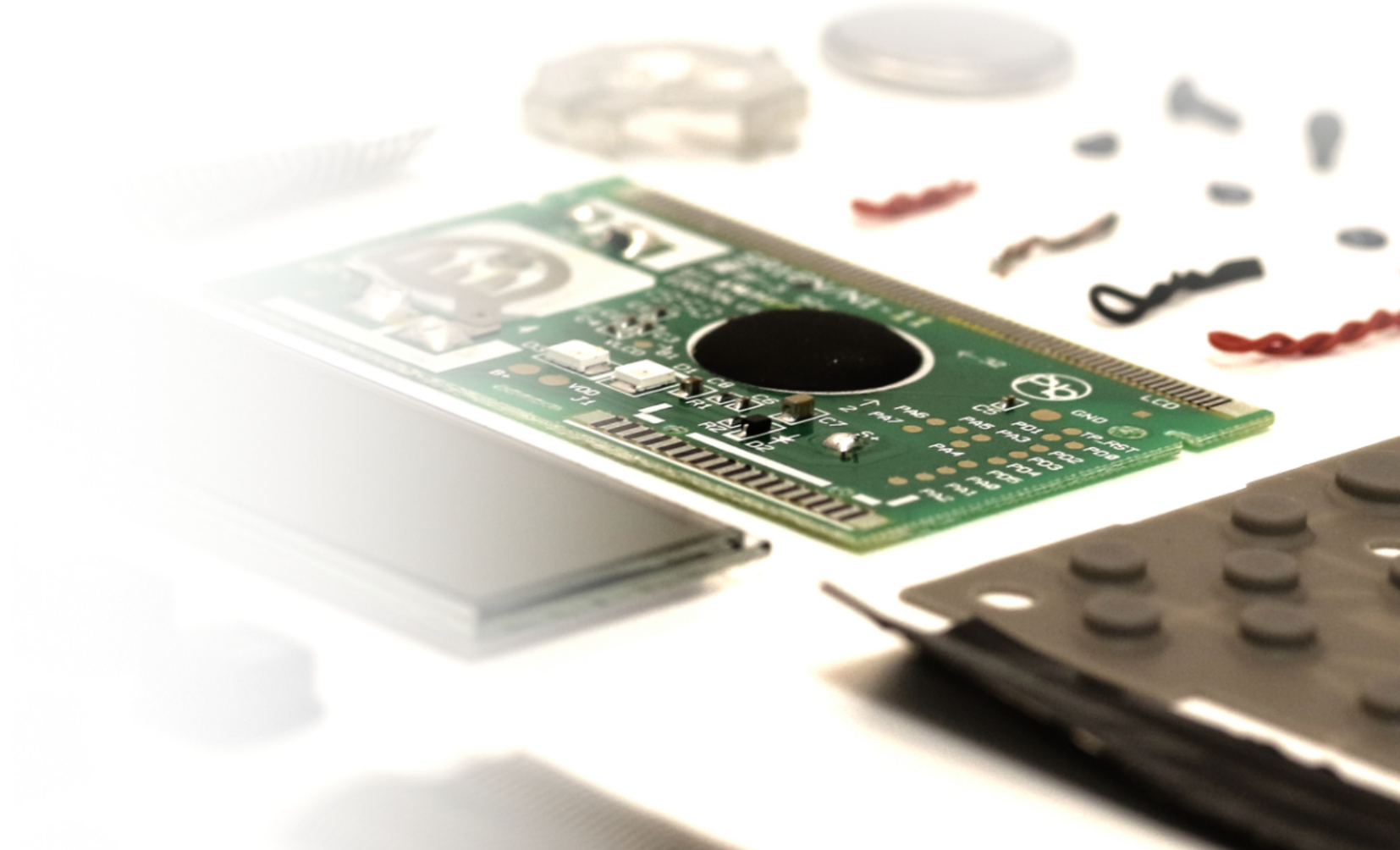
Claigan
Less Journey. More Results.

