

ecetoc

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PLANETARY BOUNDARY FOR NOVEL ENTITIES

DEFINING A SAFE OPERATING SPACE FOR CHEMICALS WITH ACTIONABLE TARGETS TO PROGRESS A TRANSITION TO A SUSTAINABLE FUTURE

This workshop is part of ECETOC's 2026 NEXUS WEEK

Operationalising the planetary boundary for novel entities: From an abstract warning light towards an actionable management framework

Report of the Ecetoc workshop on planetary boundaries for novel entities, Brussels, 6-7 May 2026. Event page: Planetary boundary for novel entities - Ecetoc

Abstract

The planetary boundaries framework identifies novel entities including chemicals such as pharmaceuticals, pesticides, plastics, nanomaterials, and metals mobilised by human activity, as a category whose boundary is assessed as transgressed. Despite its recognised importance, this boundary remains the least characterised and among the most challenging to operationalise. No practically applicable quantitative control variable (metric) has yet been agreed on, and no threshold defined, which can inform governance mechanisms to translate scientific insights regarding adverse novel entity impact into measurable management action. The ECETOC workshop convened in Brussels on 6-7 May 2026 brought together representatives of academia, industry, regulatory bodies, and civil society across the science-policy-industry interface to address these gaps. This report synthesises the workshop proceedings, analyses the breakout session outputs, and consolidates them into six coordinated workstreams that may be considered for developing a phased roadmap with indicative responsible stakeholders and timelines. We conclude that a more viable boundary may be achievable in the near-term, for instance through a comprehensive Drivers-Pressures-State-Impact-Response (DPSIR)-aligned indicator dashboard, aggregated into a small number of impact-proximal control variables. Such an approach allows for flexibility in choice of metrics, but with toxic pressure identified as a promising near-term candidate for the aquatic compartment, complemented by persistence- and equity-based metrics.

One of the key outcomes of the workshop was the agreement to establish a multi-sectoral ECETOC Task Force on the planetary boundary for novel entities, along with a commitment to align with the strategic objectives of others, including initiatives under the Global Framework on Chemicals, the Intergovernmental Science-Policy Panel on Chemicals, Waste and Pollution (ISP-CWP), established in 2025 to strengthen the science-policy interface on chemicals, waste, and pollution prevention, the Potsdam Institute for Climate Impact Research (PIK) and Stockholm Resilience Centre (SRC) which host key Earth system sustainability initiatives, including the Earth Commission 2.0.

Keywords: *planetary boundaries; novel entities; chemical and material pollution; Earth-system boundaries; Drivers-Pressures-State-Impact-Response (DPSIR) framework; chemical footprint; safe and just operating space; toxic pressure; roadmap*



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1. Introduction

The planetary boundary theory is a framework defining the "safe operating space" for humanity based on nine critical Earth-system processes that regulate planetary stability. By monitoring these boundaries, it may be possible to track how human activity risks pushing the Earth past critical, irreversible environmental tipping points. When the planetary boundaries framework was introduced, it conveyed a deceptively simple message: there are finite limits to the anthropogenic stress that Earth's systems can absorb before destabilisation occurs, thereby defining a safe operating space for humanity. More than a decade later, seven of the nine boundaries (Sakschewski et al., 2025) are assessed as transgressed including climate change, biosphere integrity, land-system change, freshwater change, biogeochemical flows, ocean acidification, and novel entities. Novel Entities comprises a broad and heterogeneous group of anthropogenic chemicals and materials, including synthetic compounds, plastics, nanomaterials, and human-mobilised metals, whose production and release may occur at scales sufficient to perturb Earth system processes (Jahnke et al. 2026). Among the planetary boundaries, novel entities are distinctive because they lack a single, globally applicable control variable. In contrast, most of the other boundaries can, at least in principle, be monitored using a small number of globally meaningful control variables such as atmospheric carbon dioxide concentration for climate change, surface-ocean pH for ocean acidification, and forest cover for land-system change. Novel entities have no such single, indicative control variable. The 2023 update (Richardson et al. 2023) operationalised the boundary using a proxy (i.e., the proportion of chemicals released without prior assessment (Persson et al. 2022)). While this metric reflects the growing disparity between chemical production and the capacity to assess associated risks, it does not directly capture ecological or human-health impacts.

This absence of scientifically robust, impact-based control variables is a central challenge in operationalising the novel entities boundary. The workshop set out to address this challenge. The boundary of novel entities (or chemical and material pollution) differs from the other planetary boundaries in three structural respects that seemingly complicate single-variable monitoring. Firstly, heterogeneity: hundreds of thousands of substances are used commercially, each with distinct hazard profiles, environmental fate characteristics, and exposure pathways. Secondly, spatiotemporal variability: emissions and exposures are often local and dynamic, even though some substances disperse globally. Thirdly, an irreducible equity dimension: exposures and impacts may be unevenly distributed, with vulnerable communities often bearing the greatest burden. Taken together, these characteristics make it unlikely that a single global control variable could adequately represent the novel entities boundary. Instead, operationalisation will likely require a suite of complementary indicators spanning the causal chain from drivers and pressures to environmental states, and impacts, while remaining scalable across spatial and temporal dimensions.

The workshop was designed as a consultative co-creation phase within a well-established scientific trajectory. This trajectory begins with the original planetary boundaries framework (Rockström et al., 2009a, 2009b), followed by work exploring conditions under which novel entities may threaten Earth-system functioning (Persson et al. 2013, MacLeod et al. 2014, Diamond et al., 2015). It then progresses

to the weight-of-evidence assessment, concluding that the safe operating space has been exceeded (Persson et al., 2022; Richardson et al., 2023). Most recently, Smit et al. (2026) propose a framework that introduces an action-oriented approach to operationalisation. The workshop objectives were to:

- Strengthen understanding of the planetary boundary for novel entities;
- Enhance industry engagement in planetary boundary research;
- Explore the relationship between a planetary boundary for novel entities and 'zero pollution' goals;
- Discuss opportunities to advance the planetary boundary for novel entities towards practical, safe, and just boundaries with actionable control variables;
- Identify metrics, tools, data, and key performance indicators (KPIs) to assess the state of anthropogenic stress relative to the planetary boundary; and
- Define pathways with clear priorities and next steps to further operationalise safe and just boundaries across short-, mid-, and long-term horizons.

