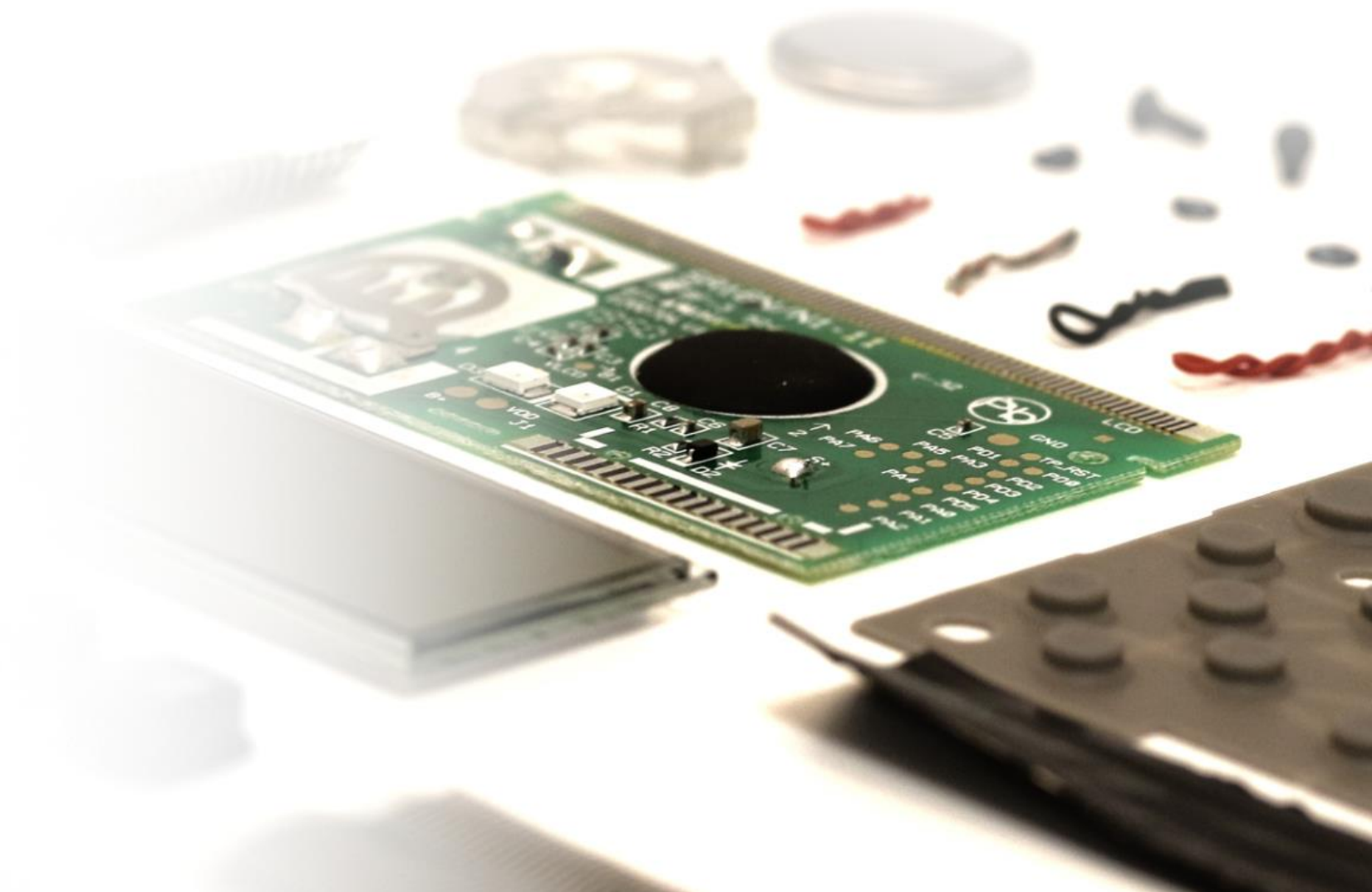


Budgeting for 2027

Restricted Materials

Presented by:
Bruce Calder
VP Consulting Services
Claigan Environmental



Who we are?

We make sure the products you sell



**HIGH-EFFICIENCY GAS
FURNACE & HEAT PUMP**



**COMMERCIAL ROOFTOP
PACKAGED UNIT (AC/RTU)**



**HEAT RECOVERY
VENTILATOR (HRV)**



Don't cause



**UNCONTROLLED CELL
PROLIFERATION (CANCER).**

Cancer



**ATTENTION
DYSREGULATION (ADHD)**

ADHD

And get pulled off the market

We also are very good at

Life Cycle Assessment / Green House Gas

CEPA Section 71 Surveys



LIFE CYCLE ASSESSMENT (LCA) SERVICES

Measuring Your Product's True Environmental Footprint
As the demand for transparent, quantifiable environmental data surges, understanding the precise carbon footprint of your products is no longer optional. Claigan's comprehensive Life Cycle Assessment (LCA) services break down the complexities of measuring emissions so you can make informed, sustainable design decisions and maintain global compliance.

WHAT IS A LIFE CYCLE ASSESSMENT?

An LCA is a quantitative assessment of the environmental impact caused by an individual product across every stage of its life. Claigan's LCA methodology strictly follows internationally recognized standards ISO 14040 and ISO 14044 to ensure consistency, transparency, and scientific credibility.

