STATUTORY INSTRUMENTS

2024 No. 352

HEALTH AND SAFETY

The Biocidal Products (Health and Safety) (Amendment and Transitional Provision etc.) Regulations 2024

Made - - - -	*11th March 2024*
Laid before Parliament	*13th March 2024*
Coming into force - -	*6th April 2024*

The Secretary of State in exercise of the powers conferred by Article 85(1) and Article 83A(2) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products(**1**), and with the consent of the Scottish Ministers and of the Welsh Ministers(**2**), makes the following Regulations.

Citation, commencement, extent and interpretation

1.—(1) These Regulations may be cited as the Biocidal Products (Health and Safety) (Amendment and Transitional Provision etc.) Regulations 2024.

(2) These Regulations come into force on 6th April 2024(**3**).

(3) An amendment made by these Regulations has the same extent as the provision being amended.

(4) In these Regulations, "Regulation (EU) No 528/2012" means Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products(**4**).

Amendment of Regulation (EU) No 528/2012

2.—(1) Regulation (EU) No 528/2012 is amended as follows.

(2) Schedule 1 makes amendments to Annex 2.

(3) Schedule 2 makes amendments to Annex 3.

(**1**) EUR 2012/528 was incorporated by virtue of section 3(1) of the European Union Withdrawal Act 2018 (c.16). Article 85(1) was amended by S.I. 2019/720.
(**2**) Consent of the Scottish Ministers and of the Welsh Ministers is required pursuant to Articles 83B and 85(2) of EUR 2012/528.
(**3**) But see regulation 3(1) for the date the amendments begin to apply.
(**4**) EUR 2012/528, amended by S.I. 2019/720, S.I. 2020/1567, S.I. 2022/1037 and S.I. 2022/1291.

Transitional and saving provision

3.—(1) Subject to paragraph (2), the amendments made by these Regulations apply only in relation to applications made to the competent authority(**5**) on or after 6th October 2025.

(2) For the period beginning on 6th April 2024 and ending on 5th October 2025, in their application to the competent authority, applicants may either—

(a) comply with the requirements in Annex 2 and Annex 3 of Regulation (EU) No 528/2012 as amended by Schedules 1 and 2; or

(b) comply with the requirements in Annex 2 and Annex 3 of Regulation (EU) No 528/2012 as they were immediately before the coming into force of these Regulations.

(3) The amendments made by these Regulations do not affect any applications made to the competent authority before the coming into force of these Regulations.

Younger
Parliamentary Under Secretary of State
Department for Work and Pensions

11th March 2024

(**5**) See Article 81(1)(a) of EUR 2012/528 for the definition of "competent authority".

Schedules

Schedule 1

Regulation 2(2)

Amendments to Annex 2 to Regulation (EU) No 528/2012
(*Information Requirements for Active Substances*)

1.—(1) Annex 2 to Regulation (EU) No 528/2012 (*Information Requirements for Active Substances*) is amended as follows.

(2) In Point 2, for the fifth paragraph, substitute—

"The applicant must initiate a pre-submission consultation with the competent authority. In addition to the obligation set out in Article 62(2), the applicant may also consult with the competent authority with regard to the proposed information requirements and in particular the strategy for avoiding new testing on vertebrates alongside any testing on vertebrates that the applicant proposes to carry out. The applicant must document such pre-submission consultations and their outcomes and must include the relevant documents in the application.".

(3) In Point 5—

(a) after "…Restriction of Chemicals (REACH).", insert "Where a revised version of a test method described in Commission Regulation (EC) No 440/2008 is available, but not included in that Regulation, the revised version may be used with the agreement of the competent authority.".

(b) after "…if a method is inappropriate or not described", insert "in Commission Regulation (EC) No 440/2008".

(c) omit ", whenever possible internationally recognised,".

