SRA 2022

Global Risks @ the Tipping Point

Risk Analysis & Policy Driving Systemic Change

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Life-cycle Risk Assessment of Consumer Applications of Graphene: Outcomes, Data Gaps and Priorities

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Raising the Bar on Sustainability in Innovation

Project DIAGONAL

- Horizon 2020
- 24 Partners
  - Industrial demonstrators
  - Private consultant
  - Academic experts

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Project DIAGONAL

- New methodologies for HARN/MCNM long-term nanosafety
- Developing risk assessment, risk management and risk governance approaches

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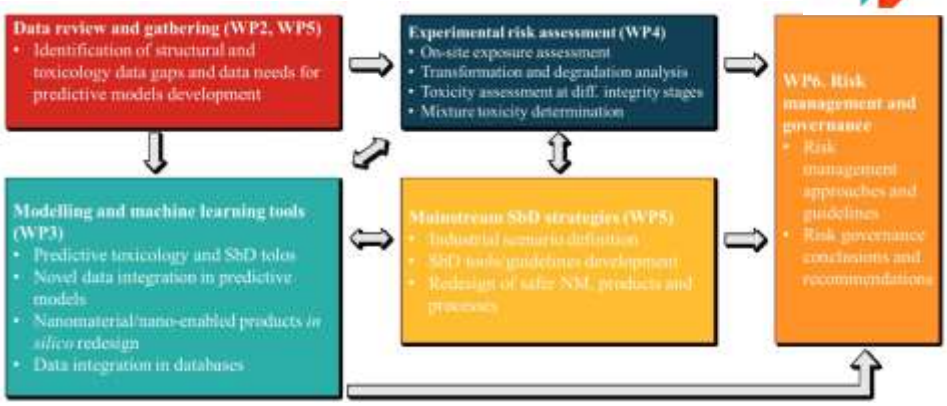
Project DIAGONAL



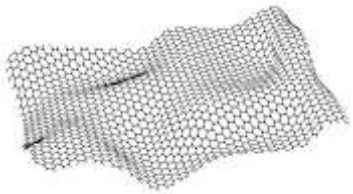
7 Work Packages (WPs)

- WP2/WP5: Data Review, Gathering & Mainstream SbD strategies
  - Vireo's contribution: LCRA of graphene enabled textile
  - Industrial demonstrator case study
  - Data gap analysis & data needs for risk assessment → WP4

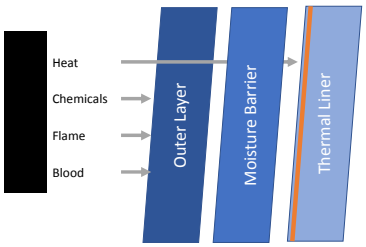
INDUSTRIAL CASE STUDY:

GRAPHENE-XT
NEXT GENERATION MATERIAL

Graphene Functional Fabrics
- Graphene-enabled thermal liner
- G nanoplatelets
- GXT method: screen-printed, acrylic dispersion



NFPA, CSN standards
- Design, Care, Disposal



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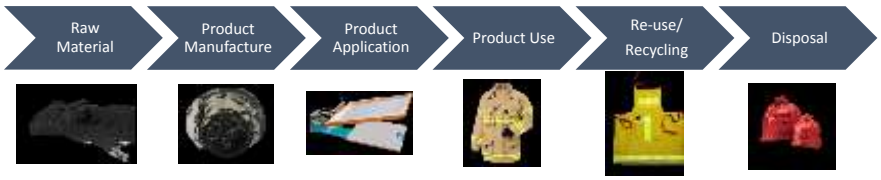
LIFE CYCLE RISK ASSESSMENT



1. Identify and Characterize Potential Hazards

2. Assess Exposure Potential and Risk

3. Prioritize Data Gaps

4. Address Data Gaps (E.g., Toxicity Studies)

Output: EHS Strategy

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EXPOSURE SCENARIO DEVELOPMENT & RANKING

For each life-cycle stage, possible scenarios that could lead to occupational, public or environmental exposure are identified.

1. Raw Material
2. Product Manufacture
3. Product Application
4. Product Use
5. Re-use/Recycling
6. Disposal

Scenario Ranking

Scenarios are ranked by applying four exposure criteria (relative scores: 1-3). Highest cumulative scores become the top-ranked scenarios.