We examine every critical stage, including:

- Raw material extraction and refinement.
- Complex product manufacturing.
- Distribution and transportation networks.
- Product use, maintenance, and end-of-life disposal.

UNDERSTANDING THE CO2 EMISSIONS ASSOCIATED WITH YOUR PRODUCT GIVES YOU A MEASURABLE VIEW OF ITS ENVIRONMENTAL IMPACT.

UNDERSTANDING YOUR GHG EMISSIONS PROFILE

To effectively measure environmental impact, companies must categorize their Greenhouse Gas (GHG) footprint into specific scopes. **Scope 1:** direct emissions generated by the company, (i.e. combustion by company-owned vehicles or escaped refrigerants).

Scope 2: indirect emissions stemming from energy purchased by the company.

Scope 3: indirect emissions across a company's full value chain, covering the full lifecycle of your products and contributing factors like employee travel.

CLAIGAN'S EXPERT LCA METHODOLOGY

Utilizing our experience as an ISO 17025 accredited laboratory, Claigan's LCA services combine advanced material testing with researched CO2 equivalent values. We physically break down products into individual components and apply scientifically supported emissions data to deliver actionable, product-specific insights.



WHY ARE SHAREHOLDERS DEMANDING LCAs?

Investors are increasingly prioritizing sustainability and long-term risk management in their financial decisions. By requesting an LCA, shareholders are looking to verify your company's proactive environmental risk management.

An LCA delivers immediate business value through:

→ **Cost Reduction:** identifying areas of high energy consumption across product lifecycle.

→ **Regulatory Compliance:** preparing for emerging regulatory disclosure requirements, California's SB 533 requires scope 3 GHG reporting in November 2027.

→ **ESG Verification:** demonstrating competitiveness and alignment with sustainability commitments.

GET IN TOUCH



US / Can Packaging Reporting



US Packaging EPR Data Generation

Are you compliant with California and Oregon's passed deadlines?

The deadline for submitting packaging EPR data for California (SB 54) and Oregon (SB 582) was May 31, 2026. Most companies have a 90-day grace period, making the last acceptable day to report August 31, 2026. Non-compliance carries severe consequences: daily penalties up to \$50,000, inclusion on Oregon's public shame list, and a California distributor ban. And yes, B2B operations are fully in scope!

To help you meet these deadlines, Claigan provides a comprehensive, turnkey service delivered in three distinct phases:

PHASE 1: SCOPE ANALYSIS AND PACKAGING DATA GENERATION

- Identify the scope of each regulation for your products and distributor model.
- Generate the "fundamental" data required for California and Oregon.
- Derive data from bills of materials or representative products.

PHASE 2: DATA STRUCTURING & COMPONENT ANALYSIS

Manage diverse data situations under tight deadlines, even when handling partial or missing data.

- Distinguish between "detachable" and "associated" packaging.
- Handle "pass through" items that are included with your packaging.
- Roll up the data for California and Oregon.

PHASE 3: STRATEGIC PLANS & COST REDUCTION

Develop actionable strategies to meet state-specific targets and minimize the financial impact of environmental fees.

- Formulate an individual Source Reduction (SR) plan for California.
- Utilize the option for LCAs to reduce EPR fees.

KEY TAKEAWAYS

- Address the immediate 2026 compliance deadlines.
- Generate fundamental packaging EPR data.
- Roll up the data for California and Oregon.
- Develop individual Source Reduction (SR) plans and LCAs.

As the leading provider in plastics and packaging reporting, Claigan helps turn complex regulations into a straightforward, manageable process.



Required survey under CEPA Section 71

Chemicals Management Plan - Phase 1

Section 71 Survey submissions are required in Canada under the Canadian Environmental Protection Act (CEPA). These surveys require you to evaluate and report on hundreds of chemicals in your products.

Claigan streamlines the entire process by combining a high-level risk assessment for all 184 chemicals with a focused approach to testing and gathering data on the chemicals that could be reportable in your products.

Claigan provides a comprehensive, three-step service to help you meet these deadlines.

What you need to know

- Phase 1 of mandatory chemical reporting under Canada CEPA updates is underway.
- Claigan has a streamlined approach to Section 71 compliance.
- Claigan has helped hundreds of companies in previous Section 71 submissions.

Claigan's three-step solution to Section 71

The Section 71 Survey is complicated and intensive. Claigan simplifies this task through our expertise and comprehensive chemical risk assessment experience.

- Risk assessment of every chemical against your products and components.
- Identification of substances that could be present at a detectable level.
- Develop a plan for high risk substances.

CLAIGAN MAKES COMPLICATED CHEMICAL REPORTING SIMPLE

What's your plan, Talk



CLAIGAN PROP 65 SERVICES

FOR THE 2028 PROP 65 UPDATES

With over 400 enforcement notices per month, California Proposition 65 (Prop 65) is the most heavily enforced product regulation in the world. And it is changing at the start of 2028.

Starting in 2028, generic warnings will no longer be allowed. Even short form warnings will require the declaration of at least one applicable carcinogen and one applicable reproductive toxin.

Key Changes Coming in 2028

WHAT'S CHANGING?

- No more generic warnings.
- A substance has to be identified.
- New labelling text options.