Keeping Up with the Regulations

How to do it

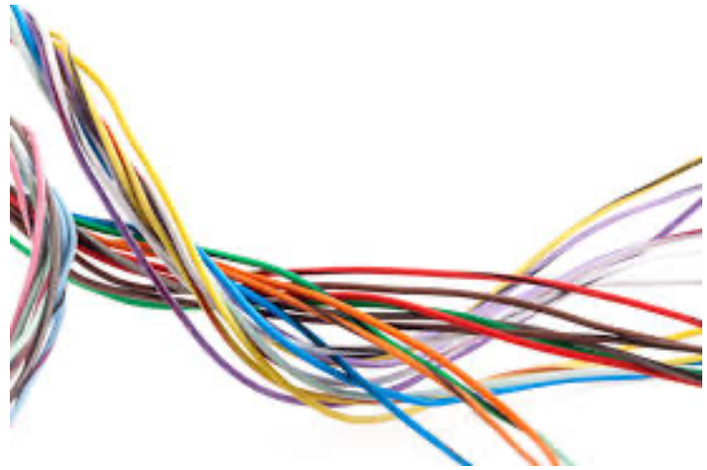
Presented by:
Bruce Calder
VP Consulting

December 6, 2023



Overview - Agenda
Keeping up to Speed

- Upcoming deadlines
- Growth of restricted material regulations
- Regulation changes
  - New regulations
  - Updates to regulations
  - Updates to restricted substance lists
  - Changes in enforcement
- Keeping up to speed
  - Including today, ongoing, and implementation
- Q&A



Restricted Materials
Constant Deadlines

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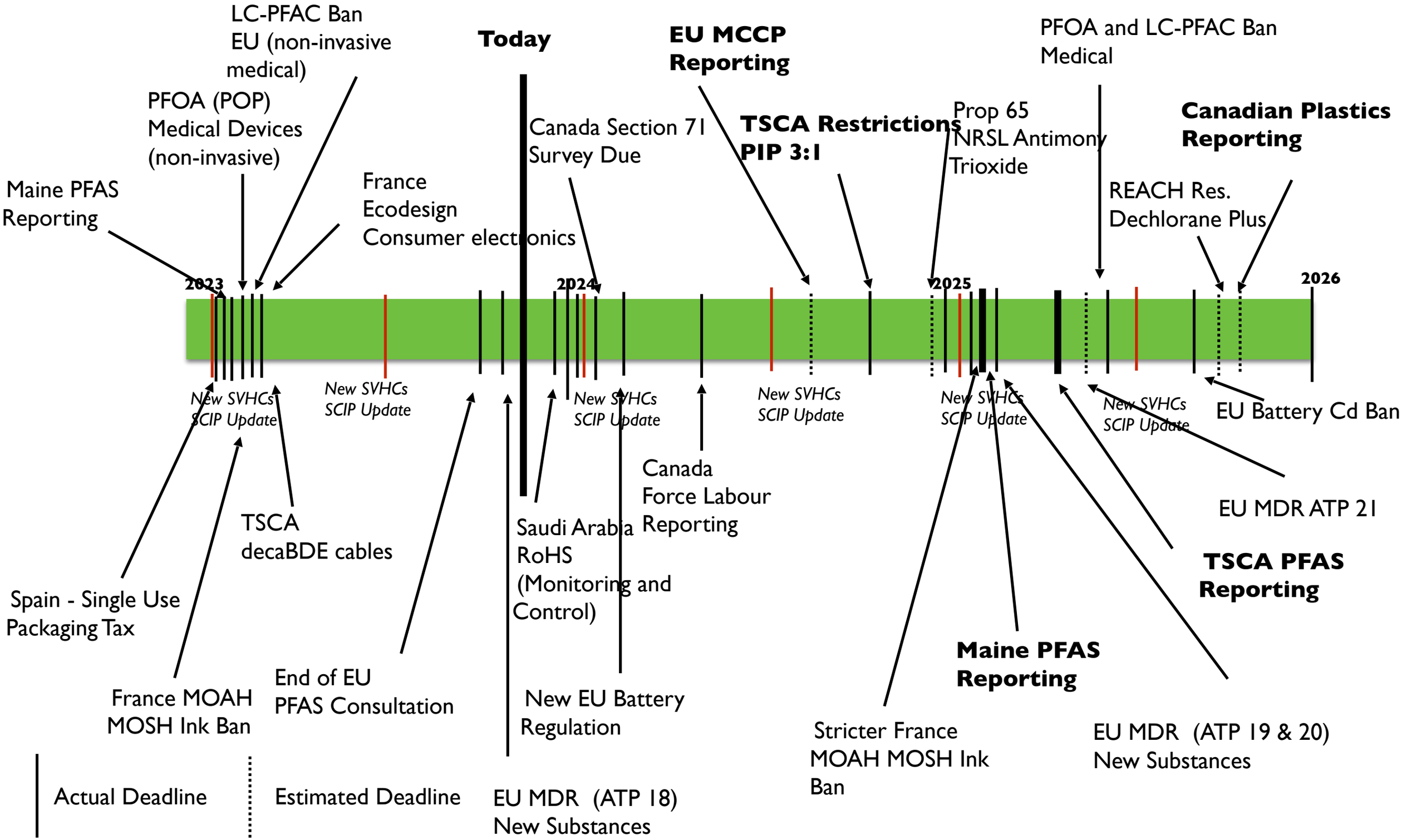


