active Substance: **Applicant:** **Date:**

Test or Study Title: **Data Point:**

Test or Study Point	Description of the requirement	Provided Y/N
9.1	Where relevant, a clear statement that the requirements relating to compliance with the principles of Good Experimental Practice (GEP) have been complied with	__
9.2	Where the requirements relating to compliance with the principles of GEP apply, whether conducted by an official or an officially recognized testing facility or organization	__
9.3	Where relevant, a justification for non compliance with the principles of GEP	__
10	A description of the test system	__
11	The identity of any statistical and other techniques applied to the data to aid interpretation, together with adequate documentation thereof and a justification for the use of the technique selected where non standard techniques are used	__
12.1	Where reference to published papers is made in *Tier I* checks as to the quality of individual test and study reports, the bibliographic references concerned	__
12.2	On request, copies of the papers concerned	__
13	Where reference to unpublished data is made in *Tier I* checks as to the quality of individual test and study reports (*e.g.* historical control data on strains of test animals) a summary of such data	__

Assessment of the Acceptability of the Quality of the Report

Report of acceptable quality ☐ Yes ☐ No

Comments:

Signature: