

Proposed changes to Annexes II and III of GB BPR

This document contains tables that summarise the articles in GB BPR annexes II and III as they currently stand, alongside the suggested replacements for those points which have been drafted with input from specialist colleagues. The changes are to be made in line with article 85 of GB BPR, to ensure we are keeping step with scientific and technical advances, and these tables will form the basis of the SI instructions.

Annex II Changes

	Current GB BPR Wording	Suggested new wording
Point 2 Paragraph 5	The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set down in Article 62(2), applicants may also consult with the competent authority with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out.	The applicant shall initiate a pre-submission consultation with the prospective evaluating body. In addition to the obligation set out in Article 62(2), applicant may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out. The applicant shall document such pre-submission consultations and their outcomes and shall include the relevant documents in the application.
Point 5	3. Tests submitted for the purpose of the approval of an active substance shall be conducted according to the methods described in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ⁽¹⁾ . However, if a method is inappropriate or not described, other methods shall be used which are scientifically appropriate, whenever possible internationally recognised, and their appropriateness must be justified in the application. When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations/ adjustments that have been made in order to respond to the specific characteristics of these materials.	Tests submitted for the purpose of the approval of an active substance shall be conducted in accordance with the methods described in Commission Regulation (EC) No 440/2008 (*1), or any revised version of these methods not yet included in that Regulation. However, if a method is inappropriate or not described in Commission Regulation (EC) No 440/2008, other methods shall be used which are scientifically appropriate and their appropriateness shall be justified in the application. When test methods are applied to nano-materials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of these materials.

Title one table

	Current GB BPR Wording			Suggested new wording		
Heading of column 3	Information required	All data is CDS unless indicated as ADS	Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates	Information required	All data is CDS unless indicated as ADS	Specific rules for adaptation from column 1
row 2	IDENTITY OF THE ACTIVE SUBSTANCE - For the active substance, the information given in this Section shall be sufficient to enable the active substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated			IDENTITY OF THE ACTIVE SUBSTANCE (AND ITS PRECURSOR(S) IF THE ACTIVE SUBSTANCE IS GENERATED <i>IN SITU</i>) - For the active substance and, if applicable, its precursors, the information given in this Section shall be sufficient to enable the active substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items listed in this Section, the reasons shall be clearly stated		
row 2.5	Molecular and structural formula (including SMILES notation, if available and appropriate)			Molecular and structural formula (including SMILES notation, if available and appropriate). For precursor(s) and for active substances generated in situ, information about all generated chemical substances (intended and unintended)		In case it is not possible to exactly define the molecular structure of the precursor(s) and/or active substance, the molecular and structural formulas do not need to be provided.
row 2.8	Method of manufacture (syntheses pathway) of active substance including information on starting materials and solvents including suppliers, specifications and commercial availability			Method of manufacture (syntheses pathways) of active substance including information on starting materials and solvents including suppliers, specifications and commercial availability. For active substances generated in situ, a		

				description of the reaction schemes including all intermediate reactions and their associated chemical substances (intended and unintended) shall be provided		
row 2.11.1	N/A - NEW INSERTION			Analytical profile of at least five representative samples taken from the in situ generated substance(s), providing information on the content of the active substance(s), any other constituent above 0.1 % w/w, including residues of precursor(s), and where relevant any additional impurities referred to in 2.10.		
row 6.6	Efficacy data to support these claims on biocidal products and, where label claims are made, on treated articles, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate			Efficacy data to support: - the innate activity of the active substance for the intended use(s), and Efficacy data shall include any available standard protocols, laboratory tests or field trials and performance standards where appropriate, or data similar to those available for suitable reference products		
row 6.7.2	Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms			Observations on undesirable or unintended side effects on non-target organisms or on objects and material to be protected		
8.1.	Skin irritation or skin corrosion The assessment of this endpoint shall be carried out according to the sequential testing strategy for dermal irritation and corrosion set out in the Appendix to Test Guideline B.4. Acute Toxicity-Dermal Irritation/Corrosion			Skin corrosion or irritation The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data; (b) skin corrosion, <i>in vitro</i> testing;		The study/ies in column 1 do(es) not need to be conducted if: the available information indicates that the substance meets the criteria for classification for skin corrosion or irritation,

	(Annex B.4. to Regulation (EC) No 440/2008)			(c) skin irritation, <i>in vitro</i> testing; (d) skin corrosion or irritation, <i>in vivo</i> testing	<p>the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5), the substance is spontaneously flammable in air or in contact with water or moisture at room temperature,</p> <p>the substance meets the classification criteria for acute toxicity (Category 1) by the dermal route, or an acute toxicity study by the dermal route provides conclusive evidence on skin corrosion or irritation adequate for classification.</p> <p>If results from one of the two studies listed in point (b) or point (c) in column 1 of this row already allow conclusive decision on the classification of a substance or on the absence of skin irritation potential, the second study does not need to be conducted.</p> <p>An <i>in vivo</i> study for skin corrosion or irritation shall be considered only if the <i>in vitro</i> studies listed in points (b) and (c) in column 1 of this row are not applicable, or the results of these studies are not adequate for classification and risk assessment <i>In vivo</i> studies for skin corrosion or irritation that were carried out or initiated before [IMPLEMENTATION DATE] shall be considered appropriate to address this information requirement</p>
8.2.	<p>Eye irritation</p> <p>The assessment of this endpoint shall be carried out according to the sequential testing strategy for eye irritation and corrosion as set down in the Appendix to Test Guideline</p>			<p>Serious eye damage or eye irritation</p> <p>The assessment shall comprise the following tiers:</p>	<p>The study/ies in column 1 do(es) not need to be conducted if: the available information indicates that the substance meets the criteria</p>