Restricted Materials Regulations

- Restricted materials regulations growing **faster** than any other product regulations

The Fundamental Rule of Restricted Materials Compliance

- The requirements you are most likely not compliant with are the ones that you did not know about.

So how do you stay in the ‘know’?

Restricted Materials Changes
New Regulations

- New regulations appear

- Examples
  - US State Level PFAS Reporting
  - EU Battery Regulation
  - Canada Plastics Reporting

New Regulation
Canadian Plastic Reporting

- **Canada is planning a registry for reporting of all plastics in electronics and packaging.**

- Scope
  - Packaging
  - Electronic and electrical equipment
  - Agriculture products
  - White goods
  - Textiles
  - Automotive
  - Construction

Canadian Plastics Registry
Producer

- **Applies to**
  - A person who is a producer of a plastic product

- Producer
  - Brand owner who resides in Canada, or
  - The first resident person to manufacture or import a plastic product into Canada

- Plastic products include (amongst others)
  - Packaging
  - Single use plastics
  - EEE (electronic and electrical equipment)
    - 11 - medical devices, excluding implanted or infected devices

Canadian Plastic Reporting Update draft timeline

- **Packaging and electronics**

- By September 29, 2025
  - Reporting for 2024 calendar year
    - Identity of resins used to make plastic products
    - Source of resin (virgin, recycled) used to make plastic products
    - Category/subcategory of plastic products (single vs re-usable)
    - Total quantity (tonnes) placed on the Canadian market

- In following years
  - Information on % collected at end of life, diverted to recycling, re-processed, incinerated, composted, etc…

Canadian Plastic Reporting Example

- **Example reporting**
  - ABS resins (28111410)
    - 5 tonnes
    - Virgin fossil-based conventional resin
    - Category - EEE (11) Medical Devices
  - PVC resins (28111420)
    - 1 tonne
    - Virgin fossil-based conventional resins
    - Category - EEE (11) Medical Devices

Restricted Materials Changes
Change in Regulation Scope

- Scope of a regulation changes

- Examples
  - Changes - California Prop 65 Warnings
  - Changes - REACH and POP Derogations

California Proposition 65

- **Short Form Warnings**

- New consultation for addition of a substance to short form warnings
  - Based on the text available at the end of the previous expired consultation
  - Consultation ends December 20 2023