(4) In the TITLE 1 (*Chemical Substances*) table—

(a) For the first row, substitute—

"**Column 1** **Information required**	**Column 2** **All data is CDS unless indicated as ADS**	**Column 3** **Specific rules for adaptation from Column 1".**

(b) For row 2, substitute—

"IDENTITY OF THE ACTIVE SUBSTANCE (AND ITS PRECURSOR OR PRECURSORS IF THE ACTIVE SUBSTANCE IS GENERATED IN SITU) For the active substance and, if applicable, its precursor or precursors, the information given in this Section must 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 the information on one or more of the items listed in this Section, the reasons must be clearly stated.".	

(c) For row 2.5, substitute—

"2.5 Molecular and structural formula (including SMILES notation, if available and appropriate). For precursor or precursors and for active substances generated in situ, information about all generated chemical substances (intended and unintended).	The molecular and structural formula does not need to be provided in cases where it is not possible to exactly define the molecular structure of the precursor or the active substance.".

(d) For row 2.8, substitute—

"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) must be provided.".	

(e) After row 2.11, insert—

"2.11.1	

Analytical profile of at least five representative samples taken from the in situ generated substance or substances, providing information on the content of the active substance or substances, any other constituent above 0.1 % w/w, including residues of precursor or precursors, and where relevant any additional impurities referred to in 2.10.”.	

(f) For row 6.6, substitute—

“6.6	
Efficacy data to support the innate activity of the active substance for the intended use or uses.	
Efficacy data submitted may 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) For row 6.7.2, substitute—

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

(h) For row 8.1, substitute—

"8.1 Skin corrosion or irritation. The assessment must 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 studies in column 1 do 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 row already allow a 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 must not be conducted unless the in vitro 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. In vivo studies for skin corrosion or irritation that were initiated before 6th October 2025 will be considered appropriate to address this information requirement.”.

(i) For row 8.2, substitute—

“8.2 Serious eye damage or eye irritation. The assessment must 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 irritation, in vivo testing.	The studies in column 1 do 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 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 other in vitro studies for this endpoint must be considered. An in vivo study for serious eye damage or eye irritation must not be conducted unless the in vitro studies 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. In vivo studies for serious eye damage or eye irritation that were initiated before 6th October 2025 will be considered appropriate to address this information requirement.".

(j) For row 8.3, substitute—

"8.3 Skin sensitisation. The information must allow a conclusion as to whether the substance is a skin sensitiser and whether it can be presumed to have		The studies in column 1 do 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 potential to produce significant sensitisation in humans (Category 1A). The information should be sufficient to perform a risk assessment where required.	- 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.
The assessment must comprise the following tiers: (a) assessment of the available human, animal and non-animal data; (b) skin sensitisation, in vitro testing according to OECD TG 497; (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 must be provided.	In vitro tests do not need to be conducted if: - an in vivo study referred to in point (c) of column 1 of this row is available, or - the available in vitro or in chemico test methods of OECD TG 497 are not applicable for the substance. An in vivo study for skin sensitisation must not be conducted unless the in vitro or in chemico test methods of OECD TG 497 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 initiated before 6th October 2025 will be considered appropriate to address this information requirement.”.

(k) For row 8.6, substitute—

"8.6	ADS	The studies in column 1 do not need to be conducted if:
In vivo genotoxicity study. The assessment must 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 must 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 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 must be considered.		- 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 cell mutagen Category 2. Where in vivo genotoxicity testing is required, repeated dose toxicity studies should be integrated with appropriate genotoxicity tests where possible.".

(l) For row 8.10, substitute—

“8.10 Reproductive toxicity. 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.	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 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 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 are not conducted. 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.”.

(m) For row 8.10.1, substitute—

“8.10.1		The study on the second species must not be conducted if the study performed on the

Prenatal Developmental 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.		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.”.

(n) For row 8.10.2, substitute—

“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 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 or other systemic toxicity.		A two-generation reproductive toxicity study conducted in accordance with OECD TG 416 (adopted 2001 or later) or equivalent information will be considered appropriate to address this information requirement, if the study is available and was initiated before 6th October 2025. Wherever possible, the storage of organ samples (including serum samples) from any of the cohorts and generations of the extended one-generation reproductive toxicity study is highly recommended. These samples may be useful for follow-up investigations, without the need for further animal testing.”.