	<p>B.5.Acute Toxicity: Eye Irritation/Corrosion (Annex B.5. to Regulation (EC) No 440/2008)</p>			<p>(a) assessment of the available human, animal and non-animal data; (b) serious eye damage or eye irritation, <i>in vitro</i> testing; (c) serious eye damage or eye irritation, <i>in vivo</i> testing</p>	<p>for classification for eye irritation or causing serious damage to eyes, the substance is a strong acid ($\text{pH} \leq 2,0$) or base ($\text{pH} \geq 11,5$), the substance is spontaneously flammable in air or in contact with water or moisture at room temperature, or the substance meets the classification criteria for skin corrosion leading to classification of the substance as “serious eye damage” (category 1).</p> <p>If results from a first <i>in vitro</i> study do not allow a conclusive decision on the classification of the substance or on the absence of eye irritation potential (an)other(s) <i>in vitro</i> study(ies) for this endpoint shall be considered. An <i>in vivo</i> study for serious eye damage or eye irritation shall be considered only if the <i>in vitro</i> study(ies) listed in point (b) in column 1 of this row are not applicable, or the results obtained from these studies are not adequate for classification and risk assessment <i>In vivo</i> studies for serious eye damage or eye irritation that were carried out or initiated before [IMPLEMENTATION DATE] shall be considered appropriate to address this information requirement</p>
<p>8.3.</p>	<p>Skin sensitisation The assessment of this endpoint shall comprise the following consecutive steps: 1. an assessment of the available human, animal and alternative data 2. <i>in vivo</i> testing</p>		<p>Step 2 does not need to be conducted if: — the available information indicates that the substance should be classified for skin sensitisation or corrosivity, or — the substance is a strong acid ($\text{pH} < 2,0$) or base ($\text{pH} > 11,5$)</p>	<p>Skin sensitisation The information shall allow to conclude whether the substance is a skin sensitiser and whether it can be presumed to have the potential to produce significant sensitisation in humans</p>	<p>The study/ies in column 1 do(es) not need to be conducted if: the available information indicates that the substance meets the criteria for classification for skin sensitisation or skin corrosion,</p>

	<p>The Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for <i>in vivo</i> testing.</p> <p>If another skin sensitisation test is used justification shall be provided.</p>			<p>(Category 1A). The information should be sufficient to perform a risk assessment where required</p> <p>The assessment shall comprise the following tiers:</p> <p>(a) assessment of the available human, animal and non-animal data;</p> <p>(b) skin sensitisation, <i>in vitro</i> testing. Information from <i>in vitro</i> or <i>in chemico</i> test method(s) referred to in point 5 of the introductory part of this Annex and addressing each of the following key events of skin sensitisation:</p> <p>(i) molecular interaction with skin proteins;</p> <p>(ii) inflammatory response in keratinocytes;</p> <p>(iii) activation of dendritic cells;</p> <p>(c) skin sensitisation <i>in vivo</i> testing. The Murine Local Lymph Node Assay (LLNA) is the first-choice method for <i>in vivo</i> testing. Another skin sensitisation test may only be used in exceptional cases. If another skin sensitisation test is used, justification shall be provided</p>	<p>the substance is a strong acid ($\text{pH} \leq 2,0$) or base ($\text{pH} \geq 11,5$), or the substance is spontaneously flammable in air or in contact with water or moisture at room temperature.</p> <p><i>In vitro</i> tests do not need to be conducted if:</p> <ul style="list-style-type: none"> - an <i>in vivo</i> study referred to in point (c) of column 1 of this row is available, or - the available <i>in vitro</i> or <i>in chemico</i> test methods are not applicable for the substance or the results obtained from those studies are not adequate for classification and risk assessment. <p>If information from test method(s) addressing one or two of the key events described under point (b) in column 1 of this row allows for classification of the substance and risk assessment, studies addressing the other key event(s) do not need to be conducted.</p> <p>An <i>in vivo</i> study for skin sensitisation shall be conducted only if <i>in vitro</i> or <i>in chemico</i> test methods described under point (b) in column 1 of this row are not applicable, or the results obtained from those studies are not adequate for classification and risk assessment</p> <p><i>In vivo</i> skin sensitisation studies that were carried out or initiated before [IMPLEMENTATION DATE] shall be considered appropriate to address this information requirement</p>
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8.6.	<p>In vivo genotoxicity study</p> <p>The assessment of this endpoint shall comprise the following consecutive steps:</p> <ul style="list-style-type: none"> — If there is a positive result in any of the <i>in vitro</i> genotoxicity studies and there are no results available from an <i>in vivo</i> study already, an appropriate <i>in vivo</i> somatic cell genotoxicity study shall be proposed/conducted by the applicant — If either of the <i>in vitro</i> gene mutation tests is positive, an <i>in vivo</i> test to investigate unscheduled DNA synthesis shall be conducted — A second <i>in vivo</i> somatic cell test may be necessary, depending on the results, quality and relevance of all the available data — If there is a positive result from an <i>in vivo</i> somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence to demonstrate that the substance reached the tested organ. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered 	ADS	<p>The study/ies do(es) not generally need to be conducted if:</p> <ul style="list-style-type: none"> — the results are negative for the three <i>in vitro</i> tests and if no metabolites of concern are formed in mammals or — valid <i>in vivo</i> micronucleus data is generated within a repeat dose study and the <i>in vivo</i> micronucleus test is the appropriate test to be conducted to address this information requirement — the substance is known to be carcinogenic category 1A or 1B or mutagenic category 1A, 1B or 2. 	<p><i>In vivo</i> genotoxicity study</p> <p>The assessment shall comprise the following tiers:</p> <p>(a) If there is a positive result in any of the <i>in vitro</i> genotoxicity studies as listed in 8.5 and there are no reliable results available from an appropriate <i>in vivo</i> somatic cell genotoxicity study, an appropriate <i>in vivo</i> somatic cell genotoxicity study shall be conducted;</p> <p>(b) A second <i>in vivo</i> somatic cell genotoxicity study may be necessary depending on the <i>in vitro</i> and <i>in vivo</i> results, type of effects, quality and relevance of all available data;</p> <p>(c) If there is a positive result from an <i>in vivo</i> somatic cell genotoxicity study available, the potential for germ cell mutagenicity should be considered based on all available data, including toxicokinetic evidence to demonstrate whether the substance has the capacity to reach germ cells. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered</p>	ADS	<p>The study/ies in column 1 do(es) not need to be conducted if:</p> <ul style="list-style-type: none"> — the results are negative for the three <i>in vitro</i> tests listed in 8.5 and no other concern has been identified (e.g. metabolites of concern formed in mammals), or — the substance meets the criteria to be classified as a germ cell mutagen category 1A or 1B. The germ cell genotoxicity test does not need to be conducted if the substance meets the criteria to be classified as a carcinogen, category 1A or 1B and a germ cell mutagen category 2
8.10.	Reproductive toxicity		The studies need not be conducted if:	Reproductive toxicity		The studies do not need to be conducted if:

