Annex 9

ข้อกำหนดเกี่ยวกับมาตรฐานข้อมูลสารเคมีที่ผลิตหรือนำเข้า
ในปริมาณตั้งแต่ 100 ตัน หรือมากกว่า

ใน Column ที่ 1 ของภาคผนวกนี้เป็นข้อมูลมาตรฐานที่กำหนดขึ้นสำหรับสารเคมีทุกตัวที่มีการผลิตหรือนำเข้าในปริมาณตั้งแต่ 100 ตันขึ้นไป โดยสอดคล้องกับมาตรา 12(1)(d) โดยเฉพาะอย่างยิ่งข้อมูลที่ต้องการใน Column ที่ 1 ของมาตรา นี้เป็นส่วนที่เพิ่มเข้าไปในส่วนที่มีการร้องขอใน Column ที่ 1 ของภาคผนวก 7 และ 8 ส่วนข้อมูลอื่น ๆ ที่สัมพันธ์กันด้านเคมีกายภาพ พิษวิทยา และนิเวศพิษวิทยานั้นก็สามารถนำมาใช้ในการจัดหาได้ ส่วนใน Column ที่ 2 ของภาคผนวกนี้ เป็นรายการกฎที่เฉพาะของข้อกำหนดมาตรฐานที่อาจจะได้รับการยกเว้นซึ่งถูกแทนที่ด้วยข้อมูลอื่น ๆ โดยถูกจัดหามาในขั้นตอนที่ต่างกันหรือนำไปใช้ในทางอื่น ๆ ถ้าสภาวะต่าง ๆ อยู่ภายใต้ Column ที่ 2 ของภาคผนวกนี้ อนุญาตให้มีการนำไปใช้ได้ ในการนำข้อกำหนดไปใช้นั้นผู้จดทะเบียนควรจะมีความชัดเจนมีความเป็นจริงและมีเหตุผลภายใต้ความเหมาะสมในเอกสารการจดทะเบียน

ในการเพิ่มข้อกำหนดเฉพาะนี้ ผู้จดทะเบียนอาจจะเสนอการใช้ข้อมูลมาตรฐานที่ต้องการใน Column ที่ 1 ของภาคผนวกนี้ให้สอดคล้องกับกฎทั่วไปในภาคผนวก 11 โดยในทางที่ดีควรมีเหตุผลที่ชัดเจนในการตัดสินใจใช้ข้อมูลมาตรฐานอย่างเหมาะสมในการจดทะเบียนเอกสารโดยอ้างถึงกฎเฉพาะใน column ที่ 2 หรือในภาคผนวก 11

ก่อนที่การทดสอบใหม่ ๆ จะถูกนำออกมากำหนดรายละเอียดของคุณสมบัติในภาคผนวกนี้ ข้อมูล in vitro ข้อมูล in vivo ข้อมูลจาก (Q)SARs และข้อมูลจากสารเคมีที่สัมพันธ์กัน (read-across approach) ที่หามาได้ทั้งหมดควรที่จะประเมินเป็นอันดับแรก การทดสอบกับ in vivo ด้วยสารเคมีกัดกร่อนที่ระดับความเข้มข้น/ปริมาณ ที่ทำให้เกิดการเกิดการกัดกร่อนควรที่จะหลีกเลี่ยง โดยก่อนการทดสอบควรนำคำแนะนำในภาคผนวกนี้ไปศึกษา

7. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.15. Stability in organic solvents and identity of relevant degradation products Only required if stability of the substance is considered to be critical.	7.15. The study does not need to be conducted if the substance is inorganic.
7.16. Dissociation constant	7.16. The study does not need to be conducted if: — the substance is hydrolytically unstable (half-life less than 12 hours) or is readily oxidisable in water, or — it is scientifically not possible to perform the test for instance if the analytical method is not sensitive enough.
7.17. Viscosity	

8. TOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	8.4. If there is a positive result in any of the *in vitro* genotoxicity studies in Annex VII or VIII and there are no results available from an *in vivo* study already, an appropriate *in vivo* somatic cell genotoxicity study shall be proposed by the registrant. If there is a positive result from an *in vivo* somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered.
8.6. Repeated dose toxicity	
8.6.1. Short-term repeated dose toxicity study (28 days), one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, unless already provided as part of Annex VIII requirements or if tests according to Section 8.6.2 of this Annex is proposed. In this case, Section 3 of Annex XI shall not apply.	