(o) For row 8.10.3, substitute—

“8.10.3 Developmental neurotoxicity. Developmental Neurotoxicity Study in accordance with	ADS	The study must not be conducted if the available data: - indicate that the substance causes developmental toxicity and meets the criteria to be classified as toxic for

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.		reproduction Category 1A or 1B: May damage the unborn child (H360D), and - are adequate to support a robust risk assessment. The study must only be conducted if triggered by one of the following: - neurotoxicity occurs in adult animals, - 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.”.

(p) After row 8.10.3, insert—

“8.10.4 Further studies. A decision on the need to perform additional studies, including those providing information on the mechanisms, should be based on the outcomes of the studies listed in 8.10.1, 8.10.2, 8.10.3 and all other relevant available data.	ADS	Any additional in vivo study must be scientifically justified.”.

(q) For row 8.11.2, substitute—

"8.11.2 Carcinogenicity testing in a second species. (a) A second carcinogenicity study should be conducted using the mouse as test 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.	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.".

(r) For rows 8.12.1 to 8.12.8, substitute—

"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.".	

(s) For row 8.13.2, substitute—

"8.13.2	ADS".	
Neurotoxicity.		
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 OECD TG 419 or equivalent) will be required.		
If anticholinesterase activity is detected, a test for response to reactivating agents should be considered.		
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.		

(t) For row 8.13.3, substitute—

"8.13.3		Where sufficient weight of evidence to conclude on the presence or absence of a particular endocrine disrupting mode of action is available:
Endocrine disruption.		
The assessment of endocrine disruption must comprise the following tiers:		- further testing on vertebrate animals for that effect must be omitted for that mode of action;

(a) an assessment of the available information from the following studies, where available, and any other relevant information, including in vitro and in silico methods:

(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 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

- further testing not involving vertebrate animals may be omitted for that mode of action.

In all cases, adequate and reliable documentation must be provided.”.

	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.	
	(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 must be provided which elucidate one or more of the following, as appropriate:	
	(i) the mode or the mechanism of action;	
	(ii) 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.	

(u) After row 8.13.3, insert—

"8.13.3.1		ADS".

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;

(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 must 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.

(v) For row 8.13.4, substitute—

"8.13.4		ADS".
Immunotoxicity and developmental immunotoxicity.		
If there is any evidence from repeat dose or reproductive toxicity studies that the active substance may have immunotoxic properties, additional information or specific studies must be provided which elucidate one or more of the following, as appropriate:		
(i) the mode or the mechanism of action;		
(ii) 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.		

(w) For row 8.13.5, substitute—

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

(x) Omit row 8.18.

(y) For row 9.1.1, substitute—

"9.1.1		The study does not need to be conducted if:
Short-term toxicity testing on fish.		- a valid long-term aquatic toxicity study on fish is available;
When short-term fish toxicity data is required, the threshold approach (tiered strategy) should be applied.		- sufficient weight of evidence including the use of other data such as the Fish Embryo Acute Toxicity (FET, OECD TG 236) or results obtained from non-animal methods is available for this data requirement.".
Long-term toxicity testing on fish in accordance with point 9.1.6.1. will be considered if the substance is poorly water soluble, i.e. below 1 mg/l.		

(z) For row 9.1.6.1, substitute—

"9.1.6.1	ADS".	
Long term toxicity testing on fish.		

The information must be provided from long-term toxicity testing on fish in which early life-stages (eggs, larvae or juveniles) are exposed.	

(z1) For row 9.10, substitute—

"9.10 Endocrine disruption.	The assessment of endocrine disruption properties must 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, the studies set out in 9.10.1 or 9.10.2 will be considered taking account of any other available relevant information, including a systematic review of the literature.".