- Directness of exposure
- Magnitude
- Likelihood
- Frequency

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EXPOSURE SCENARIO PRIORITIZATION

Top Ranking Scenarios:

1. Direct occupational exposure during raw-material and product manufacturing life-cycle stages
   - Inhalation & dermal/eye exposure; raw material
2. Occupational exposure from incidental release, accidental release & cleaning during raw material production
   - Inhalation & dermal/eye exposure; raw material

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EXPOSURE ASSESSMENT: LITERATURE REVIEW

KEY FINDINGS:

- Occupational Exposure
  - Highest: milling, cleaning, handling powder
  - Low overall exposures with existing controls
- Graphene Composite Release
  - Most particulate is GBM-matrix
  - Pristine GBM release possible, variable
- Environmental Persistence
  - Not readily biodegradable
  - Possible transformation in nature

Lee et al. (2016), Yu et al. (2016), Vaquero et al. (2019), Boccuni et al. (2020), Bellegamba et al. (2020), Lavicoli et al. (2018), Spinazze et al. (2018), Loven et al. (2020), and Tombolini et al. (2021) Netkueakul et al. (2020), Cho et al. (2019, 2020), Kim et al. (2018), Goodwin et al. (2020) REACH 2022, Zhao et al. (2014), Chen et al. (2017), Martin et al. (2019), Liu et al. (2015), Zhu et al. (2014), Carniel et al. (2021)

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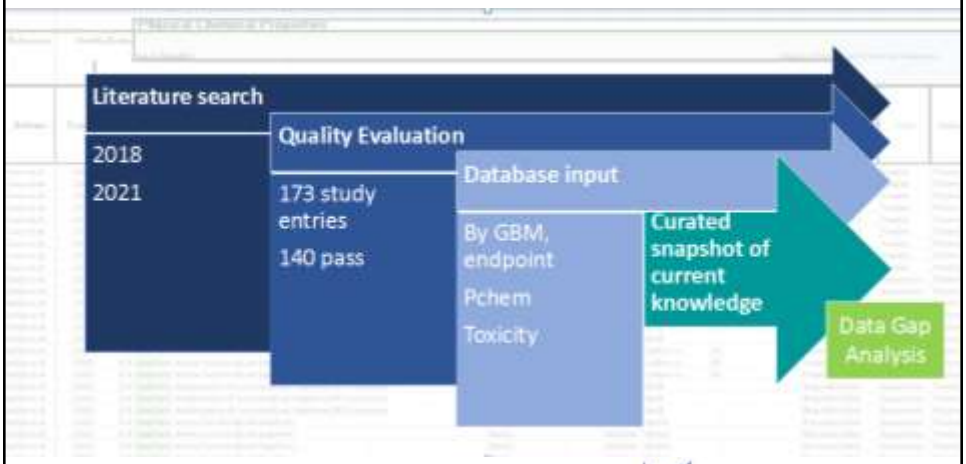
HAZARD ASSESSMENT: LITERATURE REVIEW, DATABASE DEVELOPMENT & DATA GAP ANALYSIS



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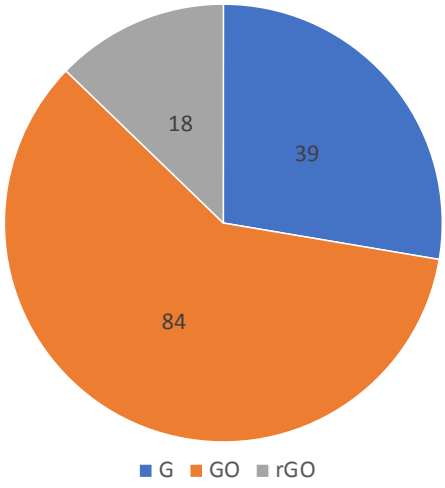
HAZARD ASSESSMENT: DATA GAP ANALYSIS



Types of Graphene Materials Studied

- Graphene oxide (GO) most studied GBM for human-health and ecotoxicological impacts
- Reduce graphene oxide (rGO) is the least studied form, with only 18 reports in the peer reviewed literature

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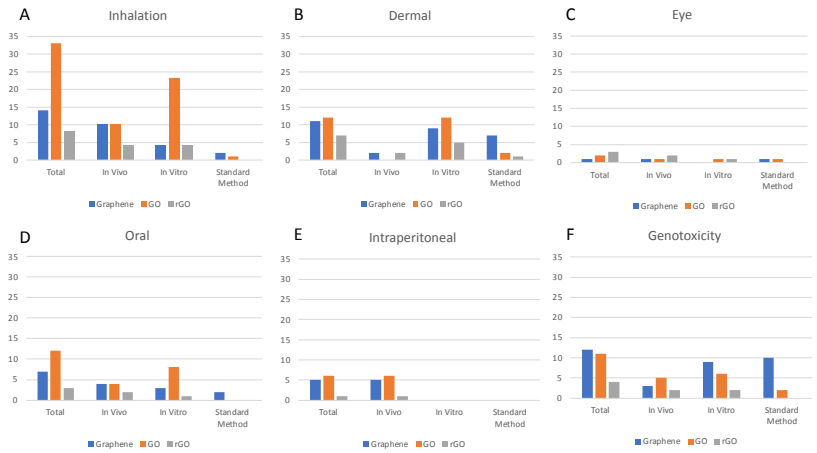
HAZARD ASSESSMENT: DATA GAP ANALYSIS