	<p>For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route</p>		<ul style="list-style-type: none"> — the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented including measures related to reproductive toxicity, or — the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented including measures related to reproductive toxicity, or - the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available provided that the dataset is sufficiently comprehensive and informative), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and the pattern of use indicates there is no or no significant human exposure 	<p>For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route</p>	<ul style="list-style-type: none"> —the substance meets the criteria to be classified as a genotoxic carcinogen (classified both as germ cell mutagen category 2, 1A or 1B and carcinogenic category 1A or 1B), and appropriate risk management measures are implemented including measures related to reproductive toxicity, —the substance meets the criteria to be classified as a germ cell mutagen category 1A or 1B and appropriate risk management measures are implemented including measures related to reproductive toxicity, —the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available provided that the dataset is sufficiently comprehensive and informative), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma or blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and the pattern of use indicates that there is no or negligible human or animal exposure, —the substance meets the criteria to be classified as reproductive toxicity category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for sexual
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						<p>function and fertility will be necessary. A full justification must be provided and documented if investigations for developmental toxicity are not conducted, or</p> <ul style="list-style-type: none"> —the substance is known to cause developmental toxicity, meeting the criteria for classification as reproductive toxicity category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. A full justification must be provided and documented if investigations for sexual function and fertility is not conducted. <p>Notwithstanding the provisions of this column of this row, studies on reproductive toxicity may need to be conducted to obtain information on endocrine disrupting properties as laid down in 8.13.3.1.</p>
8.10	<p>Reproductive toxicity</p> <p>For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route</p>		<p>The studies need not be conducted if:</p> <ul style="list-style-type: none"> — the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented including measures related to reproductive toxicity, or — the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented including measures related to reproductive toxicity, or 	<p>Reproductive toxicity</p> <p>For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route</p>		<p>The studies do not need to be conducted if:</p> <ul style="list-style-type: none"> —the substance meets the criteria to be classified as a genotoxic carcinogen (classified both as germ cell mutagen category 2, 1A or 1B and carcinogenic category 1A or 1B), and appropriate risk management measures are implemented including measures related to reproductive toxicity, —the substance meets the criteria to be classified as a germ cell mutagen category 1A or 1B and appropriate risk management measures are

		<p>— the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available provided that the dataset is sufficiently comprehensive and informative), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and the pattern of use indicates there is no or no significant human exposure.</p> <p>If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Reproductive toxicity Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered</p> <p>— If a substance is known to cause developmental toxicity, meeting the criteria for classification as ductive toxicity Cat 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered</p>		<p>implemented including measures related to reproductive toxicity,</p> <p>—the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available provided that the dataset is sufficiently comprehensive and informative), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma or blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and the pattern of use indicates that there is no or negligible human or animal exposure,</p> <p>—the substance meets the criteria to be classified as reproductive toxicity category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for sexual function and fertility will be necessary. A full justification must be provided and documented if investigations for developmental toxicity are not conducted, or</p> <p>—the substance is known to cause developmental toxicity, meeting the criteria for classification as reproductive toxicity category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental</p>
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						<p>toxicity will be necessary. A full justification must be provided and documented if investigations for sexual function and fertility is not conducted.</p> <p>Notwithstanding the provisions of this column of this row, studies on reproductive toxicity may need to be conducted to obtain information on endocrine disrupting properties as laid down in 8.13.3.1.</p>
8.10.1	<p>Pre-natal developmental toxicity study, preferred species is rabbit; oral route of administration is the preferred route.</p> <p>The study shall be initially performed on one species</p>			<p>Pre-natal development toxicity study (OECD TG 414) on two species, preferred first species is rabbit (non-rodent) and preferred second species is rat (rodent); oral route of administration is the preferred route</p>		<p>The study on the second species shall not be conducted if the study performed on the first species or other available data indicate that the substance causes developmental toxicity meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment</p>
8.10.2	<p>Two-generation reproductive toxicity study, rat, oral route of administration is the preferred route.</p> <p>If another reproductive toxicity test is used justification shall be provided. The extended one-generation reproductive toxicity study adopted at OECD level shall be considered as an alternative approach to the multi-generation study</p>			<p>Extended One-Generation Reproductive Toxicity Study (OECD TG 443), with cohorts 1A and 1B and extension of cohort 1B to include the F2 generation with the aim to produce 20 litters per dose group, F2 pups must be followed to weaning and investigated similarly as F1 pups. Rat is the preferred species and oral route of administration is the preferred route.</p> <p>The highest dose level should be based on toxicity and selected with the aim to induce reproductive and/or other systemic toxicity</p>		<p>A two-generation reproductive toxicity study conducted in accordance with OECD TG 416 (adopted 2001 or later) or equivalent information shall be considered appropriate to address this information requirement, if the study is available and was initiated before [IMPLEMENTATION DATE].</p>

