Substances Covered by Industry Submissions & Actions to Meet REACH Requirements

[Note: REACH exempts for all actions any substances that are: non-isolated intermediates; wastes; radioactive substances; substances under customs supervision; in transit by rail, road, inland waterway, sea, or air; and substances that Member States exempt in the interest of defence (Article 2(1), (2), & (3)).]

Industry Submission or Action	Substances Covered By Actions [And Specifically Included or Excluded]
Pre-Registration of substance, including in articles, to allow Agency to exchange info. and establish SIEF (Article 28)	Phase-in substances at or above 1 tonne per year. Includes substance in preparations and in articles with releases in normal or foreseeable use. Substances first meeting quantity limits after pre-registration ended on 1 December 2008, if manufacture or importer provides required info. in 6 months of first manufacturing or importing the substance, and before 12 months of deadline. Excludes substances considered already registered as notified per 67/548/EEC and in ELINCS (Article 24), plant protection products, and biocide products (Article 15).
Inquiry on substance registration status; allows Agency connect potential registrants (Article 26)	Non-phase in substances and phase-in substances that have not been pre-registered, but are at or above 1 tonne per year. Includes substance in preparations and in articles intended to release the substance during normal or foreseeable use. Excludes substances considered already registered as notified under 67/548/EEC, which are in ELINCS (Article 24).
Registration Dossier including classification and labeling (Article 10)	Substances at or above 1 tonne per year. Includes substances in preparations & articles intended to release substance in normal or foreseeable use. Excludes substances considered already registered (as notified under 67/548/EEC (in ELINCS) (Article 24), and biocides & plant protection products (Article 15)). On-site and non-transported isolated intermediates (see below) (Article 17, 18). The 68 Substances listed in Annex IV (793/93/EEC) and those meeting 9 criteria in Annex V (67/548/EEC) including: results of chemical reactions (e.g., incidental to storage, exposure to env. factors, end use, additives, byproducts, physiochemical function, adding water); not chemically modified (e.g., minerals, ores & concentrates, cement clinker, natural gas & condensate, liquefied petroleum gas, process gases & components, crude oil, coal & coke); hydrogen, oxygen, argon, helium, neon, xenon, & nitrogen (Article 2(7a, b)). Substances registered, then exported, and re-imported as the same substance (Article 2(7c)). Substances registered, then recovered as the same substance (Article 2(7d)). Use regulated by other legislation: medicinal products for human (726/204/EC & 2001/83/EC) or veterinary use (2001/82/EC); food & feedingstuffs (178/2002/EC) incl. additives & flavorings (Article 2(5)). Substances used in product & process oriented R&D (PPORD) are exempt for 5 years (Article 9).
Registration Dossier and **Chemical Safety Report** (Article 10(b))	All substances at or above 10 tonnes per year. Includes substances in preparations and in articles intended to release the substance during normal or foreseeable use. Excludes same exclusions as for Registration Dossier (above). CSR may exclude consideration of risks to human health from food contact materials (1935/2004/EC) and in cosmetic products (76/768/EEC) (Article 14(5).
Registration Dossier, CSR, and **Use and Exposure Scenario** (Article 14, 37)	Dangerous substances, PBTs, or vPvBs, at or above 10 tonnes per year, and meeting or exceeding any of six concentration limits (i.e., PBTs or vPvBs at 0.1%) (Article 14(2)). Includes substances in preparations & articles intended to release the substance during normal or foreseeable use. Excludes same exclusions as Registration Dossier & CSR (above).
Registration of On-site Isolated Intermediate (Article 17, 19)	On-site isolated intermediate, manufactured at 1 tonne or more, which is manufactured and used under strictly controlled conditions, rigorously contained by technical means during the lifecycle, and with controls & procedural technologies to minimize emissions & resulting exposure.
Registration of Transported Isolated Intermediate (Article 18, 19)	Transport of an isolated intermediate, manufactured or imported at 1 tonne or more, used in the synthesis of another substance under strictly controlled conditions, rigorously contained by technical means during the entire lifecycle, with strict controls & procedural technologies to minimize emissions & resulting exposure, and only handled by trained & authorized personnel.

