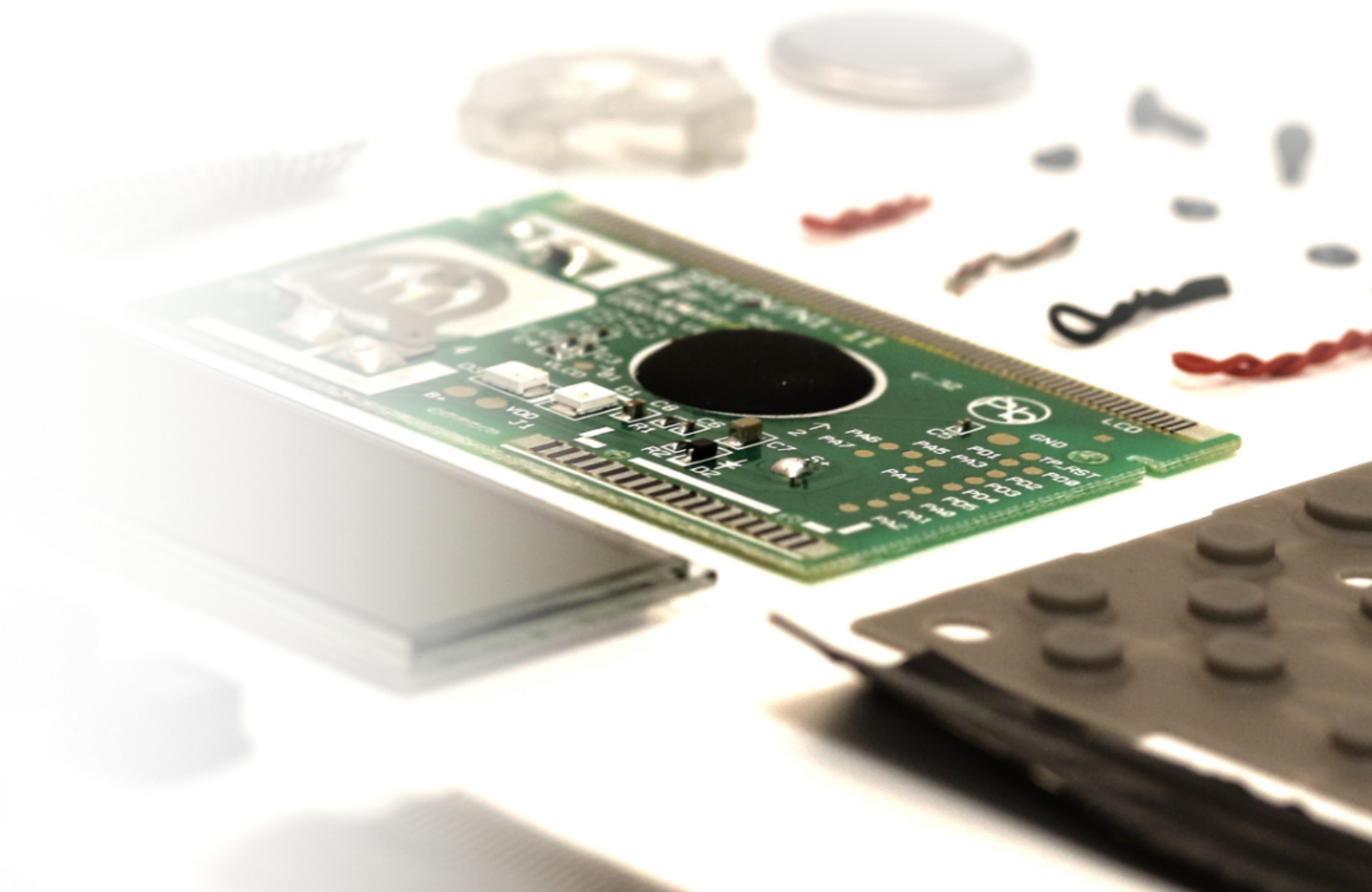


Unfortunately - Ignorance is no excuse

Critical Lesser Known Requirements

Presented by:
Bruce Calder
VP Consulting

September 11, 2024



Overview - Agenda

- Introduction
- Summary
- What are the criteria for ‘Placed on the Market’?
- Scope of the Canadian Plastics registry
- Is my product in or out of scope for REACH authorisation?
- Are RoHS exemptions expiring this year?
- Are all PFAS about to be banned?
- Are my products in scope of Canadian PFAS reporting?
- How do Prop 65 prosecutions work?
- Is nickel in steel a prop 65 risk?
- EU MDR Cat I CMR rules
- What are the asbestos risks in normal products?
- Recap
- Q&A

Intended to be 50
minutes
/w 10 min Q&A

Claigan Environmental



Consulting



Testing



Declarations

EU Placed on the Market

- **What is the definition of “Placed on the market”?**



Completed manufacturing



Transferred to the stage of distribution



Inside the EU



Available for Sale

EU Placed on the Market



Completed manufacturing

- **Completed manufacturing**
 - Has completed all manufacturing steps
 - Ready for the end user
- Note - 'Kitting', software loads, installation are generally not considered to be manufacturing steps

EU Placed on the Market



Inside the EU

- **Inside the EU**
 - From a customs perspective
 - Note - usually the key date for imported products
 - Date that the product cleared customs

EU Placed on the Market



Transferred to the stage of distribution

- **Transferred to distribution**
 - Transferred to the stage of distribution
 - Simplest method
 - Transferred to entity of distribution
 - Which can be an owned company
 - Importation will usually involve transfer
- Generally the key date for products manufactured in the EU

EU Placed on the Market



Available for Sale

- **Available for Sale**
 - A customer could buy it
 - Not available for sale