2. Workshop proceedings

The workshop was structured over two days. Day 1 addressed the conceptual ground including the scientific basis of the boundary, the safe-and-just framing, the global policy architecture, the justice imperative, and existing reporting structures. Day 2 addressed methods and action including chemical footprint methodology, priority setting and governance, machine learning for data-gap closure, industry progress, and a sector-specific case, followed by structured breakout sessions whose outputs are analysed in the Breakout analysis of this report. The summaries below are organised thematically rather than strictly chronologically.

2.1. Status of the planetary boundary framework for novel entities

Matthew MacLeod *Stockholm University*

"Status of the Planetary Boundary for Novel Entities"

Matthew MacLeod's presentation emphasised that the Planetary Boundary for Novel Entities (PB-NE) is fundamentally about confronting ignorance. Chemical pollution is already part of the planetary boundaries framework, but the challenge is that many chemical-related planetary risks may not yet be recognised, measured, or understood. The presentation argued that the greatest concern is not only known chemical hazards, but unknown planetary boundary threats: cases where a chemical or mixture disrupts a vital Earth-system process, the effect is discovered only when it has already become a planetary-scale problem, and the damage cannot easily be reversed. Thus, the presentation made an important conceptual contribution by clarifying why the PB-NE is different from many other planetary

boundaries. Novel entities are not only pollutants with measurable local effects; like other boundaries they can also create hidden, delayed, or irreversible disruptions to Earth-system functioning. This requires a framework that looks beyond conventional risk assessment.

A key message was that traditional chemical hazard criteria such as persistence, bioaccumulation, toxicity, and long-range transport potential are useful but insufficient for identifying unknown planetary boundary threats. They provide partial information about risks, but they do not fully address ignorance, delayed discovery, irreversibility, or systemic Earth-scale impacts. Therefore, the current PB-NE framework remains precautionary because it must account for risks that cannot yet be confidently identified or quantified while the impacts can be severe. MacLeod highlighted that the combination of extensive chemical diversity and significant uncertainty about impacts distinguishes this boundary and makes it difficult to define a single control variable.

For science, research must improve understanding of how chemicals and mixtures can affect Earth-system processes, including biodiversity, climate-related processes, biogeochemical cycles, ecosystem resilience, and long-term planetary stability. Scientific work must also develop better methods for identifying early-warning signals, assessing irreversibility, and detecting risks before they become global-scale problems. MacLeod proposed three conditions for identifying unknown planetary boundary threats: disruption of a vital Earth-system process, late discovery at planetary scale, and low reversibility.

For policy, the message is that waiting for full proof may be inappropriate where impacts could be serious, global, and irreversible. The PB-NE requires precautionary governance that can act under conditions of uncertainty and ignorance. Policy frameworks should therefore strengthen pre-market assessment, monitoring, transparency, restrictions on poorly characterised persistent substances, and global cooperation on chemicals management. The presentation supports a more preventive policy approach rather than relying only on damage control after impacts become visible.

For industry, the presentation implies that compliance with existing hazard criteria may not be sufficient to demonstrate alignment with a safe operating space. Companies may need to assess products and portfolios not only for known hazard, exposure, and risk, but also for persistence, reversibility, global dispersion, mixture effects, and uncertainty. Industry has an important role in generating data, improving transparency, reducing emissions of poorly understood substances, and designing chemicals and materials that are safer by design.

Overall, the presentation positioned the PB-NE as a boundary designed to deal with scientific ignorance, not only known pollution. Its central contribution is to explain why precaution is scientifically justified when novel entities may create delayed, irreversible, and planetary-scale effects that conventional chemical assessment may fail to detect in time.

Annika Jahnke *Helmholtz Centre for Environmental Research (UFZ)*

"Planetary Boundary for Novel Entities: Time for a Reboot"

Reporting the main outcome of the UFZ Planetary Solutions expert workshop (conducted in November 2025 and reported in Jahnke et al., 2026), Jahnke argued that the boundary requires a conceptual and operational "reboot." The current quantitative boundary of zero (Richardson et al., 2023) is scientifically precautionary, but difficult to apply in practice because modern societies rely on services provided by many chemicals, materials, and technologies. The presentation therefore proposed moving from pure precaution towards operational precaution: a workable, non-zero space of uncertainty that can guide decision-making while still protecting Earth-system resilience. An important aspect is that the level of precaution should be adjusted to how well or poorly characterised a novel entity type is.

The authors of the related study suggest using the subtitle "chemicals and materials" to allow for more transparent communication (Jahnke et al. 2026). The key contribution of this presentation was to reframe the boundary as a dynamic and measurable system and to emphasise the need for complementary control variables covering pressure, state, and impact. This approach would allow the boundary to account for the diversity of novel entities, their interactions with other planetary boundaries, and varying levels of uncertainty. On closing data gaps, Jahnke pointed to the planned EU Common Data Platform on Chemicals, human biomonitoring as an indicator of exposure-related stress on the biosphere, and a toolkit of low-cost standardised sampling, effect-based methods, remote sensing, and AI, stressing that the regions with the highest pollution burdens often have the weakest monitoring capacity. The key take-home message was that the PB-NE framework must become operational, measurable, and useful for governance:

- Use complementary, multi-layer control variables spanning pressure, state, and impact, rather than a single metric.
- Refine scope: include anthropogenically mobilised elements as drivers of toxic effects; consider engineered biological systems under Biosphere Integrity.
- Treat the boundary as a dynamic, measurable system useful for governance, and recognise regulatory success stories as models of protective, operational governance that should be extended for more types of novel entities and better global coverage.
- Invest in monitoring capacity where pollution burdens are the highest, since these regions can be the ones that are least monitored.

2.2. Global and regional policy architecture

Kay Williams *United Nations Environment Programme (UNEP)*

"Establishing Indicators under the Global Framework on Chemicals"

Williams presented the architecture of the Global Framework on Chemicals (GFC), adopted in 2023, as a key international governance platform for translating ambition into measurable action, comprising five strategic objectives and 28 targets for the safe and sustainable management of chemicals and waste to

2030 and beyond. The presentation emphasised that chemicals and waste pollution continue to pose growing risks to human health, ecosystems, and economic development, and that progress depends on clear indicators, reporting mechanisms, and implementation support.

The contribution to PB-NE was the link between planetary boundary thinking and global chemicals governance. The GFC offers a structure through which countries, sectors, and stakeholders can align around measurable objectives, capacity building, financing, and partnerships. The take-home message was that the planetary boundary concept will only influence real-world outcomes if it is connected to global implementation frameworks and measurable progress indicators.

UNEP/GFC is a primary alignment stakeholder, and the GFC's first International Conference is a key window for the workshop's framework outputs.

Julien Fabre *European Commission, DG Environment (Unit ENV.C4, Safe and Sustainable Chemicals; Directorate for Zero Pollution, Water Resilience & Green Urban Transition)*

"EU pollution monitoring"

Fabre presented the EU Chemicals Indicator Framework, developed under the Chemicals Strategy for Sustainability. The framework is designed to monitor drivers and impacts of chemical pollution and to assess the effectiveness of chemicals legislation. Led by DG ENV with EEA and ECHA as technical co-leads, the framework comprises 25 indicators (quantitative variables tracking EU-level trends) and 22 signals (more limited in spatial or temporal coverage), organised across the life cycle from manufacturing, use in production, product use, to waste treatment, and across three tiers: "safe and sustainable chemicals," "minimise and control the risks," and "eliminate and remediate chemical pollution."

On status, the framework indicates that the transition to safer and more sustainable chemicals is progressing in some areas and only beginning in others; that action by authorities and industry has helped minimise and control risks from several hazardous chemical groups; and that there is little evidence of progress in eliminating substances of concern from waste and secondary materials, even though emissions of certain chemicals to air and water have fallen following EU regulation. Human biomonitoring was highlighted as a means of understanding exposure from multiple sources. Fabre connected this monitoring infrastructure to the Zero Pollution Action Plan (2050 vision, 2030 targets), noting the second Zero Pollution Monitoring & Outlook (March 2025) and the framework's support by the 'One Substance One Assessment' package and the planned Common Data Platform on Chemicals, with EEA exploring new indicators including an aggregated, territory-based risk indicator.

The contribution to PB-NE was practical and policy-oriented. The presentation showed how indicator systems can make chemical pollution visible, track trends, and identify whether policy measures are reducing harm. The take-home message was that monitoring infrastructure is essential for

operationalising planetary boundaries, because boundaries cannot guide governance unless changes in pressure, exposure, and impact can be measured over time.

Kristina Flexman *WSP*

"Study on planetary boundaries for chemical pollution for the European Commission"

Flexman presented the draft findings of a European Commission study examining planetary boundaries for chemical pollution. The study sought to advance scientific understanding of whether chemical pollution has exceeded a safe operating space for humanity and to identify approaches for future assessments and directly addressed challenges with the current PB-NE definition. Two objectives were highlighted: developing methods to quantitatively define planetary boundaries for chemical pollution and conducting an interim assessment using currently available evidence.

Four potential approaches for future assessments were presented. These included (1) a biodiversity-based approach linking chemical impacts to Earth system functioning, (2) an environmental risk threshold exceedance approach based on NE monitoring data exceeding accepted risk levels, (3) an ecotoxic pressure approach that uses ecotoxicity indicators and exposure estimates, and (4) a Life Cycle Assessment (LCA) or Absolute Environmental Sustainability Assessment (AESA) approach that evaluates broader environmental impacts associated with chemical production. Existing applications of the ecotoxic pressure approach suggest substantial exceedance of proposed freshwater ecotoxicity boundaries, while LCA studies indicate that many chemical products contribute to exceeding one or more planetary boundaries.

Evidence reviewed showed that chemical pollution is widespread worldwide, with more than 350,000 chemicals and chemical mixtures in commerce and environmental contamination detected across multiple regions and ecosystems. Global assessments have also identified ecological risks associated with pesticides, pharmaceuticals, and other contaminants. As such, the study concluded that chemical pollution is likely exceeding planetary boundaries and constitutes a significant environmental threat. However, substantial uncertainties remain regarding the magnitude of exceedance and the resulting impacts on Earth system functioning. The presentation therefore emphasised the need for further methodological development, improved monitoring, and better data to support robust future assessments of planetary boundaries for chemical pollution. These recommendations were used as direct input for further discussions during the breakout sessions on a suitable PB-NE definition and further development needs for metrics and measurability of the PB-NE.

