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ANNEXES 1 to 2

ANNEXES

to the

Commission Delegated Regulation (EU) .../...

amending Annexes II and III to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

ANNEX I

Annex II to Regulation (EU) No 528/2012 is amended as follows:

(1) the introductory part is amended as follows:

(a) the fifth paragraph of point 2 is replaced by the following:

'The applicant shall initiate a pre-submission consultation with the prospective evaluating body. In addition to the obligation set out in Article 62(2), applicants 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.'

(b) point 5 is replaced by the following:

'5. 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[*], 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.

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[*] 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) (OJ L 142, 31.5.2008, p. 1).'

(2) the table in Title 1 is amended as follows:

(a) the heading of the third column is replaced by the following:

		'Column 3 Specific rules for adaptation from column 1';

(b) row 2 is replaced by the following:

'2	IDENTITY OF THE ACTIVE SUBSTANCE (AND ITS PRECURSOR(S) IF THE ACTIVE SUBSTANCE IS GENERATED *IN SITU*) 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.'		

(c) row 2.5 is replaced by the following:

'2.5	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

(d) row 2.8 is replaced by the following:

'2.8	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.'		

(e) the following row 2.11.1 is inserted:

'2.11.1	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) and any other constituent above 0,1% w/w, including residues of precursor(s).'		

(f) row 6.6 is replaced by the following:

'6.6	Efficacy data to support: – the innate activity of the		

	active substance for the intended use(s) and – any claims made on treated articles regarding the biocidal properties conferred to the article. 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.'		

(g) row 6.7.2 is replaced by the following:

'6.7.2	Observations on undesirable or unintended side effects on non-target organisms or on objects and material to be protected.'		

(h) rows 8.1, 8.2 and 8.3 are replaced by the following:

'8.1	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, *in vitro* testing (c) skin irritation, *in vitro* testing (d) skin corrosion or irritation, *in vivo* 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, – 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, – 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. If results from one of the two studies listed in point (b) or point (c) in column 1 of this subsection 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. An *in vivo* study for skin corrosion or irritation shall be considered only if the *in vitro* studies listed in points (b) and (c) in column 1 of this subsection are not applicable, or the results of these studies are not adequate for classification and risk assessment. *In vivo* studies for skin corrosion or irritation that were carried out or initiated before … (*OJ please insert the date of application of this amending Regulation*) shall be considered appropriate to address this information requirement.

8.2	Serious eye damage or eye irritation The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data (b) serious eye damage or eye irritation, *in vitro* testing (c) serious eye damage or eye		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 eye irritation or causing serious damage to

irritation, *in vivo* testing		eyes, – 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 or, – the substance meets the classification criteria for skin corrosion leading to classification of the substance as 'serious eye damage' (category 1). If results from a first *in vitro* study do not allow a conclusive decision on the classification of the substance or on the absence of eye irritation potential (an)other(s) *in vitro* study(ies) for this endpoint shall be considered. An *in vivo* study for serious eye damage or eye irritation shall be considered only if the *in vitro* study(ies) listed in point (b) in column 1 of this subsection are not applicable, or the results obtained from these studies are not adequate for classification and risk assessment. *In vivo* studies for serious eye damage or eye irritation that were carried out or initiated before … (*OJ please insert the date of application of this amending Regulation*) shall be considered appropriate to address this information requirement.

‘8.3 Skin sensitisation 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. The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data (b) skin sensitisation, *in vitro* testing. Information from *in vitro or in chemico* 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: (i)molecular interaction with skin proteins; (ii)inflammatory response in keratinocytes; (iii)activation of dendritic cells. (c) skin sensitisation *in vivo* testing. The Murine Local Lymph Node Assay (LLNA) is the first-choice method for *in vivo* testing. Another skin sensitisation test may only be used in exceptional cases. If another skin sensitisation test is used, justification shall be provided.		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, – the substance is a strong acid (pH≤2,0) or base (pH≥11,5) or – the substance is spontaneously flammable in air or in contact with water or moisture at room temperature. *In vitro* tests do not need to be conducted if: – an *in vivo* study referred to in point (c) of column 1 of this subsection is available or, – the available *in vitro or in chemico* test methods are not applicable for the substance or the results obtained from those studies are not adequate for classification and risk assessment If information from test method(s) addressing one or two of the key events described under point (b) in column 1 of this subsection allows for classification of the substance and risk assessment, studies addressing the other key event(s) do not need to be conducted.

