Annex I

List of Regulations including requests for confirmatory information under Regulation (EC) No 1107/2009

Regulation	Entries in Part B of Annex to Reg. 540/2011	Confirmatory information	type of request
Commission Implementing Regulation (EU) 2015/1192 of 20 July 2015 approving the active substance terpenoid blend QRD 460 (OJ L 193, 21.7.2015, p. 124)	84 - terpenoid blend	The applicant shall submit confirmatory information as regards: (1) the technical specification of the active substance as manufactured (5 batch analysis for the blend should be provided), supported by acceptable and validated methods of analysis. It should be confirmed that there are no relevant impurities present in the technical material; (2) the equivalence of the material used in the toxicological and ecotoxicological studies with the confirmed technical specification. The applicant shall submit that information to the Commission, the Member States and the Authority by 10 February 2016.	Technical specification of the active substance & equivalence of material used in tox. and ecotox. testing.
Commission Implementing Regulation (EU) 2015/1165 of 15 July 2015 approving the active substance halauxifen-methyl (OJ L 188, 16.7.2015, p. 30)	86 - halauxifen-methyl	The applicant shall submit confirmatory information as regards: — The technical specification of the active substance as manufactured (based on commercial scale production). The relevance of impurities present in the technical material should be confirmed, — The compliance of the toxicity batches with the technical specification. The applicant shall submit that information to the Commission, the Member States and the Authority by 5 February 2016.	Technical specification of the active substance & equivalence of material used in tox. and ecotox. testing
Commission Implementing Regulation (EU) 2015/1295 of 27 July 2015 approving the active substance sulfoxaflor (OJ L 199, 29.7.2015, p. 8)	88 - Sulfoxaflor	The applicant shall submit confirmatory information as regards: (1) the risk to honey bees via the different routes of exposure, in particular nectar, pollen, guttation fluid and dust; (2) risk to honey bees foraging in nectar or pollen in succeeding crops and flowering weeds; (3) the risk to pollinators other than honey bees; (4) the risk to bee brood. The applicant shall submit that information to the Commission, the Member States and the Authority by 18 August 2017.	Bee and other pollinators risk assessment

Commission Implementing Regulation (EU) 2015/2084 of 18 November 2015 approving the active substance flupyradifurone (OJ L 302, 19.11.2015, p. 89)	91 - flupyradifurone	The applicant shall submit confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of some individual impurities, (2) the compliance of the toxicity batches with the confirmed technical specification, (3) the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water. The applicant shall submit to the Commission, the Member States and the Authority the information requested under point (1) and (2) by 9 June 2016, the information requested under point (3) within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.	Technical specification of the active substance & equivalence of material used in tox. and ecotox. testing effect of water treatment processes
Commission Implementing Regulation (EU) 2015/2085 of 18 November 2015 approving the active substance mandestrobin (OJ L 302, 19.11.2015, p. 93)	93 Mandestrobin	The applicant shall submit confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of some individual impurities; (2) the compliance of the toxicity batches with the confirmed technical specification. The applicant shall submit that information to the Commission, the Member States and the Authority by 9 June 2016.	Technical specification of the active substance & equivalence of material used in tox. and ecotox. testing
Commission Implementing Regulation (EU) 2015/2033 of 13 November 2015 renewing the approval of the active substance 2,4-D (OJ L 298, 14.11.2015, p. 8)	94 - 2,4 D	The notifier shall submit to the Commission, the Member States and the Authority: (1) confirmatory information in the form of the submission of the complete study results from the existing extended one-generation study; (2) confirmatory information in the form of the submission of the Amphibian Metamorphosis Assay (AMA) (OECD (2009) Test No 231) as to verify the potential endocrine properties of the substance. The information set out in point (1) shall be submitted by 4 June 2016 and the information set out in point (2) by 4 December 2017.	studies related to potential ED properties
Commission Implementing Regulation	96 - Iprovalicarb	The applicant shall submit to the Commission, the Member	confirm non-genotoxicity of

