HANDBOOK OF CHEMICAL REGULATIONS

Benchmarking, Implementation, and Engineering Concepts

EDITED BY MARTHA J. BOSS
BRAD BOSS
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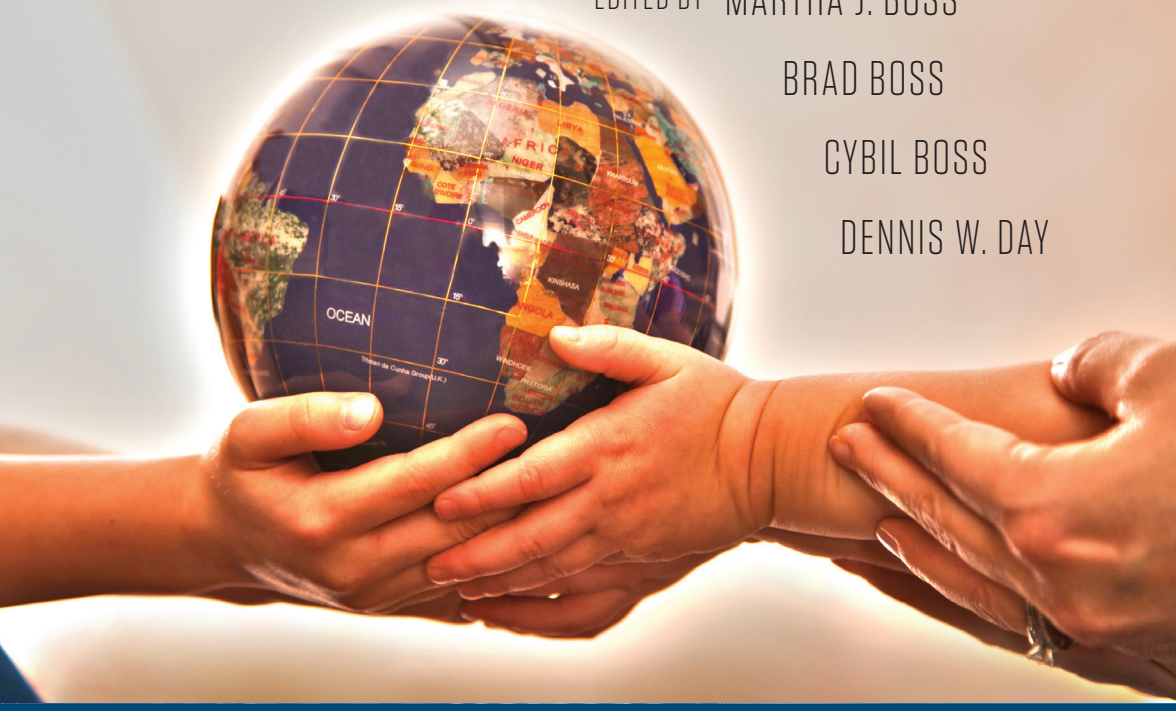

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Contents

List of Acronyms

°C	degrees Celsius
°F	degrees Fahrenheit
>	greater than
≥	greater than or equal to
<	less than
%	percent
9CI	Ninth Collective Index
ΔHc	chemical heat of combustion
ΔHcomb	theoretical heat of combustion
ACGIH	American Conference of Government Industrial Hygienists
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
AFNOR	Association française de normalisation (French Standards)
ANE	ammonium nitrate emulsion
ASTM	ASTM International
ATE	Acute Toxicity Estimates
ATP	adaptations to technical progress
BCF	bioconcentration factor
BCOP	Bovine Cornial Opacity and Permeability
CA	Chemical Abstracts
CAS	Chemical Abstracts Service
CASRN	Chemical Abstracts Service Registry Number
CDC	Center for Disease Control and Prevention
CEN	European Committee for Standardization
CFR	Code of Federal Regulations
CLP	classification, labelling, and packaging
CMR	carcinogenic, mutagenic or toxic for reproduction
CR	conditionally required
CSA	chemical safety assessment
CSR	chemical safety report
DIN	Deutsches Institut für Normung (German Institute for Standardisation)
DNA	Deoxyribonucleic acid
DNEL	derived no-effect level
DOT	Department of Transportation (United States)
DU	downstream user
EC	European Community
EC_{10}	effective concentration 10
ECVAM	European Centre for the Validation of Alternative Methods

EDTMPA	Phosphonic acid, [1,2-ethanediyl-bis[nitrilobis-(methylene)]]tetrakis
EEC	European Economic Community
EHS	Extremely Hazardous Substances
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Substance
EPCRA	Emergency Planning and Community Right-to-Know Act (USEPA)
EU	European Union
FDA	Food and Drug Administration (United States)
FELS	Fish early-life stage
FEMA	Federal Emergency Management Agency
FFDCA	Federal Food, Drug and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act (USEPA)
FR	Federal Register
FYI	for your information
GLP	good laboratory practices
GHS	Global Harmonization System
GMP	good manufacturing practices
HazCom	Hazard Communication (OSHA)
HCS	Hazard Communication Standard
HMT	Human Maximization Test
HRIPT	Human Repeat Insult Patch Test
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC	International Bulk Chemical
IBR	incorporated by reference
ICAO	International Civil Aviation Organization
IgE	Immunoglobulin E
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
IPCS	International Programme on Chemical Safety
ISBN	International Standard Book Number
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
J/g	Joules/gram
kgs	kilograms
kJ/g	kilojoule/kilogram
K_{ow}	octanol–water partition coefficient
kPa	kilopascal
lb	pound
LC_{50}	lethal concentration 50
LD_{50}	lethal dose 50
LEPC	Local Emergency Planning Committee
LLNA	Local Lymph Node Assay
LOAEL	lowest observed adverse effect level
LPG	Liquefied Petroleum Gas
M-factor	multiplying factor

MARPOL	International Convention for the Prevention of Pollution from Ships
MBOCA	4,4′-methylenebis(2-chloroaniline)
MEPC	Marine Environment Protection Committee
MEST	Mouse Ear Swelling Test
mg/kg	milligrams per kilogram
mg/l	milligrams per liter
M/I	manufacture(d) or import(ed)
MI	manufacturer or importer
MIP	manufacturer or importer or producer
ml	milliliter
MMAD	mean mass aerodynamic diameter
mm/s	millimeter/second
NAICS	North American Industry Classification System
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NLP	no longer polymer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NTP	National Toxicology Program
OECD	Organization for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
P	persistence criterion
P-TBB	*p-tert*-butylbenzaldehyde
P-TBBA	*p-tert*-butylbenzoic acid
P-TBT	*p-tert*-butyltoluene
PBT	persistent, bioaccumulative, and toxic
PCB	polychlorinated biphenyl
PEL	permissible exposure limit
P/I	produce(d) or import(ed)
PI	producer or importer
PIP	plant-incorporated protectant
PMN	premanufacture notice
PNEC	predicted no-effect concentration
PPE	personal protective equipment
ppmV	parts per million per volume
PPORD	process orientated research and development
PRC	People's Republic of China
psi	pounds per square inch
(Q)SAR	(quantitative) structure–activity relationship
R	required
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
RQ	reportable quantity
RTI	respiratory tract irritation
SADT	self-accelerating decomposition temperature

SAE	Society of Automotive Engineers
SAR	structure/activity relationship
SARA	Superfund Amendments and Reauthorization Act of 1986
SCE	Sister Chromatid Exchanges
SDS	safety data sheet
SEA	socio-economic analysis
SERC	State Emergency Response Commission
SIEF	substance information exchange forum
S/M/A	substance, mixture, or article
SME	small, medium size enterprises
SMILES	simplified molecular input line entry system
SNU	significant new use
SNUN	significant new use notice
SNUR	Significant New Use Rules
STOT-RE	specific target organ toxicity after repeated exposure
STOT-SE	specific target organ toxicity single exposure
T	toxicity criterion
T	toxic
T+	very toxic
TER	transcutaneous electrical resistance
TLV	threshold limit value
TPQ	threshold planning quantity
TSCA	Toxic Substance Control Act
UDS	unscheduled DNA synthesis
UN	United Nations
UNEC	United Nations Economic Commission for Europe
UNS	unified numbering system
U.S.	United States
U.S.C.	United States Code
USC	United States Code
USEPA	United States Environmental Protection Agency
U.S.P.	United States Pharmacopoeia
vB	“very bioaccumulative” criterion
vP	“very persistent” criterion
vPvB	very persistent and very bioaccumulative
WSSD	World Summit on Sustainable Development
w/w	weight by weight
Xn	harmful

Preface

I am a student
Like minded and ready to learn
However
I have learned all I can know

poem courtesy of Bryce Boss

What we considered safe yesterday may not be true today. Picture job sites of the past where workers routinely dismantled asbestos-laden buildings without respiratory protection, sand blasted lead-based paint walls without regard to dust generation, or disposed of chemical substances without concern for the environment. These types of practices were common and were attributed, in part, to a lack of chemical knowledge and regulatory onus to make better decisions. Fortunately, when we learn a better way and especially the "reasons why," change generally happens.

Many like-minded people have contributed to the knowledge base of the guidance documents and regulatory text represented in this book. Binding these ideas together forms a threshold for future endeavors to evaluate chemical risk and present the categorical hazards associated with chemical usage. By understanding the risks and hazards, better judgments can be made—as to which chemicals to use and how to properly inform both workers and the general population of chemical exposure potentials.

Just as science and education need an interwoven framework upon which to grow new ideas, regulatory thresholds are necessary to grow new awareness. This awareness pushes the boundaries of knowledge higher.

So that I may know all that you have learned.

Editors

Martha J. Boss is a certified industrial hygienist and certified safety professional with expertise in REACH, CLP, OSHA, GHS, FIFRA, TSCA, USEPA (United States Environmental Protection Agency), and EU global harmonization requirements. Boss has over 24 years of experience in risk management including analysis of statistical parameters, severity and probability associated with health risks, toxicological profiles (including those associated with active pharmaceutical ingredients), occupational exposure limits, biological safety levels, physical hazards (electromagnetic, ionizing, and nonionizing radiation), and hazardous or mixed (radiological and chemical) materials. Martha has audited international programs to determine client compliance with United States, EU, and Asia-Pacific requirements. Boss has authored guidance documents, safety and environmental manuals for the Department of Defense (DoD), safety and industrial hygiene training materials for the Department of Labor, risk management documents for the National Institute for Occupational Safety and Health/Centers for Disease Control and Prevention, investigative reports for the Federal Emergency Management Agency, design analysis for the Department of Homeland Security, training texts for the Department of Interior/Bureau of Indian Affairs, and numerous reports for the USEPA. Boss has provided compliance auditing, contractor oversight, industrial hygiene, safety engineering, emergency response, and risk management planning. She has authored original safety program documents, authored guidance documents, and audited compliance for management systems, environmental regulations, safety, and industrial hygiene. Boss has expertise in indoor air quality and ventilation evaluation, due diligence assessments, biological risk assessment, pollution prevention and waste minimization studies, and industrial hygiene/safety engineering design analysis. She has provided clients with interdisciplinary expertise in hazard analysis and the required planning to mitigate hazards. Martha is co-editor and author of the *Building Vulnerability Assessments*, *Biological Risk Engineering Handbook*, *Air Sampling and Industrial Hygiene Engineering*, and *Electrical Safety Sustainability and Stewardship* texts published by the CRC Press division of Taylor & Francis.

