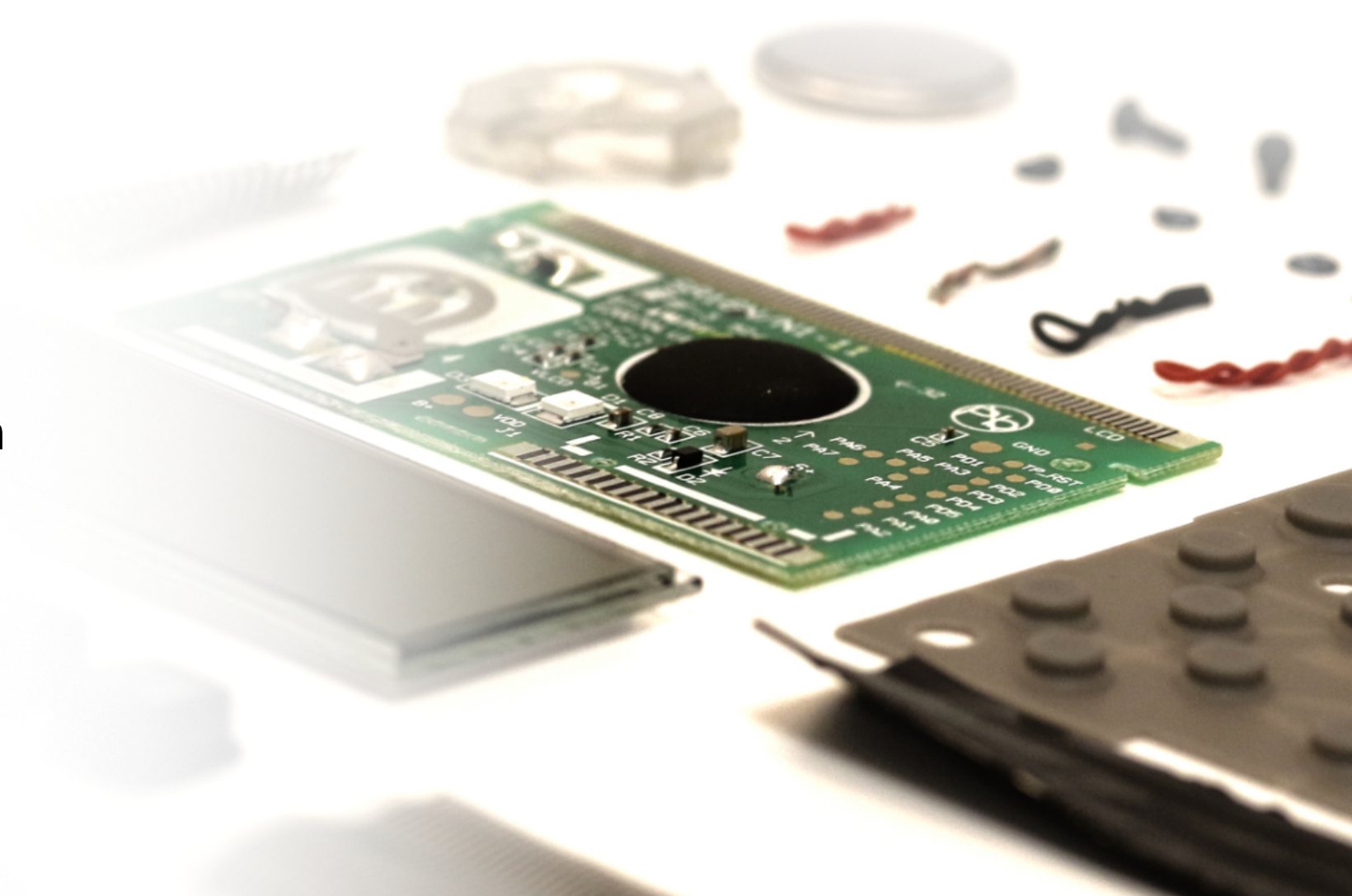


Claigan Webinar

Restricted Materials Services

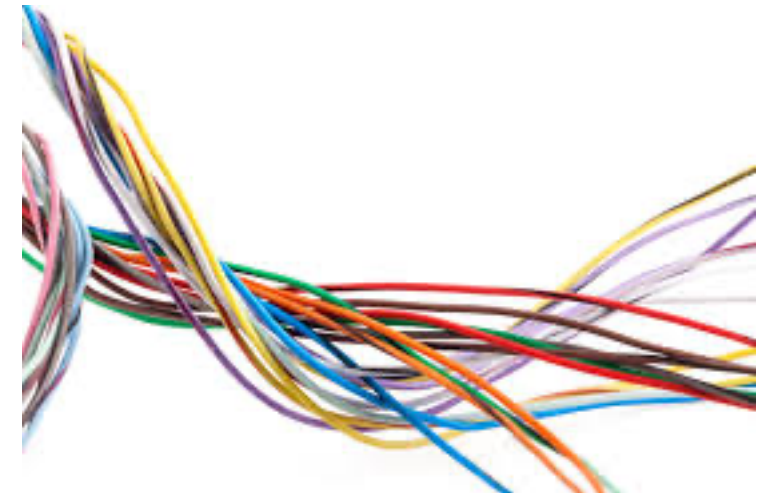
Presented by:
Bruce Calder
VP Consulting Services at Claigan