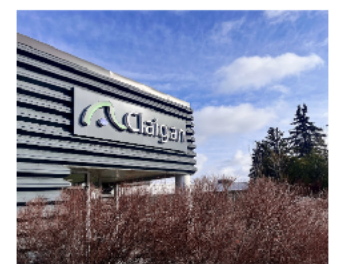
PREPARATION FOR PROP 65 IS THE KEY TO COMPLIANCE

Are you ready to identify a carcinogen or reproductive toxin to your customers? You likely do not have to. If you test your product properly, you will have an iron clad answer without declaring that your product causes cancer or reproductive harm.

- There are good effective methods to identify Prop 65 substances.
- Exposure testing is streamlined now- not a PhD adventure.
- A test report is your defense against the Prop 65 'bounty hunters.'

Claigan is the best in the business at Prop 65 compliance.

Prop 65



THE CLAIGAN EXPERIENCE

California requires companies to provide warnings for overexposure to Prop 65 listed chemicals. Claigan's services have you covered with Prop 65 testing and reporting.

- 15+ Years of Prop 65 experience.
- We've tested thousands of products for Prop 65 compliance.
- Solutions for every situation.

KEY TAKEAWAYS

Prepare for the 2028 Prop 65 updates with Claigan.

- In 2028 you will not be able to use generic warnings. Test reports are the only defense to Prop 65 notices.
- With more than 15 years of Prop 65 experience, Claigan provides trusted Prop 65 compliance testing and reporting services.

Claigan is the best in the world at Prop 65 compliance. Talk with one of our experts today.

Overview - Agenda

- CEPA Section 71 Surveys
- New Prop 65 Warnings
- Life Cycle Assessment
- EU MDR CMR compliance
- Packaging Re-design
- Minor items for 2027
- Reoccurring (annual) items
- Q&A



New Section 71 Mandatory Surveys

- Phase 1
 - 184 chemicals
 - **Due March 2027**
 - Includes common chemicals in
 - Lubricants, pharmaceuticals, food
 - Electronics and textiles
 - Medical Devices
- Phase 2
 - 16 chemicals
 - **Due September 2027**
 - Common chemicals in
 - Lubricants and PVC

New Section 71

Mandatory Surveys

- Scope
 - **Chemicals** (liquids, powders, gases) - includes oils
 - **Specific** manufactured items (articles)
 - Intended to be used for or by children <14
 - Intended to come into contact with mucosa (not eyes)
 - Intentionally released and may be inhaled or dermal
 - Cookware in contact with heated food or beverage
 - Food packaging in contact with food or beverage
 - Clothing or footwear
 - Bedding, sleeping bags, and towels
 - Furniture, mattress, etc include foam
 - Carpet or flooring

New Section 71

High Risk Materials

- Example reportable substances in chemicals
 - **Lubricant oils and Degreasers**
 - Ex. Heavy Alkylbenzenes (HABs), Xylene
 - **Pharmaceuticals**
 - Ex. Salicylates & Benzoic Acid Derivatives
 - **Food**
 - Ex. Linalool (lemon flavouring), Methyl salicylate (wintergreen)
- But **only if sold separately** from equipment

VERY
COMMON

VERY
COMMON

VERY
COMMON

High Risk Materials - Articles

- Examples reportable chemicals in Articles
 - **Rubber**
 - 2-MBT, Irganox 1520, dibutyl adipate, PPD
 - **Electronics**
 - Phosphated flame retardants, melamine
 - **High grade polymers** (medical, food, automotive)
 - Irganox 1520
 - **PVC**
 - Dibutyl adipate
- If your articles are in scope of Section 71



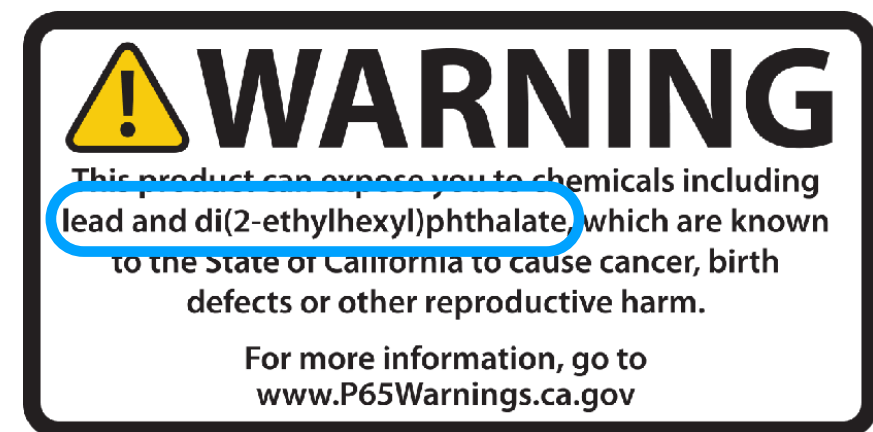
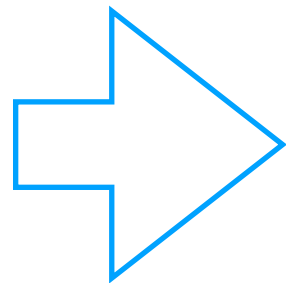
Section 71

- If you are in scope
 - **You will have substances to report**
- Plan for
 - A significant lack of data
 - Especially articles manufacturers
 - A risk assessment will reduce your costs a lot
 - **Claigan conducts industry wide risk assessments**
 - You probably need education of some sort
 - A very technical one time event.
 - So likely not worth developing the skill internally