8.10.3	Further pre-natal developmental toxicity study. A decision on the need to perform additional studies on a second species or mechanistic studies should be based on the outcome of the first test (8.10.1) and all other relevant available data (in particular rodent reprotox studies). Preferred species is rat, oral route of administration			Developmental neurotoxicity Developmental Neurotoxicity Study in accordance with OECD TG 426, or any relevant study (set) providing equivalent information, or cohorts 2A and 2B of an Extended One-Generation Reproductive Toxicity study (OECD TG 443) with additional investigation for cognitive functions.	ADS	<p>The study shall not be conducted if the available data:</p> <ul style="list-style-type: none"> —indicate that the substance causes developmental toxicity and meets the criteria to be classified as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and —are adequate to support a robust risk assessment <p>The study shall be conducted only if triggered by one of the following:</p> <ul style="list-style-type: none"> - neurotoxicity occurs in adult animals; or - the active substance interacts with molecules in the nervous system of the target organism; or - thyroid toxicity (including changes in thyroid hormones) occurs in adult animals
8.10.4	N/A – new insertion			Further studies A decision on the need to perform additional studies including those informing on the mechanisms should be based on the outcomes of the studies listed in 8.10.1, 8.10.2 and 8.10.3 and all other relevant available data	ADS	
8.11.2	Carcinogenicity testing in a second species			Carcinogenicity testing in a second species (a)A second carcinogenicity study should be conducted using the mouse as test species;		The second carcinogenicity study does not need to be conducted if the applicant can justify on the basis of scientific grounds that it is not necessary

	<ul style="list-style-type: none"> — A second carcinogenicity study should normally be conducted using the mouse as test species — For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route 			(b)For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		
8.12.1 – 8.12.8 are replaced by 8.12.1 – 8.12.3	<p>8.12.1 Medical surveillance data on manufacturing plant personnel</p> <p>8.12.2. Direct observation, e.g. clinical cases, poisoning incidents</p> <p>8.12.3. Health records, both from industry and any other available sources</p> <p>8.12.4. Epidemiological studies on the general population</p> <p>8.12.5. Diagnosis of poisoning including specific signs of poisoning and clinical tests</p> <p>8.12.6. Sensitisation/allergenicity observations</p> <p>8.12.7. Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known</p> <p>8.12.8. Prognosis following poisoning</p>			<p>8.12.1 Information on signs of poisoning, clinical tests, first aid measures, antidotes, medical treatment and prognosis following poisoning</p> <p>8.12.2 Epidemiological studies</p> <p>8.12.3 Medical surveillance data, health records and case reports</p>		
8.13.2	<p>Neurotoxicity including developmental neurotoxicity</p> <ul style="list-style-type: none"> — The preferred test species is the rat unless another test species is justified to be more appropriate — For delayed neurotoxicity tests the preferred species will be the adult hen — If anticholinesterase activity is detected a test for response to reactivating agents should be considered 	ADS		<p>Neurotoxicity</p> <p>If the active substance is an organophosphorus compound or if there is an indication, knowledge of the mechanism of action or knowledge from acute or repeated dose studies that the active substance may have neurotoxic properties, additional information or specific studies (such as OECD TG 424 or OECD TG 418 or 419 or equivalent) will be required</p>	ADS	

	<p>If the active substance is an organophosphorus compound or if there is any evidence e.g. knowledge of the mechanism of action or from repeat dose studies that the active substance may have neurotoxic or developmental neurotoxic properties then additional information or specific studies will be required.</p> <p>For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route</p>			<p>If anticholinesterase activity is detected a test for response to reactivating agents should be considered</p> <p>For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route</p>	
8.13.3	<p>Endocrine disruption</p> <p>If there is any evidence from <i>in vitro</i>, repeat dose or reproduction toxicity studies, that the active substance may have endocrine disrupting properties then additional information or specific studies shall be required to:</p> <ul style="list-style-type: none"> — elucidate the mode/mechanism of action — provide sufficient evidence for relevant adverse effects <p>For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route</p>	ADS		<p>Endocrine disruption</p> <p>The assessment of endocrine disruption shall comprise the following tiers:</p> <p>(a)An assessment of the available information from the following studies and any other relevant information, including <i>in vitro</i> and <i>in silico</i> methods:</p> <ul style="list-style-type: none"> (i)8.9.1 A 28-day oral toxicity study in rodents (OECD TG 407); (ii)8.9.2 A 90-day oral toxicity study in rodents (OECD TG 408); (iii)8.9.4 A repeated dose oral toxicity study in non-rodents (OECD TG 409); (iv)8.10.1 A prenatal developmental toxicity study (OECD TG 414); (v)8.10.2 An extended one-generation reproductive 	<p>Where sufficient weight of evidence to conclude on the presence or absence of a particular endocrine disrupting mode of action is available:</p> <ul style="list-style-type: none"> —further testing on vertebrate animals for that effect shall be omitted for that mode of action, —further testing not involving vertebrate animals may be omitted for that mode of action. <p>In all cases, adequate and reliable documentation shall be provided</p>