 - Has not completed compliance
 - Not offered in the EU

EU Placed on the Market

- **What is the definition of “Placed on the market”?**



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Inside the EU



Available for Sale

Scope of the Canadian Plastics Registry

2025 Reporting
(For 2024 year)



Consumer Electronics



Consumer packaging



Specific single use plastics

2026 Reporting
(For 2025 year)



Including medical devices
Professional Electronics



Professional Packaging



Apparel

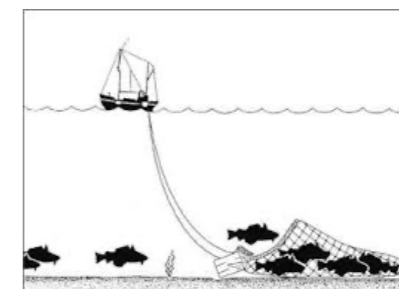
And.....



Transportation



Construction



Fishing
And agriculture

Canadian Federal Plastics Registry



Facility Waste

- **Industrial / institutional waste**
 - From
 - Manufacturing operations
 - Employee waste
 - Restaurant services
 - In Canada

2026 Reporting

For quickly approaching 2025 year

Claigan Plastic Registry

Canadian Environmental Protection Act (CEPA)

WE KNOW CANADA.

CLAIGAN IS THE MOST WELL KNOWN NAME IN CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) COMPLIANCE FOR PHYSICAL PRODUCTS (MANUFACTURED ITEMS).



Canadian Plastics Registry

Every year, companies must report the plastics in their electronics and packaging to the Canadian government. Claigan's process will create for you the plastics submission for individual products or for entire companies including:

- Electronics
- Packaging
- Waste
- Automotive
- Textiles

[PLASTICS REGISTRY FAQ](#)

[LEARN MORE ABOUT THE PLASTICS REGISTRY](#)

CLAIGAN PLASTICS REGISTRY SERVICE – PRODUCTS

Plastics in packaging and products (including electronics, automotive, food take-out, and apparel) are required to be reported to the Canadian Plastics Registry.

Claigan has extensive experience with creating submissions for plastics reports for simple and very complex products – including the industry's best models for dense electronics.