California Proposition 65

New Warnings

- **New Warnings for California**
- **Prop 65 - Jan 1 2028 Requirements**
 - Substance needs to be identified on the warning label
 - They will be on most North American products



Prop 65

Today's Warning

- **Search results using current warning**
 - What is on your product today



**WARNING: Cancer
and Reproductive Harm -
www.P65Warnings.ca.gov**

Search results and the official state website (www.P65Warnings.ca.gov) typically clarify the following points for consumers:

- **It is a Right-to-Know Law:** The warning is mandated by the State of California to inform citizens about potential exposures to any of the 900+ chemicals known by the state to cause cancer, birth defects, or other reproductive harm.
- **Strict Thresholds:** The label is extremely common because California's threshold for requiring a warning is often significantly lower than federal safety limits (such as those set by the FDA or EPA).
- **Not a Safety Ban:** Explanations emphasize that the presence of a Prop 65 label does not necessarily mean a product is unsafe or in violation of federal safety standards. It simply means the manufacturer is complying with California's notification requirement to avoid costly lawsuits.

- **Search results using current warning**

Prop 65 2028 Warning

- Search results using the new warning

Q&A



WARNING

This product can expose you to chemicals including lead and di(2-ethylhexyl)phthalate, which are known to the State of California to cause cancer, birth defects or other reproductive harm.

For more information, go to
www.P65Warnings.ca.gov

- **Reproductive and Developmental Toxicity:** DEHP acts as an anti-androgen, meaning it can inhibit or interfere with male hormones. Exposure during pregnancy is closely linked to altered fetal development and birth defects, particularly affecting the development of the male reproductive tract. It is also associated with broader fertility issues in both men and women.
- **Cancer Risk:** Several health and environmental agencies, including the EPA, the International Agency for Research on Cancer (IARC), and the State of California, classify DEHP as a possible or probable human carcinogen.
- **Organ Damage:** Prolonged or high-level exposure to DEHP has been associated in studies with damage to the liver and kidneys.
- **High Risk of Leaching:** A major reason DEHP is problematic is its physical behavior. It is not chemically bound to the plastics it softens (like PVC), meaning it easily leaches out into food, water, household dust, or human tissue over time.

- This will cause fear in your customers

Key Details

- **Key differences**
 - New warning require substance to be identified
 - Adding a substance will change search results by customers
 - Most products **do not need a warning**
 - A test report is your only defence
 - In 50+ defenses I have participated in
 - **No test report. No win.**
 - But I have supplier data!
 - **No test report. No win.**
- **Claigan can help**

Note on Generic Warning

- **Prop 65** is also governed by the concept of
 - No **False** or **misleading** statements
- Short summary
 - You cannot provide a warning for a substance that is
 - **Not present**, or
 - **Not a potential exposure**
- This fundamental statement has to be **true**
 - "This product **can expose you** to chemicals"

Note on Generic Warning

- **Speculative or Harmless Warnings**
 - **Speculative Warnings Void "Safe Harbor" Protection**
 - To use California's approved Safe Harbor warning text (which protects a business from Proposition 65 litigation), the regulations require you to name at least one listed chemical that is actually in the consumer product and capable of causing an exposure.
 - If a company names a chemical that might not be there, the warning is factually false. If a bounty hunter later tests the product, finds a *different* listed chemical (like lead), and proves the named chemical wasn't present, the business's warning is invalid, and they can be sued for failing to warn about the lead.

Budgeting Summary

Prop 65

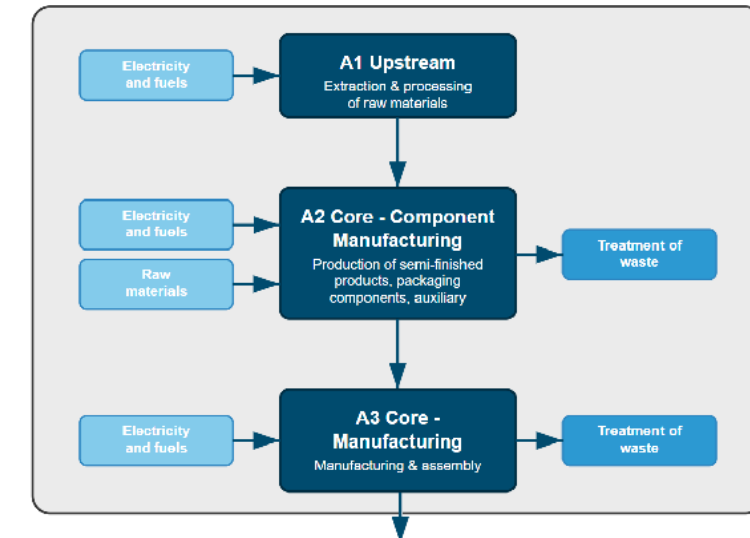
- Key rules
 - You will likely **not need a warning**
 - But you need a test report to justify it
 - You can only use a warning for a substance that is
 - Present and can expose you
 - But you need a test report to justify it
- Plan for
 - At least **testing of representative products for Prop 65**
 - If done properly, just key high risk materials for testing
 - Not the entire product

Life Cycle Assessment (LCA)