				<p>toxicity study (OECD TG 443) or two-generation reproductive toxicity study (OECD TG 416);</p> <p>(vi)8.10.3 A developmental neurotoxicity study (OECD TG 426);</p> <p>(vii)8.11.1 A combined carcinogenicity study and long-term repeated dose toxicity study (OECD TG 451-3);</p> <p>(viii)A systematic review of the literature including studies on mammals and non-mammalian organisms;</p> <p>(b)If there is any information suggesting that the active substance may have endocrine disrupting properties, or if there is incomplete information on key parameters relevant for concluding on endocrine disruption, then additional information or specific studies shall be required to elucidate:</p> <p>(1)the mode or the mechanism of action; and/or</p> <p>(2)potentially relevant adverse effects in humans or animals</p> <p>For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to consider the oral</p>		
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				route and conduct animal studies by the oral route		
8.13.3.1	N/A new insertion			<p>Specific additional studies to investigate potential endocrine disrupting properties may include, but are not limited to the following:</p> <p>(a) the mammalian toxicity studies listed in 8.13.3(a);</p> <p>(b) the <i>in vitro</i> assays:</p> <p>(i) Estrogen receptor transactivation assay (OECD TG 455);</p> <p>(ii) Androgen receptor transactivation assay, (OECD TG 458);</p> <p>(iii) H295R steroidogenesis assay (OECD TG 456);</p> <p>(iv) the Aromatase assay (human recombinant) OPPTS 890.1200;</p> <p>(c) Uterotrophic bioassay in rodents (OECD TG 440) and Hershberger bioassay in rats (OECD TG 441);</p> <p>(d) Pubertal development and Thyroid Function in Intact Juvenile or Peripubertal Male Rats (OPPTS 890.1500).</p> <p>The decision to carry out studies in mammals shall be taken based on all available information, including a systematic review of the literature (including</p>	ADS	

				information on endocrine disrupting effects in non-target organisms) and the availability of suitable <i>in silico</i> or <i>in vitro</i> methods		
8.13.4	<p>Immunotoxicity including developmental immunotoxicity</p> <p>If there is any evidence, from skin sensitisation, repeat dose or reproduction toxicity studies, that the active substance may have immunotoxic properties then additional information or specific studies shall be required to:</p> <ul style="list-style-type: none"> - elucidate the mode/mechanism of action - provide sufficient evidence for relevant adverse effects in humans <p>For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route</p>	ADS		<p>Immunotoxicity and developmental immunotoxicity</p> <p>If there is any evidence from repeat dose or reproductive toxicity studies that the active substance may have immunotoxic properties, then additional information or specific studies shall be required to elucidate:</p> <p>(1)the mode or the mechanism of action; and/or</p> <p>(2)potentially relevant adverse effects in humans or animals.</p> <p>For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to consider the oral route and conduct animal studies by the oral route</p>	ADS	<p>Immunotoxicity and developmental immunotoxicity</p> <p>If there is any evidence from repeat dose or reproductive toxicity studies that the active substance may have immunotoxic properties, then additional information or specific studies shall be required to elucidate:</p> <p>(1)the mode or the mechanism of action; and/or</p> <p>(2)potentially relevant adverse effects in humans or animals.</p> <p>For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to consider the oral route and conduct animal studies by the oral route</p>
8.13.5	Mechanistic data — any studies necessary to clarify effects reported in toxicity studies	ADS		<p>Further mechanistic studies</p> <p>A decision on the need to perform additional studies should be based on all relevant data</p>	ADS	<p>Further mechanistic studies</p> <p>A decision on the need to perform additional studies should be based on all relevant data</p>
8.18	<p>Summary of mammalian toxicology</p> <p>Provide overall evaluation and conclusion with regard to all toxicological data and any other information concerning the active substances including NOAEL</p>			DELETED		

9.1.1.	<p>Short-term toxicity testing on fish</p> <p>When short-term fish toxicity data is required the threshold approach (tiered strategy) should be applied</p>		<p>The study does not need to be conducted if:</p> <p>— a valid long-term aquatic toxicity study on fish is available</p>	<p>Short-term toxicity testing on fish</p> <p>When short-term fish toxicity data is required, the threshold approach (tiered strategy) should be applied.</p> <p>Long-term toxicity testing on fish in accordance with point 9.1.6.1 shall be considered if the substance is poorly water soluble, i.e. below 1 mg/L</p>		<p>The study does not need to be conducted if:</p> <p>—a valid long-term aquatic toxicity study on fish is available,</p> <p>—sufficient weight of evidence including the use of other data such as the Fish Embryo Acute Toxicity (FET, OECD TG 236) and/or results obtained from non-animal methods is available for this data requirement.</p>
9.1.6.1	<p>Long term toxicity testing on Fish</p> <p>(a) Fish Early Life Stage (FELS) Test</p> <p>(b) Fish short term toxicity test on embryo and sack fry stages</p> <p>(c) Fish juvenile growth test</p> <p>Fish full life cycle test</p>	ADS		<p>Long term toxicity testing on fish</p> <p>The information shall be provided from long-term toxicity testing on fish in which early life-stages (eggs, larvae or juveniles) are exposed</p>	ADS	
9.10	Identification of endocrine activity	ADS		<p>Endocrine disruption</p> <p>The assessment of endocrine disruption properties shall comprise the following tiers:</p> <p>(a)An assessment of the mammalian data set in accordance with 8.13.3 to assess whether the substance has endocrine disrupting properties based on data in relation to mammals;</p> <p>(b)If it cannot be concluded based on the mammalian data in accordance with 8.13.3 or 9.1.6.1 that the substance has endocrine disrupting properties, then</p>		

				studies set out in 9.10.1 or 9.10.2 shall be considered taking account of any other available relevant information, including a systematic review of the literature.	
9.10.1	N/A New insertion			<p>Endocrine disruption in fish</p> <p>Specific studies to investigate potential endocrine disrupting properties may include, but are not limited to the following data requirements:</p> <p>(a) Medaka extended one-generation test (MEOGRT, OECD TG 240);</p> <p>(b) Fish life cycle toxicity test (FLCTT, OPPTS 850.1500) covering all the 'estrogen-, androgen- and steroidogenic-mediated' (EAS) parameters foreseen to be measured in the MEOGRT study</p>	<p>The study does not need to be carried out if:</p> <p>—there is no indication for endocrine activity or endocrine related effects from a sufficient mammalian data set in accordance with 8.13.3 or from any other relevant information (e.g. literature), and</p> <p>—valid <i>in vivo</i> data is available, with no information suggesting that the active substance may elicit endocrine activity or effects potentially related to endocrine activity in either the Fish short term reproduction assay (FSTRA; OECD TG 229), or the 21-days fish assay (OECD TG 230) or Fish sexual developmental test (FSDT, OECD TG 234).</p> <p>If other data are available covering the estrogenic, androgenic and steroidogenic, (EAS) related modalities or parameters investigated in OECD TG 229 or OECD TG 230 or OECD TG 234, then those data can be used instead</p>
9.10.2	N/A New insertion			<p>Endocrine disruption in amphibians</p> <p>Specific additional studies to investigate potential endocrine disrupting properties may include, but are not limited to Larval amphibian growth and</p>	<p>The study does not need to be carried out if:</p> <p>—there is no indication for endocrine activity or endocrine related effects from a sufficient mammalian data set in accordance with 8.13.3 or</p>