Michelle Bloor *University of Glasgow; SETAC CheM Panel*

"Priority setting for chemicals, waste and pollution: a risk-based strategy for environmental and human health protection"

Bloor connected the methodological work to the emerging governance architecture. The Intergovernmental Science-Policy Panel on Chemicals, Waste and Pollution (ISP-CWP) was formally established in mid-2025, joining the Intergovernmental Panel on Climate Change (IPCC) and Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) as the third Earth-system science–policy interface. Bloor presented an iterated, DPSIR-anchored conceptual framework for risk-based prioritisation of chemicals, waste, and pollution, developed under the Society of Environmental Toxicology And Chemistry (SETAC) CheM Panel and published in 2025 (Bloor et al., 2025). Risk-based prioritisation, anchored in a DPSIR causal chain, offers a practical way to decide where action should be focused first across legacy and emerging chemical issues. The presentation recognised that chemical pollution and waste are complex global challenges involving many substances, exposure pathways, ecosystems, human systems, and socioeconomic drivers, and argued that limited resources must be directed towards the highest-priority risks. Bloor stressed that durable progress requires binding global commitments and accountability mechanisms, not voluntary measures alone.

2.3. Methodology: chemical footprints and the feasibility proximity trade-off

Peter Fantke *Goethe University Frankfurt; University of South Africa; substitute ApS*

"Chemical footprint methodologies"

Fantke presented methodological core aspects that render the anchor framework operable. The chemical footprint was introduced as a tool for quantifying the potential environmental impact associated with chemical usage and related emissions, which is defined to align with the carbon footprint (ISO 14067) and water footprint (ISO 14046) and to follow the overall life-cycle assessment methodology (ISO 14040/14044). A chemical footprint is cumulative from sources across all life cycle stages to impact on human health and ecosystem quality, and supports aggregation across chemicals, processes and life-cycle stages. Mapping the chemical footprint elements onto the DPSIR chain (driver → pressure → state → impact → response), Fantke presented examples of available methods and their limitations: chemical usage data (e.g. spatialised pesticide use, available for few countries and often proprietary for industrial chemicals); chemical emission data via material-flow analysis (available for a few hundred chemicals); and impact-potential quantification methods for aquatic ecotoxicity and human toxicity built on the open UNEP/SETAC USEtox reference model, https://usetox.org (providing impact characterisation factors for >10,000 chemicals and 500 products). The presentation highlights that while comprehensive impact-based assessment is scientifically desirable, practical implementation currently relies on a spectrum of approaches ranging from readily available pressure indicators (e.g., production volumes and emissions) to more complex and less feasible impact indicators (e.g., biodiversity damage and ecosystem services loss) that require diverse substance-, product- and/or ecosystem-specific inputs to model impacts.

Overall, the presentation positions chemical footprint assessments as one promising tool for linking the PB-NE to measurable, actionable, and decision-relevant indicators. While substantial methodological and data challenges remain, advances in digitalisation, toxicity modelling, biodiversity assessment, and environmental benchmarking are making implementation increasingly feasible.

Kerstin von Borries *Technical University of Denmark (DTU)*

"Can Machine Learning Guide Us to a Safe Operating Space for Chemical Impacts?"

Von Borries addressed the issue of data scarcity as a key bottleneck for assessing the Planetary Boundary for Novel Entities. Based on a report by the European Environment Agency (EEA), out of > 100,000 chemicals in commerce, only around 500 are extensively characterised with respect to hazard and exposure, while up to 10,000 are partially characterised. Traditional data generation cannot scale to the pace and volume required for comprehensive assessment of both existing and newly developed chemicals. Machine learning (ML) offers potential to help close this gap; however, its predictive reliability is constrained to chemicals that are sufficiently similar to those represented in existing datasets. By defining the current space of marketed chemicals as a reference, the presentation highlighted that ML could "reliably" expand data availability to approximately 46% of marketed chemicals, leaving more than half of chemical space unaddressed. To overcome this limitation, Von Borries proposed the development of uncertainty-aware ML approaches that provide calibrated confidence intervals alongside predictions. This enables decision-making under explicit consideration of uncertainty, for example by assigning conservative first estimates or propagating uncertainty through assessment frameworks. By developing such approaches across input properties needed to model chemical impacts, they enable generating system-level insights, quantifying both the magnitude and likelihood of potential toxicity impacts across many chemicals under current knowledge constraints with a quantified (non-zero) risk of overlooking chemical impacts explicitly. In addition, identifying uncertainty hotspots can guide targeted data generation and model development to improve performance for specific chemical classes. This supports more strategic use of limited testing capacity by prioritising chemicals associated with high uncertainty and/or potentially large impacts. This could improve resource efficiency both at the level of individual assessments (e.g. safe and sustainable by design or SSbD) and globally by increasing confident coverage of chemical space and continuously reducing uncertainty in chemical impact estimation, thereby strengthening confidence in assessments of novel entities.

2.4. Industry perspectives and existing infrastructure

Wibke Lölsberg *(BASF)*

"Planetary Boundaries for Novel Entities Existing metrics"

Lölsberg set out the reporting and assessment infrastructure already operating within a major chemical producer. A portfolio-steering classification sorts products by sustainability performance; product-carbon-footprint infrastructure has engaged several thousand suppliers and validated more than two thousand footprints covering a substantial share of upstream emissions; and the company participates in method development bridging life-cycle assessment and risk assessment, and in industry transparency initiatives on additives in commerce. Mandatory sustainability disclosure under the EU Corporate Sustainability Reporting Directive (ESRS E2, pollution prevention) provides annual figures on emissions to air and water and on tonnages of substances of very high concern entering the downstream value chain. The implication drawn for the workshop was that the reporting guardrails largely exist; what is missing is their alignment with planetary-boundary control variables — the central operationalisation gap identified by the anchor framework and reinforced across the breakouts.