May 3, 2023



Overview - Agenda

- Regulation timeline update
- Services
 - Education
 - Consulting
 - Opinions
 - Testing
 - Material identification
 - Exposure calculation - Prop 65
 - Toxic risk assessment
 - EU MDR justification
 - Data gathering
 - Supplier specifications
 - Non-compliance and enforcement
 - Software
 - Conflict minerals
- Q&A

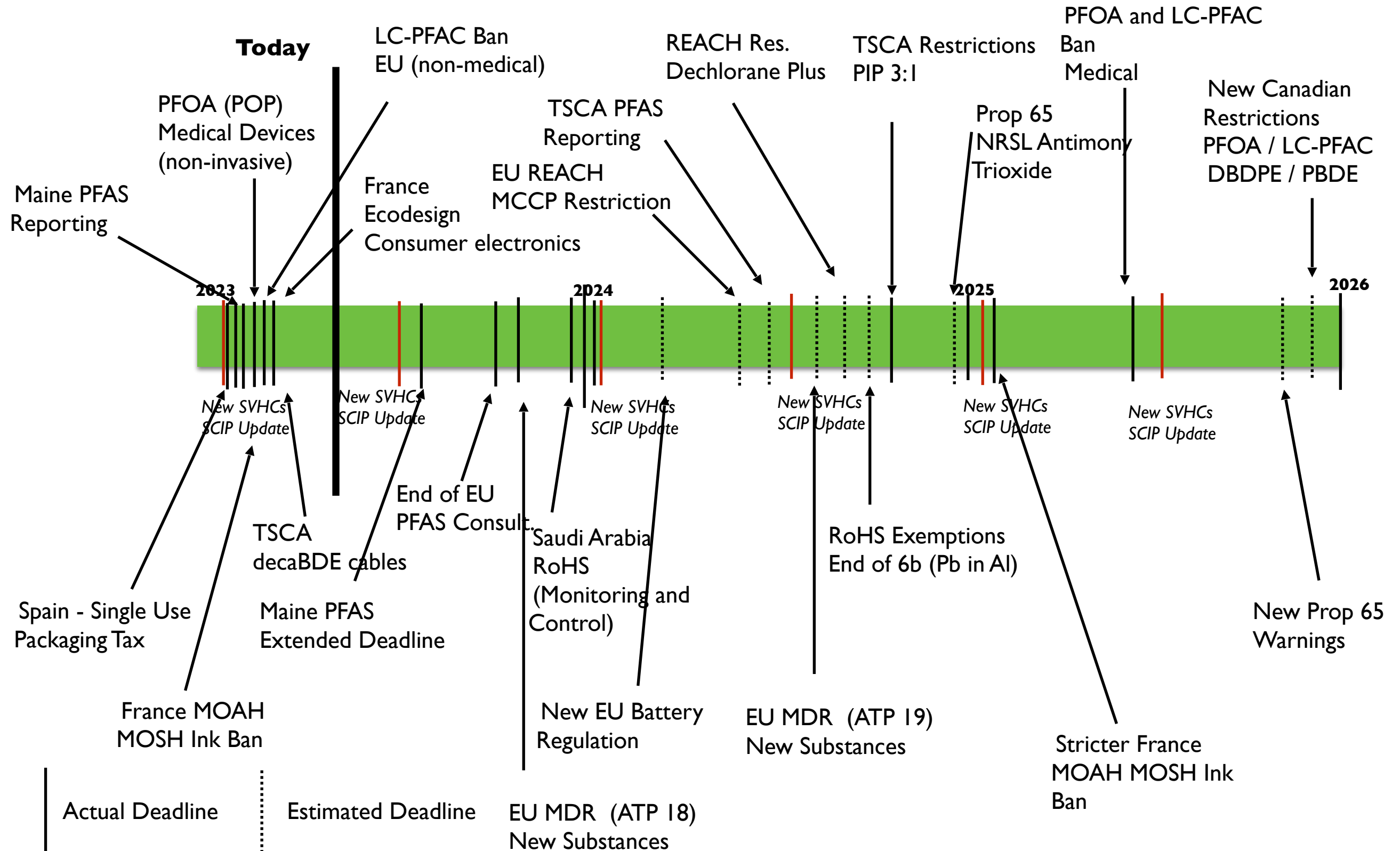


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Restricted Materials

Constant Deadlines



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Education - Claigan Approach

- **Restricted materials education**

- In person or web education

- **Recommended education**

- Combination of
 - Standard explanation of requirements and compliance options
 - Hands on review of a product against the requirements
- Interactive with lots of opportunity for questions and in-depth discussions



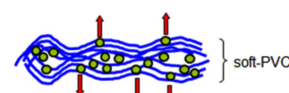
Outputs for RoHS - Finished Products

- Compliance outputs
 - Product compliant with materials restrictions at the homogenous level
 - Technical file including
 - supporting documentation
 - risk assessment
 - Declaration of conformity to
 - Decision 768/2008
 - CE mark
 - To the exact size, shape, and spacing required by EU



Where are phthalates used?