				development assay (LAGDA; OECD TG 241)		from any other relevant information (e.g. literature), and —valid <i>in vivo</i> data is available, with no information suggesting that the active substance may have endocrine disrupting properties in an Amphibian metamorphosis assay (AMA; OECD 231)
9.10.3	N/A New insertion			<p>If there is information suggesting that the active substance may have endocrine disrupting properties, or if there is incomplete information on key parameters relevant for concluding on endocrine disruption, additional information or specific studies, as necessary, shall be required to elucidate:</p> <p>(a) the mode or the mechanism of action; and/or</p> <p>(b) potentially relevant adverse effects in humans or animals.</p>	ADS	<p>If there is information suggesting that the active substance may have endocrine disrupting properties, or if there is incomplete information on key parameters relevant for concluding on endocrine disruption, additional information or specific studies, as necessary, shall be required to elucidate:</p> <p>(a) the mode or the mechanism of action; and/or</p> <p>(b) potentially relevant adverse effects in humans or animals.</p>

(3) Title 2 table

	Current GB BPR Wording			Suggested new wording		
Heading of column 3	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates	Column 1 Information required	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from column 1

2.4	Methods, procedures and criteria used to establish the presence and identity of the micro-organism			Specification of the technical grade active ingredient		
2.4.1	N/A new insertion			Content of the active micro-organism and identity and content of relevant metabolites or toxins		
2.4.2	N/A new insertion			Identity and content of impurities, additives, contaminating micro-organisms		
2.4.3	N/A new insertion			Analytical profile of batches		
2.5	Specification of the technical grade active ingredient			Method of production and quality control		
2.6	Method of production and quality control			DELETED		
2.7	Content of the micro-organism			DELETED		
2.8	Identity and content of impurities, additives, contaminating micro-organisms			DELETED		
2.9	Analytical profile of batches			DELETED		
3.5	Information on the production of metabolites (especially toxins)			Information on the production of relevant metabolites and toxins		
4.1	Analytical methods for the analysis of the micro-organism as manufactured			Methods, procedures and criteria used to establish the presence and identity of the micro-organism		
4.2	Methods used for monitoring purposes to determine and quantify residues (viable or non-viable)			Analytical methods for the analysis of the micro-organism as manufactured		

4.3	N/A new insertion			Methods used for monitoring purposes to determine and quantify residues (viable or non-viable)		
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Annex III Changes

Introductory part

	Current GB BPR Wording	Suggested new wording
Point 2 Paragraph 4	For some of the information requirements set out in this Annex, it may be possible to satisfy these requirements based on available information of the properties of the active substance(s) contained in the product and the properties of non-active substance(s) included in the product. For non-active substances, applicants shall use the information provided to them in the context of Title IV of Regulation (EC) No 1907/2006, where relevant, and the information made available by the competent authority in accordance with point (e) of Article 77(2) of that Regulation.	For some of the information requirements set out in this Annex, it may be possible to satisfy these requirements based on available information of the properties of the active substance(s) contained in the product and the properties of non-active substance(s) included in the product. For non-active substances, applicants shall use the information provided to them in the context of Title IV of Regulation (EC) No 1907/2006, where relevant, and the information made available by the Agency in accordance with point (e) of Article 77(2) of that Regulation. However, the information may be not sufficient or adequate to determine whether a non-active substance contained in a biocidal product has hazardous properties and the evaluating body may conclude that further data are required.
Point 2 paragraph 7	The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set out in Article 62(2), applicants may also consult with the competent authority with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out.	The applicant shall initiate a pre-submission consultation with the prospective evaluating body. In addition to the obligation set out in Article 62(2), the applicant may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out. The applicant shall document such pre-submission consultations and their outcomes and shall include the relevant documents in the application
Point 5	5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Regulation (EC) No 440/2008. However, if a method is inappropriate or not described, other methods shall be used which are scientifically appropriate, whenever possible internationally recognised, and their appropriateness must be justified in the application. When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and, where applicable, of the technical adaptations/adjustments that have been made in order to respond to the specific characteristics of these materials.	Tests submitted for the purpose of authorisation shall be conducted in accordance with the methods described in Commission Regulation (EC) No 440/2008, or any revised version of these methods not yet included in that Regulation. However, if a method is inappropriate or not described in Commission Regulation (EC) No 440/2008, ^(*) other methods shall be used which are scientifically appropriate and their appropriateness shall be justified in the application. When test methods are applied to nano-materials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of these materials.