		An *in vivo* study for skin sensitisation shall be conducted only if *in vitro or in chemico* test methods described under point (b) in column 1 of this subsection are not applicable, or the results obtained from those studies are not adequate for classification and risk assessment. *In vivo* skin sensitisation studies that were carried out or initiated before … (*OJ please insert the date of application of this amending Regulation*) shall be considered appropriate to address this information requirement.'

(i) row 8.6 is replaced by the following:

'8.6	*In vivo* genotoxicity study The assessment shall comprise the following tiers: (a) If there is a positive result in any of the *in vitro* genotoxicity studies as listed in 8.5 and there are no reliable results available from an appropriate *in vivo* somatic cell genotoxicity study, an appropriate *in vivo* somatic cell genotoxicity study shall be conducted. (b) A second *in vivo* somatic cell genotoxicity study may be necessary depending on the *in vitro* and *in vivo* results, type of effects, quality and relevance of all available data (c) If there is a positive result from an *in vivo* somatic cell study available, the potential for germ cell mutagenicity should be considered based on all available data, including toxicokinetic evidence to demonstrate that the	ADS	The study/ies in column 1 do(es) not need to be conducted if: – the results are negative for the three *in vitro* 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

	substance reached the tested organ. If no clear conclusions about germ cells mutagenicity can be made, additional investigations shall be considered		cell mutagen category 2.’

(j) rows 8.10 to 8.10.3 are replaced by the following:

‘8.10	Reproductive toxicity For evaluation of consumer and animal safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route.		The studies do not need to be conducted if: – 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 there is no or negligible significant 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 function and fertility will be necessary. A full justification must be provided and documented if investigations for developmental toxicity are not conducted or, – 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. Notwithstanding the provisions of this column of this subsection, studies on reproductive toxicity may need to be conducted to obtain information on endocrine disrupting properties as laid down in 8.13.3.1.

8.10.1	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.		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.

‘8.10.2	Extended One-Generation Reproductive Toxicity Study (OECD TG 443), with cohorts 1A and 1B and extension of cohort 1B to include the		A two-generation reproductive toxicity study conducted in accordance with OECD TG 416 (adopted 2001 or later) or

	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. The highest dose level should be based on toxicity and selected with the aim to induce reproductive and/or other systemic toxicity.		equivalent information shall be considered appropriate to address this information requirement, if the study is available and was initiated before … (*OJ please insert the date of application of this amending Regulation*).

8.10.3	Developmental neurotoxicity Developmental Neurotoxicity Study in accordance with OECD TG 426, or any relevant study (set) providing equivalent information, or by cohorts 2A and 2B of an Extended One-Generation Reproductive Toxicity study (OECD TG 443) with additional investigation for cognitive functions.		The study shall not be conducted if the available data: – 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.’

(k) the following row 8.10.4 is inserted:

‘8.10.4	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’	

(l) row 8.11.2 is replaced by the following:

‘8.11.2	Carcinogenicity testing in a second species (a) A second carcinogenicity study should be conducted using the mouse as test		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. In such cases, scientifically

	species. (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.		validated alternative carcinogenicity models may be used instead of a second carcinogenicity study.'

(m) rows 8.12.1 to 8.12.8 are replaced by the following:

'8.12.1	Information on signs of poisoning, clinical tests, first aid measures, antidotes, medical treatment and prognosis following poisoning		
8.12.2	Epidemiological studies		
8.12.3	Medical surveillance data, health records and case reports.'		

