SCHC Fall Conference 2023

The Impact of the Chemicals Strategy for Sustainability on REACH and CLP

Karin F. Baron, MSPH
Bergeson & Campbell, P.C.

Overview

- Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
- Regulation (EC) No 1272/2008 on the Classification, Labeling and Packaging of Substances and Mixtures (CLP)
- Chemicals Strategy for Sustainability (CSS)
  - Impact to REACH
  - Impact to CLP
  - Supply chain implications

REACH

- **REACH = Registration, Evaluation, Authorization and Restriction of Chemicals**
- **Duty of care and precautionary principle**
  - Ensure a high level of protection of human health and the environment
  - Based on the principle that it is for manufacturers, importers, and downstream users to ensure that they manufacture, place on the market, or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle
- **Regulation is complex**
  - 140+ Articles and 17 Annexes
  - Currently over 500 pages of (reformatted) text
  - Thousands of pages of guidance

REACH

- **Core elements of REACH**
  - **Registration** with European Chemicals Agency (ECHA) of substances manufactured/imported at or above 1 metric ton per year (mt/y)
    - Over 100,000 registrations for approximately 22,000 substances
  - **Evaluation** of substances by ECHA and member states
  - **Authorization** needed for substances of very high concern (SVHC)
    - 235 entries for SVHCs on Candidate List for Authorization
    - 59 entries on the Authorization List (Annex XIV)
  - **Restriction** process as “safety net”
    - 76 entries for various restrictions (Annex XVII)

REACH

- Title IV states that a supplier of a substance shall provide the Safety Data Sheet (SDS) when specific conditions are met
- Annex II sets out the requirements for compiling the SDS, includes obligations and a specific format
- SDS for registered substances shall be consistent with the registration and the Chemical Safety Report (CSR) (includes requirement for e-SDS or extended SDS with exposure scenarios)
- SDS shall be prepared by a competent person who is appropriately trained, including refresher training
- The SDS shall be supplied in the official language of the member state where it is placed on the market

REACH

- **Annex II incorporates into the SDS elements that are unique to REACH**
  - PBT (persistent, bioaccumulative, and toxic)
  - vPvB (very persistent and very bioaccumulative)
  - Endocrine disrupting properties (transition period ended December 31, 2022)
  - Nanoforms (transition period ended December 31, 2022)
  - SVHC
- **There are specific requirements within the SDS to address these endpoints**

REACH

- **Section 1.1 Product identifier**
  - Inclusion of nanoform where applicable
- **Section 2.3 Other hazards**
  - Inclusion of PBT, vPvB, and/or endocrine disrupting properties (criteria established in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605) when present at or above 0.1 percent
- **Section 11.2 Information of other hazards**
  - Inclusion of endocrine disrupting properties for human health
- **Section 12.5 Results of PBT and vPvB assessment**
  - From the CSR
- **Section 12.6 Endocrine disrupting properties**
  - Inclusion of endocrine disrupting properties for the environment

CLP

- Criteria for classification of hazards for inclusion on the SDS and label are not found in REACH
- Aims to ensure a high level of protection of human health and the environment
- Somewhat aligned with the United Nations' (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS)
- CLP is legally binding across all member states
- Over 1,500 pages of legal text

CLP

- **CLP includes:**
  - Criteria for physical, health, and environmental hazard classes
  - Criteria for labeling elements on packages (includes consumer goods)
  - Contains a list of “harmonized classification and labeling” for specific substances known as Annex VI
  - Includes procedures for harmonization efforts
  - Updates are through Adaptations to Technical Progress (ATP)
  - Includes how to address alternative chemical names
  - Provides requirement for Poison Centre Notifications (PCN)

CLP

- **Does not include all the UN GHS building blocks**
  - Not all acute environmental hazard categories adopted
- **Does not align with UN GHS mixture concentration thresholds for certain endpoints**
  - Reproductive toxicant, category 2 uses ≥ 3 percent (no mention of the ≥ 0.1 percent with applicable “note”)
- **Includes supplemental hazards**
  - EUH066 -- “Repeated exposure may cause skin dryness or cracking”