Title 1 table

		Current GB BPR Wording		Suggested new wording		
Heading of column 3	Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates	Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from column 1.
6.6	The proposed label claims for the product and, where label claims are made, for treated articles			The proposed claims for the product and, where claims are made, for treated articles regarding the biocidal properties conferred to the article.		
6.9.2	Observations on undesirable or unintended side effects e.g. on beneficial and other non-target organisms			Observations on undesirable or unintended side-effects on non-target organisms or on objects and material to be protected.		
8.1	<p>Skin corrosion or skin irritation</p> <p>The assessment of this endpoint shall be carried out according to the sequential testing strategy for dermal irritation and corrosion set out in the Appendix to Test Guideline B.4.</p> <p>Acute Toxicity-Dermal Irritation/Corrosion (Annex B.4. to Regulation (EC) No 440/2008)</p>		<p>Testing on the product/mixture does not need to be conducted if:</p> <p>— there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected</p>	<p>Skin corrosion or irritation</p> <p>The assessment shall comprise the following tiers:</p> <p>(a) assessment of the available human, animal and non-animal data;</p> <p>(b) skin corrosion, <i>in vitro</i> testing;</p> <p>(c) skin irritation, <i>in vitro</i> testing;</p> <p>(d) skin corrosion or irritation, <i>in vivo</i> testing</p>		<p>Testing of the product or mixture does not need to be conducted if:</p> <p>—there are sufficient valid data on each component of the product or mixture to allow its classification in accordance with Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected,</p> <p>—the product or mixture is a strong acid ($\text{pH} \leq 2,0$) or base ($\text{pH} \geq 11,5$),</p> <p>—the product or mixture is spontaneously flammable in air or in contact with water or moisture at room temperature,</p>

						<p>—the product or mixture meets the classification criteria for acute toxicity category 1 by the dermal route, or</p> <p>—an acute toxicity study by the dermal route provides conclusive evidence on skin corrosion or irritation adequate for classification.</p> <p>If results from one of the two studies listed in points (b) or (c) in column 1 of this row already allow conclusive decision on the classification of product or mixture or on the absence of skin irritation potential, the second study does not need to be conducted</p> <p>An <i>in vivo</i> study for skin corrosion or irritation shall be considered only if the <i>in vitro</i> studies listed in points (b) and (c) in column 1 of this row are not applicable, or the results of these studies are not adequate for classification and risk assessment and the calculation method or bridging principles laid down in Regulation (EC) No 1272/2008 are not applicable</p> <p><i>In vivo</i> studies for skin corrosion or irritation that were carried out or initiated before 15 April 2022 shall be considered appropriate to</p>
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					address this information requirement
8.2	<p>Eye irritation (¹)</p> <p>The assessment of this endpoint shall be carried out according to the sequential testing strategy for eye irritation and corrosion as set down in the Appendix to Test Guideline B.5. Acute Toxicity: Eye Irritation/Corrosion (Annex B.5. to Regulation (EC) No 440/2008)</p>		<p>Testing on the product/mixture does not need to be conducted if:</p> <ul style="list-style-type: none"> — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected 	<p>Serious eye damage or eye irritation</p> <p>The assessment shall comprise the following tiers:</p> <ul style="list-style-type: none"> (a) assessment of the available human, animal and non-animal data; (b) serious eye damage or eye irritation, <i>in vitro</i> testing; (c) serious eye damage or eye irritation, <i>in vivo</i> testing 	<p>Testing on the product or mixture does not need to be conducted if:</p> <ul style="list-style-type: none"> — there are sufficient valid data available on each component of the product or mixture to allow its classification in accordance with Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected, — the product or mixture is a strong acid ($\text{pH} \leq 2,0$) or base ($\text{pH} \geq 11,5$), — the product or mixture is spontaneously flammable in air or in contact with water or moisture at room temperature, or — the product or mixture meets the classification criteria for skin corrosion leading to its classification as “serious eye damage” category 1 <p>If results from a first <i>in vitro</i> study do not allow a conclusive decision on the classification of the product or mixture or on the absence of eye irritation potential (an) other(s) <i>in vitro</i> study(ies) for this endpoint shall be considered</p>

						<p>An <i>in vivo</i> study for serious eye damage or eye irritation shall be considered only if the <i>in vitro</i> study(ies) under point (b) in column 1 of this row are not applicable, or the results obtained from these studies are not adequate for classification and risk assessment and the calculation method or bridging principles laid down in Regulation (EC) No 1272/2008 are not applicable</p> <p><i>In vivo</i> studies for serious eye damage or eye irritation that were carried out or initiated before 15 April 2022 shall be considered appropriate to address this information requirement</p>
8.3	<p>Skin sensitisation</p> <p>The assessment of this endpoint shall comprise the following consecutive steps:</p> <p>1. an assessment of the available human, animal and alternative data 2. <i>in vivo</i> testing</p> <p>The Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for <i>in vivo</i> testing. If another skin sensitisation test is used justification shall be provided</p>		<p>Testing on the product/mixture does not need to be conducted if:</p> <ul style="list-style-type: none"> — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected — the available information indicates that the product should be classified for skin 	<p>Skin sensitisation</p> <p>The information shall allow to conclude whether the substance is a skin sensitizer and whether it can be presumed to have the potential to produce significant sensitisation in humans (Category 1A). The information should be sufficient to perform a risk assessment where required</p> <p>The assessment shall comprise the following tiers:</p> <ul style="list-style-type: none"> (a) assessment of the available human, animal and non-animal data; (b) skin sensitisation, <i>in vitro</i> testing. Information from <i>in vitro</i> or <i>in chemico</i> test 		<p>Testing on the product or mixture does not need to be conducted if:</p> <ul style="list-style-type: none"> — there are sufficient valid data available on each component of the product or mixture to allow its classification in accordance with Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected, — the available information indicates that the product or mixture should be classified for skin