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Cybil Boss is a chemical engineer and a registered professional engineer with more than 10 years of experience in hazard communication, chemical engineering, and

environmental risk management. She has authored numerous technical reports for the private sector and DoD clients and has also managed compliance and reporting for regulatory permitting programs. She has worked on a diverse portfolio of projects including pollution prevention; toxic inventory reporting; stormwater, groundwater, and soil remediation; and military munitions response. She holds a bachelor's degree in chemical engineering from the University of Nebraska.

Dennis W. Day is a certified industrial hygienist and certified safety professional with more than 25 years of experience in industrial hygiene monitoring, health, safety, machine guarding, safety engineering, product stewardship, and environmental auditing. Day has provided original safety program documents, authored guidance documents, and audited compliance for management systems, environmental regulations, safety, and industrial hygiene. He has interdisciplinary expertise in hazard analysis and the required planning to mitigate hazards. Day has expertise in risk management planning, indoor air quality and ventilation evaluation, due diligence assessments, biological risk assessment, pollution prevention and waste minimization studies, and industrial hygiene/safety engineering design analysis. He was co-editor and author of the *Building Vulnerability Assessments*, *Biological Risk Engineering Handbook*, and *Air Sampling and Industrial Hygiene Engineering* texts published by CRC Press, and was also an author for *Electrical Safety Sustainability and Stewardship.* Day has audited international programs to determine client compliance with United States–, European Union–, and Asia-specific governmental requirements and provided assistance in reducing risk within manufacturing facilities.

Contributors

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Kate Merchie is an engineer-in-training. She has developed compliance assessment documentation and work plans for environmental remediation. Her work efforts have included both hazard and risk communication for governmental and private sector clients. During the course of her career, she has provided technical and engineering expertise on numerous environmental projects for the USEPA, the Department of Homeland Security, and the DoD. She earned a bachelor's degree in civil and environmental engineering and a master's degree in environmental engineering and science from the University of Iowa.

Anu Nathan is a project manager with more than 20 years of experience in environmental and safety management consulting. Anu has developed audit protocols for environmental, health, and safety (EHS) media, served as a lead auditor for the environmental audits, coordinated audits with corporate management, and has been responsible for updating and maintaining audit databases. She is also a lead auditor for several multimedia environmental audits at mills and printing plants throughout the United States. She is an ISO facilitator and was the lead for the implantation and certification for a site in Taiwan for a major technology company.

Dawn Stock is a professional geologist with more than 15 years of experience. She has authored numerous USEPA and state-required decision documents, which are comprehensive documents describing the Comprehensive Environmental Response, Compensation, and Liability Act; the Resource Conservation and Recovery Act; and state environmental cleanup processes and how they apply to specific contaminated areas. Her career has been largely involved in applying these and other

environmental regulations to these sites in various stages of assessment and executing work to advance them in the cleanup process. Her work has included successfully documenting environmental remediation projects and proposals for the Air Force Civil Engineer Center and the US Army Corps of Engineers.

Greg Tsouprake is a registered professional engineer with 26 years of environmental engineering and compliance experience. Relevant experience includes EHS management systems, audits, and corrective actions; environmental investigations, compliance, and remediation; permitting and compliance; environmental due diligence and investigations; and EHS program development. Tsouprake is currently managing worldwide multimedia environmental, health, and safety audits; EHS program audits; development of compliance plans; corrective actions; EHS program development; and employee training at multiple manufacturing facilities.

John Wang is an EHS principal consultant at URS Greater China. He has more than 26 years of experience in environment, health, and safety in consulting as well as in industrial sectors in the United States, Taiwan, mainland China, Singapore, Malaysia, and the Philippines. In industry, Wang was the Asia-Pacific Regional Director, EHS, for AlliedSignal (now Honeywell) responsible for compliance assurance on EHS-pertaining requirements including RoHS, REACH, and GHS for manufacturing sites in Asia. Wang has expertise in the OHSAS18001 Management System, risk assessment, occupational exposure monitoring and assessment, and chemical management. He is a certified OHSAS18001 lead auditor, is both a labor safety and health specialist and a toxic substance management specialist in Taiwan, and is a certified corporate auditor in AlliedSignal. He has performed more than 40 EHS compliance audits, due diligence assessments, and EICC audits in the region. He has also performed indoor air quality sampling, analysis, and ventilation system evaluation for manufacturing factories in the New York City and New Jersey vicinity. Wang is familiar with the environment, health, and safety regulations and practices in the region.

Introduction

Sometimes great ideas require many words. However, navigating those words can be difficult. As similar concepts and methodologies are used to discuss the risk associated with chemical usage, the body of regulatory dialogue is increasing from nation to nation. This book was designed to provide a road map between regulations from the European Union (EU), the United States, and other countries who adopt similar regulations. With any road map, not every feature along the road is mapped; however, what is shown are the markers leading to a point where more effective stewardship of your industrial base is possible.

Chapter 1 introduces the concept of global harmonization and interlinks between regulations.

Chapters 2 through 9 discuss Regulation (EC) No 1907/2006—*Registration, Evaluation, Authorization, and Restriction of Chemicals* (REACH). Chapters 2 through 4 provide a synopsis of REACH Articles that directly affect chemical registration and safety data sheet (SDS) authorship. Chapter 5 provides information on preparation of a chemical safety assessment. Chapter 6 discusses SDS development from both the REACH and Occupational Safety and Health Administration (OSHA) perspectives, which is important, because SDSs may now follow both requirements. Chapter 7 provides REACH registration criteria, followed by Chapter 8, which contains information regarding downstream users and criteria for the identification of persistent, bioaccumulative, and toxic substances and very persistent and very bioaccumulative substances. Chapter 9 discusses the list of substances subject to authorization, criteria for dossier development; means for socio-economic development; and restrictions on the manufacture, placing on the market, and use of certain dangerous substances, mixtures, and articles. Chapter 9 also outlines the information per the REACH Appendices on listings for carcinogens, mutagens, and toxins, which are cross-referenced within REACH Annexes XIV to XVII, and provides tables that include substance designations; Index, EC, and Chemical Abstracts Service numbers; and notes. The definition of the notes used is provided. This chapter also presents labeling of asbestos-containing articles and an outline of the appendices for azocolorant properties, azodye listing, azocolorant testing methods, and derogations for detergents appendices.

Chapters 10 through 20 discuss Regulation (EC) No 1272/2008—*Classification, labeling, and packaging of substances and mixtures* (CLP) and the OSHA regulatory requirements. Chapter 10 provides a synopsis of CLP articles in a manner similar to the REACH article presentation, with components that align with global harmonization of the OSHA hazard communication standard (HCS) presented. Chapter 11 presents OSHA programmatic, training, and trade secret requirements. Chapter 12 describes the implementation of CLP and OSHA and labeling requirements. Chapters 14 through 17 textually and through harmonized example labels illustrate the interpretation of physical, health, and environmental hazard categorization for SDS and label decision making. Chapter 18 presents special rules for

labeling and Chapter 19 includes the lists of hazard and precautionary statements used in the SDS and labeling. Chapter 20 provides additional labeling hazard classification information and focuses on certain hazardous substances.

Chapters 23 and 24 discuss the Toxic Substances Control Act (TSCA). Chapters 25 and 26 discuss the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The TSCA Inventory list and the FIFRA Registration list have similarities to the REACH *List of Substances Subject to Authorization*. Consequently, TSCA and FIFRA are presented so that the reader can judge the equivalency of the regulatory framework that led to each list. These lists are too lengthy for inclusion in this book but are available on the cited websites. By knowing the rationale behind each list, their relevance to one another will be easier to discern. Consequently, the major points in REACH, TSCA, and FIFRA regarding chemical characterization requirements that led to labeling and SDS information presentation are provided.

While this book focuses on the juxtaposition of the EU guidance documents and the US regulations, similar interpretations are occurring worldwide. The People's Republic of China (PRC) has promulgated *General Rules for Preparation of Precautionary Labels*, which adds to the body of regulatory discussions of chemical labels. These regulations and others rely on the basic concepts developed by the EU in REACH and CLP, which share many similarities with other concepts that have been around for a while, as evidenced by similar great ideas in the US OSHA, TSCA, and FIFRA regulations. A synopsis of the PRC regulations as regards SDS is presented in Chapter 6.

This compendium of information is intended to aid in the successful integration and implementation of the regulatory requirements. The hope is that this integration will lead to more efficient and effective business decisions. Rather than reacting to one regulation at a time, making policy decisions that reflect the underlying conceptual framework of GHS (Globally Harmonized System of Classification and Labeling of Chemicals) will lead to safer products and safer industrial production sites.

1 Chemical Regulation—Global Perspectives

Martha J. Boss, Brad Boss, Cybil Boss, Dennis W. Day, and John Wang

CONTENTS

As continuing scrutiny of chemical usage leads to diverse regulatory requirements, global harmonization is the logical transition from formerly nation-defined requirements. Harmonization is necessary to provide the global community with a sound scientific basis for providing consistent and appropriate information on chemical manufacture and usage, production of articles that contain chemicals, and article usage.

1.1 GLOBAL HARMONIZATION

Global harmonization is the process of bringing the world's governmental regulatory and guidance documents into conformance. Led by various governmental and United Nations (UN) initiatives, the intent of harmonization is to provide a better means to manage chemical, biological, and radioactive risks.

In 2003, the UN adopted the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS). The GHS includes criteria for the classification of health, physical, and environmental hazards, as well as specifying what information should be included on labels of hazardous chemicals as well as safety data sheets (SDSs). Many nations actively participated in the development of the GHS and are members of the UN bodies established to maintain and coordinate implementation of the system.

The GHS is now ready for worldwide implementation. A Plan of Implementation (para 22.(c)) was adopted in Johannesburg on September 4, 2002, at the World Summit on Sustainable Development. This Plan encouraged countries to implement the new GHS as soon as possible.