- Rigid plastics
 - example - PVC
- Phthalates create flexibility
 - by getting in between the vinyl chloride strand and forcing them apart
 - leading to weaker forces of attraction
 - creating fluidity (flexibility)



● = Plasticizer molecules like phthalates
 — = Polymer chains composed of polyvinyl chloride plastic



Principal Requirements Packaging of Professional Products



#3 Labelling

Consulting - Claigan Approach

- **Consulting - Restricted Materials**
 - Expert in field is on-call for any consulting questions
- **Typical uses**
 - Topics
 - Interpretations of regulations
 - Scope questions
 - Materials questions
 - Review of supplier statements
 - Labelling requirements
 - Declaration requirements



रजिस्ट्री सं. डी.एल.- 33004/99

REGD. No. D. L.-33004/99


भारत का राजपत्र
The Gazette of India

Global Requirements - Claigan Approach

- **Identification of global restricted materials requirements**
 - Providing a baseline of all applicable global restricted materials requirement
- **Matrix of requirements**
 - ‘Cheat sheet’ sortable spreadsheet of applicable requirements

- Jurisdiction
- Legislation
- Scope
- Applicability
- Enforcement risks
- Links to sources

Jurisdiction	Classification	Regulation	Substances	Scope	Labelling/Warr
Australia	Restrictions	Assurances that Products do not contain Asbestos	Asbestos	All products	No
Canada	Restrictions	Prohibition of Asbestos and Products Containing Asbestos Regulations: SOR/2012-285	Asbestos	All	No
Canada	WEEE (E-Waste)	Provincial E-Waste Legislation	N/A	Varies by Province	No
Canada	Restrictions	Prohibition of Certain Toxic Substances Regulations	27 Persistent and Bioaccumulative substances. Notably PFOA, PFOS, PBB, PBDE, DBDPE, SCCPs/SCCAs, Dechlorane Plus	Varies by substance. SCCPs/SCCAs currently in scope for products Regulation Update Proposal includes: PFOA,PFOS,PBB,PBDE,DBDPE, Dechlorane Plus, in scope for products likely 2028	No
Canada	Restrictions	Products Containing Mercury Regulations	Hg	All Products Specific exemptions listed in Schedule	For products containin "Contains mercury / Contie Safe handling proc Disposal instruc

Updates - Claigan Approach

- **Regulatory updates**

- How to keep up to date on the variety and complexity of restricted materials requirements



Monthly Update
ACME

Presented by:
Bruce Calder
VP Consulting and Chief Scientist

April 27, 2023



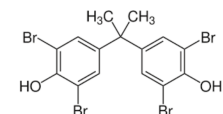
- **Quarterly (or Monthly) Updates**

- Quarterly web meeting with stakeholders to
 - Explain changes in restricted materials requirements
 - Scope
 - Deadlines
 - Applicability to company's products
 - Risk materials
- Includes risk assessments for new substances
- Full interactive with lots of Q&A

RoHS Update New Substances



- Two new (2) substances were under consideration for addition to [RoHS](#)
- MCCPs
 - Medium chain chlorinated paraffins
 - Withdrawn from addition to RoHS. Will be restricted under REACH
- TBBPA
 - [Tetrabromobisphenol A](#)
 - [Agreed](#) to become RoHS substance
 - To be published by end of 2023
 - Restriction ~2027?



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Kanata, ON, Canada, K2K 2B5

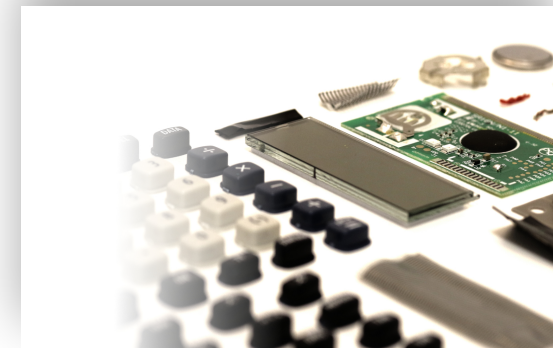
Final assessment on potential presence in physical products (articles) of the nine (9) REACH SVHC substance added to the EU Candidate List for Authorisation on January 17th, 2023 (233 substances).

Substance	Risk	Justification	Materials of Risk
Melamine	High	Melamine cyanurate used as halogen free flame retardant in thin walled plastics; PBT and nylon connectors. Residual unbounded melamine possible in melamine cyanurate electronic components >1,000 ppm.	PBT based plastic components, Laminates, Flame retarded nylon
Bis(2-ethylhexyl) tetrabromophthalate (TBPH)	High	Additive flame retardant, primary replacement for pentaBDE in polyurethane foam. Also used as flame retardant and plasticizer in	Flexible PVC (cables, power cords, wiring, etc.)

Testing - Claigan Approach

- **Restricted materials testing**

- Testing of products for compliance to restricted materials requirements



- **Testing**

- Screening
 - Screening uses XRF, FTIR, and swab chemistry to cheaply solve 98% of the compliance requirements
 - Identify specifics for follow up testing of remaining 2% of risks
- Follow up testing
 - Follow up testing for specific complicated situations
 - I.e. phthalate concentration, Prop 65 exposure



Example - Claigan PFAS Testing



REPORTABLE PFAS

- detect F over 50 ppm
- /w FTIR also identifies
 - CAS #
 - Use

Handles

- Maine reporting
- Canada Section 71
- US TSCA reporting
- EU PFAS consultation
- + *Pre-screening for restricted PFAS*