			<p>sensitisation or corrosivity; or</p> <p>— the substance is a strong acid (pH < 2,0) or base (pH > 11,5)</p>	<p>method(s) conducted in accordance with point 5 of the introductory part of this Annex and addressing each of the following key events of skin sensitisation:</p> <p>(i) molecular interaction with skin proteins;</p> <p>(ii) inflammatory response in keratinocytes;</p> <p>(iii) activation of dendritic cells.</p> <p>(c) skin sensitisation <i>in vivo</i> testing. The Murine Local Lymph Node Assay (LLNA) is the first-choice method for <i>in vivo</i> testing. Another skin sensitisation test may only be used in exceptional circumstances. If another skin sensitisation test is used, scientific justification shall be provided.</p>		<p>sensitisation or skin corrosion,</p> <p>—the product or mixture is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5), or</p> <p>—the product or mixture is spontaneously flammable in air or in contact with water or moisture at room temperature.</p> <p><i>In vitro</i> tests do not need to be conducted if:</p> <p>—an <i>in vivo</i> study referred to in point (c) in column 1 of this row is available, or</p> <p>—the available <i>in vitro</i> or <i>in chemico</i> test methods are not applicable for the product or mixture or the results obtained from these studies are not adequate for classification and risk assessment.</p> <p>If information from test method(s) addressing one or two of the key events described in point (b) in column 1 of this row already allows for classification of the substance and risk assessment, studies addressing the other key event(s) do not need to be conducted</p> <p>An <i>in vivo</i> study for skin sensitisation shall be considered only if <i>in vitro</i> or <i>in chemico</i> studies referred to in point (b) in column 1 of this</p>
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						<p>row are not applicable, or the results obtained from these studies are not adequate for classification and risk assessment and the calculation method or bridging principles laid down in Regulation (EC) No 1272/2008 are not applicable</p> <p><i>In vivo</i> studies for skin sensitisation that were carried out or initiated before 15 April 2022 shall be considered appropriate to address this information requirement.</p>
8.7	<p>Available toxicological data relating to:</p> <ul style="list-style-type: none"> — non-active substance(s) (i.e. substance(s) of concern), or — a mixture that a substance(s) of concern is a component of <p>If insufficient data are available for a non-active substance(s) and cannot be inferred through read-across or other accepted non-testing approaches, targeted test(s) described in Annex II shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of</p>		<p>Testing on the product/mixture does not need to be conducted if:</p> <ul style="list-style-type: none"> — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP) 	<p>Available toxicological data relating to:</p> <ul style="list-style-type: none"> (a) non-active substance(s) (i.e. substance(s) of concern); and (b) a mixture that a substance(s) of concern is a component of <p>Tests listed in Section 8 of the table in Title 1 of Annex II shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of if insufficient data are available and cannot be inferred through read-across, <i>in silico</i> or other accepted non-testing approaches</p>		<p>Testing on the product or mixture does not need to be conducted if all of the following conditions are met:</p> <ul style="list-style-type: none"> — there are valid data available on each of the components in the mixture to allow classification of the mixture in accordance with the rules laid down in Regulation (EC) No 1272/2008, — a conclusion can be made whether the biocidal product can be considered as having endocrine disrupting properties, — synergistic effects between any of the components are not expected.
9.1	<p>Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning</p>			<p>Available ecotoxicological data relating to:</p>		<p>Testing on the product or mixture does not need to be</p>

	<p>the classification of the product is required</p> <p>— Where there are valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected, classification of the mixture can be made according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/ 2008 (CLP)</p> <p>— Where valid data on the components are not available or where synergistic effects may be expected then testing of components and/or the biocidal product itself may be necessary</p>			<p>(a) non-active substance(s) (i.e. substance(s) of concern);</p> <p>(b) a mixture that a substance(s) of concern is a component of</p> <p>Tests listed in Section 9 of Title 1 of Annex II shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of if insufficient data are available and cannot be inferred through read-across, <i>in silico</i> or other accepted non-testing approaches</p>		<p>conducted if all the following conditions are met:</p> <p>— there are valid data available on each of the components in the mixture to allow classification of the mixture in accordance with the rules laid down in Regulation (EC) No 1272/2008,</p> <p>— a conclusion can be made whether the biocidal product can be considered as having endocrine disrupting properties,</p> <p>— synergistic effects between any of the components are not expected.</p>
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Title 2 table

	Current GB BPR Wording			Suggested new wording		
Heading of column 3	Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates	Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from column 1
2.3	Detailed quantitative (g/kg, g/l or % w/w (v/v)) and qualitative information on the constitution, composition and function of the biocidal product, e.g. micro-organism, active substance(s) and product non-active substances			Detailed quantitative (g/kg, g/l, % w/w (v/v), cfu/g, cfu/l or IU/mg or any other appropriate unit) and qualitative information on the constitution, composition and function of the biocidal product, e.g. micro-organism, active substance(s) and non-active		

	and any other relevant components. All relevant information on individual ingredients and the final composition of the biocidal product shall be given			substances and any other relevant components All relevant information on individual ingredients and the final composition of the biocidal product shall be given		
3.6.8	Burning rate — smoke generators			DELETED		
3.6.9	Burning completeness — smoke generators			DELETED		
3.6.10	Composition of smoke — smoke generators			DELETED		
3.6.11	Spraying patterns — aerosols			DELETED		
3.6.12	Other technical characteristics			DELETED		
3.6.8	N/A – new insertion			Spraying patterns – aerosols		
3.6.9	N/A – new insertion			Other technical characteristics		
4.	PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS			4.PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS		
4.1.	Explosives			4.1. Explosives		
4.2.	Flammable gases			4.2. Flammable aerosols		
4.3.	Flammable aerosols			4.3. Flammable liquids		
4.4.	Oxidising gases			4.4. Flammable solids		
4.5.	Gases under pressure			4.5. Oxidising liquids		
4.6.	Flammable liquids			4.6. Oxidising solids		
4.7.	Flammable solids			4.7. Corrosive to metals		
4.8.	Oxidising liquids			4.8. Other physical indications of hazard		

4.9.	Oxidising solids			4.8.1. Auto-ignition temperatures of products (liquids and gases)		
4.10.	Organic peroxides			4.8.2. Relative self-ignition temperature for solids		
4.11.	Corrosive to metals			4.8.3. Dust explosion hazard		
4.12.	Other physical indications of hazard					
4.12.1.	Auto-ignition temperatures of products (liquids and gases)					
4.12.2.	Relative self-ignition temperature for solids					
4.12.3.	Dust explosion hazard					
10.3.	Leaching behaviour	ADS		Leaching behaviour and/or mobility	ADS	