Directive 2008/112/EC and Regulation European Community (EC) No 1336/2008 implemented the GHS by amending Council Directives relating to cosmetic products; safety of toys; limitation of emissions of volatile organic compounds as a result of the use of organic solvents in certain activities and installations; end-of-life vehicles; waste electrical and electronic equipment; limitation of emissions of volatile organic compounds as a result of the use of organic solvents in certain paints, varnishes, and vehicle refinishing products; and detergents.

1.2 REACH, TSCA, CLP, AND OSHA INTERLINKS

The United States developed United States Environmental Protection Agency (USEPA) regulations, including the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and Occupational Safety and Health Administration (OSHA) regulations, in the 1970s. The first US regulation globally harmonized was OSHA's 29 Code of Federal Regulations (CFR) 1910.1200, Hazard Communication. The Hazard Communication Standard (HCS) was harmonized to include advances in hazard communication developed and directed by REACH and then CLP.

REACH is Regulation (EC) No 1907/2006 *Registration, Evaluation, Authorization and Restriction of Chemicals* dated December 18, 2006, and its amendments via European Directives. REACH is a directive document issued by the European Union (EU). Since its inception, many of the EC Member States have adopted REACH

into their national regulations. This regulation will hereafter be designated by the acronym *REACH*. Some aspects of REACH were already present in US regulations. As an example, TSCA provides the USEPA with authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances or mixtures. Many of these provisions are similar to REACH. The OSHA HCS has been harmonized with REACH as regards SDSs. Chemical manufacturers or importers (MIs) are required to classify the hazards of chemicals and to provide SDSs and labeling requirements. Employers are required to provide this information to their employees. Distributors are also required to transmit this information to downstream users (REACH, 2006; OSHA, 2012; TSCA, 2012).

CLP is Regulation (EC) No 1272/2008 for *classification, labeling and packaging of substances and mixtures* dated December 16, 2008, and is aligned with the REACH provisions. CLP was changed via adaptations to technical progress to the CLP Regulation. These adaptations have added new subcategories for respiratory and skin sensitization, revised the classification criteria for long-term hazards (chronic toxicity) to the aquatic environment, presented new hazard classes for substances and mixtures hazardous to the ozone layer, provided labeling provisions to protect individuals already sensitized to a specific chemical that may elicit a response at very low concentrations, and updated the list of substances with harmonized classification and labeling in CLP Annex VI, Part 3, and included in CLP Annex VI, new or updated harmonized classification and labeling for a number of substances. This regulation will be hereafter designated by the acronym *CLP*. The OSHA HCS has been harmonized with CLP as regards hazard classification and resultant labeling (CLP, 2008).

1.3 TOXIC SUBSTANCES CONTROL ACT

The TSCA provides USEPA with authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances or mixtures. TSCA addresses the production, importation, use, and disposal of specific chemicals including polychlorinated biphenyls, asbestos, radon, and lead-based paint. Sections within the TSCA provisions that address general chemical production and importation

- Require, under Section 5, premanufacture notification for “new chemical substances” before manufacture.
- Require, under Section 4, testing of chemicals by MIs and processors, where risks or exposures of concern are found.
- Issue Significant New Use Rules, under Section 5, when it identifies a “significant new use” that could result in exposures to, or releases of, a substance of concern.
- Maintain the TSCA Inventory, under Section 8, which contains more than 83,000 chemicals. As new chemicals are commercially manufactured or imported, these chemicals are placed on the list.
- Require those importing or exporting chemicals, under Sections 12(b) and 13, to comply with certification reporting and other requirements.

- Require, under Section 8, reporting and record-keeping by persons who manufacture, import, process, and distribute chemical substances in commerce.
- Require, under Section 8(e), that any person who manufactures, imports, processes, or distributes in commerce a chemical substance or mixture and who obtains information that this substance or mixture presents a substantial risk of injury to health or the environment to immediately inform USEPA, except where USEPA has already been adequately informed (TSCA, 2012).

1.4 FIFRA TITLE 40

FIFRA contains prescriptives for pesticide labels that may be in addition to or contrary to other US regulatory requirements. During the pesticide registration process, these label requirements should be identified; however, additional analysis will be required to assure that labels are in conformance with OSHA requirements. If these products will be supplied outside the United States, international requirements must also be evaluated to determine overall labeling onus (FIFRA, 2003).

1.5 OSHA HCS

The HCS requires that hazards of all chemicals produced/imported are classified and that information concerning the classified hazards is transmitted to employers and employees. The 2012 revision to 29 CFR 1910.1200 incorporated aspects of the GHS. The transmittal of information is through comprehensive hazard communication programs that include container labeling and other forms of warning, SDSs, and employee training.

The HCS is intended to comprehensively address the issue of classifying potential hazards of chemicals and communicating information concerning hazards and protective measures to employees. Classifying the potential hazards of chemicals and communicating information concerning hazards and protective measures to employees may include, but is not limited to, provisions for developing and maintaining a written hazard communication program for the workplace, including lists of hazardous chemicals present; labeling of containers of chemicals in the workplace and chemicals being shipped to other workplaces; preparation and distribution of SDSs to employees and downstream employers; and development and implementation of employee training programs regarding hazards of chemicals and protective measures.

Per Section 18 of TSCA, no US state or political subdivision of a state may adopt or enforce any requirement relating to the issue addressed by this Federal standard, except pursuant to a federally approved state plan.

The UN recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition (UN ST/SG/AC.10/Rev.4), 2003, is used to determine hazard classification methods. This document is incorporated by reference into 29 CFR 1910.1200 (OSHA, 2012).

1.5.1 Laboratories

Laboratory employers that ship hazardous chemicals are considered to be either a chemical manufacturer or a distributor and thus must ensure that any containers of hazardous chemicals leaving the laboratory are labeled and that an SDS is provided to distributors and other employers.

1.5.2 When Only Sealed Containers Are Handled or Stored

In work operations where employees only handle chemicals in sealed containers that are not opened during normal use (e.g., are found in marine cargo handling, warehousing, or retail sales), employees will

- Ensure that labels on incoming containers of hazardous chemicals are not removed or defaced.
- Maintain copies of any SDSs that are received with incoming shipments of the sealed containers of hazardous chemicals, will obtain an SDS as soon as possible for sealed containers of hazardous chemicals received without an SDS if an employee requests the SDS, and will ensure that SDSs are readily accessible during each work shift to employees when they are in their work area(s).
- Ensure that employees are provided with information and training (except for the location and availability of the written hazard communication program), to the extent necessary to protect them in the event of a spill or leak of a hazardous chemical from a sealed container.

1.6 EXCLUSIONS/EXEMPTIONS

1.6.1 Food, Drugs, and Cosmetics

Food, drugs, and cosmetics are generally excluded from the aforementioned guidance documents and regulations. Regulations that address the manufacture and use of food, drugs, and cosmetics include the following: (1) Regulation (EC) No 1935/2004 *on materials and articles intended to come into contact with food*, (2) the US Food and Drug Administration (FDA) regulations CFR Title 21, and (3) Directive 76/768/EEC on cosmetics products.

Active ingredients produced for use as biologic modifiers are regulated separately from other substances in many countries. In the United States, these substances are part of Title 21's regulatory onus. All imported active substances to the EU must be manufactured in compliance with standards of good manufacturing practices (GMP) at least equivalent to the GMP of the EU. The manufacturing standards in the EU for active substances are those included in the International Conference on Harmonization of Technical Requirements of Pharmaceuticals for Human Use, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Q7.

1.6.2 Biocides, Pesticides, and Rodenticides

Certain aspects of the USEPA's FIFRA are now present in the CLP directive, Directive 98/8/EC, Annexes I, IA, or IB (February 16, 1998) *concerning the placing of biocidal products on the market*, and Council Directive 91/414/EEC, Annex I (July 15, 1991) *on placing of plant protection products on the market*.

1.6.3 Exemptions to Register per REACH Article 2(7)(b)

Substances from a chemical reaction that occurs incidental to

- Exposure of another substance or article to environmental factors (e.g., air, moisture, microbial organisms, or sunlight)
- Storage of another substance, mixture, or article

Substances not themselves manufactured, imported, or placed on the market and from a chemical reaction that occurs

- Upon end use of other substances
- When a stabilizer, colorant, flavoring agent, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequestrant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended
- When a substance solely intended to provide a specific physicochemical characteristic functions as intended

By-products, unless imported or placed on the market themselves

Hydrates of a substance or hydrated ions formed by association with water, provided the substance is registered by the manufacturer/importer using this exemption

Naturally occurring substances, not chemically modified including

- Minerals, ores, ore concentrates, raw and processed natural gas, crude oil, and coal
- Other naturally occurring substances classifiable as dangerous per CLP or persistent, bioaccumulative, and toxic (PBT) or very persistent and very bioaccumulative (vPvB) per REACH Annex XIII
- Identified per REACH Article 59 at least 2 years previously as a substance giving rise to an equivalent level of concern per REACH Article 57

Substances obtained from natural sources, not chemically modified, unless

- Classifiable as dangerous per Directive 67/548/EEC, excluding substances only classified as flammable [R10], skin irritant [R38] or eye irritant [R36]
- PBT or vPvB per REACH Annex XIII

- Identified per REACH Article 59 at least 2 years previously as a substance giving rise to an equivalent level of concern per REACH Article 57: vegetable fats/oils/waxes; animal fats/oils/waxes; fatty acids from C6 to C24 and their potassium, sodium, calcium, and magnesium salts; glycerol

Substances not chemically modified including

- Liquefied petroleum gas, natural gas condensate, process gases and components thereof, coke, cement clinker, and magnesia
- Glass and ceramic frits
- Compost and biogas
- Hydrogen and oxygen

1.6.4 Exclusions from CLP, TSCA, and OSHA Hazard Communication

CLP, TSCA, and OSHA HCS exclude cosmetics, foods (animal and human), drugs and medical products, and ionizing radiation.

1.6.5 OSHA Exclusions

OSHA does not require labeling of the following:

- Any pesticide (FIFRA governs)
- Chemical substance/mixture subject to the TSCA labeling requirements and regulations
- Food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, and ingredients in such products (e.g., flavors and fragrances) (either FDA or the Department of Agriculture governs)
- Any drug or cosmetic (FDA governs)
- Distilled spirits (beverage alcohols), wine, or malt beverage intended for nonindustrial use (Bureau of Alcohol, Tobacco, Firearms, and Explosives governs)
- Consumer product or hazardous substance (Consumer Product Safety Commission governs)
- Agricultural or vegetable seed treated with pesticides (Department of Agriculture governs)
- Hazardous waste (USEPA governs)
- Tobacco or tobacco products
- Wood or wood products (wood or wood products treated with a hazardous chemical, and wood that may be subsequently sawed or cut, generating dust, are not exempted)
- Articles that are a manufactured item (other than a fluid or particle) that (1) is formed to a specific shape or design during manufacture; (2) has end use function(s) dependent upon its shape or design during end use; and (3) during normal use does not release more than very small quantities

(e.g., minute, trace amounts) of a hazardous chemical and does not pose a physical hazard or health risk to employees
- Nuisance particulates that do not pose any physical hazard or health risk
- Biological hazards

1.7 PEOPLE'S REPUBLIC OF CHINA

The National Standard of the People's Republic of China has been harmonized as follows: Guidance on Compilation of Safety Data Sheet for Chemical Products (GB/T 17519-2013), General Rules for Preparation of Precautionary Label for Chemicals (GB 15258-2009), and General Rules for Classification and Hazard Communication of Chemicals (GB 13690-2009).