CSS

- Part of the European Green Deal, which aims to be “climate neutral” by 2050
- Adopted by the European Commission on October 14, 2020
- Includes ambitious action plan that will substantially alter REACH and CLP

CSS

- Aims to establish a stronger European Union (EU) legal framework to address environmental and health concerns
- Focus on REACH and CLP regulations
- Centralized approach to chemical assessment
- New approaches to risk management, including expanded generic approach
- New approaches to hazard and risk assessment

CSS and REACH

- **REACH re-design**
  - Revisions to the evaluation process and establishment of "one-substance, one assessment" process
    - Integrated Regulatory Strategy (IRS) annual report notes that in 2023 ECHA will initiate a review to "take stock of the achievements and progress to-date and to align with the future ECHA's priorities and strategic focus …"
    - The IRS annual report states that from 2019 to 2022 around 5,000 substances have been assessed
      - 60% require no further action
      - 30% may require risk management actions
      - 10% require further data
    - 2,000 of the substance assessments were initiated in 2022

CSS and REACH

- **REACH re-design**
  - Improvement of enforcement of chemicals legislation
  - Increase of information requirements for all carcinogenic substances
  - Duty to perform chemical safety assessments (CSA) for substances at 1 – 10 metric tons per year
  - Standard information requirements for certain polymers requiring registration
  - New data requirements to address new hazards

CSS and CLP

- **CLP re-design**
  - CLP regulation is the central piece for hazard classification
  - Review definition of nanomaterial to "… ensure its coherent application across legislation using legally binding mechanisms"
  - Introduction of new hazard classes
    - Legislative proposal issued December 19, 2022, published April 20, 2023
    - Endocrine disruption in humans and the environment
    - PBT and vPvB
    - PMT (persistent, mobile, and toxic) and very persistent and very mobile (vPvM)

CSS and CLP

- **Nanomaterial**
  - Commission Recommendation 2011/696/EU
    - Nanomaterial means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm
    - Particle means a minute piece of matter with defined physical boundaries
    - Agglomerate means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components
    - Aggregate means a particle comprising of strongly bound or fused particles

CSS and CLP

Endocrine disruption for human health

- Endocrine disruptor means a substance or a mixture that alters one or more functions of the endocrine system and consequently causes adverse effects in an intact organism, its progeny, populations or subpopulations
- Endocrine disruption means the alteration of one or more functions of the endocrine system caused by an endocrine disruptor
- Endocrine activity means an interaction with the endocrine system that may result in a response of that system, of target organs or target tissues, and that confers on a substance or the mixture the potential to alter one or more functions of the endocrine system
- Adverse effect means a change in morphology, physiology, growth, development, reproduction or lifespan of an organism, system, population, or subpopulation that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences
- Biologically plausible link means the correlation between an endocrine activity and an adverse effect, based on biological processes, where the correlation is consistent with existing scientific knowledge

CSS and CLP

- **Endocrine disruption for human health**
  - Category 1 classification criteria
    - Known or presumed endocrine disruptors for human health
    - The classification in Category 1 shall be largely based on evidence from at least one of the following:
      - Human data
      - Animal data
      - Non-animal data providing an equivalent predictive capacity as data in points above
    - Such data shall provide evidence that the substance meets all the following criteria:
      - Endocrine activity
      - An adverse effect in an intact organism or its offspring or future generations
      - A biologically plausible link between the endocrine activity and the adverse effect
    - Where there is information that raises serious doubt about the relevance of the adverse effects to humans, classification in Category 2 may be more appropriate

CSS and CLP

- **Endocrine disruption for human health**
  - Category 2 classification criteria
    - Suspected endocrine disruptors for human health
    - A substance shall be classified in Category 2 where all the following criteria are fulfilled:
      - There is evidence of:
        - An endocrine activity; and
        - An adverse effect in an intact organism or its offspring or future generations
      - The evidence referred to in the point above is not sufficiently convincing to classify the substance in Category 1
      - There is evidence of a biologically plausible link between the endocrine activity and the adverse effect