(z2) After row 9.10, insert—

"9.10.1	The study does not need to be carried out if:

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 Reproduction 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.	- 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, 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	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

and Development Assay (LAGDA; OECD TG 241).		
		- 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	ADS".	
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, must be provided which elucidate one or more of the following:		
(a) the mode or the mechanism of action;		
(b) potentially relevant adverse effects in humans or animals.		

(5) In the TITLE 2 (*Micro-organisms*) table—

(a) For the first row, substitute—

"**Column 1**	**Column 2**	**Column 3**
Information required	**All data is CDS unless indicated as ADS**	**Specific rules for adaption from Column 1".**

(b) For row 2.4, substitute—

"2.4		

	Specification of the technical grade active ingredient.”.

(c) After row 2.4, insert—

“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) For row 2.5, substitute—

“2.5	Method of production and quality control.”.

(e) Omit rows 2.6 to 2.9.

(f) For row 3.5, substitute—

“3.5	Information on the production of relevant metabolites and toxins.”.

(g) For row 4.1, substitute—

“4.1	

Methods, procedures and criteria used to establish the presence and identity of the micro-organism.”.	

(h) For row 4.2, substitute—

“4.2	
Analytical methods for the analysis of the micro-organism as manufactured.”.	

(i) After row 4.2, insert—

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

Schedule 2

Regulation 2(3)

Amendments to Annex 3 to Regulation (EU) No 528/2012 (*Information Requirements for Biocidal Products*)

1.—(1) Annex 3 to Regulation (EU) No 528/2012 (*Information Requirements for Biocidal Products*) is amended as follows.

(2) In Point 2, paragraph 4—

(a) for “competent authority” substitute “the Agency”.

(b) at the end, insert “. However, the information may not be sufficient or adequate to determine whether or not a non-active substance contained in a biocidal product has hazardous properties and the competent authority may conclude that further data are required”.

(3) In Point 2, for the seventh paragraph, substitute—

“The applicant must initiate a pre-submission consultation with the competent authority. In addition to the obligation set out in Article 62(2), the applicant may also consult with the competent authority with regard to the proposed information requirements and in particular the strategy for avoiding new testing on vertebrates alongside any testing on vertebrates that the

applicant proposes to carry out. The applicant must document such pre-submission consultations and their outcomes and must include the relevant documents in the application".

(4) In Point 5—

(a) after "Regulation (EC) No 440/2008.", insert "Where a revised version of a test method described in Commission Regulation (EC) No 440/2008 is available, but not included in that Regulation, the revised version may be used with the agreement of the competent authority.".

(b) after "…if a method is inappropriate or not described", insert "in Commission Regulation (EC) No 440/2008,".

(c) omit ", whenever possible internationally recognised,".

(5) In the TITLE 1 (*Chemical Products*) table—

(a) For the first row, substitute—

"**Column 1** **Information required**	**Column 2** **All data is CDS unless indicated as ADS**	**Column 3** **Specific rules for adaption from Column 1".**

(b) For row 6.6, substitute—

"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) For row 6.8.2, substitute—

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

(d) For row 8.1, substitute—

"8.1 Skin corrosion or irritation.		Testing of the product or mixture does not need to be conducted if:

The assessment must 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.	- 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 row already allow a 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.

	An in vivo study for skin corrosion or irritation must not be conducted unless the in vitro 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. In vivo studies for skin corrosion or irritation that were initiated before 6th October 2025 will be considered appropriate to address this information requirement only if they lead to a more severe classification than the calculation method of Regulation (EC) No 1272/2008.”.

(e) For row 8.2, substitute—

“8.2 Serious eye damage or eye irritation. The assessment must 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;	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 product or mixture is a strong acid (pH≤ 2.0) or base (pH≥ 11.5), - the product or mixture is spontaneously flammable in

(c) serious eye damage or eye irritation, in vivo testing.	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, other in vitro studies for this endpoint must be considered. An in vivo study for serious eye damage or eye irritation must not be conducted unless the in vitro studies 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. In vivo studies for serious eye damage or eye irritation that were initiated before 6th October 2025 will be considered appropriate to address this information requirement only if they lead to a more severe classification than the calculation method of Regulation (EC) No 1272/2008.”.