Jo Lloyd *World Business Council for Sustainable Development (WBCSD)*

"Towards Planet Positive Chemicals"

Lloyd presented the WBCSD Chemical Transformation Roadmap, which sets out a vision for a just, net-zero, and nature-positive chemicals sector by 2050. The roadmap is built around systems-thinking and value-chain collaboration, spanning feedstocks, business models, end-of-life management, circularity, and regeneration. Rather than focusing only on reducing harm, it positions the chemical sector as an enabler of climate, nature, safety, and equity outcomes, illustrating how industry transformation can support a return to a safe operating space. The key messages are:

- Achieving planetary boundaries requires transformation across entire value chains, not isolated improvements within individual companies.
- A systems-thinking, collaboration-based roadmap can reframe the chemical sector as an enabler of climate, nature, safety, and equity outcomes, not only a source of harm to be reduced.
- Feedstocks, business models, circularity, end-of-life, and regeneration are the key levers for a just, net-zero, nature-positive sector by 2050.

Eric De Deckere *Cefic (European Chemical Industry Council)*

"Red lines in the context of Planetary Boundary for novel entities"

De Deckere presented the chemical industry perspective on "red lines" within the planetary boundaries framework. The concept of "red lines" refers to clear, measurable limits that can guide decision making and indicate when human activities are approaching or exceeding the safe operating space defined by the planetary boundaries framework. Setting the scene with the 2025 status (seven of nine boundaries breached) and the framework's evolution since 2009, he linked planetary boundaries to sustainable development, the UN SDGs (United Nations Sustainable Development Goals), and Cefic's four key sustainability areas (low-carbon transition, resource efficiency, circular economy, and preventing harm across the life cycle). Mapping the industry's impact across boundaries, he showed that for some areas

including ocean acidification, freshwater change, climate change, "red lines" already exist, grounded in environmental impact assessment, permitting, EU climate law, and sector or company commitments, supported by measurable downward emission trends. The challenge, he argued, lies in defining "red lines" for the boundaries not yet addressed by existing indicators, notably novel entities where the task is to weigh negative impacts against the positive contribution of chemicals (the "handprint").

De Deckere illustrated how the socio-economic dimension and the interactions between ecological and social elements (via the doughnut-economics lens) make the problem more complex and proposed integrating "red lines" into a Safe & Sustainable-by-Design approach that assesses both positive and negative impacts on material elements and strives for continuous improvement. He situated this within Cefic's Network of Experts on Planetary Boundaries, which conceptualises the framework as guidance for the sector's sustainability agenda and follows relevant global and regional developments.

Key messages are:

- Industry needs clear, science-based "red lines" and practical tools to assess both the positive and negative impacts of chemical innovation, operating within an ecological ceiling.
- For some boundaries (climate, ocean acidification, freshwater) workable "red lines" already exist via regulation, permitting, and commitments; the hard case is novel entities, where they do not.
- The positive contribution of chemicals (the "handprint") and the socio-economic dimension make defining novel entity "red lines" genuinely complex.
- Safe & Sustainable-by-Design, linked to the planetary boundaries and doughnut models, offers a practical vehicle for continuous improvement.

Alistair Boxall *University of York*

"Pharmaceuticals and Planetary Boundaries: An Environmentally Safe and Just Pharmacy"

Boxall applied the boundary discussion to pharmaceuticals as a sector-specific case. Active pharmaceutical ingredients (APIs) reach the environment via multiple routes including manufacturing, human and veterinary use, and disposal with documented consequences spanning ecology (e.g. the diclofenac-driven vulture collapse in South Asia; endocrine effects in fish), human health (APIs detected in drinking water and taken up by crops), and antimicrobial resistance (a recognised driver of an estimated 1.27 million deaths in 2019). A global reconnaissance of over a thousand river sites across 104 countries found most monitored APIs present, with a quarter of sites exceeding safe predicted-no-effect concentrations. Because pharmaceuticals deliver major societal benefits, Boxall framed the goal as a safe and just solution rather than simple restriction.

He presented a definition and framework for an Environmentally Safe and Just Pharmacy (Boxall et al., 2026), structured around four overarching criteria (sustainable design and distribution; effective regulation and monitoring; minimising harm to ecosystems and human health; and societally just controls) and twelve sub-criteria spanning the full life cycle. An expert assessment against these criteria

concluded that current pharmaceutical development, manufacturing, use, and disposal are at best partially aligned, and in several respects not aligned, with the principles of a safe and just pharmacy, actively contributing to transgression of the PB-NE. A roadmap to 2050 for academia (developed in part at a Bellagio residency) sets out nine life cycle solutions and five crosscutting enabling actions sequenced as funding → research and data → governance → scale-up → education.

Key messages are:

- Pharmaceuticals are a clear example of how essential, beneficial products can still drive transgression of the PB-NE unless the full life cycle is redesigned.
- A single quantitative threshold for APIs is impractical; a structured framework of 4 criteria and 12 sub-criteria across the life cycle is more workable and is transferable to other classes of novel entities.
- Current practice is only partially or non-aligned with a safe and just pharmacy; justice (access, cultural equity) is the hardest dimension to operationalise and the most data-poor, especially in low- and middle-income countries.
- Future work should quantify exceedance (e.g. share of sites exceeding safe thresholds; share of countries monitored) and sequence solutions through funding, research, governance, scale-up, and education.

2.5. The safe-and-just framing and the justice imperative

Zhanyun Wang *University of Southern Denmark*

"Towards Safe and Just Planetary Boundaries for Novel Entities"

Wang expanded the discussion from a "safe" planetary boundary that focus on Earth system only to "safe and just" boundaries that additionally include maximum pressure to minimise significant harm to people, arguing that maintaining Earth-system stability is not sufficient if harms are distributed unequally across populations, generations, species, or regions. A just boundary must therefore consider who benefits from chemicals and who carries the risks. Wang presented major challenges in assessing and addressing novel entities, highlighting the need for comprehensively considering known knowns, unknown knowns, known unknowns, and unknown unknowns. Wang also introduced the concept of lock-ins as complex social, economic, technological and political interactions that perpetuate unsafe chemical use long after harms are recognised. Then, Wang presented a conceptual framework for assessing and addressing safe and just boundaries for novel entities, including the following three pillars, together with an overview of key activities under the Earth Commission 2.0: i) synthesising known global and regional impacts of novel entities through literature review, database collation, and case studies; ii) horizon scanning of overlooked, emerging and potential novel entities/issues that may

transgress boundaries; and iii) identifying transformation pathways towards sustainable production, consumption and disposal systems of novel entities (Diamond et al., 2026).