CSS and CLP

- **Endocrine disruption for human health**
  - Classification of mixtures applies where data are available for all components or only some components of the mixture
    - Category 1 at or above 0.1 percent
    - Category 2 at or above 1 percent (SDS required at 0.1 percent)
  - Label elements
    - EUH hazard statements (may cause … or suspected of causing)
    - Danger and Warning signal words
    - No pictogram
    - Several precautionary statements

CSS and CLP

Endocrine disruption for the environment

- Endocrine disruptor means a substance or a mixture that alters one or more functions of the endocrine system and consequently causes adverse effects in an intact organism, its progeny, populations or subpopulations
- Endocrine disruption means the alteration of one or more functions of the endocrine system caused by an endocrine disruptor
- Endocrine activity means an interaction with the endocrine system that may result in a response of that system, of target organs or target tissues and that confers on a substance or mixture the potential to alter one or more functions of the endocrine system
- Adverse effect means a change in morphology, physiology, growth, development, reproduction or lifespan of an organism, system, population or subpopulation that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences
- Biologically plausible link means the correlation between an endocrine activity and an adverse effect, based on biological processes, where the correlation is consistent with existing scientific knowledge

CSS and CLP

- **Endocrine disruption for the environment**
  - Category 1 classification criteria
    - Known or presumed endocrine disruptors for the environment
    - The classification in Category 1 shall be largely based on evidence from at least one of the following:
      - Animal data
      - Non-animal data providing an equivalent predictive capacity as data in the point above
    - Such data shall provide evidence that the substance meets all the following criteria:
      - Endocrine activity
      - An adverse effect in an intact organism or its offspring or future generations
      - A biologically plausible link between the endocrine activity and the adverse effect
    - Where there is information that raises serious doubt about the relevance of the adverse effects identified at population or subpopulation level, classification in Category 2 may be more appropriate

CSS and CLP

- **Endocrine disruption for the environment**
  - Category 2 classification criteria
    - Suspected endocrine disruptors for the environment
    - A substance shall be classified in Category 2 where all the following criteria are met:
      - There is evidence of:
        - An endocrine activity; and
        - An adverse effect in an intact organism or its offspring or future generations
      - The evidence referred to in the point above is not sufficiently convincing to classify the substance in Category 1
      - There is evidence of a plausible biological link between the endocrine activity and the adverse effect

CSS and CLP

- **Endocrine disruption for the environment**
  - Classification of mixtures applies where data are available for all components or only some components of the mixture
    - Category 1 at or above 0.1 percent
    - Category 2 at or above 1 percent (SDS required at 0.1 percent)
  - Label elements
    - EUH hazard statements (may cause … or suspected of causing)
    - Danger and Warning signal words
    - No pictogram
    - Several precautionary statements

CSS and CLP

- **PBT**
  - Persistence
    - A substance shall be considered to fulfill the persistence criterion (P) where any of the following conditions is met:
      - The degradation half-life in marine water is higher than 60 days
      - The degradation half-life in fresh or estuarine water is higher than 40 days
      - The degradation half-life in marine sediment is higher than 180 days
      - The degradation half-life in fresh or estuarine water sediment is higher than 120 days
      - The degradation half-life in soil is higher than 120 days
  - Bioaccumulation
    - A substance shall be considered to fulfill the bioaccumulation criterion (B) where the bioconcentration factor in aquatic species is higher than 2000

CSS and CLP

- **PBT**
  - Toxicity
    - A substance shall be considered to fulfill the toxicity criterion (T) in any of the following situations:
      - The long-term no-observed effect concentration (NOEC) or EC_X for marine or freshwater organisms is less than 0.01 mg/L
      - The substance meets the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B, or 2) …
      - There is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) …
      - The substance meets the criteria for classification as endocrine disruptor (Category 1) for humans or the environment …

CSS and CLP

- **vPvB**
  - A substance shall be considered to fulfill the “very persistent” criterion (vP) where any of the following conditions is met:
    - The degradation half-life in marine, fresh or estuarine water is higher than 60 days
    - The degradation half-life in marine, fresh or estuarine water sediment is higher than 180 days
    - Degradation half-life in soil is higher than 180 days
  - A substance shall be considered to fulfill the “very bioaccumulative” criterion (vB) where the bioconcentration factor in aquatic species is higher than 5000

