QUESTIONNAIRE: REACH INTRODUCTION

Note: For some of the questions there is more than one correct answer.

1. **What does the abbreviation REACH stand for? Please complete the letters.**

☐ Registration

☐ Evaluation

☐ Authorisation

☐ CHemicals

2. **Who is responsible under REACH for the safe use of a chemical?**

☒ The manufacturer of a chemical

☐ The user of a chemical

☒ The manufacturer together with the user of a chemical

☐ The competent authorities

3. **What is a Downstream User of a substance?**

☐ The user of an article containing the substance

☐ A consumer applying a product

☒ All actors who use a substance in industrial or professional processes

☐ Traders of chemical products

4. **What is the purpose of risk management measures?**

☒ To ensure safe use of chemicals regarding human health and the environment

☐ To identify the most beneficial measures for workers protection

☐ To exclude emissions into the environment

5. **What has to be registered under REACH?**

☐ All chemicals and mixtures

☒ All substances produced in the EU or imported into the EU in amounts ≥ 1 tonne per year

☐ All dangerous chemicals imported into the EU in amounts > 10 tonnes per year.

☐ All dangerous chemicals in articles

6. Which information has to be submitted by the registrant as part of the registration dossier?

☐ Details on whom he does not want to register with in a consortium

☒ Information on the inherent properties of the substance

☒ Information on the uses of the substance

☒ Details on the produced or imported amounts of the substance

☒ Identified uses

☐ All uses

7. When do phase-in substances in amounts < 100 tonnes per year have to be registered (excluding any CMR substances)?

☐ Before 1 December 2010

☐ Before 1 June 2013

☒ Before 1 June 2018

☒ 11 years after the REACH regulation entered into force

8. Which of the following sentences are correct?

☒ Each registrant has to submit his own registration dossier for all substances produced or imported in amounts ≥ 1 tonne per year

☐ All manufacturers/importers of a substance have to register in a consortium without exception (OneSubstanceOneRegistration-principle) to avoid double work

☒ A SIEF aims at facilitating the sharing of substance data

☐ All manufacturers/importers submit one registration dossier, which includes all information on the inherent properties of the substances, all identified uses and the respective risk management measures

9. Which of the mentioned substances are exempted from the registration?

☒ Vitamin A

☒ Substances in waste

☐ Monomers

☒ Polymers

☒ New substances included in ELINCS

☒ Substances used in food

10. Which substances need a SDS in order to be put on the market?

☒ Substances classified according to 67/548/EEC

☐ Substances in Annex XVII in REACH

☐ PBT substances

☒ CMR substances

☐ Substances on the candidate list to Annex XIV

☐ All substances

11. For which substances can an extended safety data sheet be expected?

☐ All substances

☐ All substances classified as dangerous

☐ All substances, for which a chemical safety report has been prepared

☒ All substances, for which a chemical safety report has been prepared, and where the report includes one or more exposure scenarios

12. When does a downstream user have to make an exposure scenario?

☐ Never

☐ When he imports a dangerous substance from the non-EU in amounts < 10 tonnes per year and the non-EU manufacturer won't register the substance himself

☒ When the exposure scenario of the supplier doesn't comply with the actual conditions of the downstream user, and the downstream user does not want to inform the supplier about it, and he wants to use the substance in amounts > 1 tonne per year

13. Which substances in articles should be registered?

☒ Substances, which are intended to be released from articles and which are included into these in amounts ≥ 1 tonnes per year and per producer of articles/importer

☐ CMR and PBT substances in articles if they are included in amounts 1 ≥ tonne per year and per producer of articles/importer

☐ All substances in articles if they are included in amounts ≥ 1 tonne per year and per producer of articles/importer

14. For which substances is it needed to include a chemical safety report as part of the registration?

☐ All substances

☐ All dangerous substances

☒ All substances ≥ 10 tonnes per year and per manufacturer/importer

☐ All dangerous substances ≥ 10 tonnes per year and per manufacturer/importer

15. Which main elements are contained in the registration process?

☒ A technical dossier, which is sent to the chemicals agency

☐ A detailed review of the technical dossier by the agency

☒ A chemical safety report if the substance is produced/imported in amounts ≥ 10 tonnes per year per manufacturer/importer

☒ An exposure scenario as part of the chemical safety report, if the substance is dangerous or identified as PBT/vPvB

16. What is the objective of the evaluation?

☐ To assess if all registrants have submitted complete registration dossiers

☒ To assess the quality of the data included in the technical dossier

☐ To control that chemicals are used under safe conditions throughout the EU

☐ To check whether all tests are made as GLP tests

17. Which substances are only allowed to be applied after an authorisation has been granted?

☒ All substances listed in Appendix XIV

☐ All substances listed on Annex XVII

☐ All substances with particularly hazardous properties, e.g. CMRs or PBTs

☐ All substances produced in amounts ≥ 1000 tonnes per year and per manufacturer/importer

18. Which obligations does a distributor have to fulfil?

☐ He has to register all the products that he trades inside and outside the EU

☐ A trader is also a downstream user and therefore he has to fulfil the obligations of a downstream user

☒ A distributor has to forward information up and down the supply chain

☐ A distributor has to implement the conditions of safe use of a chemical and communicate information up and down the supply chain

19. **How do you plan to decide on which REACH roles you have?**

Analysis of raw material portfolio, identification of role(s), derivation of obligations.

20. **Who examines the registration dossier for completeness? Who examines the registration dossier for quality?**

Completeness check: All registration dossiers are automatically checked by the European Chemicals Agency (ECHA).

Quality evaluation: The ECHA will check only 5% of all the registration dossiers.

21. **What are the two functions of an exposure scenario?**

- Communication means to forward information together with safety data sheet about safe conditions of use
- Used in the chemicals safety assessment for derivation of safe conditions of use

22. **Which questions do the exposure scenario answer regarding the use of substances and preparations? How is it provided? (keywords only)**

How can a substance/preparation be used safely?

It assesses and describes the risks of the respective uses

Provision: Compilation and analysis of information on hazardous properties of a substance, derivation on safe thresholds for human health and the environment, assessment of exposure from the respective uses; Iterative process: Making of a tentative exposure scenario, comparing of calculated exposure level und safe level (thresholds), if the result is that there is no risk: stop → final exposure scenario, if there is a risk: refinement of iteration.

23. **When will industry have registered all phase-in substances?**

2018

24. **What do you think are the fundamentally changes in the chemicals legislation under REACH?**

E.g., change of responsibility: Industry is responsible for the safe use of their substances during their whole life cycle, substance are not allowed to be marketed without data, new and old substances have to fulfil the same requirements.

25. **Why is it important not to miss the pre-registration phase?**

Only then it is possible to use the later registration deadline. Only if a chemical substance is pre-registered, it can be marketed until the respective registration deadline.

26. What is new for a downstream user under REACH?

E.g., they will receive more information on the chemical substances and the conditions of safe use, and they have the obligation to implement the recommended risk management measures for the identified uses.