RESTRICTED PFAS

- detect PFOA family to 25 ppb

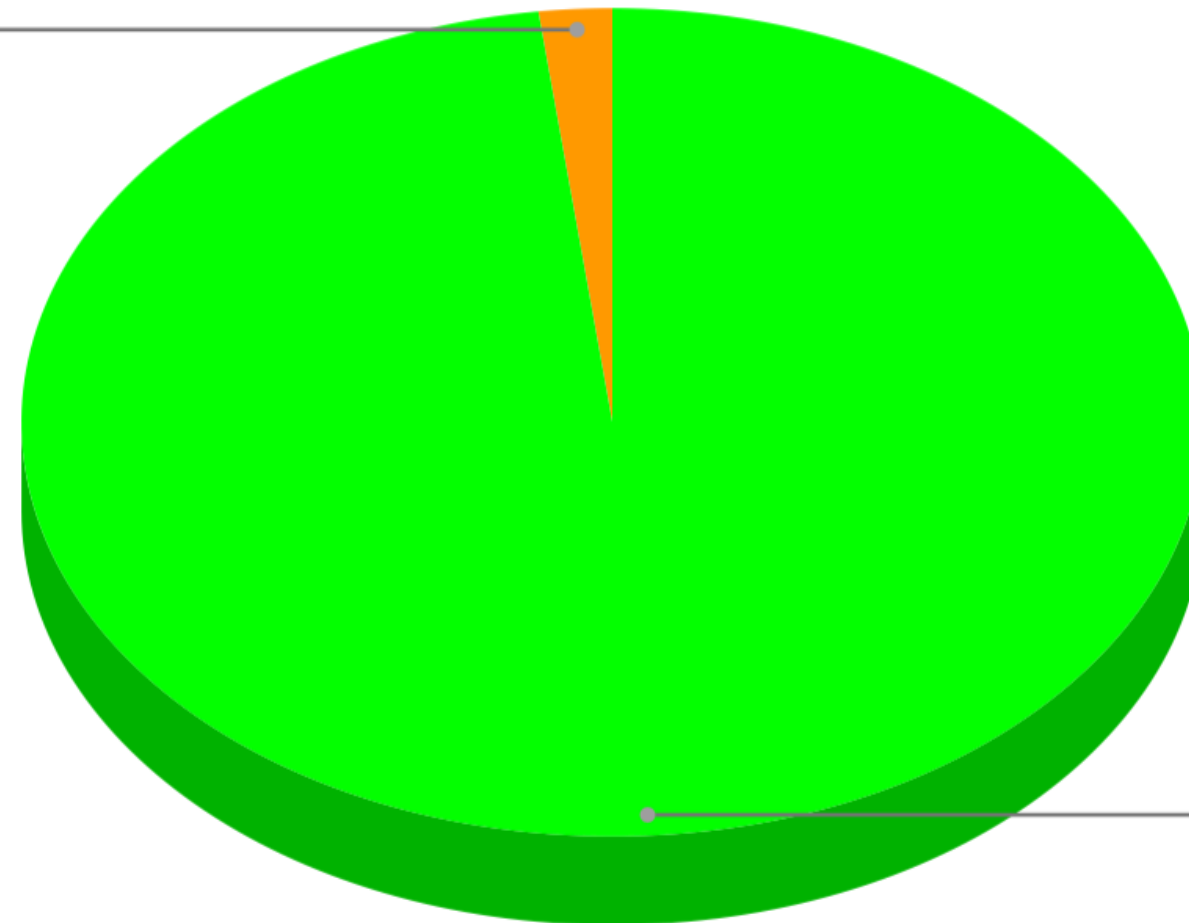
Handles

- Prop 65
- EU POP and REACH restrictions
- US TSCA SNUR
- Upcoming Canadian restrictions

Testing - Claigan Approach

% Parts solved - Claigan Process

Follow up
2.0%



Screening
98.0%

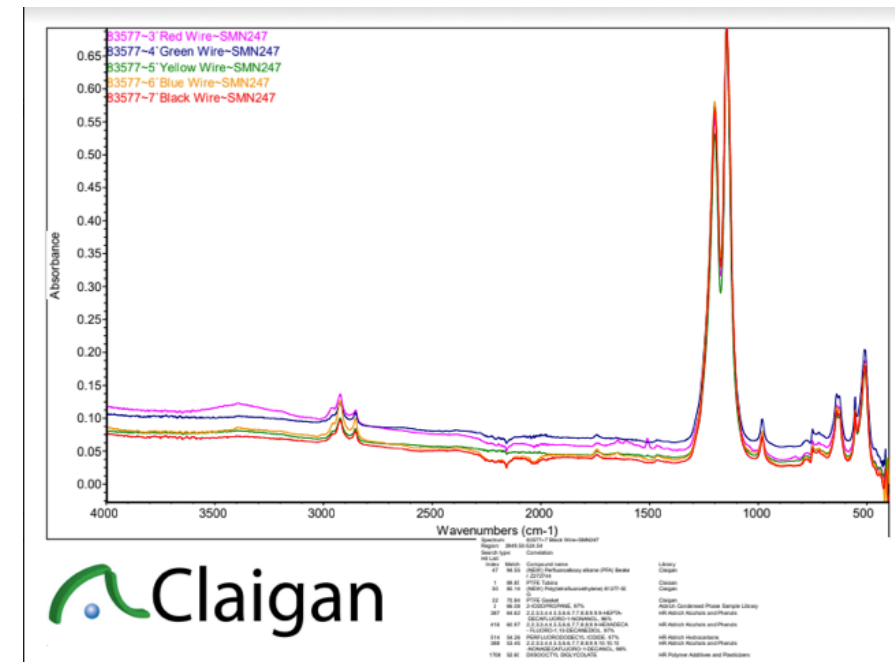
Material Matching - Claigan Approach

- **Matching materials**

- Are these materials the same?
- Is this replacement similar to the current part?
- Is their variance between parts in a batch?