[CONTACT US](#)



Claigan - Plastics Registry - Products

Canadian Plastics Registry FAQ

Note – the FAQ below is a streamlined interpretation of the Canadian Plastics Registry. For full details see Canadian Plastics Registry Notice.

Who is in scope?



CLAIGAN PLASTICS REGISTRY SERVICE – WASTE AUDIT

Companies disposing of plastic waste in the industrial or institutional waste stream are required to report by plastic and product subcategory to the Canadian Federal Plastics Registry.

Claigan's Federal Plastics Registry Waste Audit is designed for a range of companies, including manufacturers, restaurants, office buildings, schools, and retirement homes. Claigan's plastic waste audit is a simple and direct way for businesses to report their plastics waste to the Plastics Registry.

Claigan - Plastics Registry - Waste

www.claigan.com

<https://www.claigan.com/canada-cepa/>

Am I in scope of EU REACH Authorisation?

- **Chemical product**

- Yes

- **Article**

- No



Guidance on requirements for substances in articles

June 2017
Version 4.0

p. 67

- Authorisation is not required if the substance is imported into the EU as an integral part of the imported articles.
- The content of substances in articles can be restricted or banned under the restrictions procedure. Article producers and importers have the obligation to comply with the restrictions and conditions set out in Annex XVII of the REACH Regulation.

Are RoHS exemptions expiring this year?

No.

RoHS Exemptions Consultation Summary

- **RoHS Exemptions**

- All exemptions in renewal are still valid

First preview of new exemptions

- **Timeline**

- Have your say consultation - Fall 2024
- Final versions - ~End of 2025
- Earliest possible date for ending of an exemption
 - Middle of 2027

Are all PFAS being banned?

Also no.

Are my products in scope of Canadian PFAS reporting?

Yes. * **

** except for some very specific laboratory, pesticide, waste, feed, and seed categories*

*** as long as you meet certain PFAS weight per year*


PFAS Reporting Canada


January 2025 - **SIMPLIFIED**

- **Who has to report**

- Brand owner (if located in Canada),
- Importer (if brand owner is NOT located in Canada)

- **Reporting requirements**

- 
- >100kg of a reportable fluoropolymer or fluoroether per annum in your product (chemical or article), or
 - >10g of a reportable fluorosalt per annum in your product (chemical or article)

- However, reporting requirements are much lower if the product is an article (manufactured item) and the PFAS does not meet certain human contacting criteria
- 

Key take aways

Canadian PFAS Reporting

- **Due January 25 2025**
 - **One time reporting**
 - **Significant overlap with US TSCA PFAS**
 - Due (**UPDATED**) Jan 2026
 - **Significant overlap with Canadian Plastics Registry**
 - Due September 2025
- **When in doubt, contact Claigan**

How do Prop 65 Prosecution Work?

Oddly.

How do Prop 65 Prosecution Work? Claigan Simplified



Law firm or NGO makes a purchase
Usually online



Law firm has laboratory perform standard test



If the product 'fails'



OEHHA
California Office of Environmental
Health Hazard Assessment

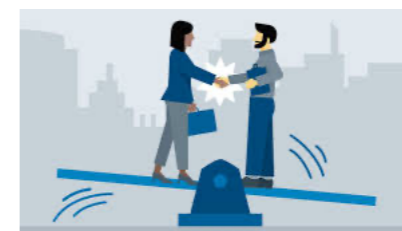
Law firm submits to OEHHA



Law firm sends 60 day notice to seller and brand owner



Brand owner hires external counsel



External counsel and law firm negotiate

Product change
+
How much the company has to pay the law firm

Does the Plaintiff (Law Firm) always win?

