

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: PHEROMONE

Applicant:

Date: APRIL 2001

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	Documentation relating to the joint submission of dossiers - * Claim that all reasonable steps were taken * Documentation to support the claim made - required for existing active substances for which there is more than one notifier, where a joint dossier was not submitted by all notifiers	— —	— —
C	Existing or proposed labels, and where relevant leaflets for each preparation for which an Annex III 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 EU, presented using the appropriate form - always required	—	—
D-2	A list of the authorized uses in the EU, an indication of whether actually used and of the extent of use, presented using the appropriate form - required for existing active substances	—	—

* To be completed by the Competent Authority of the Member State to which application is made

[#] Y = yes; N = no

Active substance:

Applicant:

Date:

Document	Description of the document - circumstances in which required	Document provided Y/N	Official use only Data Gap Y/N
F	A copy of each notification submitted to the Commission - required for existing active substances	—	—
G	Whether permitted in food, animal feeding stuffs, medicines or cosmetics in accordance with EU legislation - required for each formulant unless an Annex II dossier is provided for the formulant	—	—
H	Safety data sheet prepared in accordance with Directive 67/548/EEC - 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	— — — —	— — — —