- **Analysis**

- Elemental analysis
 - Comparison of elements and alloys
- Plastics
 - Spectral overlap of different materials
 - Interpretation of similarity
- Also used in non-compliance work to determine if part variation plays a factor



WEEE Treatment Instructions and Claigan

Single Use Packaging

- **Recycling documentation**

- WEEE treatment instructions (Article 15)
- Single Use Packaging (for EU reporting)

- **Reports**

- WEEE treatment instructions
 - Mandatory report for WEEE
- Single use packaging report
 - To meet reporting requirements in EU member states
- Straight forward to accomplish in parallel to testing

 **Treatment instructions for**

Producer:	
Product Name/Part Number:	
Date of Report:	May 1, 2023

This sheet is intended to provide instructions to recycling facilities to identify materials, components, and sub-assemblies of interest for the end-of-life treatment in compliance with the WEEE (2012/19/EU) and Batteries (2006/66/EC) Directives.

Summary

Component or Material	Present / Not Present
Capacitors containing polychlorinated biphenyls (PCBs)	Not Present
Batteries	Not Present
Mercury containing components, such as switches or backlighting lamps	Not Present
Printed circuit boards of mobile phones generally, and of other devices if the surface of the printed circuit board is greater than 10 square centimeters	Not Present
Toner cartridges, liquid and paste, as well as colour toner	Not Present
Plastic containing brominated flame retardants weighing > 25 g	Not Present
Asbestos waste and components which contain asbestos	Not Present
Cathode ray tubes	Not Present
chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC) or hydrofluorocarbons (HFC), hydrocarbons (HC)	Not Present
Gas discharge lamps	Not Present
Liquid crystal displays (together with their casing where appropriate) of a surface greater than 100 square centimeters and all those back-lighted with gas discharge lamps	Not Present
External electric cables	Not Present
Refractory ceramic fibers	Not Present
Radio-active substances	Not Present
Electrolyte capacitors containing substances of concern (height > 25 mm, diameter > 25 mm or proportionately similar volume)	Not Present
Stored mechanical or electrical energy (e.g. sources of stored energy in high tension circuits, capacitors and springs in compression or tension)	Not Present

Single Use Packaging

Prepared for: _____
Product Name: _____
Date of Report: _____

Summary

Plastic Totals	Weight (g)
#1 PET	23.69
#2 HDPE	0
#3 PVC	0
#4 LDPE	43.18
#5 PP	24.95
#6 PS	0
Other	0.26
N/A	4.48

Details

Single Use Packaging	Weight (g)	Plastic Type
Bag	19.69 g	#4 LDPE
Clear Tape from	0.05 g	Other
Cushion Template	4.48 g	N/A
Clear Packaging	24.95 g	#5 PP
Clear Tape from Bag	0.07 g	Other
Clear Bag	9.11 g	#4 LDPE
Clear Bag	14.38 g	#4 LDPE
Clear Packaging	23.69 g	#1 PET
Clear Tape from Bag	0.14 g	Other

WEEE and Packaging Registration & Takeback

- **Registration and takeback**

- Registration with local authorities
- Joining take back system appropriate to products
- Regular reporting

- **Details**

- Every jurisdictions has
 - Different requirements
 - Different registration entities
 - Different take back options
 - Different reporting cycles
- This is a local issue (similar to tax) and is better handled by the local distribution entity



Exposure Testing - Claigan Approach

- **Testing for exposure**

- Determination of exposure model
- Measurement of exposure
- Calculating of daily exposure rate



- **Testing for / calculating exposure**

- There are standard solutions for
 - Prop 65
 - Casual contact, repeat contact, inhalation
 - EU MDR
 - Exposure and safety margin from 10993 testing (toxicological risk assessment)
 - Food contacting materials



Data Gathering

- **Data gathering for restricted materials**
 - Gathering restricted materials data from suppliers
- **Data gathering**
 - Claigan exited data gathering from suppliers 6+ years ago due to blatant quality issues
 - Notes
 - Supplier data is always incomplete
 - Telephone game (data gathering) creates incredible errors
 - No data summary **ever** matches the test data.
 - You can do a more accurate job in a two hour engineering review than 8 months of data gathering



Supplier Specification - Claigan Approach

- **Supplier specification for restricted materials**
 - Supplier specification on compliance requirements
- **Supplier specification**
 - Fundamental rule of restricted materials compliance
 - You need to tell your supplier (and design team) what is expected before the part is made / purchased.
 - Clear specification to suppliers
 - On what is required
 - Can be referenced in purchases or drawings
 - Can be committed to by supplier
 - Can be revised on a regular interval
 - Claigan builds these regularly

Software

- **Where to house compliance?**
- **Compliance data**
 - Recommended
 - By product family
 - Product level compliance data
 - Supplier specification
 - Test report for representative product
 - Where
 - In either
 - A system you use for other reasons, or
 - In a simple revision controlled system



Compliance Tracking - Claigan Approach

- **Tracking product compliance**

- With ever changing product compliance,
 - How do you track product compliance?
 - How do you declare compliance

- **Compliance tracker**

- By product or product family
- Details
 - Compliance to each regulation
 - Which revision of regulation product is compliant to
- As regulations change, use the best available process to update compliance