(n) rows 8.13.2 and 8.13.3 are replaced by the following:

'8.13.2	Neurotoxicity 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 If the active substance is an organophosphorus compound or if there is an indication, knowledge of the mechanism of action or knowledge from repeat dose studies that the active substance may have neurotoxic properties, additional information or specific studies will be required. 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.	ADS	

8.13.3	Endocrine disruption The assessment of endocrine disruption shall comprise the following tiers: (a) An assessment of the available information from the following studies and any other relevant information, including *in vitro* and *in silico* methods: (i)8.9.1 A 28-day oral study in rodents (OECD TG 407) (ii)8.9.2 A 90-day oral study in rodents (OECD TG 408) (iii)8.9.4 A repeated dose oral 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 toxicity study (OECD TG 443) or two-generation reproductive toxicity study (OECD TG 416) (vi)8.10.3 A developmental neurotoxicity study (OECD TG 426) (vii)8.11.1 A combined carcinogenicity study and long-term repeated dose toxicity study (OECD TG 451-3) (viii)A systematic review of the literature including studies on mammals and non-mammalian organisms.		Where sufficient weight of evidence to conclude on the presence or absence of a particular endocrine disrupting mode of action is available: – 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. In all cases, adequate and reliable documentation shall be provided.’

	(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 any of the following: (1) the mode or the mechanism of action; (2) potentially relevant adverse effects in humans or animals. 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.		

(o) the following row 8.13.3.1 is inserted:

‘8.13.3.1	Specific additional studies to investigate potential endocrine disrupting properties may include, but are not limited to the following: (a) the mammalian toxicity studies listed in 8.13.3 (a) (b) the *in vitro* assays: (i) Estrogen receptor transactivation assay (OECD TG 455), (ii)Androgen receptor transactivation assay, (OECD TG 458), (iii)H295R steroidogenesis assay (OECD TG 456) (iv)the Aromatase assay (human recombinant)OPPTS 890.1200	ADS’	

	(c) Uterotrophic bioassay in rodents (OECD TG 440) and Hershberger bioassay in rats (OECD TG 441) (d) Pubertal development and Thyroid Function in Intact Juvenile or Peripubertal Male Rats (OPPTS 890,1500). The decision to carry out studies in mammals shall be taken based on all available information, including a systematic review of the literature (including information on endocrine disrupting effects in non-target organisms) and the availability of suitable *in silico or in vitro* methods.		

(p) rows 8.13.4 and 8.13.5 are replaced by the following:

‘8.13.4	Immunotoxicity and developmental immunotoxicity 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 any of the following: (1) the mode or the mechanism of action; (2) potentially relevant adverse effects in humans or animals. 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.	ADS	

8.13.5	Further mechanistic studies A decision on the need to perform additional studies should be based on all relevant data.	ADS’	

(q) row 8.18 is deleted.

(r) row 9.1.1 is replaced by the following:

‘9.1.1	Short-term toxicity testing on fish When short-term fish toxicity data is required, the threshold approach (tiered strategy) should be applied. A 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.		The study does not need to be conducted if: – a valid long-term aquatic toxicity study on fish is available – sufficient weight of evidence including the use of existing 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.’

(s) row 9.1.6.1 is replaced by the following:

‘9.1.6.1	Long term toxicity testing on fish The information shall be provided from long-term toxicity testing on fish in which early life-stages (eggs, larvae or juveniles) are exposed.	ADS’	

(t) row 9.10 is replaced by the following:

‘9.10	Endocrine disruption The assessment of endocrine disruption properties shall comprise the following tiers: ~~(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 (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 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.'		

(u) the following rows 9.10.1, 9.10.2 and 9.10.3 are inserted:

'9.10.1	Endocrine disruption in fish Specific studies to investigate potential endocrine disrupting properties may include, but are not limited to the following data requirements: (a) Medaka extended one-generation test (MEOGRT, OECD TG 240), (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.		The study does not need to be carried out if : – 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 – valid *in vivo* 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). 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.