Key messages are:

- A "safe" boundary that focuses on the stability of Earth system functioning may still be insufficient if it permits disproportionate harm to vulnerable and at-risk communities and future generations.
- Justice must be a design principle from the start spanning interspecies, intragenerational, and intergenerational dimensions, not a later overlay.
- While understanding and assessing the planetary boundary for novel entities is essential, parallel efforts are needed to identify and implement transformative pathways towards a sustainable future.
- Lock-ins perpetuate the continued use of harmful chemicals and materials through technological, economic, regulatory, and behavioural dependencies, making their identification and removal an important component of pathways towards a safe operating space for novel entities.

Sally Beckenham *University of York*

"Just earth system boundaries for novel entities"

Beckenham translated the abstract "safe and just" principle into three concrete frontier challenges, each with associated implications and actions. Firstly, justice under conditions of uncertainty follows from the defining feature of novel entities, that harm is frequently detected only after widespread exposure, which produces injustice both in the distribution of risk and in the very production of uncertainty; the indicated responses include limiting non-essential uses, reducing reliance on industry-generated data, and shifting the burden of proof towards demonstration of safety before release. Secondly, justice across persistent and irreversible exposures, follows from bioaccumulation and the absence of regulation for persistence, generating intergenerational and corrective injustice; responses include phase-out of highly persistent entities, design-for-degradation requirements, long-term monitoring mandates, and institutional representation of future interests. Thirdly, justice in the face of uneven visibility recognises that the invisibility of exposures is produced rather than accidental, a phenomenon Beckenham characterised as toxic colonialism, and calls for expanded monitoring, open-access contaminant databases, research led by affected regions, and participatory approaches embedded across the life cycle. The five canonical forms of justice including distributive, procedural, recognition, epistemic, and corrective serve as the analytical framework underpinning the workshop's recommendations.

3. Breakout analysis

A first and clarifying conclusion was that the workshop should not attempt to redefine the Stockholm Resilience Centre's Planetary Boundary for Novel Entities itself, but operationalise the concept by identifying the criteria, control variables and indicators that allow its objectives to be met. Within that

remit, several positions that might appear as live disagreements were in fact settled in the breakout discussions.

A single boundary expressed through multi-aspect aggregation. While the diversity of novel entities makes a single control variable seemingly scientifically untenable, this constraint can be reconciled with the need for concise operational indicators. Several participants supported a multi-aspect boundary, aggregated via a transparent and adjustable weighting scheme connecting variables. The planetary boundaries framework requires a limited number of clear indicators that can be communicated, monitored, and reported.

A range, not a line. The safe operating space should be presented as a range. Well-characterised substances (knowns) inform a lower-bound impact boundary, while unknowns define an extrapolated upper zone of concern. This communicates both a minimum and a conservative estimate of exceedance and embeds precaution without sacrificing operability. The tension between risk-based assessment, in which industry has substantial investment, and precaution under uncertainty, urged by the justice frontier, can be sequenced rather than arbitrated. A risk-based approach is defensible for chemicals within the validated applicability domain of existing models and approaches, the minority of marketed substances for which characterisation is adequate, while a precautionary approach governs the remainder until targeted data generation or uncertainty-aware prediction narrows the gap.

Absolute versus relative limit. The two framings are not mutually exclusive within the Plan–Do–Check-Act (PDCA) logic, which is designed to drive directional improvement (relative) towards a quantified target (absolute). Given present uncertainties, a relative or directional limit showing whether pressures are moving towards or away from a safe operating space is more feasible in the near term than an absolute ceiling. The two framings are complementary within a PDCA logic, which drives directional improvement towards a quantified target as data mature.

Impact-proximal where possible; pressure and state proxies where necessary. Impact-based control variables are preferred in principle, but where impact data are lacking, they must be complemented by more feasible pressure- and state-level proxies. For practicality, ecotoxicity pressure can serve as a proxy for biodiversity impact with persistent, bioaccumulative, toxic (PBT) substances (present as legacy contamination) as an exception, for which pressure (emission) and state (distribution) trends suffice.

DPSIR as the organising spine. The Driver-Pressure-State-Impact-Response framework was adopted to organise indicators systematically and link them to decision making, so that local and regional pressures which aggregate into global effects can be tracked across air, water, soil, sediment, and the biosphere.

Justice as a design requirement. Environmental justice was treated as a core design dimension rather than a later overlay: prioritising knowledge of and protection for Indigenous peoples, vulnerable

communities, and key Earth-systems (for example the Amazon and polar regions), and embedding justice in the design of indicators, monitoring and governance responses.

In conclusion, the complexity of many interlinked NE and environmental factors (and uncertainties) means no single existing metric - whether based on hazard, exposure, risk, persistence, or toxicity - can serve as a standalone solution. Proxies for data gaps and a multi-pronged approach are needed to combine and weigh existing tools and data with the latest research. A dashboard was suggested as an operational tool for managing and maintaining PB-NE information.

Table 1. Output of the metrics inventory and DPSIR-mapping exercise.