(f) For row 8.3, substitute—

"8.3 Skin sensitisation. The information must allow a conclusion as to 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 must comprise the following tiers: (a) assessment of the available human, animal and non-animal data; (b) skin sensitisation, in vitro testing according to OECD TG 497; (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 circumstances. If another skin sensitisation test is used, scientific justification must be provided.	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 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 row is available, or - the available in vitro or in chemico test methods

	of OECD TG 497 are not applicable for the product or mixture or the results obtained from these studies are not adequate for classification and risk assessment. An in vivo study for skin sensitisation must not be conducted unless the in vitro or in chemico studies of OECD TG 497 referred to 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 and the calculation method or bridging principles laid down in Regulation (EC) No 1272/2008 are not applicable. In vivo studies for skin sensitisation that were initiated before 6th October 2025 will be considered appropriate to address this information requirement.”.

(g) For row 8.5, substitute—

“8.5 Acute toxicity. Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach and should include an assessment of information from in silico approaches.	Testing on the product/mixture does not need to be conducted if: - 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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.”.

(h) For row 8.7, substitute—

"8.7 Available toxicological data relating to: (a) a non-active substance or substances (i.e. substance or substances of concern); (b) a mixture containing a substance or substances of concern. Targeted tests listed in Section 8 of the table in Title 1 of Annex 2 must be carried out, with consideration of reduction of animal use, for the substance or substances of concern or a mixture containing a substance or substances of concern 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 as to whether the biocidal product can be considered as having endocrine disrupting properties; - synergistic effects between any of the components are not expected.".

(i) For row 9.1, substitute—

"9.1 Available ecotoxicological data relating to: (a) a non-active substance or substances (i.e. substance or substances of concern);	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 rules laid

		down in Regulation (EC) No 1272/2008;
(b) a mixture containing a substance or substances of concern.		
		- a conclusion can be made as to whether the biocidal product can be considered as having endocrine disrupting properties;
Tests listed in Section 9 of Title 1 of Annex 2 must be carried out for the substance or substances of concern or a mixture containing a substance or substances of concern if insufficient data are available and cannot be inferred through read-across, in silico or other accepted non-testing approaches.		- synergistic effects between any of the components are not expected.”.

(6) In the TITLE 2 (*Micro-organisms*) table—

(a) For the first row, substitute—

“**Column 1** **Information required**	**Column 2** **All data is CDS unless indicated as ADS**	**Column 3** **Specific rules for adaption from Column 1”.**

(b) For row 2.3, substitute—

“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 substances and non-active substances and any other relevant components. All relevant information on individual ingredients and the final composition of the		

biocidal product must be given.”.	

(c) For row 3.6.8, substitute—

“3.6.8	Spraying patterns – aerosols”.

(d) For row 3.6.9, substitute—

“3.6.9	Other technical characteristics”.

(e) Omit rows 3.6.10 to 3.6.12.

(f) For rows 4.1 to 4.12.3, substitute—

“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".

(g) For row 10.3, substitute—

"10.3 ADS".

Leaching behaviour or mobility

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (EUR 2012/528) ("Regulation (EU) No 528/2012").

These Regulations make amendments to Annex 2 and Annex 3 to Regulation (EU) No 528/2012. Annex 2 and Annex 3 set out the information requirements for active substance applications and biocidal products applications respectively. The amendments update the information requirements in line with scientific and technical advances.

Regulation 3 of these Regulations makes transitional and saving provision.

An impact assessment on the effect that these Regulations will have on the cost of business is available from the Health and Safety Executive, Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS. The impact assessment is annexed to the Explanatory Memorandum which is available alongside these Regulations on the UK legislation website at http://www.legislation.gov.uk.