- **Going to be one of the largest demands from**
 - Large and institutional customers
 - Which are kind of important to your business :-)
- **Manufacturers should expect**
 - A 200% increase in LCA/GHG information demand in 2026
 - Heavily from
 - Large customers
 - To meet corporate and California Scope 3 reporting requirements
 - Tenders from large entities
 - Such as institutional or government tenders

Life Cycle Assessment Terms

- **Life Cycle Assessment (LCA)**
- What yours should look like
 - Follows the general rules in
 - ISO 14040 and ISO 14044
 - **More importantly**, comply to the appropriate
 - Product Category Rule (PCR)



4.1 Impact Categories

Table 6: Impact Categories from EF v3.1 LCA calculation

Indicator	Unit	A1-A3 (Manufacturing)	A4 (Distribution)	A5 (Installation)	B1-B7 (Use)	C1-C4 (End of Life)	D (Recovery)	TOTAL (A+B+C)
GWP-total	kg CO2 eq	1.17E+02	4.96E+01	0.00E+00	6.15E+02	1.63E+01	0.00E+00	7.98E+02
GWP-GHG	kg CO2 eq	1.16E+02	4.96E+01	0.00E+00	6.14E+02	1.60E+01	0.00E+00	7.96E+02
ODP	kg CFC-11 eq	3.30E-05	6.88E-07	0.00E+00	1.04E-05	2.35E-07	0.00E+00	4.43E-05
AP	mol H+ eq	6.79E-01	2.63E-01	0.00E+00	2.12E+00	7.00E-02	0.00E+00	3.13E+00
EP-fresh	kg P eq	7.40E-02	8.00E-03	0.00E+00	5.11E-01	4.00E-03	0.00E+00	5.97E-01
POCP	kg NMVOC eq	5.00E-01	3.28E-01	0.00E+00	1.24E+00	5.60E-02	0.00E+00	2.13E+00
ADP-min	kg Sb eq	1.26E-02	4.00E-04	0.00E+00	5.60E-03	5.77E-05	0.00E+00	1.87E-02
ADP-fossil	MJ	1.65E+03	6.46E+02	0.00E+00	1.08E+04	1.95E+02	0.00E+00	1.31E+04
WDP	m3 eq	4.46E+01	4.56E+00	0.00E+00	1.56E+02	5.94E+00	0.00E+00	2.11E+02

Product Category Rules (PCRs) to Use

- **PCR** (Product Category Rule)
 - Provides a standard for **LCA** (Life Cycle Assessment) for specific products
- **Electronics** (including medical electronics) use the PCR for Electronics
 - PCR 2024:06 for Electronic and electric equipment and electronic components)
- **Non-electronic medical devices**
 - Do not currently have a PCR. Generally follow electronics PCR
- **Pharmaceuticals**
 - Use the new PCR PAS 2090:2025

Life Cycle Assessment (LCA)

- **Going into 2027**
 - ‘Working on it’ will not be sufficient
 - You will need completed LCAs
- Key questions
 - Are you a company with over \$1B / year of revenue?
Or
 - Do you sell to companies with over \$1B / year in revenue?
Or
 - Do you plan to sell to companies with over \$1B / year in revenue?
Or
 - Do you plan to sell to governments or large institutions?
- **Then you better have LCAs and GHG numbers in 2027**

LCAs

- For 2027
- Plan
 - To complete an LCA for one product by start of year
 - Complete. Not work on.
 - This initial LCA will give you the basis on what to do
 - LCA data is **different** than for other regulations
 - And you will be pushed for **primary data**
 - To complete LCAs for, at least, representative products
 - By mid year
 - And have a comprehensive approach by end of year
 - To prepare to shift gears midstream due to customer demand

Packaging Redesign

- Driving packaging re-design
 - **Packaging EPR reporting fees**
 - **Mandatory plastic packaging reduction in California**

Example Fees Difference California

- **2027 fees**
 - Cardboard with
 - /wo plastic adhesive, or plastic stickers or tape
 - \$0.02 per lb
 - /w plastic adhesive, or plastic stickers or tape
 - \$0.23 per lb



- Which will appear in **more and more jurisdictions**

California EPR Fees

- **EPR Fees (Generalized)**
 - Averages ~\$0.50 to \$2.00 for an average air conditioner
 - Depends heavily on amount and type of packaging
 - Which for ~\$50M of sales in California
 - ~\$150,000 per annum (if cardboard as **no** plastic)
 - ~\$400,000 per annum (if cardboard has plastic)
- **Will trigger**
 - Budget attention
 - Packaging re-design
 - Not even including plastic reduction plan
 - And will also be needed for **EU PPWR changes in 2028**

Medical Devices and CMRs

- **Section 10.4 of EU Medical Device Regulation**
 - Carcinogens, mutagens, and reproductive toxins (CMRs)
 - In the invasive, fluid, or gas path
 - Over 0.1% w/w

- **Are required to be**
 - Identified
 - Labelled
 - Justified

Also includes Endocrine Disruptors (Health)

But pretty overlapping with repr. toxins

Due date for most Class II Devices

10.4.1

Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.

Devices, or those parts thereof or those materials

- are invasive and come into direct contact
- (re)administer medicines, body liquids or
- transport or store such medicines, body fluids or

Dec 31 2028

shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:

- (a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽¹⁾, or
- (b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽²⁾ or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council ⁽³⁾, in accordance with the criteria that are relevant to human health amongst the criteria established therein.