Yes. * **

** Because the vast majority of companies do not have the knowledge or desire to fight it.*

And the plaintiffs are used to that

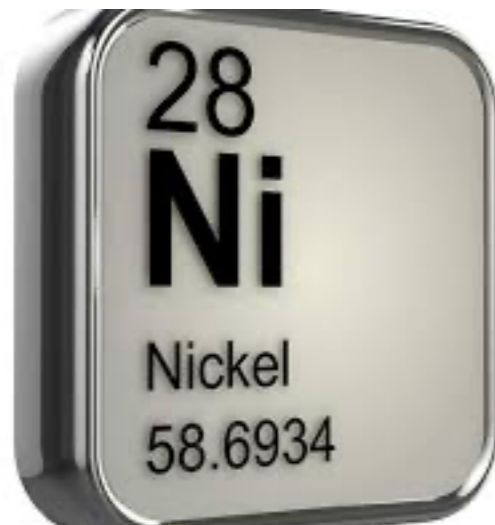
*** But companies would win the vast majority of time if they had the knowledge or will to fight it.*

Is Nickel a Prop 65 substance?

Yes.

But only if you wear it or snort it

Nickel - Prop 65



- **Prop 65**
 - From Title 22 of the California Code of Regulations Section 12707(b)(5)
 - ...for purposes of Proposition 65, nickel and nickel compounds present no significant risk of cancer by the route of ingestion
 - Which eliminates casual hand contact leading to ingestion
 - Which leaves only
 - Dermal (wearables)
 - Inhalation (nickel dust)
- Which reduces the impact significantly

Carcinogens, Mutagens, Reproductive Toxins

If no CMR or endocrine disruptors leak from a medical device

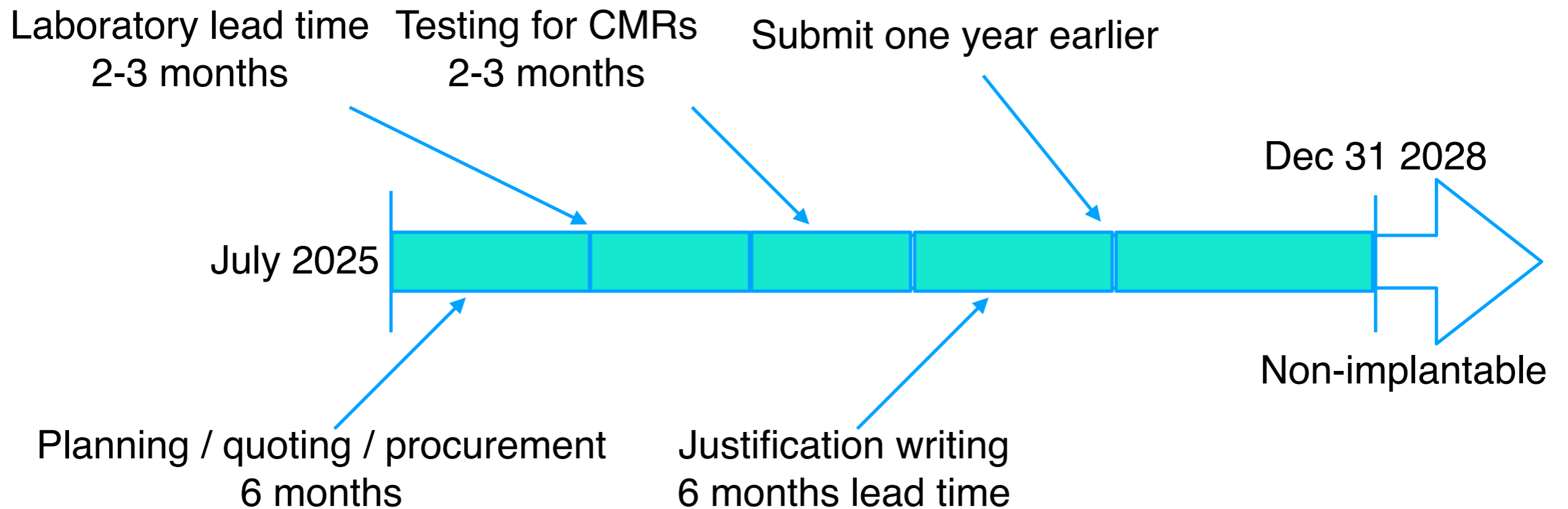
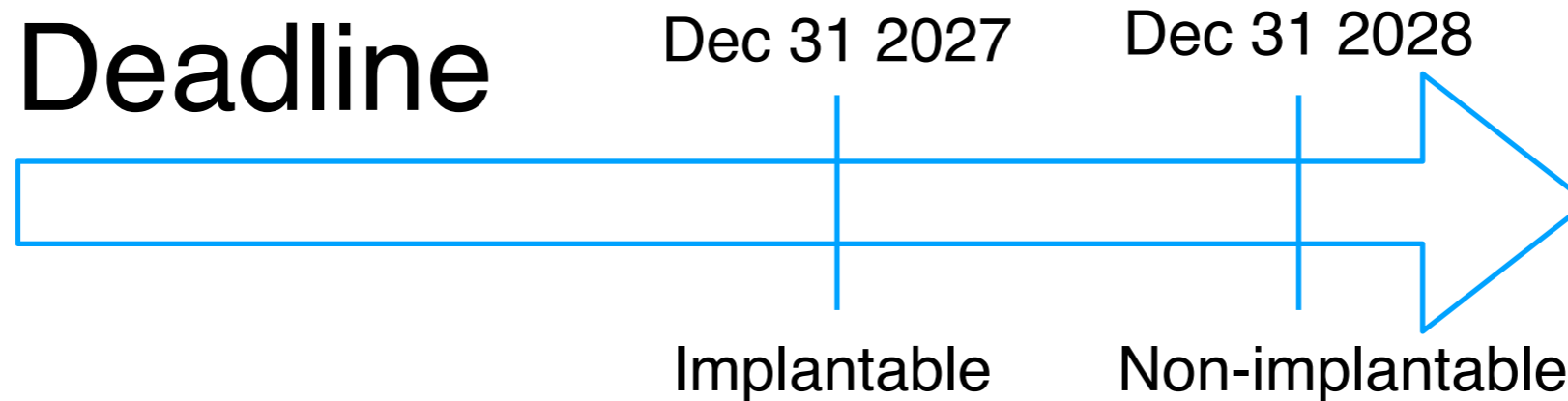
Is it compliant?

