EU Regulation Pesticides

History of plant protection product registration

Plant protection products are substances or formulations that are used to protect plants or plant products against harmful organisms, to influence the life of the plant (except for nutrients), preserve plant products, destroy undesired plants, and to prevent the growth of undesired plants. Their wide use in agriculture and horticulture means it is inevitable for them to come into contact with users, producers and/or consumers. The EU, in the wide-reaching Directive 91/414, has evaluated over 1200 existing substances, as well as continually evaluating newly-developed substances under Regulation 1107/2009, for their use in plant protection product formulations. Only those substances which have minimal risk to human, animal and the environment were included in Annex I of Council Directive 91/414/EEC until 2011 and are now approved as active substances under Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. Under 91/414/EEC, the existing active substances were grouped into 4 individual lists governed by individual sets of legislation for their respective regulatory procedures. Lists 2, 3 and 4 were subject to revised procedures, which were laid down in the following pieces of legislation:

- COM REG 1095/2007 (071120) laying down further detailed rules for the implementation of the 3rd and 4th stage of the program of work
- COM REG 33/2008 regular and accelerated procedure for the assessment of active substances
- COM REG (EU) No 741/2010 of 17 August 2010 amending Regulations (EC) No 1490/2002 and (EC) No 2229/2004 as regards the date until which authorizations may continue to be in force in cases where the notifier has submitted an application in accordance with the accelerated procedure under Regulation (EC) No 33/2008
- COM DECISION of 13 August 2010 amending Decisions 2008/934/EC and 2008/941/EC as regards the date until which authorizations may continue to be in force and the period of grace, in cases where the notifier has not submitted an application in accordance with the accelerated procedure under
Renewal of approval of active substances is laid down in Commission implementing regulation (EU) No 844/2012 of 18 September 2012, setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009. The timeline to submit the supplementary dossier for renewal is three years prior to the expiry date of the active substance, with pre-notification given another six months prior to dossier submission.

Renewal procedure

Four groups of substances (AIR 1 to AIR 5) are distinguished for renewal by the following legislation:

AIR 1
- COMMISSION DIRECTIVE 2007/21 lays down the renewal of the first group of active substances, with procedure for renewal described in COMMISSION REGULATION 737/2007

AIR 2
- COMMISSION REGULATION 1141/2010 lays down the renewal of the second group of active substances, with SANCO/11808/2011 describing the procedure of the renewal
- COMMISSION IMPLEMENTING REGULATION (EU) 2015/1885 of 20 October 2015 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-D, acibenzolar-s-methyl, amitrole, bentazone, cyhalofop butyl, diquat, esfenvalerate, famoxadone, flumioxazine, DPX KE 459 (flupyrsulfuron-methyl), glyphosate, iprovalicarb, isoproturon, lambda-cyhalothrin, metalaxyl-M, metsulfuron methyl, picolinafen, prosulfuron, pymetrozine, pyraflufen-ethyl, thiametoxam, thifensulfuron-methyl and triasulfuron
- COMMISSION REGULATION (EU) 2015/1475 of 27 August 2015 amending Regulation (EU) No 284/2013 as regards the transitional measures applying to procedures concerning plant protection products
- COMMISSION IMPLEMENTING REGULATION (EU) 2016/549 of 8 April 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances bentazone, cyhalofop butyl, diquat, famoxadone, flumioxazine, DPX KE 459 (flupyrsulfuron-methyl), metalaxyl-M, metsulfuron, prosulfuron, pymetrozine, thiametoxam and thifensulfuron-methyl

AIR 3
- COMMISSION IMPLEMENTING REGULATION (EU) No 686/2012 lays down the renewal of the third group of active substances, with SANCO/2012/11251 rev. 4 DRAFT as a guidance document on the renewal of approval of active substances
- COMMISSION REGULATION (EU) No 823/2012 of 14 September 2012 derogating from Implementing Regulation (EU) No 540/2011 as regards the expiry dates of the approval of the active substances 2,4-DB, benzoic acid, beta-cyfluthrin, carfenptrazole ethyl, Coniothyrium minitans Strain CON/M/91-08 (DSM 9660), cyazoxyfifamid, cyfluthrin, deltamethrin, dimethenamid-P, ethofumesate, ethoxysulfuron, fenamidone, flazasulfuron, flufenacet, flurtamone, foramsulfuron, fosfiazate, imazamox,
iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mecoprop, mecoprop-P, mesosulfuron, mesotrione, oxadiargyl, oxasulfuron, pendimethalin, picoxystrobin, propiconazole, propineb, propoxycarbazone, propyzamide, pyraclostrobin, silthiofam, trifloxystrobin, warfarin and zoxamide


**AIR4**

- A regulation is under discussion (status 2015), laying down the renewal of the forth group of active substances

- COMMISSION IMPLEMENTING REGULATION (EU) 2016/183 of 11 February 2016 amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest


- COMMISSION IMPLEMENTING REGULATION (EU) 2018/155 of 31 January 2018 amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of active substances

- COMMISSION IMPLEMENTING REGULATION (EU) 2016/183 of 11 February 2016 amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest

- COMMISSION IMPLEMENTING REGULATION (EU) 2016/183 of 11 February 2016 amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest

- SANTE-2016-10616–rev 6, February 2017 - DRAFT WORKING DOCUMENT AIR IV RENEWAL PROGRAMME

**AIR5/6**


- COMMISSION IMPLEMENTING REGULATION (EU) No 686/2012 of 26 July 2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest

- COMMISSION IMPLEMENTING REGULATION (EU) 2018/155 of 31 January 2018 amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of active substances

- SANTE-2018-10048–rev 1, June 2018 - DRAFT WORKING DOCUMENT ESTABLISHING THE FIFTH RENEWAL PROGRAMME

Please refer to SCC’s home page (https://www.scc-gmbh.de/business-units/agrochemicals)
The information regarding the topic "EU Regulation Pesticides" displayed on this website were provided by SCC.

During our more than 25-year history Scientific Consulting Company – SCC GmbH – has become one of Europe's largest privately-owned and independent consulting companies supporting global customers in the regulatory affairs business.

SCC is located in Bad Kreuznach, Germany, an hour's drive west of Frankfurt am Main. Please refer to SCC's home page (https://www.scc-gmbh.de/business-units/agrochemicals-biorational) for more information about available services relating to EU Regulation Pesticides.

Discover the world of SCC on our website: www.scc-gmbh.de

Contact us: Open Contact form or send us an email at scc@scc-gmbh.de