DPSIR stage	Candidate	Basis
Driver (underlying societal needs, consumption patterns and economic activities)	-	-
Pressure (production and use over entire life cycle)	Extraction and global production, use, and waste characterised by NE volume produced, volume emitted incl. emission route, NE diversity, persistence, and mobility	Highest feasibility (industry datasets); weak link to impact; does not capture legacy pollution
State (concentrations in the environment)	Current NE levels in the environment (measured or modelled). Global accumulation in remote regions and long-term reservoirs; pollutant mass in soil, water, sediment, air; concentration in sentinel species	Captures NE distribution, including legacy NE and (re)distribution; retrospective; limited preventive potential for persistent pollution
Impact (risk exceedance)	Risk-threshold exceedance: proportion of environmental entity (e.g. water bodies) where a level of concern is exceeded	Tractable for data-rich regions and known chemicals; monitoring bias towards known substances and effects; bias towards NE with established/ regulatory levels of concern, and freshwater compartment
Impact (ecotoxic pressure)	Comparative toxic units (CTU) and potentially affected fraction (PAF) of species, per unit mass emitted over time and volume	Near-term anchor candidate for the aquatic compartment; usable proxy for biodiversity impact (PBTs excepted)
Impact (biodiversity damage)	Biodiversity-based assessment as a proxy for Earth-system functioning (biodiversity as a proxy of planetary health; ecotoxicity as a proxy for	Most impact-proximal; lowest current feasibility (ecological risk assessment, biomonitoring); long-term development target

	biodiversity, epidemiological data for human health)	
Response (action to prevent, mitigate, correct or compensate environmental or health impact)	-	-

NE environmental (chemical- and effect based monitoring) and human biomonitoring are the routes to understanding real state, impact, and response trends, and to verifying model-based predictions; potential hotspots (manufacturing and release sites, user population centres), sensitive or vulnerable biosphere, and key Earth-systems may be targets for monitoring.

The boundary should rest on a minimum common denominator usable globally, with explicit attention to a level playing field across regions on emissions, mitigation, resources, and infrastructure, for which the Global Framework on Chemicals is a natural vehicle.

Participants identified the unpredictable, late-emerging character of novel entity-related effects (i.e., harm frequently detected only after widespread exposure) as an important distinction between this boundary and the others. Addressing this aspect will require advances in early-warning monitoring, effect-based methods, and precautionary treatment of poorly characterised entities, and should be an explicit research priority.

A consistent message emerged across all breakout groups: start simple with what is already available, avoid “paralysis by analysis”, rely on pragmatic proxies, and introduce additional complexity such as mixtures, justice dimensions, biodiversity, and ecosystem services after chemical footprinting approaches are further developed. Cross-cutting conclusions were:

- A single one-dimensional boundary may not be operationally sufficient; however, practical application necessitates aggregating a multi-aspect construct into overarching control variables.
- While impact-proximal metrics are conceptually preferable, they may be complemented by more feasible and accessible pressure- and state-level proxies where impact data are limited.
- Human biomonitoring and environmental monitoring are essential for characterising Earth system state and impact, and for validating model outputs.
- The framework should be deliberately simple at the outset, with added nuance introduced progressively as the evidence base strengthens.

4. Consolidated workstreams and recommendations

The candidate actions raised during the workshop cluster into six coherent workstreams (WS).

4.1. WS-1 Boundary definition and conceptual architecture

R1. Adopt a two-tier boundary architecture: a comprehensive DPSIR-aligned indicator dashboard, aggregated e.g. through chemical footprint approaches into impact-proximal overarching control variables. Define and document the aggregation and weighting scheme, including the means of adjusting weights.

R2. Express the boundary as a range, with a lower bound derived from well-characterised substances (knowns) and an extrapolated upper bound for unknowns, so that the boundary communicates both a minimum and a conservative estimate of exceedance.

R3. Agree on a common working definition of pollution for the purpose of the boundary and pragmatically delineate no more than approximately five novel-entity subcategories by, e.g., use and chemical type.

R4. State explicitly the intended purpose of the boundary as a directional reference for governance and resolve this challenge early, since downstream metric and threshold choices depend on it.

4.2. WS-2 Control variables and the measurement system

R5. Adopt (eco)toxic pressure (comparative toxic units; potentially affected fraction of species) as an anchor control variable for the aquatic compartment, in data-rich regions, while documenting its uncertainty and scope limitations transparently.

R6. Complement toxic pressure with an emission-of-persistent-materials metric to capture substances of concern with high persistence, and with an equity-in-exposure metric developed via biomonitoring and exposure surveys, so that persistence and justice are built into the measurement system from the outset.

R7. Keep the overarching control variable set deliberately small. Two to four indicators spanning pressure, state, and impact, consistent with the workshop's explicit preference for simplicity at the outset.

R8. Prioritise environmental and human biomonitoring of key drivers of impact, both to characterise state directly and to verify model-based predictions, among others, particularly for persistent substances, with continued global accumulation and potential exposure long after use has stopped. Additionally, use hotspot identification (manufacturing and release sites, population centres) to target monitoring efficiently.

4.3. WS-3 Data infrastructure, machine learning, and uncertainty

R9. Develop and apply uncertainty-aware in silico approaches to fill gaps along the DPSIR chain, reporting quantified confidence intervals, and using uncertainty hotspots to direct targeted data generation, making smarter use of limited testing capacity.

R10. Establish a shared evidence base by aggregating scientific and grey-literature data, with auditable provenance and visualisation across defined chemical domains based on structure, use, hazard, and exposure characteristics, and resolve access constraints (including bulk-access and confidential-business-information barriers) as an explicit task.
R11. Adopt computational approaches under explicit justice safeguards, accounting for the resource footprint of those approaches.

4.4. WS-4 Justice and equity

R12. Map the justice implications of chemical emissions, and candidate mitigations measures as an early deliverable, considering both the distribution of environmental burdens and the societal benefits enabled by chemicals and materials. Equity considerations should be embedded within the measurement system (R6) rather than treated as a later overlay (Diamond el al., 2026).