9.10.2	Endocrine disruption in amphibians Specific additional studies to investigate potential endocrine disrupting properties may include, but are not limited to Larval amphibian growth and development assay (LAGDA; OECD TG 241).		The study does not need to be carried out if: – 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 – valid *in vivo* 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	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 any of the following: (a)the mode or the mechanism of action; (b)potentially relevant adverse effects in humans or animals.	ADS’	

(3) the table in Title 2 is amended as follows:

(a) the heading of the third column is replaced by the following:

		‘Column 3 Specific rules for adaptation from column 1’,

(b) row 2.4 is replaced by the following:

‘2.4	Specification of the technical grade active ingredient.’		

(c) the following rows 2.4.1, 2.4.2 and 2.4.3 are inserted:

‘2.4.1	Content of the active micro-organism and identity and content of relevant metabolites or toxins.		
2.4.2	Identity and content of impurities, additives, contaminating micro-organisms.		
2.4.3	Analytical profile of batches.’		

(d) row 2.5 is replaced by the following:

‘2.5	Method of production and quality control.’		

(e) rows 2.6 to 2.9 are deleted

(f) row 3.5 is replaced by the following:

‘3.5	Information on the production of relevant metabolites and toxins.’		

(g) rows 4.1 and 4.2 are replaced by the following:

‘4.1	Methods, procedures and criteria used to establish the presence and identity of the micro-organism.		
4.2	Analytical methods for the analysis of the micro-organism as manufactured.’		

(h) the following row 4.3 is inserted:

‘4.3	Methods used for monitoring purposes to determine and quantify residues (viable or non-viable).’		

ANNEX II

Annex III to Regulation (EU) No 528/2012 is amended as follows:

(1) the introductory part is amended as follows:

(a) 'the fourth paragraph of point 2 is replaced by the following:

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.'

(b) The seventh paragraph of point 2 is replaced by the following:

'The applicant shall initiate a pre-submission consultation with the prospective evaluating body. In addition to the obligation set out in Article 62(2), applicants 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.'

(c) point 5 is replaced by the following:

'5. 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.

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* 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) (OJ L 142, 31.5.2008, p. 1).'

(2) The table in Title 1 is amended as follows:

(a) the heading of the third column is replaced by the following:

		'Column 3 Specific rules for adaptation

		from column 1’,

(b) row 6.6 is replaced by the following:

‘6.6 The proposed claims for the product and, where claims are made, for treated articles regarding the biocidal properties conferred to the article.’		

(c) row 6.8.2 is replaced by the following:

‘6.8.2 Observations on undesirable or unintended side-effects on non-target organisms or on objects and material to be protected.’		

(d) Rows 8.1, 8.2 and 8.3 are replaced by the following:

‘8.1 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, *in vitro* testing (c) skin irritation, *in vitro* testing (d) skin corrosion or irritation, *in vivo* testing		Testing of the product or mixture does not need to be conducted if: – 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, – the product or mixture is a strong acid (pH≤2,0) or base (pH≥11,5), – the product or mixture is spontaneously flammable in air or in contact with water or moisture at room temperature, – the product or mixture 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. If results from one of the two studies listed in points (b) or (c) in column 1 of this subsection already allow conclusive decision on the classification of product or mixture or on the absence of skin corrosion or irritation potential, the second study does not need to be conducted. An *in vivo* study for skin corrosion or irritation shall be considered only if the *in vitro* studies listed in points (b) and (c) in column 1 of this subsection 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. *In vivo* studies that were carried out or initiated before … [*OJ please insert the date of application of this amending Regulation]* shall be considered appropriate to address this information requirement.'