No.

Compliance is related to whether any CMR or endocrine disruptor is above 1,000 ppm in an invasive, fluid, or gas path

If a CMR or EDC is, it needs to be labelled and justified.

EU MDR Reminder



What are the risks of asbestos in Claigan general products?

Talc.

Asbestos and Talc

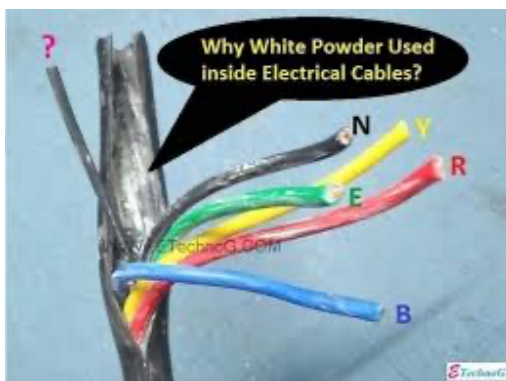


- **Talc**

- Talc is basically asbestos with better marketing
- They generally exist in the same deposits
- Asbestos contamination of talc is relatively common

- **Risks**

- Cosmetics
- Large cables



Recap

Hold on to your seats...

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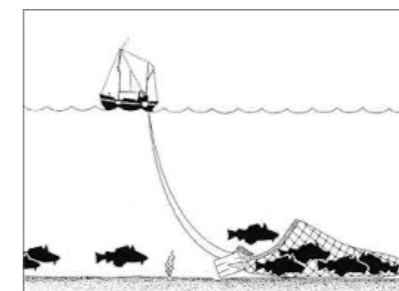
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