1.7.1 Management Measures on Chemicals Physical Hazards Identification and Classification

The Management Measures on Chemicals Physical Hazards Identification and Classification regulation was ratified by the Commissioner of the State Administration of Work Safety of China, announced on July 10, 2013, and became effective on September 1, 2013.

1.7.1.1 Main Content of the Management Measures

The Measures include four chapters and 23 articles covering Physical Hazards Identification and Classification, Legal Responsibility, and Annex information. The Measures clarify the scope, definition, identification, and classification; responsibilities of the Administration of Work Safety and associated departments; and the content, procedure, and requirements of chemical and physical hazard identification, classification, and determination. The essence of United Identification and Series Identification as a regulation is also presented.

1.7.1.2 Applicable Scope

The Measures are applicable to physical hazard identification and classification and its correlated works on chemicals whose hazard characteristics are unclear. According to the Measures, the State Administration of Work Safety will publish an exempt chemical list for physical hazard identification and classification. If the hazard of the chemical on the list has been already mastered, its physical hazard identification and classification can be excused. Moreover, chemicals used for scientific study or product development, or its annual production or consumption quantity if less than 1 ton, can be excluded from the physical hazard identification and classification.

1.7.1.3 Content of Identification

The chemical physical hazard identification has two aspects. The first is the required parameters or indicators in the identification of the 16 classes of physical hazards. The second is the parameters or indicators of physical chemical characters corresponding to the physical hazard classification and chemical stability (see Table 1.1).

TABLE 1.1
Content of Physical Hazards Identification

Classification	No	Hazard Type	Parameters or Indicators
Corresponding parameters and indicators of physical hazards	1	Explosives	Sensitivity for collision, abrasion sensitivity, heating effect under closure environment
	2	Flammable gases	Flammable limits
	3	Aerosols	Ignition distance, heat of combustion
	4	Oxidizing gases	Gas oxidation character
	5	Gases under pressure	Gas pressure
	6	Flammable liquids	Flash point (close cup), initial boiling point
	7	Flammable solids	Speed of combustion
	8	Self-reactive substances	Self-accelerated decomposition temperature, heating effect under closure condition
	9	Pyrophoric liquids	Pyrophoric character
	10	Pyrophoric solids	Pyrophoric character
	11	Self-heating substances	Self-heating character
	12	Substances that in contact with water emit flammable gases	Rate of emitting flammable gases upon contacting with water
	13	Oxidizing liquids	Oxidizing of the liquids
	14	Oxidizing solids	Oxidizing of the solids
	15	Organic peroxides	Conductive explosion, effect of heating at closure condition
	16	Substances corrosive to metals	Corrosive to metals
Others	17	Other indicators related to physical hazard classification	Steam pressure, melting point, boiling point, status, self-ignition temperature, chemical stability, reactivity

1.7.1.4 Classification of Chemical Physical Hazards

It is an essential requirement for the GHS system to classify the chemicals. In order to ensure the accuracy and consistency of the classification results, the Measures require the chemical owner (Unit) to compile a physical hazard classification report on the basis of the identification report and other physical hazard data information. The registration center will then perform an overall evaluation to the classification report and respond with review comments to the chemical Unit within 30 days (PRC, 2013).

1.7.1.5 Technical Support Institutes for Identification and Classification Tasks

Regulatory methods for establishing an expert pool are defined, which are in addition to considering specified experimental methods, experimental conditions, and

instruments in the chemical physical hazard identification. The Measures govern three types of technical support institute:

1. One is the State Office to set up a chemical physical hazard identification and classification technical committee that is responsible for arbitration in the identification or classification results and to publish the consequence of chemical physical hazard identification outcomes.
2. The second is the chemical physical hazard identification institutes. These institutes will be recognized by the State Office. The institute's main task is to identify the chemical physical hazards and to issue an identification report.
3. The third one is the registration center of State Administration of Work Safety. This center is in charge of the evaluation and review of the chemical physical hazard identification and classification consequence, establishment of the information management system of the national chemical physical hazard identification and classification, and accountability of the technical committee.

1.7.1.6 Series Identification and United Identification

Since chemicals may have similar application with alike composition and indistinguishable physical hazards, the Measures stipulates that such chemicals satisfy three conditions simultaneously: (1) similar application, (2) alike composition, and (3) indistinguishable in physical hazard.

In order to reduce the burden on the industries, multiple chemical organizations (Units) can jointly apply for physical hazard identification for the same chemical produced or imported by various parties. Given that the physical appearance, could affect the hazard property; the appearance of the chemical for united identification plays no role in changing the physical hazard classification.

These multiple organizations will assign one representative organization to be the lead application Unit for such united identification.

1.7.1.7 Implementation by Stage

Since the undefined chemicals for hazard identification are in considerable quantities, technical requirements are strong in identification and classification, and workload is high, chemical physical hazard identification and classification works will be focused and implemented step by step on the basis of the production or import quantity of the chemicals, hazard characteristics, and incident conditions. The State Administration of Work Safety will organize and draw up the step-by-step implementation plan.

1.7.1.8 Meaning of Implementation of the Measures

These Measures are vital corresponding rules to implement the Hazardous Chemical Safety Management Regulation. The intent is to enhance corporate social responsibility, manage the chemical hazard from the sources, build up a nationwide completed chemical hazard data information, promote the synchronizing of the chemical

safety management with the world, and play a key role in incident prevention and hazard control.

1.8 IMPORTS

Imported substances and mixtures are subject to customs supervision and temporary storage, such as in a free zone or free warehouse; with the intent to re-export or conduct in-country transit. In the EU and the United States, customs agents deliver the substance/mixture to the importer's site. In these cases, the substance/mixture remains in control of customs until delivery to the site. Upon delivery to the site, the CLP (EU) and OSHA Hazard Communication (United States) rules are applicable. In the PRC, the customs agents may release the substance/mixture to the importer for transfer to the importer's site. During this transfer, the substance/mixture is in control of the importer and the Chinese CN GBT 17519-2013 requirements are applicable and should be determined for each import site, as regulatory onus varies (PRC, 2009).

REFERENCES

Council Directive (EEC) No 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (76/768/EEC), OJ L262, 1976, pp. 169–200.

Council Directive (EEC) No 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, OJ L230/1, 1991.

Directive (EC) No 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, OJ L123/1, 1998.

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 and 387) Title 21—Food and Drugs, 2013.

National Standard of the People's Republic of China, General Rules for Classification and Hazard Communication of Chemicals (GB 13690-2009), 2009.

National Standard of the People's Republic of China, Guidance on Compilation of Safety Data Sheet for Chemical Products (GB/T 17519-2013), 2013.

Regulation (EC) No 1336/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, OJ L354/60, 2008.

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L338/4, 2004.

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Council Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling, and packaging of substances and mixtures, OJ L353/1, 2008; and as amended to date, see http://eur-lex.europa.eu/.

Emergency Planning and Community Right-To-Know (42 U.S.C. C 116) (EPCRA) Title 42 The Public Health and Welfare, Chapter 116 Emergency Planning and Community Right-To-Know, 2011.

Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) (FIFRA) Title 40—Protection of Environment, Chapter I—Environmental Protection Agency, Subchapter E—Pesticide Programs, Part 152—Pesticide Registration and Classification Procedures, July 1, 2003.

National Standard of the People's Republic of China, General Rules for Preparation of Precautionary Label for Chemicals (GB 15258-2009), 2009.

National Standard of the People's Republic of China, Management Measures on Chemicals Physical Hazards Identification and Classification Regulation, 2013.

Occupational Health and Safety Act (Public Law 91-596, 84 STAT. 1590) Standards—29 CFR, Part 1910 Occupational Safety and Health Standards, Subpart Z Toxic and Hazardous Substances, Hazard Communication, 2012.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), OJ L396/1, 2006; and as amended to date, see http://eur-lex.europa.eu/.

Toxic Substances Control Act (15 U.S.C. 2625 and 2665, 44 U.S.C. 3504) (TSCA) Title 40—Protection of Environment, Chapter I—Environmental Protection Agency, Subchapter R—Toxic Substances Control Act, August 3, 2012.

2 REACH Articles 5 to 24

Brad Boss, Cybil Boss, Martha J. Boss, and Kate Merchie

CONTENTS

The following subsections define REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) Articles relevant to chemical hazard communication and labeling. REACH is organized into Articles that define regulatory requirements. The REACH Annexes detail how the Articles must be interpreted to categorize and ultimately register chemicals. The Agency is the Chemical Agency established by REACH in the European Union (EU). The Community is the community of EU's Member States. The Commission is the EU commission with authority given a particular Article. The Committee is the EU committee with authority given a particular Article.

Article when capitalized refers to an Article of a regulation. Article when not capitalized refers to an article produced, which may contain a substance.

2.1 TITLE I—GENERAL ISSUES: CHAPTER 1—AIM, SCOPE, AND APPLICATION

2.1.1 REACH Article 2—Application

This Regulation does not apply to substances/mixtures registered per REACH Title II, exported from the Community by a supply chain actor, and then reimported into the

Community by an actor in the same supply chain if (1) the substance being reimported is the same as the exported substance or (2) safety data sheet (SDS) information has been provided (to the supplier) per REACH Article 31 or 32. Hence, if you export to yourself as the importer, you may be able to use this exclusion as regards registration and, if so, must provide the SDS with the shipment to yourself.

2.2 TITLE II—REGISTRATION OF SUBSTANCES: CHAPTER 1—GENERAL OBLIGATION TO REGISTER AND INFORMATION REQUIREMENTS

2.2.1 REACH Article 5—No Data, No Market

Substances on their own, in mixtures, or in articles must not be manufactured or placed on the market in the Community unless registered. These substances/mixtures/articles are subject to REACH Articles 6, 7, 21, and 23.