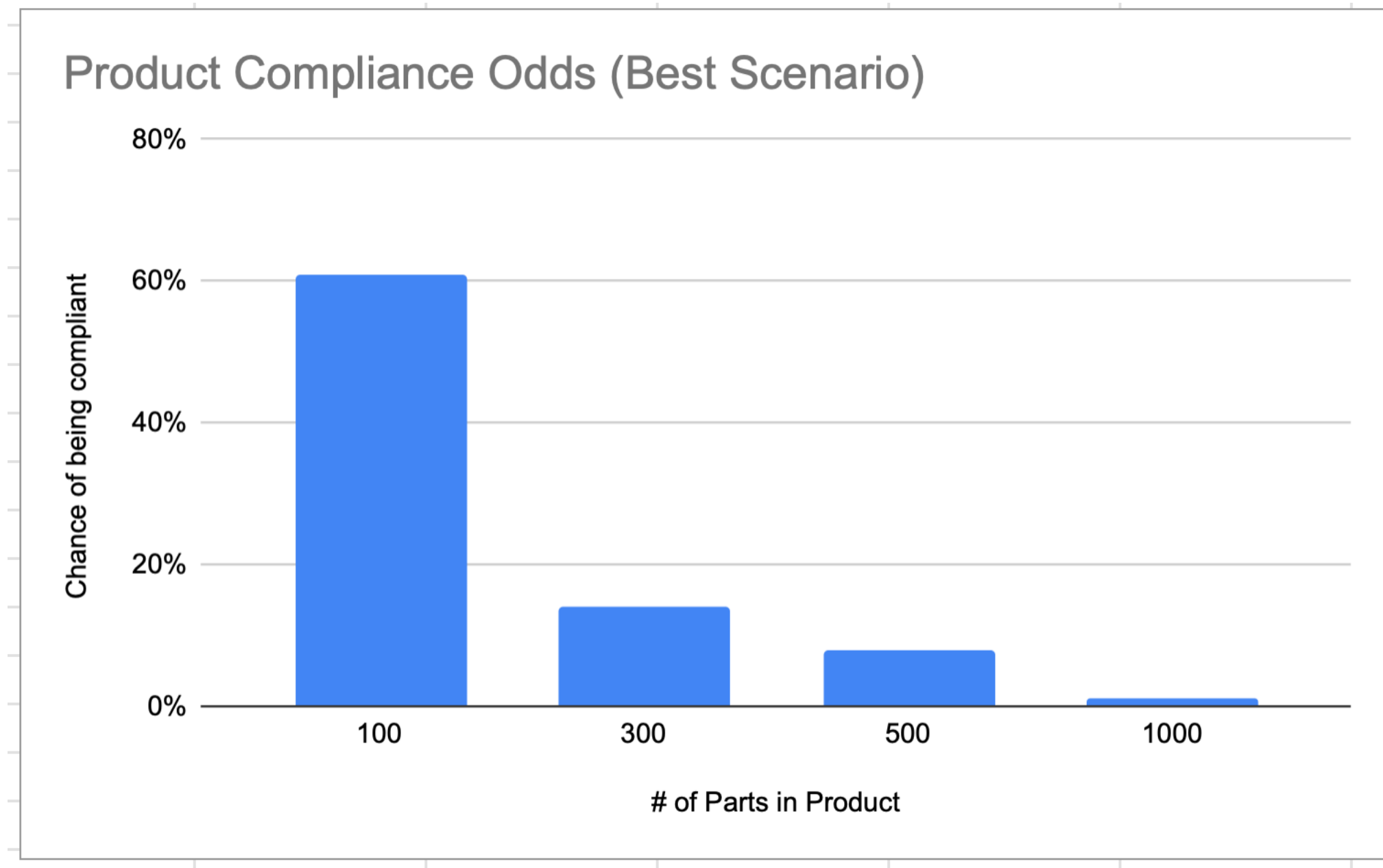
CertLink	"X"	Product	Fam. ID	Product Link	REACH SVHC	SCIP	REACH Restriction	POP	WEEE
		REGULATIO			☒	☐	☐	☐	☐
AH1 Server	Cert created: February 10, 2023	AH1 Server	Servers	Link	Jan 2023	Jan 2023	Aug 2021	December 2020	Jul 2012
Declaration - September 9, 2021	Decl. created: September 9, 2021	BD2 Dock	Docks	Link	Jul 2021	Jan 2021	Jan 2021	Aug 2020	Jul 2012
Declaration - September 9, 2021	Decl. created: September 9, 2021	Alpha Scope	Scopes	Link	Jun 2018	Jan 2019	Jan 2019	Mar 2016	Jul 2012
A900 and similar	Cert created: September 9, 2021	A900	Catheters	Link	Jan 2019	Jan 2020	Jan 2021	Jun 2019	Jul 2012
Declaration - July 19, 2021	Decl. created: July 19, 2021	V550	Ventilators		Jul 2019	Jul 2021	Jan 2021	Aug 2020	Jul 2012
Product A	Cert created: February 21, 2023	Product A		Link	Jan 2020				
					Jun 2020				
					Jan 2021				
					Jul 2021				

Non-Compliance Support - Claigan

- **Support for when non-compliance happens**
 - Detected internally,
 - Identified by suppliers, or
 - Enforcement by an authority
- **Support**
 - Non-compliance
 - If you have testing data, you are going to be fine
 - If you relied on supplier data, the situation is more dire
 - Important fundamental rule of restricted materials compliance
 - **Authorities do NOT care what your supplier said**

Data Gathering

- **Best in class data gathering**
 - Imagine 99.5% of parts are compliant
 - *Far above real world. Best case*



Note on Enforcement

- **Restricted materials enforcement is up significantly this year**
 - FDA
 - EU member states (RoHS)
 - California Proposition 65
- **In all cases**
 - Here is our test report
 - Where is yours?