COLUMN 1 STANDARD INFORMATION REQUIRED		COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
8.6.2.	Sub-chronic toxicity study (90-day), one species, rodent, male and female, most appropriate route of administration, having regard to the likely route of human exposure.	8.6.2. The sub-chronic toxicity study (90 days) does not need to be conducted if: — a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure, or — a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used, or — a substance undergoes immediate disintegration and there are sufficient data on the cleavage products (both for systemic effects and effects at the site of uptake), or — the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure. The appropriate route shall be chosen on the following basis: Testing by the dermal route is appropriate if: (1) skin contact in production and/or use is likely; and (2) the physicochemical properties suggest a significant rate of absorption through the skin; and (3) one of the following conditions is met: — toxicity is observed in the acute dermal toxicity test at lower doses than in the oral toxicity test, or — systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies, or — *in vitro* tests indicate significant dermal absorption, or — significant dermal toxicity or dermal penetration is recognised for structurally-related substances.
		Testing by the inhalation route is appropriate if: — exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size. Further studies shall be proposed by the registrant or may be required by the Agency in accordance with Articles 40 or 41 in case of: — failure to identify a NOAEL in the 90 days study unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects, or — toxicity of particular concern (e.g. serious/severe effects), or — indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity), or — particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected).
8.7.	Reproductive toxicity	8.7. The studies do not need to be conducted if: — the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented, or — the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented, or — the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), 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 there is no or no significant human exposure.

COLUMN 1 STANDARD INFORMATION REQUIRED		COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
		If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1 or 2: R60, and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered. If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1 or 2: R61, 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.
8.7.2.	Pre-natal developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (B.31 of the Commission Regulation on test methods as specified in Article 13(3) or OECD 414).	8.7.2. The study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data.
8.7.3.	Two-generation reproductive toxicity study, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, if the 28-day or 90-day study indicates adverse effects on reproductive organs or tissues.	8.7.3. The study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available date.

9. ECOTOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED		COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
9.1.	Aquatic toxicity	9.1. Long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.
9.1.5.	Long-term toxicity testing on invertebrates (preferred species *Daphnia*), (unless already provided as part of Annex VII requirements)	
9.1.6.	Long-term toxicity testing on fish, (unless already provided as part of Annex VIII requirements) The information shall be provided for one of the Sections 9.1.6.1, 9.1.6.2 or 9.1.6.3.	

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
9.1.6.2. Fish early-life stage (FELS) toxicity test	
9.1.6.2. Fish short-term toxicity test on embryo and sac-fry stages	
9.1.6.3. Fish, juvenile growth test	
9.2. Degradation	9.2. Further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media (e.g. water, sediment or soil).
9.2.1. Biotic	
9.2.1.2. Simulation testing on ultimate degradation in surface water	9.2.1.2. The study need not be conducted if: — the substances is highly insoluble in water, or — the substance is readily biodegradable.
9.2.1.3. Soil simulation testing (for substances with a high potential for adsorption to soil)	9.2.1.3. The study need not be conducted: — if the substance is readily biodegradable, or — if direct and indirect exposure of soil is unlikely.
9.2.1.4. Sediment simulation testing (for substances with a high potential for adsorption to sediment)	9.2.1.4. The study need not be conducted: — if the substance is readily biodegradable, or — if direct and indirect exposure of sediment is unlikely.
9.2.3. Identification of degradation products	9.2.3. Unless the substance is readily biodegradable
9.3. Fate and behaviour in the environment	
9.3.2. Bioaccumulation in aquatic species, preferably fish	9.3.2. The study need not be conducted if: — the substance has a low potential for bioaccumulation (for instance a log Kow ≤ 3) and/or a low potential to cross biological membranes, or — direct and indirect exposure of the aquatic compartment is unlikely.
9.3.3. Further information on adsorption/desorption depending on the results of the study required in Annex VIII	9.3.3. The study need not be conducted if: — based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient), or — the substance and its degradation products decompose rapidly.
9.4. Effects on terrestrial organisms	9.4. These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment. In particular for substances that have a high potential to adsorb to soil or that are very persistent, the registrant shall consider long-term toxicity testing instead of short-term.
9.4.1. Short-term toxicity to invertebrates	
9.4.2. Effects on soil micro-organisms	
9.4.3. Short-term toxicity to plants	