CSS and CLP

- **PBT and vPvB**
  - There are no classification categories
  - Mixtures are assumed to be classified if at least one component contained in the mixture is classified at or above 0.1 percent
  - Label elements
    - EUH hazard statements (accumulates or strongly accumulates with long lasting effects)
    - Danger signal word
    - No pictograms
    - Several precautionary statements

CSS and CLP

- **PMT**
  - Persistence
  - Mobility
    - A substance shall be considered to fulfill the mobility criterion (M) when the log K_{oc} is less than 3. For an ionizable substance, the mobility criterion shall be considered fulfilled when the lowest log K_{oc} value for pH between 4 and 9 is less than 3
  - Toxicity
- **vPvM**
  - Very persistent
  - Very mobile
    - A substance shall be considered to fulfill the “very mobile” criterion (vM) when the log K_{oc} is less than 2. For an ionizable substance, the mobility criterion shall be considered fulfilled when the lowest log K_{oc} value for pH between 4 and 9 is less than 2

CSS and CLP

- **PMT or vPvM**
  - There are no classification categories
  - Mixtures are assumed to be classified if at least one component contained in the mixture is classified at or above 0.1 percent
  - Label elements
    - EUH hazard statements (persistent or very persistent which can pollute water resources)
    - Danger signal word
    - No pictograms
    - Several precautionary statements

Supply Chain Implications

- Additional disconnects from UN GHS
- New hazard classes that impact substances and mixtures
- New language on the SDS
- New labeling elements
- Consider existing hazard classes and impact on new hazard classes
  - Acute and chronic aquatic
  - CMR
  - STOT RE
- Review PBT and vPvB from REACH CSA and CSR

BERGESON & CAMPBELL PC

Supply Chain Implications

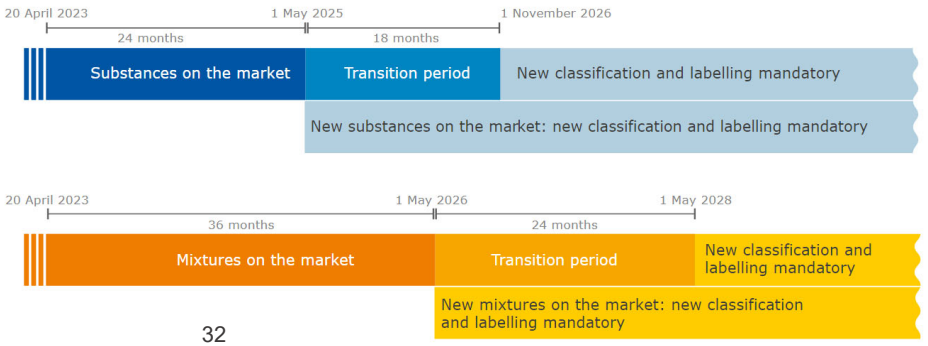
Timing

Substances

- From **1 May 2025** substances shall be classified with the criteria included
- Substances placed on the market **before 1 May 2025** are not required to be classified **until 1 November 2026**

Mixtures

- From **1 May 2026** mixtures shall be classified
- Mixtures placed on the market **before 1 May 2026** are not required to be classified **until 1 May 2028**



RESOURCES

BLOGS:

TSCAblog®

PESTICIDE LAW AND POLICY BLOG

BIOBASED PRODUCTS BLOG

Nano Blog

PODCAST:

All Things Chemical™

BERGESON & CAMPBELL PC

ONLINE, ON-DEMAND TRAINING:

TSCA TUTOR® (Toxic Substances Control Act)

FIFRA TUTOR™ (Federal Insecticide Fungicide Rodenticide Act)

GHS TUTOR™ (Globally Harmonized System)

UPCOMING WEBINARS:

https://www.lawbc.com/seminars-webinars

Vxevfuleh#wr#Ilup#Dohuw

BERGESON & CAMPBELL PC

ACTA ASIA EUROPE THE AMERICAS

B&C CONSORTIA MANAGEMENT

Thank You

Karin F. Baron, MSPH

kbaron@lawbc.com

202-266-5022