10.4.2. Justification regarding the presence of CMR and/or endocrine-disrupting substances

The justification for the presence of such substances shall be based upon:

- (a) an analysis and estimation of potential patient or user exposure to the substance;
- (b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives;
- (c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and
- (d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4.

ATP Updates to CMR

- **ATP 23**
 - [Published](#) June 6 2025
 - In effect - February 2027
 - Twenty-two (22) new classifications
 - Eleven (11) are new Cat 1 CMRs
 - **Two (2) are high risk in medical devices**



Official Journal
of the European Union

EN
L series

2025/1222

20.6.2025

COMMISSION DELEGATED REGULATION (EU) 2025/1222

of 2 April 2025

amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council as regards the harmonised classification and labelling of certain substances

(Text with EEA relevance)

Required for EU Medical Device Compliance

Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ⁽¹⁾, and in particular Article 37(5) thereof,

ATP Updates to CMR

ATP 24

- **ATP 24**
 - Expected to be published ~Nov 2026
 - *WTO [Notification](#) occurred in Dec 2025*
 - In effect - ~June 2028
 - Thirty-Four (34) new classifications
 - Thirty (30) are new Cat 1 CMRs
 - **Eight (8) are high risk in medical devices**



Brussels, **XXX**
[...](2025) **XXX** draft
ANNEX

Required for EU Medical Device Compliance

COMMISSION DELEGATED REGULATION (EU) .../... of XXX

amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council
as regards the harmonised classification and labelling of certain substances

Claigan Risk Assessment

- Everyone who has monthly/quarterly updates with Claigan
 - Receives risk assessment for new regulated substances
 - Such as

Plus

EU POP

EU REACH

Prop 65



ATP 23

Claigan Environmental Inc.
10 Brewer Hunt Way, Suite 200
Kanata, ON, Canada, K2K 2B5

EU MDR - 23rd Adaptation to Technical Progress

Risk assessment of potential presence in EU medical devices for new substances identified as category 1 carcinogens, mutagens, or reproductive toxins (CMR) under the **23rd Adaptation to Technical Progress**¹ and have been classified under REACH as Endocrine Disrupting Chemicals (EDC)² since the previous ATP update.

ATP 23 - Added

Substance	Risk	Justification	Materials of Risk
2-ethylhexanoic acid, monoester with propane-1,2-diol	Low	Used in coating products and inks and toners. Lubricant additive. Used in plastics, coatings and adhesives to improve flexibility and durability. Not expected to be present in significant concentrations in finished articles.	N/A
α,α'-propylenedinitriliolodiol	Low	Used in fuels and lubricants and greases. Added to adhesives, paints and coatings to prevent microbial degradation. Used as an antimicrobial agent.	N/A
dinitrogen oxide	Low	Used as an anesthetic and analgesic in medical industry and propellant in the food industry. Not expected to be present in consumer electronics.	N/A
barium chromate	Low	Used in corrosion-resistant pigment in paints, primers, and coatings. Increases durability and enhances colour in glass/ceramics. Can be used as a component in some battery cathodes. Used in pyrotechnics and explosives. Not expected to be present in consumer electronics above 0.1% w/w.	N/A



ATP 24

Claigan Environmental Inc.
10 Brewer Hunt Way, Suite 200
Kanata, ON, Canada, K2K 2B5

24th Adaptation to Technical Progress

*This is a **Risk Assessment** of the substances planned to be released as ATP 24. These substances have been notified to the WTO, but have not yet been released in the Official Journal of the EU.*

Risk assessment of potential presence in medical devices for new substances identified as category 1 carcinogens, mutagens, or reproductive toxins (CMR) under the expected **24th Adaptation to Technical Progress**¹.

ATP 24 - Substances added

Substance	Risk	Justification	Materials of Risk
lithium carbonate [1]; lithium chloride [2]; lithium hydroxide [3]	Low	[1] Used primarily in pharmaceuticals. Also used as an accelerator in fast setting cement/concrete adhesives and precursor for cathode materials in lithium ion batteries. [2] Used in desiccant wheels and systems, brazing fluxes and pyrotechnics. No current application in invasive medical devices. [3] Used in lubricating greases and heat transfer liquids. Substances are not expected to be present above 1000ppm in any invasive/fluid or gas path contacting medical products.	N/A
sodium metaborate, anhydrous [1]; boric acid (HBO ₂), sodium salt, tetrahydrate [2] and any other hydrated form (>3,000 ppm)	Low	Variety of uses including preservative/fungicide in treated wood, flame retardant in cellulose based insulation, used in starch-based adhesives in paper and corrugated boards. Not expected to be present in any patient contacting articles.	N/A

Budgeting Summary

EU MDR

- For 2027
 - A big year for EU MDR
- Plan
 - Be up to date to ATP 23 for submission
 - Complete ATP 24 compliance during 2026
 - Principal strategy
 - Risk assessment of new chemicals
 - Focus on specific risks
 - Don't trust historical materials gathering
 - Substances may not have been declarable even on SDS
 - Be **sure**. High cost of non-compliance for medical devices

Other items in 2027

- Regulations that may cause stress but are simpler
 - Changes in **RoHS exemptions**
 - **MCCP restriction** under EU POP
 - **PFOA restriction** in Canada
- More complicated requirements for which work should begin in 2027
 - Packaging labelling for EU PPWR
 - Especially for **consumer products**