8.2	Serious eye damage or eye irritation The assessment shall comprise the following tiers:		Testing on the product or mixture does not need to be conducted if:

(a) assessment of the available human, animal and non-animal data (b) serious eye damage or eye irritation, *in vitro* testing (c) serious eye damage or eye irritation, *in vivo* testing		– 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 (pH≤2,0) or base (pH≥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. If results from a first *in vitro* 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) *in vitro* study(ies) for this endpoint shall be considered. An *in vivo* study for serious eye damage or eye irritation shall be considered only if the *in vitro* study(ies) under point (b) in column 1 of this subsection 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. *In vivo* studies for skin corrosion or irritation that were carried out or initiated before … (*OJ please insert the date of application of this amending Regulation*) shall be considered appropriate to address this information requirement.

8.3	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 (Category 1A). The information should be sufficient to perform a risk assessment where required. The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data (b) skin sensitisation, *in vitro.* Information from *in vitro or in chemico* test 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: (i)molecular interaction with skin proteins; (ii)inflammatory response in keratinocytes; (iii)activation of		Testing on the product or mixture does not need to be conducted if: – 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 sensitisation or skin corrosion, – the product or mixture is a strong acid (pH≤2,0) or base (pH≥11,5) or, – the product or mixture is

dendritic cells. (c) skin sensitisation *in vivo*. The Murine Local Lymph Node Assay (LLNA) is the first-choice method for *in vivo* testing. Another skin sensitisation test may only be used in exceptional circumstances. If another skin sensitisation test is used, scientific justification shall be provided.		spontaneously flammable in air or in contact with water or moisture at room temperature. *In vitro* tests do not need to be conducted if: – an *in vivo* study referred to in point (c) in column 1 of this subsection is available or, – the available *in vitro or in chemico* 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. If information from test method(s) addressing one or two of the key events described in point (b) in column 1 of this subsection already allows for classification of the substance and risk assessment, studies addressing the other key event(s) do not need to be conducted. An *in vivo* study for skin sensitisation shall be considered only if *in vitro or in chemico* studies referred to in point (b) in column 1 of this subsection 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.

		In vivo studies that were carried out or initiated before … (*OJ please insert the date of application of this amending Regulation*) shall be considered appropriate to address this information requirement.'

(e) row 8.7 is replaced by the following:

'8.7 Available toxicological data relating to: (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 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, *in silico* or other accepted non-testing approaches.		Testing on the product or mixture does not need to be conducted if all of the following conditions are met: – 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.'

(f) row 9.1 is replaced by the following:

'9.1 Available ecotoxicological data relating to: (a) non-active substance(s) (i.e. substance(s) of concern), (b) a mixture that a substance(s) of concern is a component of 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		Testing on the product or mixture does not need to be conducted if all the following conditions are met: – there are valid data available on each of the components in the mixture to allow classification of the mixture in accordance with the

	component of if insufficient data are available and cannot be inferred through read-across, *in silico* or other accepted non-testing approaches.		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.’

(3) the table in Title 2 is amended as follows:

(a) the heading of the third column is replaced by the following:

		‘Column 3 Specific rules for adaptation from column 1’,

(b) row 2.3 is replaced by the following:

‘2.3	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 substances and any other relevant components. All relevant information on individual ingredients and the final composition of the biocidal product shall be given.’		

(c) rows 3.6.8 to 3.6.12 are deleted

(d) the following rows 3.6.8 and 3.6.9 are inserted:

‘3.6.8 Spraying patterns - aerosols		

3.6.9 Other technical characteristics’		

(e) rows 4 to 4.12.3 are replaced by the following

4. PHYSICAL HAZARDS AND		

RESPECTIVE CHARACTERISITICS		
‘4.1. Explosives		
4.2. Flammable aerosols		
4.3. Flammable liquids		
4.4. Flammable solids		
4.5. Oxidising liquids		
4.6. Oxidising solids		
4.7. Corrosive to metals		
4.8. Other physical indications of hazard		
4.8.1. Auto-ignition temperatures of products (liquids and gases)		
4.8.2. Relative self-ignition temperature for solids		
4.8.3. Dust explosion hazard’		

(f) row 10.3 is replaced by the following:

‘10.3 Leaching behaviour and mobility in soil	ADS’	