Example Large Scale Enforcement

- **US FDA - DART-MS**
- Brominated flame retardants, PAA, and phthalates

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

R. Paseiro-Cerrato¹, L.K. Ackerman¹, K.Bentayeb², Y. Abe³, L. DeJager¹, T. H. Begley¹.

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 years¹⁻¹⁰. 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 retardants, photo-initiators, polyester oligomers) have been rapidly identified in several matrices such as food contact polymers (e.g. nylon), food (e.g. milk) and food simulants (e.g. 50 % ethanol) obtaining satisfactory results in just a few minutes. Some polymers have been identified, and the presence of ink-setoff was detected as well.

Conclusions

DART-HRMS is a powerful analytical technique with potential application as rapid identification technique for regulatory screening purposes.

Introduction

Direct analysis in real time (DART) coupled to a high-resolution mass spectrometer (HRMS) is an analytical technique that be used for the rapid screening of chemical compounds in almost any type of matrix, including Food Contact Articles (FCAs). One of the main advantages is that it needs little to no sample preparation and results can be obtained in minutes. In our laboratory we have been using this technique in the field of food safety for over a decade obtaining very good results. Here we summarize the main findings obtained to date by using DART-HRMS.

Materials and Methods

DART-HRMS consisted of a DART ion source and a HRMS. The DART flows excited helium (between 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 ~5-15 seconds using previously cleaned tweezers or glass capillary tips. In some cases, the use of dopants such as solution of 20% NH₄ was used^{2,3}. Data processing is conducted by using appropriate software (e.g. QualBrowser, TOX ID, Excel) and settings (e.g. mass tolerance of 5 ppm).

Results and Discussion

Analysis of primary aromatic amines (PAA) analysis in kitchen utensils⁴.

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.

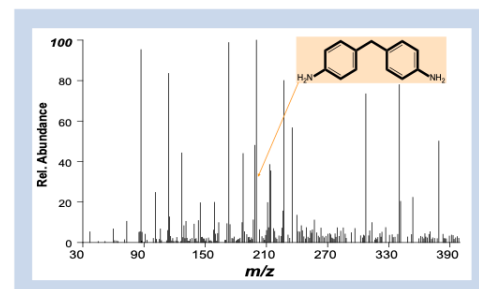


FIGURE 1 Example of DART-MS spectra of PAAs.

Determination of brominated flame retardants (BFRs) by using DART-HRMS^{5,6}.

Previous work has found BFRs in FCM. The use of BFRs in FCM and therefore as food additives is not allowed in the United States. We use DART-HRMS to rapidly identify BFRs in food contact polymers, food as well as food simulants. In the analyzed food contact articles⁶ we found that DART-HRMS 79% of the samples were in good agreement with the results obtained by GC-MS (used as reference) in the combined sample set. Estimated false positive incidences were 5% and false negative incidences of 4%. False-negative rates were 25% and false-positive rate of 6%. We also conducted migration studies in food and food simulants. By using DART-HRMS we were able to identify BFRs in in both including milk, chicken bouillon soup and 50 % ethanol food simulant.

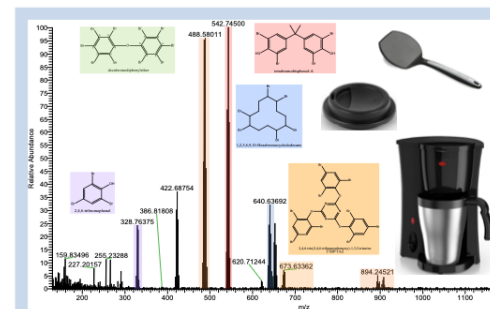


FIGURE 2 DART-MS spectra of Brominated Flame Retardants found in FCAs^{5,6}.

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 practice. This transfer is problematic because most printing materials typically have not been authorized for direct food contact. Also, set-off is not always visible to the human eye, and prints often contain numerous, variable, and reactive mixtures (ie UV photoinitiators etc). Rapid non-targeted methods were needed to detect and identify print set-off incidence in packaging.

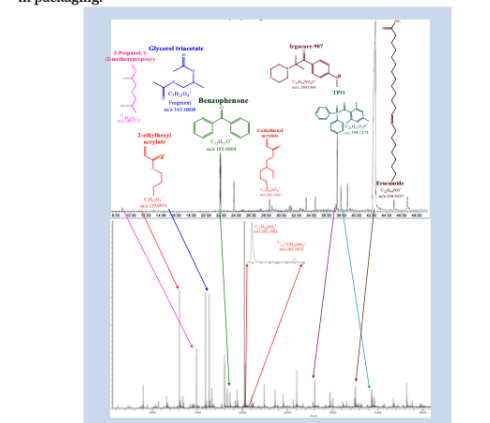


FIGURE 3 GC-MS vs DART-MS ID of print compounds on food contact surfaces

The use of DART-HRMS for the rapid identification of polyamides (nylon) polymers¹⁰.

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.