2.2.2 REACH Article 6—General Obligation to Register Substances on Their Own or in Mixtures

A registration must be submitted to the Agency by the manufacturer or importer (MI) for any substance/mixture manufactured or imported (M/I) in quantities of ≥1 ton per year. However, REACH Articles 17 and 18 do not apply for monomers used as on-site or transported that are isolated intermediates. A registration must be submitted for a polymer to include the unregistered monomer/other substance(s) if (1) a polymer consists of ≥2% weight to weight (w/w) of monomer/other substance(s) in monomeric units and (2) chemically bound substance(s) and the total quantity of monomer/other substance(s) is ≥1 ton per year.

2.2.3 REACH Article 7—Registration and Notification of Substances in Articles

If any substance identified per REACH Article 59 has been identified by the producer or importer (PI) as present in an article, a REACH registration may be required. Registration is required if the substance (1) is present in quantities >1 ton per year and (2) is intended to be released for normal use. The Agency will be notified by the PI if a substance in an article (1) meets the criteria in REACH Article 57, (2) is identified per REACH Article 59, and (3) is present in quantities totaling >1 ton per PI per year and above a concentration of 0.1% w/w.

This provision will not apply where the PI can exclude exposure to humans or the environment during use or disposal. In such cases, the PI must supply instructions to the recipient of the article. The information supplied to the recipient must include

- Identity and contact details of the PI (with the exception of their own use sites)
- Registration number(s)
- Identity of the substance

- Classification of the substance(s)
- Brief description of the use(s) of the substance(s)
- Tonnage range of the substance(s) (e.g., 1–10 tons, 10–100 tons)

Specific information on these items is included in REACH Annex VI. Registration may be required by the Agency for any substance in those articles if the substance is present in articles in quantities totaling >1 ton per PI per year, suspected of being released from the articles, and the release presents a risk to human health/the environment and not subject to the above requirements. These requirements must not apply to substances already registered for the same use. The requirements apply 6 months after a substance is identified per REACH Article 59. Measures for implementation of these requirements must be adopted per the procedure referred to in REACH Article 133.

2.2.4 REACH Article 8—Only Representative of a Non-Community Manufacturer

A person established in the Community may be appointed as a representative to fulfill the obligations of a person outside the Community who manufactures substances/mixtures/articles, formulates a mixture, or produces an article imported into the Community. The representative must (1) have a sufficient background in the practical handling of substances and this regulation and (2) keep up-to-date information on quantities imported, customers sold to, and latest SDSs. Importer(s) within the same supply chain must be informed by the manufacturer of the representative's appointment. These importers will be regarded as downstream users (DUs).

2.2.5 REACH Article 9—Exemption from the General Obligation to Register for Product and Process Orientated Research and Development

REACH Articles 5, 6, 7, 17, 18, and 21 will not apply for 5 years for a substance MI for product and process orientated research and development (PPORD) (1) by a manufacturer, importer, or producer (MIP) of articles; (2) by the MI; or (3) in cooperation with listed customers. The quantity must be limited to that required for PPORD.

2.2.5.1 Notification

The MIP of articles must notify the Agency per REACH Annex VI of the MIP's identity, substance identity, substance classification, estimated quantity, and the customer's names and addresses. The Agency will check the completeness of the information and REACH Article 20 will apply with adaptations as necessary. The notification must be assigned a number and date.

2.2.5.2 Conditions

Conditions may be imposed by the Agency so that the substance/mixture/article can be handled only by staff of listed customers in controlled conditions and per protection of

workers and the environment given Member State regulations. The Agency may also decide to not allow availability to the general public at any time or require remaining quantities be recollected for disposal after the emption period. In such cases, the Agency may ask the notifier to provide additional necessary information.

2.2.5.3 Time Interval

Substances may be M/I and articles may be produced or imported (P/I) from 2 weeks after the notification, unless otherwise notified by the Agency. The Agency may extend the initial 5-year exemption, upon request, if the MIP of articles can demonstrate that an extension is justified by the research and development program.

2.2.6 REACH Article 10—Information to Be Submitted for General Registration Purposes

Registration required by REACH Article 6 or REACH Article 7 must include a technical dossier and a chemical safety report (CSR), when required per REACH Article 14. The CSR must be in the format described in REACH Annex I and may include the relevant use and exposure categories.

2.2.6.1 Technical Dossier

The technical dossier must include the identity of the MI, identity of the substance, and information on the manufacture and use(s) of the substance. The technical dossier must represent all the registrant's identified use(s) and may include relevant use and exposure categories, classification and labeling of the substance, guidance on safe use of the substance, study summaries, robust study summaries, and a determination if information submitted has been reviewed by a competent assessor chosen by the MI.

2.2.7 Study Reports, Proposals, Exposure Information, and Requests

Full study reports summarized for the purpose of registration must be in the registrant's legitimate possession or the registrant must have permission to refer to the full study, except in cases covered per REACH Article 25, 27, or 30. Proposals for testing for substances in quantities of 1–10 tons, exposure information per REACH Annex VI, Section 6, and requests per REACH Article 119 may also be included. Preclusions against Internet release of information may be provided with justification.

2.2.8 REACH Article 11—Joint Submission of Data by Multiple Registrants

The registration must include information and relevant indications per REACH Article 10 when a substance is intended to be manufactured in the Community by multiple manufacturers and imported by multiple importers or is subject to registration. The registration must first be submitted by the lead registrant; one registrant acting with the agreement of the assenting registrant(s). Each registrant must then submit separately

information and any relevant indications per REACH Article 10. The registrants may decide whether to provide these submittals separately or if one lead registrant will provide submittals on behalf of all. Each registrant need only comply for items within their own tonnage band per REACH Article 12. A registrant may submit information separately if joint submittals are deemed too costly, if they would lead to disclosure of commercially sensitive information that could cause commercial detriment, or the registrant disagrees with the lead registrant on the information selection. The registrant must submit, along with the dossier, an explanation as to why joint submittal was not practicable.

2.2.9 REACH Article 12—Information to Be Submitted Depending on Tonnage

The technical dossier per REACH Article 10 must include all physicochemical, toxicological, and ecotoxicological information that is relevant and available to the registrant. At a minimum, include information specified in

- REACH Annex VII for non-phase-in substances and for phase-in substances meeting one or both criteria per Annex III if M/I quantities are >1 ton per year per MI
- REACH Annex VII, Section 7 for phase-in substances (which do not meet criteria per REACH Annex III) if M/I quantities are >1 ton per year per MI
- REACH Annexes VII and VIII for substances if M/I quantities are >10 tons per year per MI
- REACH Annexes VII and VIII and testing proposals per REACH Annex IX for substances if M/I quantities are >100 tons per year per MI
- REACH Annexes VII and VIII and testing proposals per REACH Annexes IX and X for substances if M/I and quantities are >1000 tons per year per MI

The MI must inform the Agency immediately of the additional information required when the quantity of a substance reaches the next tonnage threshold. REACH Article 26 must apply and must be adapted as necessary. REACH Article 12 must apply to producers of articles and must be adapted as necessary.

2.2.10 REACH Article 13—General Requirements for Generation of Information on Intrinsic Properties of Substances

Intrinsic properties information may be generated by means other than tests, if the conditions per REACH Annex XI are met. For human toxicity, information must be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods (e.g., in vitro methods, qualitative or quantitative structure–activity relationship models, or information from structurally related substances). Testing per REACH Annex VIII, Section 8, REACH Annex IX, and REACH Annex X may be omitted (1) where justified given information on exposure and (2) when risk management measures per REACH Annex XI, Section 3, are implemented.

2.2.10.1 Amendments

The Commission may amend the Regulation on test methods per REACH Article 133 and the REACH Annexes in order to replace, reduce, or refine animal testing. Amendments to the REACH Annexes must be adopted per REACH Article 133.

2.2.10.2 Intrinsic Property Tests

Where tests are required to determine intrinsic properties, these tests must be conducted per the test methods in the Commission Regulations or using international test methods recognized by the Commission/Agency. Information on intrinsic properties of substances may be generated using other test methods if the REACH Annex XI specified conditions are met. Ecotoxicological and toxicological tests and analyses must use good laboratory practices per Directive 2004/10/EC or other international standards recognized as being equivalent and be conducted given the provisions of Directive 86/609/EEC, if applicable.

2.2.10.3 Reference to Study/Robust Study Summaries

If a substance has been registered, a new registrant may refer to the study/robust study summaries if the substance (1) is the same as the one previously registered, (2) has the same degree of purity, and (3) has the same nature of impurities. The previous registrant(s) must have given permission to refer to the full study reports. A new registrant must not refer to such studies in order to provide the information required in REACH Annex VI, Section 2.

2.2.11 REACH Article 14—Chemical Safety Report and Duty to Apply and Recommend Risk Reduction Measures

A CSR must be completed for all substances subject to registration in quantities of ≥10 tons per year per registrant. The CSR must document the chemical safety assessment (CSA) conducted per REACH Annex I for each substance on its own, in a mixture, in an article, or in a group of substances.

2.2.11.1 Exclusions

A CSA need not be performed for a substance present in a mixture if the concentration of the substance in the mixture is less than the lowest of any of the following:

- Specific concentration limits per CLP Annex VI, Part 3
- Substances classified as hazardous to the aquatic environment. The cutoff value in CLP Annex I, Table 1.1 as modified using the calculation in CLP Annex I, Section 4.1 to adjust for a multiplying factor (M-factor) set in CLP Annex VI, Part 3 (for substances classified as hazardous to aquatic environment)
- Specific concentration limit entries in the classification and labeling inventory per CLP Article 42
- Substances classified as hazardous to the aquatic environment. The cutoff value in CLP Annex I, Table 1.1 as modified using the calculation in CLP

Annex I, Section 4.1 to adjust for an M-factor set as an entry in the classification and labeling inventory referred to in CLP Article 42 (for substances classified as hazardous to aquatic environment)
- 0.1% w/w if the substance meets the criteria in REACH Annex XIII

In addition, the CSA need not include consideration of the risks to human health from food contact materials within the scope of Regulation (EC) No 1935/2004—*on materials and articles intended to come into contact with food* and in cosmetic products within the scope of Directive 76/768/EEC.

2.2.11.2 Required CSA Assessments and Hazard Classes

A CSA must include the following assessments: human health hazard, physicochemical hazard, and environmental hazard (persistent, bioaccumulative, and toxic [PBT] and very persistent and very bioaccumulative [vPvB]). The MI must then determine (given the CSA results) if the substance has any of the following per CLP Annex I:

- Hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, and 2.15 types A to F
- Hazard classes 3.1 to 3.6, 3.7 (adverse effects on sexual function and fertility or on development), 3.8 (effects other than narcotic effects), 3.9, and 3.10
- Hazard class 4.1
- Hazard class 5.1
- Assessed to be a PBT or vPvB

2.2.11.3 Exposure Scenarios, Categories, Estimation, and Risk Characterization

If a substance is determined to have the above listed hazards, the CSA must include an exposure assessment including generation of exposure scenario(s) or identification of relevant use and exposure categories, exposure estimation, and risk characterization. All identified uses must be evaluated. Any registrant must identify and apply the measures to adequately control the risks identified and recommend control measures in the SDS supplied per REACH Article 31. Any registrant required to conduct a CSA must keep the CSR available and up to date.