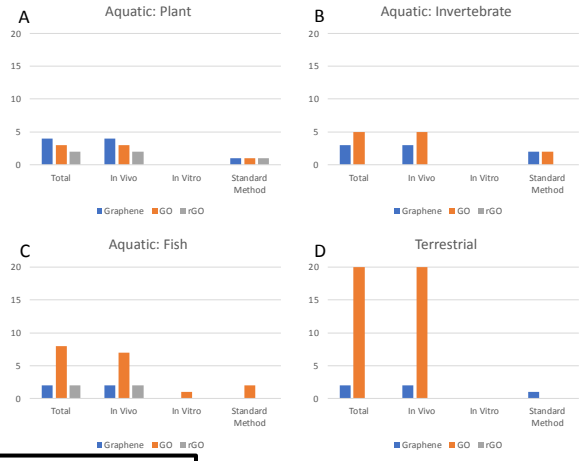
Human Health Studies

- Inhalation most common exposure route investigated. Followed by dermal, oral, intraperitoneal, and eye exposure.
- More studies employed *in vitro* test methods (126 entries) than *in vivo* (75 entries)
- Most studies did not use standard methods. Highest use in genotoxicity and dermal studies.
- No studies were located evaluating impacts from chronic GBM exposure.

HAZARD ASSESSMENT: DATA GAP ANALYSIS

Ecotoxicity Studies

- Terrestrial exposure most evaluated in the literature
- Low test species diversity across all exposure routes
- Majority of ecotoxicity studies were *in vivo*
- Standard methods were more commonly adopted for ecotoxicological evaluations, but were still low overall.



Data gaps (exposure; toxicological) inform experiments performed by WP4 in DIAGONAL

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QUALITATIVE HEALTH AND ENVIRONMENTAL RISK CHARACTERIZATION

- Potential risks for top ranking scenarios at each life-cycle stage characterized using hazard and exposure data developed in previous steps

SNAPSHOT:

Raw Material and Product Manufacture

- Occupational inhalation exposure scenarios ranked highest
- Occupational exposures easiest to mitigate/control
- Hazard data suggests relatively low pulmonary hazard; data gap in chronic, low-dose exposures

Product Application and Use

- Once incorporated into acrylic paste, lower potential for exposure to workers, public and environment
- Limited data characterizing (1) hazard and (2) potential release of graphene from graphene-acrylic composites

End-of Life: Recycling, Reuse & Disposal

- Low potential for environmental release; low environmental hazard (mg/L; g/kg soil)
- Uncertainty due to data gap in environmental transformation and persistence

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QUALITATIVE HEALTH AND ENVIRONMETNAL RISK CHARACTERIZATION

- Potential risks for top ranking scenarios at each life-cycle stage characterized using hazard and exposure data developed in previous steps

OUTPUT: EHS Strategy

- Recommended exposure testing to fill data gaps
  - *E.g.* release of graphene from acrylic composites; OEA
- Recommended safety testing based on data gaps
  - *E.g.* chronic, low-dose exposures; inhalation and dermal endpoints; standard methods
- Recommended research areas to promote graphene safety
  - *E.g.* Detection and quantification techniques of graphene in biological and environmental matrices

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THE TEAM AT VIREO

Dr. Jo Anne Shatkin is an expert in novel product safety and environmental and health policy issues, with over 20 years experience leading projects in risk analysis, safety and regulatory policy work including numerous publications.

She is founder and president of Vireo Advisors in Boston, Massachusetts.

Dr. James D. Ede is a toxicologist experienced in testing strategies for novel materials, including molecular, biochemical and cellular techniques, and is experienced in life cycle risk assessment.

Dr. Kimberly J. Ong is a biologist and environmental scientist. Dr. Ong is an expert in developing protocols specific for novel material testing to improve reliability for risk and exposure assessment and is experienced in regulatory analysis for novel products.

Dr. Shaun Clancy is a chemist with over 30 years experience in the chemicals industry, directing programs in health, safety, and regulatory affairs in major corporations. He is ANSI Co-Chair and participates in ISO TC229 and other international safety committees.

Fiona Case is a content writer with more than 20 years experience covering scientific innovations in foods, personal and home care products, sustainability, and computer-aided materials design.

Patricia Hodgkinson is Vireo's research consultant with a background in Food Policy law.

Leslie Hockman has industry experience working for a commercial manufacturer of cellulose nanomaterials and is Vireo's administrator.

Yueyang (Brian) Zhang is a toxicologist and a post doctoral fellow at University of Alberta and a MITACS Fellow with Vireo.

Wei Ng is an intern and is currently pursuing her PhD in Biological and Biomedical Science from Yale University.

Angel Precious-Egere is an intern and is pursuing a master's degree with a focus on antimicrobial nanotechnology.

Kora Kukk is a fellow and a UMaine graduate with an M.S. in Biomedical Engineering.

Padmapriya Srinivasan is an intern and is pursuing a Bachelors of Science degree from Mount Allison University.

Tatiana von Rheinbaben is a fellow and a M.S. Environmental Engineering and Science graduate of Stanford University.

Ana Diges recently completed her fellowship with Vireo and is furthering her education. She contributed greatly to the Life-cycle Risk Assessment of Consumer Applications of Graphene: Outcomes, Data Gaps and Priorities work.

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Thank you!

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