New California Proposition 65 Short Summary

- Today
  - Short form warnings do not require a substance to be identified

- New
  - Short form warning will require a substance to be identified
    - One (1) reproductive toxin and one (1) carcinogen
      - Or just one (1) substance if it is both a reproductive toxin and a carcinogen
      - Example - Pb

New California Proposition 65 Example

- **Short Form Warnings**

(C) For exposures to both listed carcinogens and reproductive toxicants, the words:

1. "Risk of cancer from exposure to [name of chemical] and reproductive harm from exposure to [name of chemical]. See www.P65Warnings.ca.gov."; or

2. "Can expose you to [name of chemical], a carcinogen, and [name of chemical], a reproductive toxicant. See www.P65Warnings.ca.gov."

New California Proposition 65 Deadlines

- Deadlines
  - Consultation End - Dec 20, 2023
  - Expected publication ~ Mar 2024
  - In effect - two (2) years later (~ Mar 2026)

- In effect
  - Two (2) years from the date of publication
  - Based on the date of manufacturing of the specific item

Restricted Materials Changes
Additions to Substances Lists

- Additions to restricted substance lists

- Examples
  - Additions - June and December REACH SVHC updates
  - Additions - REACH Formaldehyde restriction
  - Additions - REACH Microplastics restriction
  - Additions - POP PFHxS restriction
  - Additions - PFOA and Dechlorane Plus Canadian Prohibition
  - Additions - California Prop 65 substance updates

EU REACH Restrictions Microplastics

- **Published**
  - Restriction of micro plastics in mixtures (not articles)
    - 0.01%

- **Details (Restrictions - consumer only)**
  - Microbead abrasives (rinse-off products) - Oct 17, 2023
  - Rinse off products (non-industrial or abrasive) - Oct 17, 2027
  - Detergents - Oct 17, 2028
  - Fertilizers - Oct 17, 2028
  - Fragrances - Oct 17, 2029
  - Medical devices Oct 17, 2029
  - Leave on products - Oct 17, 2029
  - Plant Protection Products - Oct 17, 2031
  - Sports Fields - Oct 17, 2031
  - Make-up (including lip and nail products) - Oct 17, 2035

EU REACH Restrictions Microplastics

- **Requirements**
  - Mixtures
    - Consumer - restrictions
      - Starting in 2023
    - Industrial / Professional - labelling and reporting
      - Starting in 2025

Restricted Materials Changes
Change in Enforcement

- Change in enforcement

- Examples
  - US FDA Direct mass spec testing
  - Prop 65 PFOA prosecutions

Example Enforcement Change
FDA Direct MS

- **Testing by Direct Mass Spec. (DART-MS)**

- At import direct testing for
  - Phthalates
  - Flame retardants
  - Amines

The use of DART-HRMS for the rapid identification chemical substances in food contact materials

R. Paseiro-Cerrato[1], L.K. Ackerman[1], K.Bentayeb[2], Y. Abe[3], L. DeJager[1], T. H. Begley[1].
1- US FDA, CFSAN, 5001 Campus Drive, College Park, MD, 20740, USA. 2- Rolabo Ltd, Department of R&D, Zaragoza, 50016, Spain.
3- National Institute of Health Sciences, Kawasaki, Kanagawa, Japan

Abstract

Background
In 2005, Cody et al. introduced a new ionization source: Direct analysis in real time (DART), which when coupled to a high-resolution mass spectrometer (HRMS), can be used as ambient mass spectrometric sample introduction technique. The main advantage of this technique is that can identify chemical substances in different types of matrices and obtain reliable results in minutes without any sample preparation.
Purpose
The Division of Analytical Chemistry (DAC) at the Center for Food Safety and Applied Nutrition (CFSAN) has been using DART-HRMS for the rapid identification of potential migrants in food contact materials (FCMs) for over 10 years[1-10]. Monomers and additives used in the manufacture of FCMs as well contaminants, have been successfully identified in almost any type of analyzed matrix (e.g. plastics, food simulants, and foods). Thus, the purpose of this poster is to summarize the obtained identification results to date and the implications for future research in the food safety field.
Methodology
DART-HRMS is a DART ion source and a HRMS. The DART flows excited helium ~300-500 °C) to liberate and ionize chemicals from samples. The HRMS spectra (positive and negative mode) were typically collected from 85 to 1200 Da, although MS/MS was occasionally used as well. Samples (food packaging, food contact articles, food, and food simulating liquids) are placed in between the DART source and the HRMS for approx. 5 seconds using previously cleaned tweezers or glass capillary tips.
Results
Several potential migrants such as starting substances used in the FCM as well as non- intentionally added substances (e.g. brominated flame