2.3 TITLE II—REGISTRATION OF SUBSTANCES: CHAPTER 2—SUBSTANCES REGARDED AS BEING REGISTERED

2.3.1 REACH Article 15—Substances in Plant Protection and Biocidal Products

2.3.1.1 Plant Protection Products

Active substances and coformulants M/I for use in plant protection products only must be considered as registered if used as a plant protection product only (REACH

Chapters 1 through 5) and as included in either Directive 91/414/EEC, Commission Regulation (EEC) No 3600/92, Commission Regulation (EC) No 703/2001, Regulation (EC) No 1490/2002, or Commission Decision 2003/565/EC.

2.3.1.2 Active Substances—Biocidal Products

Active substances M/I must be considered registered if for use in biocidal products only (REACH Chapters 1 through 5) and as included in either Directive 98/8/EC, Annexes I, IA, or IB; or Regulation (EC) No 2032/2003.

2.3.2 REACH Article 16—Duties of the Commission, the Agency, and Registrants of Substances Regarded as Being Registered

The Commission or the relevant Community body must make information equivalent to that required by REACH Article 10 available to the Agency for substances registered per REACH Article 15. The Agency will include this information or a reference thereto in its databases and notify the competent authorities. REACH Articles 21, 22, and 25 to 28 will not apply to uses of substances registered per REACH Article 15.

2.4 TITLE II—REGISTRATION OF SUBSTANCES: CHAPTER 3—OBLIGATION TO REGISTER AND INFORMATION REQUIREMENTS FOR CERTAIN TYPES OF ISOLATED INTERMEDIATES

The requirements of Chapter 3 are applicable only if quantities of ≥1 ton are M/I. Articles 17 and 18 apply only to on-site isolated intermediates if the manufacturer confirms that (1) the substance is only manufactured and used per strictly controlled conditions, (2) the substance is rigorously contained by technical means during its whole life cycle, (3) control and procedural technologies will be used to minimize emission and any resulting exposure, (4) only properly trained and authorized personnel handle the substance, and (5) substance-handling procedures are well documented and strictly supervised by the site operator. If these conditions are not fulfilled, the registration must include the information per REACH Article 10. The registrant's full study report must be in the registrant's legitimate possession or the registrant must have permission to refer to the full study except in cases covered per REACH Article 25, 27, or 30.

2.4.1 REACH Article 17—Registration of On-Site Isolated Intermediates

REACH Article 17 applies only to on-site isolated intermediates if the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions and rigorously contained by technical means during its whole life cycle. Control and procedural technologies must be used to minimize emission and any resulting exposure. If these conditions are not fulfilled, the registration shall include the information specified in REACH Article 10.

Registration must be submitted for any on-site isolated intermediate in quantities of ≥1 ton per year. This registration must include (without any additional testing) the following:

- Identity of the manufacturer per REACH Annex VI, Section 1.
- Identity of the intermediate per REACH Annex VI, Sections 2.1 to 2.3.4.
- Classification of the intermediate per REACH Annex VI, Section 4.
- Any available existing information. Where a full study report is available, a study summary must be submitted.
- Brief general description of the use per REACH Annex VI, Section 3.5.
- Details of the risk management measures applied.

Except in cases covered under REACH Article 25(3), Article 27(6), or Article 30(3), the registrant must possess or have permission to refer to the full study report.

2.4.2 REACH Article 18—Registration of Transported Isolated Intermediates

The registration inclusions and the requirement to register for ≥1000 tons per year apply only to transported isolated intermediates if the MI has confirmation from the user that the synthesis of (an)other substance(s) from that intermediate takes place on other sites under the following strictly controlled conditions:

- The substance is rigorously contained by technical means during its whole life cycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification, and storage.
- Procedural and control technologies that minimize emission and any resulting exposure will be used.
- Only properly trained and authorized personnel handle the substance.
- In the case of cleaning and maintenance works, special procedures (e.g., purging, washing) are applied before the system is opened and entered.
- In cases of accident and where waste is generated, procedural and/or control technologies are used to minimize emissions and the resulting exposure during purification or cleaning and maintenance procedures.
- Substance-handling procedures are well documented and strictly supervised by the site operator.

If the conditions listed in the subparagraph are not fulfilled, the registration shall include the information specified in REACH Article 10.

A registration must be submitted to the Agency for the transported isolated intermediate in quantities of ≥1 ton per year. A registration for a transported isolated intermediate must include the following:

- Identity of the MI per REACH Annex V, Section 1.
- Identity of the intermediate per REACH Annex V, Sections 2.1 to 2.3.4.

- Classification of the intermediate per REACH Annex VI, Section 4.
- Any available existing information. Where a full study report is available, a study summary must be submitted.
- Brief general description of the use per REACH Annex VI, Section 3.5.
- Information on risk management measures applied and recommended to the user.

The assumption is that the registrant will have the full study report.

A registration for a transported isolated intermediate in quantities of ≥1000 tons per year must include the information per REACH Annex VII in addition to the information required above. For the generation of this information, REACH Article 13 will apply.

2.4.3 REACH Article 19—Joint Submission of Data on Isolated Intermediates by Multiple Registrants

The registration must include information per REACH Articles 17 and 18 when an on-site isolated intermediate or transported isolated intermediate is intended to be manufactured in the Community by multiple manufacturers and imported by multiple importers or is subject to registration. The registration must first be submitted by the lead registrant; one registrant acting with the agreement of the assenting registrant(s). Each registrant must subsequently submit separately the information per REACH Articles 17 and 18. A registrant may submit the information per REACH Articles 17 and 18 separately if deemed too costly to submit jointly, submitting jointly would lead to disclosure of information considered to be commercially sensitive and likely to cause commercial detriment, or registrant disagrees with the lead registrant on the selection of information. The registrant must submit, along with the dossier, an explanation as to why joint submittal was not practicable or state the nature of any disagreement.

2.5 TITLE II—REGISTRATION OF SUBSTANCES: CHAPTER 4—COMMON PROVISIONS FOR ALL REGISTRATIONS

2.5.1 REACH Article 20—Duties of the Agency

The Agency will assign (1) a submission number to each registration to be used for all correspondence and (2) a submission date, which must be the date of receipt of the registration at the Agency (the submission date). The Agency will conduct a completeness check per REACH Articles 10 and 12 or under REACH Article 17 or 18 within (1) 3 weeks of the submission date or (2) 3 months of the REACH Article 23 deadline for phase-in substances. For phase-in substances, the submission must be in the 2-month period immediately preceding that deadline. If a registration is incomplete, the Agency will inform the registrant and, upon completion, perform another subsequent completeness check. The Agency will reject the registration if the registrant fails to complete registration within the deadline set.

The Agency will assign (1) a registration number and (2) a registration date (the submission date), once the registration is complete, to the substance. The Agency will notify the Member State's competent authority within 30 days of the submission date that the Agency database contains

- Registration dossier with the submission or registration number
- Submission or registration date
- Result of the completeness check
- Any request for further information and subsequent deadline set

The relevant Member State is the State where the manufacture takes place and where the head office is located, or where the importer is established. The other Member States where other production sites are established will also be notified. The Agency will notify the Member State's competent authority when any further information is available on the Agency database.

An appeal may be brought, per REACH Articles 91, 92, and 93, against Agency decisions.

The Agency will notify the existing registrants if a new registrant submits additional information for a particular substance and that this new information is available on the database per REACH Article 22.

2.5.2 REACH Article 21—Manufacturing and Import of Substances

Article 21 does not apply to uses of substances registered per Article 15. All statements herein are without prejudice to REACH Article 27.

- A registrant may M/I a substance or P/I an article if no contraindication exists from the Agency per REACH Article 20 within the 3 weeks after the submission date. For phase-in substances, manufacture/import or production/import may also continue if the submission occurred within the 2-month period before the REACH Article 23 deadline and no contraindication exist from the Agency per REACH Article 20 within 3 months from that deadline.
- In the case of an update of a registration per REACH Article 22, a registrant may continue the manufacture/import of the substance or the production/import of the article if no contraindication exists from the Agency per REACH Article 20 within the 3 weeks after the update date.
- If the Agency has informed the registrant that to submit further information per REACH Article 20, the registrant may start the manufacture/import of a substance or production/import of an article if no contraindication exists from the Agency within the 3 weeks after receipt by the Agency of the further information.

If a lead registrant submits parts of the registration on behalf of one or more other registrants, per REACH Article 11 or 19, any of the other registrants may M/I the substance or P/I the articles only after the expiration of the time limits per REACH Article 21 and if no contraindication exists from the Agency in respect of the registration of the lead registrant acting on behalf of the others.

2.5.3 REACH Article 22—Further Duties of Registrants

Article 22 will not apply to uses of substances registered per Article 15.

A registrant must expeditiously update the registration if relevant new information exists and submit that new information to the Agency. Such relevant new information may include the following:

- Change in registrant (i.e., status update, name, address)
- Change in the composition of the substance per REACH Annex VI, Section 2
- Changes in the annual or total quantities M/I or in the quantities of substances present in articles P/I if these result in a change of tonnage band including cessation of M/I
- New identified uses and new uses advised against as in REACH Annex VI, Section 3.7, for which the substance is M/I
- New knowledge of the risks of the substance of which the registrant could be reasonably expected to have become aware, which leads to changes in the SDS or the CSR
- Change in the classification and labeling of the substance
- Update or amendment of the CSR or REACH Annex VI, Section 5
- Additional requirements to perform a test per REACH Annex IX or REACH Annex X (this requires a testing proposal to be developed)
- Change in the access granted to information in the registration

The Agency will communicate this information to the competent authority of the relevant Member State.

A registrant must submit an update of the registration containing the information required per REACH Article 40, 41, or 46 or per a decision made per REACH Articles 60 and 73, within the deadline. The Agency will notify the competent authority of the relevant Member State that information is available. The Agency will conduct a completeness check per REACH Article 20 of each updated registration. In cases where the update is per REACH Article 12 and annual or total quantity has changed, the Agency will check the completeness of the information and REACH Article 20 must be adapted as necessary. In cases per REACH Article 11 or 19, each registrant must submit separately the information on changes in the annual or total quantities M/I or in the quantities of substances present in articles P/I if these result in a change of tonnage band including cessation of M/I.