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Industry Submission or Action	Substances Covered By Actions [And Specifically Included or Excluded]
Notification for Articles (Article 7(2))	Substances of very high concern (SVHC) in articles at or above 1 tonne per year and present >0.1% by weight and not intended to release substance during normal or foreseeable use, but the substance is likely to be released during use, including disposal. Notifications apply from 1 June 2011, beginning 6 months after the substance is named a priority substance (Article 7(3)). Excludes when no exposure occurs, and substances registered for that use.
Notification for PPORD (Article 9)	Substances manufactured or imported for the purpose of product and process oriented research and development (PPORD) are exempt from registration requirements for 5 years (Article 9(1)).
Authorisation Application (Article 56, 62)	Substances to be in Annex XIV (PBT, vPvB, CMR (categories 1 & 2), & endocrine disruptors). Excludes on-site and non-transported isolated intermediates (Article 17, 18). Uses regulated by other legislation: medicinal products for human (726/204/EC & 2001/83/EC) or veterinary use (2001/82/EC); food or feedingstuffs (178/2002/EC) including as an additive or flavoring (Article 2(5)). Use in scientific R&D; process oriented R&D per Annex XIV; plant protection (98/70/EC); biocidal products (98/8/EC; motor fuel (98/70/EC); and fuel for mineral oil production & closed systems (Article 56(3 &4)). CMR (categories 1 & 2) if only human health hazard for use in: cosmetics (76/768/EEC) or food contact material (1935/2004/EC) (Article 56(5)). PBT, vPvB, & endocrine disruptors in preparations at <0.1%. Substances below concentration limits set by 1999/45/EC and 67/548/EEC Annex I (Article 56(5)).
Restriction by Agency (Article 67, 68)	Any substance listed in Annex XVII. Member States may continue more stringent restrictions until 1 June 2013. Excludes use in: scientific R&D; certain process oriented R&D; and human health hazard for use in cosmetics (76/768/EEC) (Article 67).
Safety Data Sheet (SDS) (Article 31, Annex II)	Dangerous substances (67/548/EEC or 199/45/EC) and in preparations; PBT, vPvB; & requiring authorization per Annex XIV. SDS must be in language of country where marketed. Excludes products intended for final user: medicinal products for human use (726/204/EC & 2001/83/EC); cosmetic products (76/768/EEC); medical devices contacting human body (1999/45/EC); food or feedingstuffs incl. additives & flavorings (178/2002/EC) (Article 2(6)).
Info. in Lieu of Safety Data Sheet (Article 32)	Substances & preparations not requiring an SDS; with first delivery after 1 June 2007. Excludes products intended for final user: medicinal products for human use (726/204/EC & 2001/83/EC); cosmetic products (76/768/EEC); medical devices contacting human body (1999/45/EC); food or feedingstuffs incl. additives & flavorings (178/2002/EC) (Article 2(6)).
Downstream User Prepared Information (Article 37, 38, 39)	Downstream user (DU) prepares CSR or relies on exemptions either for use of a total of <1 tonne per year or for product and process oriented R&D (PPORD) (Article 38(1)). Excludes the 68 Substances listed in Annex IV (793/93/EEC) and those meeting 9 criteria in Annex V (67/548/EEC) including: results of chemical reactions (e.g., incidental to storage, exposure to env. factors, end use, additives, byproducts, physiochemical function, and adding water); not chemically modified (e.g., minerals, ores & concentrates, cement clinker, natural gas & condensate, liquefied petroleum gas, process gases & components, crude oil, coal & coke); hydrogen, oxygen, argon, helium, neon, xenon, and nitrogen (Article 2(7a, b)). Substances registered, then exported, and re-imported as the same substance (Article 2(7c)). Substances registered, and then recovered as the same substance (Article 2(7d)). Uses regulated by other legislation: medicinal products for human (726/204/EC & 2001/83/EC) or veterinary use (2001/82/EC); food & feedingstuffs (178/2002/EC) incl. additives & flavorings (Article 2(5)).
Notification for Classification & Labeling (Article 112, 113)	Substances subject to registration and substances not subject to registration that are dangerous substances (67/548/EEC, Article 1) and placed on the market above concentration limits specified in 1999/45/EC. Applies 1 December 2010. Excludes: information submitted for registration.
Information to Consumers on Articles (Article 7(3), 33)	Substances subject to authorisation in articles at or above >0.1% by weight require information to allow safe use, including, at a minimum, the name of the substance. Information must be provided within 45 of request by a consumer.

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