Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive (Text with EEA relevance)

Article 3

Dossiers

1 The summary dossier shall include the following:

a data with respect to one or more representative uses of at least one plant protection product containing the active substance, demonstrating that the requirements of Article 5 of Directive 91/414/EEC are fulfilled;

b for each point of the data requirements for the active substance referred to in Annex II to Directive 91/414/EEC, the summaries and results of tests and studies, the name of their owner and of the person or institute that carried out the tests and studies;

c for each point of the data requirements for the plant protection product referred to in Annex III to Directive 91/414/EEC, the summaries and results of tests and studies, the name of their owner and of the person or institute that carried out the tests and studies relevant to the assessment of the criteria referred to in Article 5 of that Directive taking into account that data gaps in a dossier, as set out in Annex II or Annex III to that Directive, resulting from the proposed range of representative uses, may lead to restrictions in the inclusion in Annex I to that Directive;

d a checklist demonstrating that the dossier provided for in paragraph 2 is complete;

e the reasons why the test and study reports submitted are necessary for inclusion of the active substance concerned;

f an assessment of all information submitted;

g where relevant, a copy of an application for a residue level as referred to in Article 7 of Regulation (EC) No 396/2005 of the European Parliament and of the Council[1] or a justification for not supplying such copy of an application.

2 The complete dossier shall contain the full text of the individual test and study reports concerning all the information referred to in points (b) and (c) of paragraph 1 with a list of those tests and studies.

(**1**) OJ L 70, 16.3.2005, p. 1.