2.6 TITLE II—REGISTRATION OF SUBSTANCES: CHAPTER 5—TRANSITIONAL PROVISIONS APPLICABLE TO PHASE-IN SUBSTANCES AND NOTIFIED SUBSTANCES

2.6.1 REACH Article 23—Specific Provisions for Phase-In Substances

REACH Articles 5, 6, 7, 17, 18, and 21 will not apply until June 1, 2018, to phase-in substances that are (at least once after June 1, 2007) manufactured in the Community or imported in quantities of 1 ton or greater per year per MI. A registration may,

however, be submitted at any time before the relevant deadline. This REACH Article will also apply to substances registered per REACH Article 7 adapted as necessary.

2.6.2 REACH Article 24—Notified Substances

If the quantity of a notified substance reaches the next tonnage threshold, per REACH Article 12, submission of the following is required: (1) information corresponding to that tonnage threshold, (2) information for all the lower tonnage thresholds, and (3) information per REACH Articles 10 and 12 (unless already submitted per those REACH Articles) (REACH, 2006).

REFERENCES

Commission Decision (EC) No 2003/565/EC of 25 July 2003 extending the time period of Council Directive 91/414/EC, OJ L192/40, 2003.

Commission Regulation (EC) No 703/2001 of 6 April 2001 laying down the active substances of plant protection products to be assessed in the second stage of the programme, OJ L98/6, 2001.

Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme, OJ L224/23, 2002.

Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme concerning the placing of biocidal products on the market, OJ L307/1, 2003.

Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work concerning the placing of plant protection products on the market, OJ L366/10, 1992.

Council Directive (EEC) No 76/768/EEC of 27 July 1976 on the approximately of the laws of Member States relating to cosmetic products, OJ L262/169, 1976.

Council Directive (EEC) No 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, OJ L230/1, 1991.

Directive (EC) 2004/10/EC of the European Parliament and of the Council on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version), 2004.

Directive (EC) No 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, OJ L123/1, 1998.

Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes, 1986.

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food, OJ L338/4, 2004.

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Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH), OJ L396/1, 2006; and as amended to date, see http://eur-lex.europa.eu/.

3 REACH Articles 25 to 59

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CONTENTS

This chapter is a continuation of Chapter 2. The focus is on data sharing prerogatives, dossier evaluations, chemical testing provisos, and authorization requirements.

3.1 TITLE III—DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING: CHAPTER 1—OBJECTIVES AND GENERAL RULES

3.1.1 REACH Article 25—Objectives and General Rules

Article 25 does not apply to uses of substances registered per Article 15. Testing on vertebrate animals must be undertaken only as a last resort. Measures must be taken to limit duplication of other tests. Sharing and joint submission of information must include technical data and information on intrinsic properties. Registrants should refrain from exchanging information concerning their market behavior (e.g., production capacities, production or sales volumes, import volumes, or market shares). Any study/robust study/summaries of studies submitted at least 12 years previously can be used for registration by another manufacturer or importer (MI).

3.2 TITLE III—DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING: CHAPTER 2—RULES FOR NON-PHASE-IN SUBSTANCES AND REGISTRANTS OF PHASE-IN SUBSTANCES WHO HAVE NOT PREREGISTERED

Articles 26 and 27 will not apply to uses of substances registered per Article 15.

3.2.1 REACH Article 26—Duty to Inquire before Registration

Every potential registrant of a non-phase-in substance, or potential registrant of a phase-in substance who has not preregistered per REACH Article 28, must ask the Agency whether a registration for the same substance has already been submitted. All of the following information must be submitted to the Agency with the inquiry:

- Identity with the exception of the use sites (REACH Annex VI, Section 1)
- Identity of the substance per REACH Annex VI, Section 2
- Information requirements that would require new studies involving vertebrate animals or other new studies

The Agency will inform the potential registrants if the same substance has not been previously registered. The Agency will inform the potential registrants of names and addresses of the previous registrant(s) and relevant or robust study summaries already submitted if the same substance has been previously registered for less than 12 years. The Agency will inform all potential registrants of the name and address of the other potential registrants if several potential registrants have made an inquiry in respect to the same substance. The Agency will simultaneously inform the previous registrants of the name and address of the potential registrant. The available studies will be shared with the potential registrant per REACH Article 27. The intent will be to reduce unnecessary vertebrate studies.

3.2.2 REACH Article 27—Sharing of Existing Data in the Case of Registered Substances

A potential registrant must request whether a relevant study is available for use in the registration process per REACH Articles 10 and 26. Relevant studies involving tests on vertebrate animals must be requested. Relevant studies not involving tests on vertebrate animals may be requested. The potential and the previous registrant(s) must make every effort to reach an agreement on the sharing of the information or to an arbitration board and accept the arbitration order.

The previous and potential registrant(s) must make every effort to share the information costs in a fair, transparent, and nondiscriminatory way (cost sharing guidance per REACH Article 77). Registrants are only required to share in the costs of information required for registration. The previous registrant must make available the agreed information and give the new registrant the permission to refer to the previous registrant's full study report. The potential registrant(s) must inform the Agency and the previous registrant(s) of the name and address of the previous registrant(s) who failed to provide information if such an agreement cannot be reached after a minimum of 1 month. The Agency will give the potential registrant permission to reference the requested information in the registration dossier within 1 month from the receipt of the information request failure.

- Permission will be subject to the potential registrant providing, upon Agency request, proof that a previous registrant(s) has been paid for that information. The previous registrant(s) will have a claim on the potential registrant for a proportionate share of the costs incurred. Calculation of the proportionate cost may be facilitated per REACH Article 77. The previous registrant(s) will have a claim on the potential registrant for an equal share of the cost incurred and this claim will be enforceable in the national courts if the full study report is available to the potential registrant. The registration waiting period per REACH Article 21 for the new registrant will be extended by 4 months, if the previous registrant so requests.
- An appeal may be brought, per REACH Articles 91, 92, and 93, against Agency decisions.

3.3 TITLE III—DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING: CHAPTER 3—RULES FOR PHASE-IN-SUBSTANCES

3.3.1 REACH Article 28—Duty to Preregister for Phase-In Substances

Article 28 will not apply to uses of substances registered per Article 15.

Each potential registrant of a phase-in substance in quantities of ≥1 ton per year, including intermediates (without limitation), must submit the following:

- Name of the substance as specified in REACH Annex VI, Section 2, including the European Inventory of Existing Commercial Chemical Substance number, Chemical Abstract Service number, or other identity codes
- Name and address of the registrant, contact person, and any person representing the registrant per REACH Article 4 per Annex VI, Section 1
- Predicted deadline for the registration and the tonnage band
- Name(s) of substance(s) (per REACH Annex VI, Section 2) that are relevant to the application of REACH Annex XI, Sections 1.3 and 1.5

Registrants who do not submit the previous information will not be able to rely on REACH Article 23. The Agency website includes a list of the substances with the substance names and the first registration deadline. Downstream users (DUs) of a substance not appearing on the list may notify the Agency of their interest in the substance, contact details, and details of their current supplier. The Agency will then publish the name of the substance and provide, on request, contact details of the DU to a potential registrant on the Agency website.

Potential registrants are those who use phase-in substances that would require registration for the first time and manufacture or import in quantities of ≥1 ton per year, use these substances in the production of articles, or import an article that contains a phase-in substance. These potential registrants may rely on REACH Article 23 if the required information is submitted to the Agency within 6 months of first manufacturing/importing/using the substance in quantities of ≥1 ton or greater per year and no later than 12 months before the relevant deadline in REACH Article 23.

Information may be submitted for inclusion in the substance information exchange forum (SIEF) for phase-in substances in quantities of <1 ton per year that appear on the Agency list. This information can be submitted by MIs, DUs, and third parties with information on listed substances.

3.3.2 REACH Article 29—Substance Information Exchange Forums

All potential registrants, DUs, and third parties who have submitted information on a substance (per REACH Article 28, REACH Article 15, or REACH Article 23) will be participants in a SIEF. SIEFs will facilitate the exchange of information for registration purposes (per REACH Article 10), coordinate classification, and harmonize classification and labeling (between registrants). SIEF participants provide other

participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies, and arrange for such studies. Each SIEF will be operational until June 1, 2018.

3.3.3 REACH Article 30—Sharing of Data Involving Tests

A SIEF participant must inquire whether a relevant study is available before testing is carried out for registration. A participant must request any relevant study involving tests on vertebrate animals. A participant may request a relevant study not involving tests on vertebrate animals. The owner of the study must provide proof of its cost to the requestor within 1 month of the request. The participant(s) and the owner must share the costs in a fair, transparent, and nondiscriminatory way (REACH Article 77). The cost will be shared equally if an agreement is not reached. The owner must give permission to refer to the full study report within 2 weeks of receipt of payment. Registrants are only required to share in the costs of information required to satisfy their registration requirements.

Only one study is to be conducted by one of the participants acting on behalf of the others if a relevant study involving tests is not available within the SIEF. All reasonable steps must be made to reach an agreement given the deadline set by the Agency. The Agency will specify which registrant or DU must perform the test if no agreement is reached. All participants of the SIEF who require a study must contribute to the costs for the elaboration of the study with a share corresponding to the number of participating potential registrants. Those participants who do not conduct the study will have the right to receive the full study report within 2 weeks after payment to the participant who carried out the study.

- If the owner of a study that involves testing on vertebrate animals refuses to provide either proof of the study cost to (an) other participant(s), the owner will not be able to proceed with registration until the information is provided. The other participant(s) will proceed with registration without fulfilling the information requirement, explaining the reason in the dossier. The study will not be repeated unless the information owner has not provided study information within 12 months of other participants' registration date and the Agency determines that test should be repeated. If a registration containing this information has been submitted by another registrant, the Agency will give the other participant(s) permission to refer to this information in the dossier(s). The other registrant will have a claim on the other participant(s), enforceable in the national courts, for an equal share of the cost, provided the full study report is available.
- If the owner of a study that does not involve testing on vertebrate animals refuses to provide either proof of the cost or the study itself to (an)other participant(s), the other SIEF participants will proceed with registration as if no relevant study was available in the SIEF.
- An appeal may be brought, per REACH Articles 91, 92, and 93, against Agency decisions.

- The owner of the study who has refused to provide either proof of the cost or the study itself will be penalized. Member States will lay down the provisions on penalties. The Member States must notify those provisions to the Commission no later than December 1, 2008, and notify without delay of any subsequent amendments.