Results and Discussion

Analysis of primary aromatic amines (PAA) analysis in kitchen utensils[4].
During the first decade of the century, several publications related with the presence of PAA in cooking utensils were published. Since those initial studies, several alerts related with PAAs in food contact materials were reported in the Rapid Alert System for Food and Feed (RASFF) in the European Union (EU). The main disadvantage in the determination of PAA is that methods can be time consuming and therefore, the development of rapid screening methods for the rapid analysis of PAAs was required.
We developed a DART-HRMS method for the analysis of PAAs in kitchen utensils. For the sample introduction, small pieces of the samples (triplicate) were cut and analyzed directly by DART. To validate the study, we compared the DART results with results obtained using a more traditional analytical technique (UPLC- MS/MS). By using DART, we were able to identify PAAs directly in the materials in just few minutes (figure 1). By using threshold of zero during the data analysis, DART was able to identify 100% of non-compliant samples. However, the number of false positives was excessive. A way to correct this high positive rate, was by increasing the threshold. By using a threshold of 1 during the data analysis, DART identified 88 % of the samples considered violative samples in the EU and significantly decreased the false positive rate. However, by increasing the threshold, false negatives were also increased. This study showed that adjusting the response threshold or further evaluate DART methods is required to use DART-MS an effective tool in PAA determination.

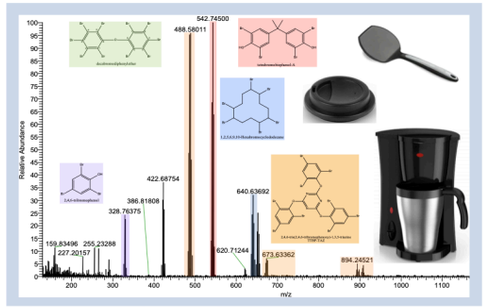


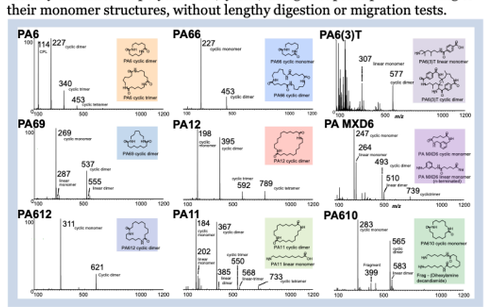
FIGURE 2 DART-MS spectra of Brominated Flame Retardants found in FCAs[5,6].

DART-HRMS detection and identification of printing ink set-off in food packaging.[7,8,9]

Since the UV ink photoinitiator (PI) isopropylthioxanthone (ITX) was discovered in packaged milk, studies of packaging have included print contamination for consideration. Set-off is the unintentional transfer of substances used in printing from the external printed surface of food packaging to the inner, food-contact surface of adjacent packages (stacked or rolled) prior to filling. It is considered an issue of good manufacturing

The use of DART-HRMS for the rapid identification of polyamides (nylon) polymers[10].

Dozens of different polymers of different chemistries are authorized for use under certain conditions. As a result regulations authorizing the use of a particular polymer, (eg nylon 6) may require limited migration of additives and monomers (ie caprolactam, CPL). In the case of nylons, many different nylons are used commercially but only nylon-6 uses CPL as a monomer. However nylons are virtually indistinguishable by conventional polymer id (FTIR). In this work we used DART-HRMS(/MS) to directly and rapidly identify the different polyamides (nylons) using first principles according to their monomer structures, without lengthy digestion or migration tests.



