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ANNEX 5

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**Report on
THE IMPACT ASSESSMENT FOR A REGULATION REPLACING DIRECTIVE
91/414/EEC ON PLANT PROTECTION PRODUCTS**

Annex 5

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Lead DG: SANCO

**Other involved services (Members of the Inter-Services Steering Group): SG, SJ,
ECFIN, ENTR, COMP, AGRI, MARKT, EMPL, ENV, TRADE, and BUDG**

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Annex 5

Measures assessed earlier in a different context

A couple of measures taken into account in the proposal have not been subject to a new, detailed assessment, because they are either required to bring the text in coherence with other EU policies or because the working experience that has been gained so far showed that some of measures contained in Directive 91/414/EEC were not sufficient to fulfil the objectives defined and therefore, those provisions are adjusted in the current proposal in order to optimise them.

These measures are:

- The legal status of the text will change from a Council Directive to a Regulation of the European Parliament and the Council (harmonised implementation throughout EU)
- Widening the scope of the text to include safeners, synergists and co-formulants: Safeners and synergists contained in plant protection products should be assessed in an approach comparable to that for active substances; harmful co-formulants should not be contained in plant protection products. (harmonised implementation throughout the EU and high level of protection of human and animal health and of the environment)
- Introducing criteria for approval of active substances at EU level (increase the efficiency of the system by streamlining the procedures)
- Setting deadlines for all stakeholders participating in the process for approval of active substances and/or authorisation of plant protection products (the aim is to increase the efficiency of the system – first objective)
- Synchronising timelines for approval of active substances and granting authorisations by Member States (simplify the procedures)
- Setting procedures for “low risk” and “basic” substances and extending the time for approval of “low risk” substances (increase the efficiency of the system)
- Defining the role of European Food Safety Authority (EFSA) (better definition of procedures)
- Avoiding duplication of tests on vertebrate animals (coherence with general EU policy)
- Setting the procedures for authorization of plant protection products containing GMOs (coherence with general EU policy)
- Labelling of plant protection products according to Directive 1999/45/EC (coherence with general EU policy)
- Obligation for record keeping by farmers as already foreseen for food producing farmers in Regulation (EC) No 882/2004 (coherence with general EU policy)
- Setting rules for the advertisement of plant protection products (coherence with general EU policy)
- Defining roles and competencies of the Commission in inspection and in monitoring inspection programmes that Member States are carrying out (better definition of procedures)
- Possibility for Member States to establish fees and charges (increase the efficiency of the system)
- Procedures for access to information (coherence with general EU policy)

- Linking the authorisation of plant protection products and the MRL setting (streamlining the procedures)
- Clarification of the status of non-approved active substances by repealing Directive 79/117/EEC (simplification of procedures)
- Synchronising the periods of approval of active substances and of authorisation of related plant protection products (streamlining of procedures)
- Speeding up the entry on the market of active substances by establishing a parallel procedure for the evaluation of the requests for approval and authorisation (streamlining of procedure)
- Setting rules for checking the equivalence of technical material (increase the level of harmonisation)
- Setting rules for issuing guidance documents (increase the level of harmonisation)
- Providing the Commission with the possibility for expenditure (increase the level of harmonisation)