Figure ES 1. Final label proposal (colour and text)



And the Usual Stuff

- Re-occurring
 - Same old, same old.
- Annual work for 2027
 - Update PFAS submission in Minnesota
 - EPR reporting (packaging and electronics)
 - New REACH SVHC in July 2027 (BPA-F)
 - Canadian Plastics reporting (consumer)
 - Conflict minerals reporting

And the Unexpected

- Expect some surprises in 2027
- Typical surprises
 - **New customer demands**
 - New regulation
 - Changes in EPR reporting
- Recommendation
 - Set aside **money / effort** equivalent to
 - Section 71 reporting, and
 - Packaging EPR reporting

How to Keep Up to Speed

- Best option
 - Claigan quarterly (or monthly) updates
 - Only about \$3,000 per annum for quarterly
- Web meeting with an expert who knows your products
 - Explaining all the new changes
 - How they do or do not apply to your products
 - Providing references and links
 - Risk assessment of all new substance updates



Quarterly Update
ACME

Presented by:
Bruce Calder
VP Consulting
September 18, 2026



EU Synthetic Polymer Microparticles

- What is a **Synthetic Polymer Microparticles (SPM)**
 - Which I am going to call 'microplastic'
- **Main criteria**
 - Solid at room temperature
 - Particles (not embedded in a solid)
 - Dimensions
 - Standard particles <= 5mm
 - Fibres
 - Length to diameter ratio > 3
 - Length <= 15mm

SB 582 Oregon - Exemptions

- **Exempted from Oregon EPR**
 - Specialty packaging items that are used exclusively in industrial or manufacturing processes, including but not limited to:
 - (i) Trays, whether designed for a single use or multiple uses, used for the transport of component parts from a parts supplier to a manufacturer that assembles those parts.
 - Rigid pallets used as the structural foundation for transporting goods lifted by a forklift, pallet jack or similar device.
 - Hazardous material packaging not for recycling
- **Still in scope**
 - Cardboard boxes, non-ESD poly bags, and similar



REACH Annex XVII Restriction on 2,4-dinitrotoluene in articles

Risk assessment of potential presence in physical products (articles) with regards to the Commission Regulation (EU) 2026/659 of 26 April 2026 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards 2,4-dinitrotoluene in articles.

Substance	Risk Level	Use/Restriction	Minerals of Risk
2,4-dinitrotoluene	Low	Principal use is in the manufacture of dinitrophenol. Dinitrophenol is used in the manufacture of polycarbonate and can be released from the article. However, concentrations of 2,4-dinitrotoluene in the dinitrophenol in the final article would be of order of magnitude below 0.1% in the final article.	Low risk in articles. Some rare not articles use such as automobiles.

Reminders

- Big things in 2027
 - **New Prop 65 warnings**
 - **Section 71 Surveys (Canada)**
 - **Life Cycle Assessments (LCA)**
 - **EU MDR CMR and Allergen compliance**
 - **Packaging re-design for EPR fees**
- Plus
 - All the annual reoccurring requirements
 - And the **unexpected**

We are here to help

Life Cycle Assessment / Green House Gas



LIFE CYCLE ASSESSMENT (LCA) SERVICES

Measuring Your Product's True Environmental Footprint
As the demand for transparent, quantifiable environmental data surges, understanding the precise carbon footprint of your products is no longer optional. Claigan's comprehensive Life Cycle Assessment (LCA) services break down the complexities of measuring emissions so you can make informed, sustainable design decisions and maintain global compliance.

WHAT IS A LIFE CYCLE ASSESSMENT?

An LCA is a quantitative assessment of the environmental impact caused by an individual product across every stage of its life. Claigan's LCA methodology strictly follows internationally recognized standards ISO 14040 and ISO 14044 to ensure consistency, transparency, and scientific credibility.

We examine every critical stage, including:

- Raw material extraction and refinement.
- Complex product manufacturing.
- Distribution and transportation networks.
- Product use, maintenance, and end-of-life disposal.

UNDERSTANDING THE CO2 EMISSIONS ASSOCIATED WITH YOUR PRODUCT GIVES YOU A MEASURABLE VIEW OF ITS ENVIRONMENTAL IMPACT.

UNDERSTANDING YOUR GHG EMISSIONS PROFILE

To effectively measure environmental impact, companies must categorize their Greenhouse Gas (GHG) footprint into specific scopes. **Scope 1:** direct emissions generated by the company, (i.e. combustion by company-owned vehicles or escaped refrigerants).

Scope 2: indirect emissions stemming from energy purchased by the company.

Scope 3: indirect emissions across a company's full value chain, covering the full lifecycle of your products and contributing factors like employee travel.

CLAIGAN'S EXPERT LCA METHODOLOGY

Utilizing our experience as an ISO 17025 accredited laboratory, Claigan's LCA services combine advanced material testing with researched CO2 equivalent values. We physically break down products into individual components and apply scientifically supported emissions data to deliver actionable, product-specific insights.



WHY ARE SHAREHOLDERS DEMANDING LCAs?

Investors are increasingly prioritizing sustainability and long-term risk management in their financial decisions. By requesting an LCA, shareholders are looking to verify your company's proactive environmental risk management.