(EU) 2016/147 of 4 February 2016 renewing the approval of the active substance (OJ L 30, 5.2.2016, p. 12)		States and the Authority, confirmatory information as regards the genotoxic potential of soil metabolite PMPA. This information shall be submitted by 30 September 2016.	metabolite
Commission Implementing Regulation (EU) 2016/389 of 17 March 2016 renewing the approval of the active substance acibenzolar-S-methyl (OJ L 73, 18.3.2016, p. 77)	98 - Acibenzolar-S-methyl	The applicant shall by 1 June 2017 submit to the Commission, the Member States and the Authority, confirmatory information as regards the relevance and reproducibility of the morphometric changes observed in the cerebellum of foetuses linked to exposure to acibenzolar-S-methyl and whether these changes may be produced via an endocrine mode of action. The information to be submitted shall include a systematic review of the available evidence assessed on the basis of available guidance (e.g. EFSA GD on Systematic Review methodology, 2010).	studies related to potential ED properties
Commission Implementing Regulation (EU) 2016/1414 of 24 August 2016 approving the active substance cyantraniliprole, (OJ L 230, 25.8.2016, p. 16)	99 - Cyantraniliprole	The applicant shall submit to the Commission, Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.)	effect of water treatment processes
Commission Implementing Regulation (EU) 2016/1425 of 25 August 2016 approving the active substance isofetamid (OJ L 231, 26.8.2016, p. 30)	100 - Isofetamid	The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities; (2) the compliance of the toxicity and ecotoxicity batches with the confirmed technical specification; (3) the effect of water treatment process chlorination on the nature of residues, including the potential for the formation of chlorinated residues that may be formed from residues present in surface water, when surface water is abstracted for drinking water. The applicant shall submit the information requested under points (1) and (2) by 15 March 2017 and the information	Technical specification of the active substance & equivalence of material used in tox. and ecotox. testing effect of water treatment processes

		requested under point (3) within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.	
Commission Implementing Regulation (EU) 2016/1424 of 25 August 2016 renewing the approval of the active substance thifensulfuron-methyl (OJ L 231, 26.8.2016, p. 25)	104 - Thifensulfuron-methyl	The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1) the absence of genotoxicity of metabolites IN-A4098 and its derivative IN-B5528, IN-A5546 and IN-W8268; (2) mechanistic data to rule out an endocrine mediated mode of action for mammary gland tumours; (3) the risk to aquatic organisms from thifensulfuron-methyl and metabolite IN-D8858 and the risk to soil organisms from metabolites IN-JZ789 and 2 acid 3 triuret; (4) the relevance of the metabolites IN-A4098, IN-L9223 and IN-JZ789 if thifensulfuron-methyl is classified as reprotoxic category 2 under Regulation (EC) No 1272/2008 and the risk that those metabolites contaminate groundwater. The applicant shall submit the information requested under point (1) by 31 March 2017, under points (2) and (3) by 30 June 2017 and under point (4) within six months after the notification of the classification decision concerning thifensulfuron-methyl	confirm non-genotoxicity of metabolites data to exclude ED properties risk to aquatic organisms and risk to soil organisms Relevance of the metabolites if the substance is classified as reprotoxic category 2 under Regulation (EC) No 1272/2008 and the risk that those metabolites contaminate groundwater
Commission Implementing Regulation (EU) 2017/157 of 30 January 2017 renewing the approval of the active substance thiabendazole (OJ L 25, 31.1.2017, p. 5)	105 - Thiabendazole	The applicant shall submit by 31 March 2019 to the Commission, the Member States and the Authority confirmatory information regarding Level 2 tests as currently indicated in the OECD Conceptual Framework investigating the potential for endocrine-mediated effects of thiabendazole.	studies related to potential ED properties
Commission Implementing Regulation (EU) 2017/239 of 10 February 2017 approving the active substance oxathiapiprolin (OJ L 36, 11.2.2017, p.39)	106 - Oxathiapiprolin	The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities; (2) the compliance of the toxicity and ecotoxicity batches with the confirmed technical specification. The applicant shall submit the information requested under	Technical specification of the active substance & equivalence of material used in tox. and ecotox. testing

		points (1) and (2) by 3 September 2017.	
Commission Implementing Regulation (EU) 2017/407 of 8 March 2017 renewing the approval of the active substance iodosulfuron (OJ L 63, 9.3.2017, p. 87)	107 - Iodosulfuron	The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1) the genotoxic potential of the metabolite triazine-amine (IN-A4098), in order to confirm that this metabolite is not genotoxic and not relevant for the risk assessment; (2) the effect of water treatment processes on the nature of residues present in drinking water. The applicant shall submit the information requested under point (1) by 1 October 2017 and the information requested under point (2) by two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.	Confirm non-genotoxicity of metabolite effect of water treatment processes
Commission Implementing Regulation (EU) 2017/805 of 11 May 2017 renewing the approval of the active substance (OJ L 121, 12.5.2017, p. 26)	108 - Flazasulfuron	The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water within a period of two years a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.'	effect of water treatment processes
Commission Implementing Regulation (EU) 2017/755 of 28 April 2017 renewing the approval of the active substance mesosulfuron (OJ L 113, 29.4.2017, p. 35)	111 - mesosulfuron	The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water within a period of two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.'	effect of water treatment processes
Commission Implementing Regulation (EU) 2017/725 of 24 April 2017 renewing the approval of the active substance mesotrione (OJ L 107, 25.4.2017, p. 24)	112 - mesotrione	The applicant shall submit confirmatory information as regards: (1) the genotoxic profile of the metabolite AMBA; (2) the potential endocrine disrupting mode of action of the active substance in particular level 2 and 3 tests, currently indicated in the OECD Conceptual framework (OECD 2012) and analysed in the EFSA Scientific opinion on the hazard assessment of endocrine disruptors; (3) the effect of water treatment processes on the nature of	Confirm non-genotoxicity of metabolite studies related to potential ED properties

		residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water. The applicant shall submit to the Commission, the Member States and the Authority the relevant information requested under point 1 by 1 July 2017 and the relevant information requested under point 2 by 31 December 2017. The applicant shall submit to the Commission, the Member States and the Authority the confirmatory information requested under point 3 within a period of two years after a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.'	effect of water treatment processes
Commission Implementing Regulation (EU) 2017/1115 of 22 June 2017 renewing the approval of the active substance propoxycarbazone (OJ L 162, 23.6.2017, p. 38)	114 - propoxycarbazone	The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water within a period of 2 years of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.	effect of water treatment processes

Regulation	Entries in Part E of Annex to 540/2011 Candidates for substitutions	Confirmatory information	Type of request
Commission Implementing Regulation (EU) 2015/2105 of 20 November 2015 approving the active substance flumetralin, as a candidate for substitution (OJ L 305, 21.11.2015, p. 31)	1 - Flumetralin	The applicant shall submit confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production); (2) the compliance of the toxicity batches with the confirmed technical specification. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in points 1 and 2 by 11 June 2016.	Technical specification of the active substance & equivalence of material used in tox. and ecotox. testing
Commission Implementing Regulation (EU) 2016/139 of 2 February 2016 renewing the approval of the active substance metsulfuron-methyl, as a candidate for substitution (OJ L 27, 3.2.2016, p. 7)	3 - Metsulfuron-methyl	The applicant shall submit to the Commission, the Member States and the Authority by 30 September 2016 confirmatory information as regards the genotoxic potential of the metabolite triazine-amine (IN-A4098) to confirm that this metabolite is not genotoxic and not relevant for risk assessment.	confirm non-genotoxicity of metabolites
Commission Implementing Regulation (EU) 2016/177 of 10 February 2016 approving the active substance benzovindiflupyr, as a candidate for substitution (OJ L 35, 11.2.2016, p. 1)	4 - Benzovindiflupyr	The applicant shall submit confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities; (2) the compliance of the toxicity and ecotoxicity batches with the confirmed technical specification; (3) the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water. The applicant shall submit to the Commission, the Member States and the Authority the information requested under points (1) and (2) by 2 September 2016 and the information requested under point (3) within two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.	Technical specification of the active substance & equivalence of material used in tox. and ecotox. testing effect of water treatment processes
Commission Implementing Regulation (EU) 2016/146 of 4 February 2016 renewing the approval of the active	5 - Lambda-Cyhalothrin	The applicants shall submit confirmatory information as regards: (1) a systematic review to assess the evidence available as regards potential sperm effects linked to exposure to lambda-cyhalothrin	Review of available evidence related to potential ED properties

substance lambda-cyhalothrin, as a candidate for substitution (OJ L 30, 5.2.2016, p. 7)		using guidance available (e.g. EFSA GD on Systematic Review methodology, 2010); (2) toxicological information to assess the toxicological profile of the metabolites V (PBA) and XXIII (PBA(OH)). The applicants shall submit those information to the Commission, the Member States and the Authority by 1 April 2018.	Information on toxicological profile of metabolites.
Commission Implementing Regulation (EU) 2017/375 of 2 March 2017 renewing the approval of the active substance prosulfuron, as a candidate for substitution, (OJ L 58, 4.3.2017, p. 3)	6 - prosulfuron	The applicant shall submit confirmatory information as regards the genotoxic potential of the metabolite triazine-amine (CGA150829) to confirm that this metabolite is not genotoxic and not relevant for risk assessment. The applicant shall submit that information to the Commission, the Member States and the Authority by 31 October 2017.	confirm non-genotoxicity of metabolite
Commission Implementing Regulation (EU) 2017/1114 of 22 June 2017 renewing the approval of the active substance pendimethalin, as a candidate for substitution (OJ L 162, 23.6.2017, p. 32)	7 - Pendimethalin	The applicant shall submit confirmatory information to the Commission, the Member States and the Authority as regards: 1. the potential for bioaccumulation, in particular a reliable BCF value for bluegill sunfish (Lepomis macrochirus); 2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water. The applicant shall submit the confirmatory information requested under point 1 by 31 December 2018. The applicant shall submit the confirmatory information requested under point 2 within a period of two years of the publication by the Commission of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.	bioaccumulation in bluegill sunfish effect of water treatment processes