Restricted Materials Changes
Change in Enforcement - Impact

- Impact of direct mass spec. testing

- Impact
  - Testing at import
  - Holding of shipments
  - Order to return or correct products

- Changes rapidly a company's approach to compliance

Next Steps

- How do you keep up with all of this?
- And understand it?
- And communicate it to other stakeholders?

What we do - here at Claigan

Global Matrix

Country	Legislation	Products	Summary of Requirements	Date	Directly / Indirectly Affecting	Group Assignment	Risk Level (Based on enforcement level)	Legislative Impact (Based on potential business impact level)
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Ecuador	Ecuadorian Technical Regulation (RTE) INEN 105 "electric batteries"	Batteries (but not button cell)	Restriction on Hg, Cd Labelling Test report	2015	Not applicable	NA	NA	NA
European Union	RoHS Recast	All electrical or electronic finished products (with some exclusions and delayed implementation) Restrictions apply to accessories intended to remain with the electronic device for its lifetime	Restriction on Pb, Cd, Hg, CrVI+, PBB, PBDE Future restriction on DEHP, DBP, BBP, DIBP CE marking Declaration of conformity Technical file	2013 (categories of EEE covered by 2002/95/EC) 2014 (medical devices) 2019 (addition of phthalates for EEE covered by 2002/95/EC)	Direct	Group 1	High Risk	High Impact

Quarterly Updates

Claigan
Less Journey. More Results.

Monthly Update

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December 5, 2023

Overview - Agenda

- Upcoming deadlines
- US TSCA PFAS Reporting
  - Requirements
- Examples PFOA non-compliance
- EU Battery regulation
  - Material restrictions
- New Prop 65 Warnings (Consultation)
- Canadian plastics reporting
  - Details
  - Scope
  - Timelines

Education

Claigan

Summary - What is an Article?

- **Component requires an SDS**
  - Not an article
  - Examples
    - solder, glue, paint

  - REACH SVHC communication requirements do not apply until added to an article
- **Component does not require an SDS**
  - Article
  - Examples
    - resistor, screw, wire

  - REACH SVHC communication requirements apply

Annual Product Updates

Claigan Update of Legacy Products
2024 Program

Claigan

Substance Risk Assessments

Claigan

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

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Starting Point
Global Matrix

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Starting Point

- Reference document for all applicable regulations
  - The **TODAY**

- Global matrix
  - Sortable excel sheet

- Each applicable restricted material legislation
  - Country / Jurisdiction
  - Legislation
  - Summary
  - Scope
  - Deadlines
  - Impact
  - Links to legislation / guidance

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Keeping up to Speed
The Ongoing

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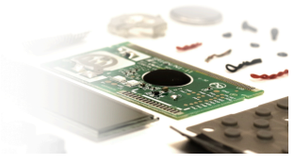

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Keeping up to Speed

- Quarterly update
  - The **ONGOING**

- Quarterly update
  - Quarterly (or monthly) web meeting
    - Expert explains
      - Changes
      - Applicability
    - Just one (1) hour to have all the changes explained
      - And can ask questions to an expert

Details and Chemistry Risk Assessment

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Quarterly Updates

Claigan
Less Journey. More Results.