An LCA delivers immediate business value through:

→ **Cost Reduction:** identifying areas of high energy consumption across product lifecycle.

→ **Regulatory Compliance:** preparing for emerging regulatory disclosure requirements, California's SB 253 requires scope 3 GHG reporting in November 2027.

→ **ESG Verification:** demonstrating competitiveness and alignment with sustainability commitments.

GET IN TOUCH



CEPA Section 71 Surveys

Q&A



Required survey under CEPA Section 71

Chemicals Management Plan - Phase 1
Section 71 Survey submissions are required in Canada under the Canadian Environmental Protection Act (CEPA). These surveys require you to evaluate and report on hundreds of chemicals in your products.

Claigan streamlines the entire process by combining a high-level risk assessment for all 184 chemicals with a focused approach to testing and gathering data on the chemicals that could be reportable in your products.

Claigan provides a comprehensive, three-step service to help you meet these deadlines.

What you need to know

- Phase 1 of mandatory chemical reporting under Canada CEPA updates is underway.
- Claigan has a streamlined approach to Section 71 compliance.
- Claigan has helped hundreds of companies in previous Section 71 submissions.

Claigan's three-step solution to Section 71
The Section 71 Survey is complicated and intensive. Claigan simplifies this task through our expertise and comprehensive chemical risk assessment experience.

1. Risk assessment of every chemical against your products and components.
2. Identification of substances that could be present at a detectable level.
3. Develop a plan for high risk substances.

CLAIGAN MAKES COMPLICATED CHEMICAL REPORTING SIMPLE



Claigan's advantage

Claigan can drill down reporting specifics for identified high risk substances with data gathering, engineering evaluation, and laboratory testing all in one place.

- Quantification of substances.
- Summaries of concentrations or disclosures.
- Support submissions.



CLAIGAN PROP 65 SERVICES

FOR THE 2028 PROP 65 UPDATES

With over 400 enforcement notices per month, California Proposition 65 (Prop 65) is the most heavily enforced product regulation in the world. And it is changing at the start of 2028.

Starting in 2028, generic warnings will no longer be allowed. Even short form warnings will require the declaration of at least one applicable carcinogen and one applicable reproductive toxin.

Key Changes Coming in 2028

WHAT'S CHANGING?

- No more generic warnings.
- A substance has to be identified.
- New labelling text options.

PREPARATION FOR PROP 65 IS THE KEY TO COMPLIANCE

Are you ready to identify a carcinogen or reproductive toxin to your customers? You likely do not have to. If you test your product properly, you will have an iron clad answer without declaring that your product causes cancer or reproductive harm.

- There are good effective methods to identify Prop 65 substances.
- Exposure testing is streamlined now- not a PhD adventure.
- A test report is your defense against the Prop 65 'bounty hunters.'

Claigan is the best in the business at Prop 65 compliance.



THE CLAIGAN EXPERIENCE

California requires companies to provide warnings for overexposure to Prop 65 listed chemicals. Claigan's services have you covered with Prop 65 testing and reporting.

- 15+ Years of Prop 65 experience.
- We've tested thousands of products for Prop 65 compliance.
- Solutions for every situation.

KEY TAKEAWAYS

Prepare for the 2028 Prop 65 updates with Claigan.

- In 2028 you will not be able to use generic warnings. Test reports are the only defense to Prop 65 notices.
- With more than 15 years of Prop 65 experience, Claigan provides trusted Prop 65 compliance testing and reporting services.

Claigan is the best in the world at Prop 65 compliance. Talk with one of our experts today.

US / Can Packaging Reporting



US Packaging EPR Data Generation

Are you compliant with California and Oregon's passed deadlines?

The deadline for submitting packaging EPR data for California (SB 54) and Oregon (SB 582) was May 31, 2026. Most companies have a 90-day grace period, making the last acceptable day to report August 31, 2026. Non-compliance carries severe consequences, daily penalties up to \$50,000, inclusion on Oregon's public shame list, and a California distributor ban. And yes, B2B operations are fully in scope!

To help you meet these deadlines, Claigan provides a comprehensive, turnkey service delivered in three distinct phases:

PHASE 1: SCOPE ANALYSIS AND PACKAGING DATA GENERATION

- Identify the scope of each regulation for your products and distributor model.
- Generate the "fundamental" data required for California and Oregon.
- Derive data from bills of materials or representative products.

PHASE 2: DATA STRUCTURING & COMPONENT ANALYSIS

Manage diverse data situations under tight deadlines, even when handling partial or missing data.

1. Distinguish between 'detachable' and 'associated' packaging.
2. Handle 'pass through' items that are included with your packaging.
3. Roll up the data for California and Oregon.

Whatever your situation, Claigan has a plan. Just reach out. We are here to help.

Info@claigan.com | claigan.com



PHASE 3: STRATEGIC PLANS & COST REDUCTION

Develop actionable strategies to meet state-specific targets and minimize the financial impact of environmental fees.

- Formulate an individual Source Reduction (SR) plan for California.
- Utilize the option for LCAs to reduce EPR fees.

KEY TAKEAWAYS

- Address the immediate 2026 compliance deadlines.
- Generate fundamental packaging EPR data.
- Roll up the data for California and Oregon.
- Develop individual Source Reduction (SR) plans and LCAs.

As the leading provider in plastics and packaging reporting, Claigan helps turn complex regulations into a straightforward, manageable process.