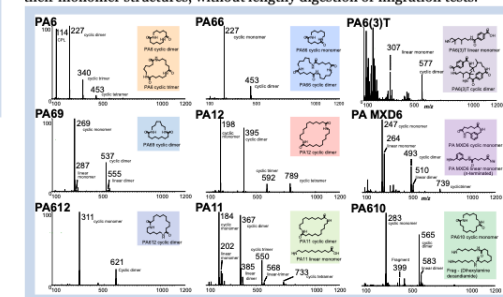


FIGURE 4 DART-MS identifications of 10 polyamides (nylons)¹⁰

Conclusion

Since 2011, ORS-DAC has developed DART-HRMS methods to:

- Identify >150 Additives & Contaminants in FCAs.
- Identify numerous migrants in FCAs, simulants, and foods.
- Identify polymer types.
- Identify the location of Additives or Contaminants in FCAs.
- Assess the incidence of Additive or Contaminant occurrence.

References

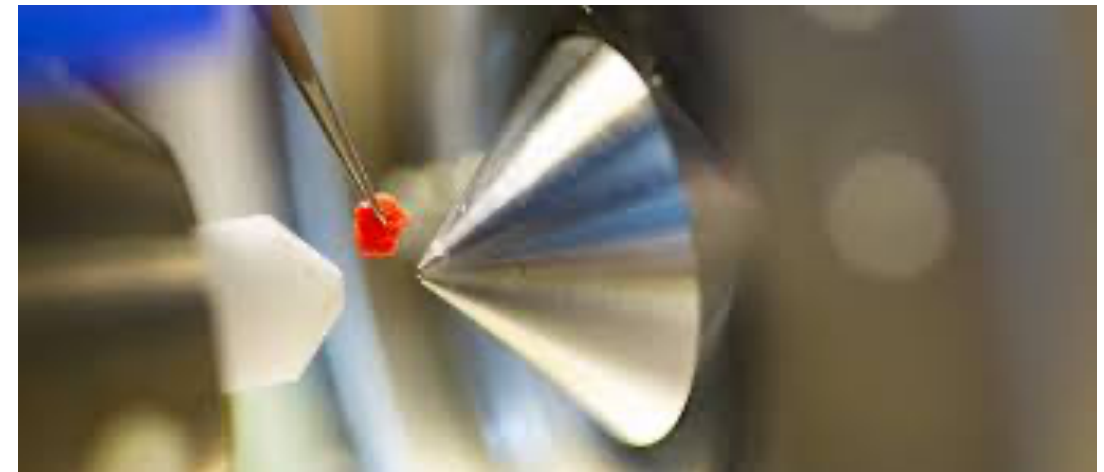
- 1) L.K. Ackerman, G.O. Noonan, T.H. Begley. Assessing direct analysis in real-time mass spectrometry (DART-MS) for the rapid identification of additives in food packaging. Food Additives & Contaminants: Part A, 2009 Dec;26(12):1611-8.
- 2) Paseiro-Cerrato, R.; MacMahon, S.; Ridge, D. C.; Noonan, G. O.; Begley, T. H. Identification of unknown compounds from polyester cane coatings that may potentially migrate into food or food simulants. Journal of Chromatography A. 1444, 106-113, 2016.
- 3) Paseiro-Cerrato, R.; DeVries, J.; Begley, T.H. Evaluation of Short-Term and Long-Term Migration Testing from Can Coatings into Food Simulants: Epoxy and Acrylic-Phenolic Coatings. Journal of Agricultural and Food Chemistry. 65 (12), 2594-2602, 2017.
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- 7) K. Bentayeb, L.K. Ackerman, T. Lord, T.H. Begley. Non-visible print set-off of photoinitiators in food packaging. Food Additives & Contaminants: Part A 2013;30(4):750-9.
- 8) K. Bentayeb, L.K. Ackerman, T.H. Begley. Ambient Ionization-Accurate Mass Spectrometry for Identification of Nonvisible Set-off in Food-Contact Materials. J. Agric. Food Chem. 2012, 60(8) 1914-20.
- 9) M. Lago, L.K. Ackerman. Identification of print-related contaminants in food packaging. Food Additives & Contaminants: Part A, 2016; 33(3), 518-529.
- 10) Y. Abe, L.K. Ackerman, M. Mutsuga, K. Sato, T.H. Begley. Rapid identification of polyamides using direct analysis in real time mass spectrometry. Rapid Communications in Mass Spectrometry. 2020; 34 (S2):e8797.

Note on Enforcement

DART-MS (Direct Analysis in Real Time)

- **DART-MS Rapid Screening**

- Fast testing of parts for
 - Flame retardants
 - Phthalates
 - Polyaromatic Amines
- Without sample preparation



- **If positive**

- Send part for full LC-MS/MS follow up test

Conflict Minerals - Claigan Approach

- **Compliance to conflict minerals requirements**
 - US Publicly traded companies (require due diligence), and
 - Non publicly traded companies (due diligence not required)
- **Includes**
 - Reasonable Country of Origin Inquiry (RCOI)
 - Data gathering inquiring on country or location of origin of the material
 - Normally to an industry standard
 - Due diligence
 - Direct research and work with all refineries on whether they source from the covered countries
 - Due diligence review of every refinery of risks

Extended CSR - Claigan Approach

- **Extended CSR Compliance for Products**
 - Extended minerals reporting template
 - Uyghur forced labour
 - Modern slavery / Transparency in Supply Chains
- **Compliance plan**
 - A RCOI and similar plan for each
 - A due diligence report for each regulation

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Q&A