3.4 TITLE VI—EVALUATION: CHAPTER 1—DOSSIER EVALUATION

3.4.1 REACH Article 40—Examination of Testing Proposals

Any substance testing proposal from a registration or a DU report must be examined by the Agency per REACH Annexes IX and X. Priority must be given to

- Persistent, bioaccumulative, and toxic (PBT); very persistent and very bioaccumulative (vPvB); sensitizing and carcinogenic; mutagenic or toxic for reproduction properties
- Substances above 100 tons per year with uses resulting in widespread and diffuse exposure per CLP Annex I
- Hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, and 2.15 types A to F
- Hazard classes 3.1 to 3.6, 3.7 (adverse effects on sexual function and fertility or on development), 3.8 (effects other than narcotic effects), 3.9, and 3.10
- Hazard class 4.1
- Hazard class 5.1.2

Information relating to testing proposals on vertebrate animals must be published on the Agency website and include (1) substance name, (2) hazard endpoint for that vertebrate testing proposed, and (3) date when any third-party information is required. Studies that address the relevant substance and hazard endpoints per the testing proposal must be submitted. The Agency will invite third parties to submit, using the format provided by the Agency. Submittals must present scientifically valid information and studies within 45 days of the date of publication. All scientifically valid information and studies received will be considered by the Agency. The required information must be submitted to the Agency, by the registrant/DU, by the deadline, generally within 90 days. The Agency may designate one registrant/DU to perform the test if multiple registrants/DUs have submitted.

3.4.2 REACH Article 49—Further Information on On-Site Isolated Intermediates

Additional information may be requested by competent authorities of the Member States. Member States may be required to request additional information owing to regulatory requirements. Confidentiality decisions must be made between the MI and the Member State(s). Neither dossier nor substance evaluation applies for on-site

isolated intermediates used in strictly controlled conditions. Further information submittal may be required by the competent authority of the Member State (in whose territory the site is located) for

- Information directly related to an identified risk to human health/the environment that is equivalent to that per REACH Article 57
- Information arising from the use of an on-site isolated intermediate when the risk is not properly controlled

Written justification from the competent authority must accompany the request. Any information submitted will be examined by the competent authority and risk reduction measures will be recommended. The competent authority will inform the Agency of the evaluation results. The Agency will then inform the competent authorities of the other Member States and make the results available.

3.5 TITLE VI—EVALUATION: CHAPTER 4—COMMON PROVISIONS

3.5.1 REACH Article 53—Cost Sharing for Tests without an Agreement between Registrants and DUs

Every effort will be made to reach a testing agreement given responsibilities between registrants. The Agency will be informed accordingly within 90 days. The Agency will designate one of the registrants/DUs to perform the test if not informed of an agreement within 90 days. If a registrant/DU performs a test on behalf of others, all registrants/DUs will share the cost of that study equally. The registrant/DU who performs the test must provide each of the other registrants/DUs with a copy of the full study report. The registrant/DU performing and submitting the study will have a claim against the other registrants/DUs. Any registrant/DU may make a claim to prohibit another registrant/DU from manufacturing/importing/placing the substance on the market if that other registrant/DU fails to (1) pay their share of the cost, (2) provide security for their share of the cost, or (3) provide a copy of the full study report. All claims will be enforceable in the national courts. Any registrant/DU may choose to submit claims for remuneration to an arbitration board and accept the arbitration order.

3.6 TITLE VII—AUTHORIZATION: CHAPTER 1—AUTHORIZATION REQUIREMENT

3.6.1 REACH Article 55—Aim of Authorization and Considerations for Substitution

The aims of Title VII are (1) to ensure the good functioning of the internal market, (2) to control the risks from substances of very high concern, and (3) to progressively replace high-risk substances with suitable alternative substances or technologies. To this end, all MIs/DUs applying for authorizations must analyze the availability of

alternatives and consider their risks and the technical and economic feasibility of substitution.

3.6.2 REACH Article 56—General Provisions

3.6.2.1 Placement on the Market

A substance must not be used or placed on the market for a use by an MI/DU if that substance is included in REACH Annex XIV unless

- Use(s) of that substance/mixture or incorporation of the substance into an article has been authorized per REACH Articles 60 to 64
- Use(s) of that substance/mixture or incorporation of the substance into an article has been exempted from the authorization requirement in REACH Annex XIV per REACH Article 58
- Date per REACH Article 58 has not been reached
- Date per REACH Article 58 has been reached and the application was made 18 months before that date but a decision on the application for authorization has not yet been taken
- In cases where the substance is placed on the market, and authorization for that use has been granted to the immediate DU

A DU may use a substance meeting the previously stated criteria if the use is per the conditions of an authorization granted to an actor up the supply chain.

3.6.2.2 Exceptions

The above criteria do not apply to use of substances

- In scientific research and development. *Note*: REACH Annex XIV must specify if the research and development exemption applies to product and process orientated research and development and the maximum quantity exempted.
- In plant protection products per Directive 91/414/EEC.
- In biocidal products per Directive 98/8/EC.
- In motor fuels per Directive 98/70/EC.
- In fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.
- Subject to authorization only due to criteria in REACH Article 57.
- Identified per REACH Article 57 only because of hazards to human health; to include uses in cosmetic products per Directive 76/768/EEC and food contact materials per Regulation (EC) No 1935/2004.
- In mixtures for substances per REACH Article 57 that are below a concentration limit of 0.1% w/w.
- Below the lowest of the concentration limits in CLP Annex VI, Part 3, that resulted in classification of the mixture as dangerous.

3.6.3 REACH Article 57—Substances to Be Included in REACH Annex XIV

Substances that may be included in REACH Annex XIV per REACH Article 58 are as follows:

- Hazard class carcinogenicity category 1A or 1B per CLP Annex I, Section 3.6
- Hazard class germ cell mutagenicity category 1A or 1B per CLP Annex I, Section 3.5
- Hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development per CLP Annex I, Section 3.7
- PBT per REACH Annex XIII
- vPvB per REACH Annex XIII
- Those that have (1) endocrine disrupting properties, (2) PBT properties, or (3) vPvB properties (and yet do not fulfill the REACH Annex XIII requirements)
- Those at an equivalent level of concern (with scientific evidence of probable serious effects) and are identified on a case-by-case basis per REACH Article 59

3.6.4 REACH Article 58—Inclusion of Substances in REACH Annex XIV

When including REACH Annex XIV substances per REACH Article 57, use the procedure in REACH Article 133 that specifies the following:

- Identity of the substance per REACH Annex VI, Section 2.
- Intrinsic property (properties) per REACH Article 57.
- Transitional arrangements. Use and placing on the market will be prohibited unless an authorization (sunset date) is granted. To obtain authorization, provide the (1) date(s) for placing on the market and (2) production cycle specified for use. If the applicant wishes to continue to use or place the substance on the market for certain uses after the sunset date(s), an application must be provided at least 18 months before the sunset date(s) expiration. These continued uses will be allowed after the sunset date until an authorization decision is made.
- Review periods for certain uses.
- Uses or categories of uses exempted from the authorization requirement and conditions for exemptions.
- Basis of existing Community legislation imposing minimum requirements for protection of human health/the environment.
- Whether the risk is properly controlled, and proportionality of risk to human health and the environment related to the nature of the substance.

The Agency will recommend priority substances to be included in REACH Annex XIV before a decision to include the substances and given the opinion of the Member State Committee. Priority must normally be given to substances with (1) PBT or vPvB properties, (2) wide dispersive use(s), or (3) high volumes. The number of substances included in REACH Annex XIV and the dates previously specified will consider the Agency's capacity to handle applications.

- The Agency will make recommendations for substances to include in REACH Annex XIV at least every second year on its website. The date of publication per REACH Articles 118 and 119 will be clearly indicated before the Agency sends recommendation to the Commission. The Agency will invite all interested parties to submit comments within 3 months of the publication date, in particular with regard to uses that should be exempt from the authorization requirement. The Agency will update recommendation, considering comments received.
- After inclusion of the substance in REACH Annex XIV, the substance will not have new restrictions per Title VIII arising from the specified intrinsic properties. The substance listed in REACH Annex XIV may, however, be subject to new restrictions per Title VIII covering the risks from the presence of the substance in (an) article(s).
- Substances with all uses prohibited per Title VIII or other Community legislation will not be included in or must be removed from REACH Annex XIV.
- Substances that no longer meet the criteria of REACH Article 57, as a result of new information, will be removed from REACH Annex XIV per REACH Article 133.

3.6.5 REACH Article 59—Identification of Substances per REACH Article 57

Article 59 presents the procedure for identifying substances per REACH Article 57 criteria and establishes a candidate list for inclusion in REACH Annex XIV. Substances that are on the Agency work program per REACH Article 83 will be indicated within the candidate list.

3.6.5.1 Dossier

The Agency will prepare a dossier per REACH Annex XV for substances meeting REACH Article 57 criteria at the request of the Commission. The dossier will be a reference entry in CLP Annex VI, Part 3. The Agency will make this dossier available to the Member States. Any Member State may prepare a dossier per REACH Annex XV for substances meeting REACH Article 57 criteria and forward the dossier to the Agency. The dossier may be a reference entry in CLP Annex VI, Part 3. The Agency will make this dossier available within 30 days of receipt to the other Member States.

3.6.5.2 Notice

A notice will be published on the Agency website that a REACH Annex XV dossier has been prepared. The Agency will invite all interested parties to submit comments. Member States or the Agency may comment per REACH Article 57 within 60 days of circulation.

- The Agency will list the substance if the Agency does not receive or make any comments. The Agency may include this substance in its recommendations per REACH Article 58.
- The Agency will refer the dossier to the Member State Committee within 15 days of the end of the 60-day circulation period when comments are made or received. The Agency will list the substance and may include that substance in recommendations per REACH Article 58 if the Member State Committee reaches a unanimous agreement on the identification within 30 days of the referral.
- The Commission will prepare a draft proposal on the substance identification within 3 months of receipt of the opinion of the Member State Committee if the Member State Committee fails to reach a unanimous agreement.

3.6.5.3 Final Decision

A final decision on the substance identification will be taken per REACH Article 133. The Agency will publish and update the list without delay (REACH, 2006).

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Council Directive (EC) No 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control, OJ L257/26, 1996.

Council Directive (EEC) No 76/768/EEC of 27 July 1976 on the approximately of the laws of Member States relating to cosmetic products, OJ L262/169, 1976.

Council Directive (EEC) No 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ L189/17, 1990.

Council Directive (EEC) No 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, OJ L230/1, 1991.

Council Directive (EEC) No 93/42/EEC of 14 June 1993 concerning medical devices, OJ L169/1, 1993.

Council Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling, and packaging of substances and mixtures, OJ L353/1, 2008; and as amended to date, see http://eur-lex.europa.eu/.

Directive (EC) No 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocial products on the market, OJ L123/1, 1998.

Directive (EC) No 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels, OJ L350/58, 1998.

Directive (EC) No 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ L337/1, 1998.

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