Monthly Update

Presented by:
Bruce Calder
VP Consulting

December 5, 2023

Overview - Agenda

- Upcoming deadlines
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  - Requirements
- Examples PFOA non-compliance
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Claigan

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Claigan

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Annual Product Updates

Claigan Update of Legacy Products 2024 Program

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Substance Risk Assessments

Claigan

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

January 17, 2023 Addition of SVHCs

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Chemistry
Substance Risk Assessment

- Evaluation of risk / applicable of new substance
  - The **TECHNICAL**

- Detailed risk assessment
  - For each list update

- Assessment of each substance
  - Risk
  - Justification
  - Materials of risk
    - (Materials likely to contain new regulated substance)

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Turning Knowledge into a Plan
Annual Product Update

Claigan

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Claigan Update of Legacy Products 2024 Program

TSCA
PIP 3:1

TSCA
PFAS

REACH
Dechlorane Plus

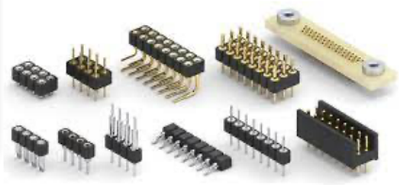
REACH / POP
PFOA+

2024

EU MDR
ATP 18,19,20

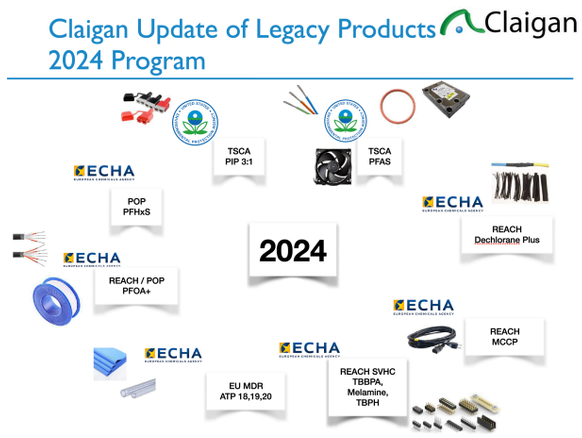
REACH SVHC
TBBPA,
Melamine,
TBPH

REACH
MCCP



Keeping Products Up to Date Annual Plan

- Annual update
  - The **COMPLIANCE**



- Annual update plan
  - Create a consolidated plan each year
- Focus on outputs
  - Meeting restrictions
  - Updating declarations
  - Updating revisions
  - Updating specifications

Details and Chemistry Risk Assessment

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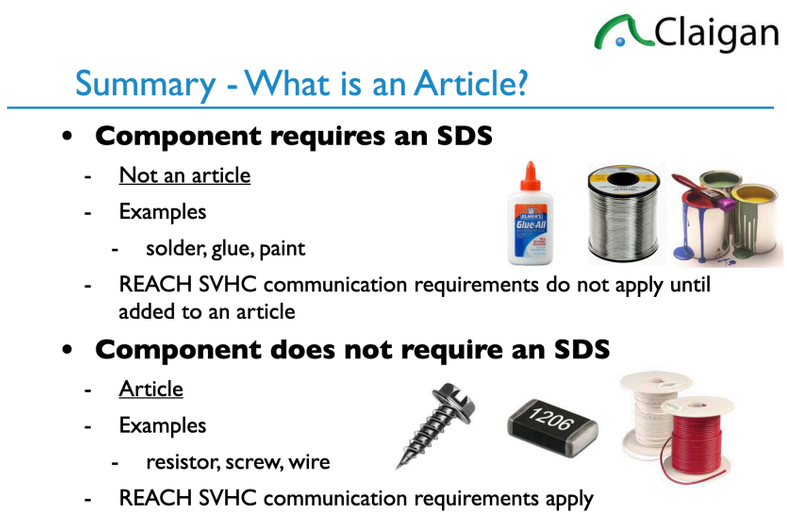
Stakeholder Knowledge Education

- Educating the stakeholders
  - The **EVERYONE ELSE**

- Education series
  - Updates
    - Quarterly updates
    - Lunch and learns
- Occasional
  - Education on base requirements
  - Claigan provides an educational series



Reminder
Restricted Materials Regulations

- Restricted materials regulations growing **faster** than any other product regulations

Q&A

What we do - here at Claigan

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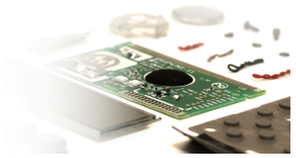

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