R13. Prioritise data and methods for the Global South: assess the transferability of data-rich-region (for example EU) methods, derive transferable approaches to fill gaps, and foster a level field across regions on emissions, mitigation, resources, and infrastructure.

R14. Embed procedural and epistemic justice through participatory approaches across the novel-entity life cycle, the inclusion of local and Indigenous knowledge, and open-access contaminant databases, advancing methodologies to better account for exposure affecting marginalised groups.

4.5. WS-5 Governance, alignment, and stakeholder engagement

R15. Map existing policy targets, indicators, and reporting metrics onto the DPSIR causal chain, making explicit for each how it links to the impact-oriented control variables, taking into account the GFC strategic objectives and targets. Provide clear guidance on management options, including mitigation strategies, innovation pathways, and circularity.

R16. Align industry sustainability reporting (including Corporate Sustainability Reporting Directive (CSRD) / European Sustainability Reporting Standard E2 (ESRS E2) and nature-related disclosure such as Taskforce on Nature-related Financial Disclosures (TNFD)) with viable, market-supportive innovation pathways and inputs used for chemical footprinting and safe-and-sustainable-by-design assessment, so that company performance can be related to planetary boundary performance.

R17. Establish and maintain active channels with key external bodies, including UNEP/GFC (towards the first International Conference), the ISP-CWP, Potsdam Institute for Climate Impact Research (PIK)[1], the Stockholm Resilience Centre, and Earth Commission 2.0 to support engagement with evolving planetary boundary assessments and related policy processes.

[1] https://www.pik-potsdam.de/en/home

4.6. WS-6 Transition pathways and implementation

R18 Based on the common working definition establish general, high-level guidance on effective novel entities management options and innovation pathways for industry and society (to be refined based on the outcomes and results of the working streams further below) including comparative assessment of management options, innovation pathways, trade-offs, leakage risks, scalability, regional applicability and environmental performance per unit of financial investment.

R19. Support product improvements and game-changer innovation through regulatory and policy transition pathways, incentivising substitution with better product ratings and linking improved profiles to credible green claims; advance the essential-use concept, chemical simplification, and standardisation.

R20. Identify non-regrettable substitutes, both chemical and non-chemical, progress along currently existing and adapt for future more sustainable production and consumption patterns, while addressing the structural reasons current risk management can fail to protect human health and the environment, including the legal but harmful export of waste to low- and middle-income countries.

R21. Mainstream the boundary into economic and financial signals over the long term, connecting it to IPBES and nature-positive initiatives, and encouraging insurers and capital providers to take planetary-boundary considerations into account and sustain continuous improvement through iterated Plan-Do-Check-Act cycles.

5. A phased roadmap

The roadmap below consolidates the workshop's actions across three time horizons, mapped to the six workstreams and to indicative owners. The horizons follow the breakout register: short term (one to two years), the runway into the GFC first International Conference and the establishment of the standing task force; medium term (three to five years), the build-out of data infrastructure, regional refinement, and the transgression test; and long term (five years and beyond), structural transformation towards substitution and the maturation of the framework into a continuous-improvement habit.

WORK STREAM	Priority action	Indicative owner(s)	Links / dependencies
Short term (1–2 years)			
WS-5	Form the standing ECETOC Task Force; publish the workshop synthesis and a framework draft for open consultation	ECETOC / Task Force	R17; basis for all subsequent work



WS-1	Map a first DPSIR-based boundary framework and populate actionable control variables and indicators	Academia / industry (Task Force)	R1; conditional on data and stakeholder agreement
WS-1	Agree on pollution definition and ≤ 5 novel-entity subcategories	Academia / regulators / industry / civil society	R3, R4
WS-2	Define and pilot (eco)toxic pressure as anchor metric in a local-to-global case study with explicit gap assessment	Academia / industry	R5; USEtox; data-rich regions first
WS-2	Define control variables that encourage reporting of production volumes, emissions, and composition	Industry / regulators	R7; aligns with CSRD
WS-3	Assess in silico capabilities to fill DPSIR-chain gaps; begin uncertainty-aware predictions	Academia	R9; von Borries approach
WS-3	Aggregate existing scientific and grey-literature evidence into a shared, auditable base	Academia / consultancy	R10; resolve access barriers
WS-4	Map justice implications of emissions and mitigations; scope a Global-South data pipeline	Academia / civil society	R13, R14
WS-5	Align assessment with GFC targets; open channels to UNEP, PIK, SRC, Earth Commission 2.0, etc.	Task Force	R16, R17; data to next Health Check
WS-6	Learn from the pharmaceutical safe-and-just framework for transposition to other spaces	Academia	Boxall et al. 2026 use case;
WS-1	Socialise the novel entities boundary across the broad community	All	R17; parity with climate agenda
Medium term (3–5 years) infrastructure, refinement, and the transgression test			
WS-2	Refine the boundary value/range to local conditions; track environment, health, justice, and economics in parallel	Academia / regulators	R2, R6
WS-3	Target data generation and model improvement in high-uncertainty domains; couple extrapolation with experimental testing to verify	Academia/ industry	R9; uncertainty hotspots
WS-2	Identify hotspots and drivers; prioritise by tonnage with respect to planetary relevance	Academia / industry	R8
WS-3	Pilot chemical footprints for general chemicals using regulatory databases (e.g. REACH) as a case study	Academia / regulators	R10; ECHA engagement
WS-5	Improve data coverage and harmonise collection and analysis methods across frameworks and regions	All	R16, R17
WS-6	Develop regulatory transition pathways supporting product improvement and game-changer innovation	Regulators / industry	WS-6; pending industry inputs
WS-4	Foster a level field across regions on emissions, mitigation, resources, and infrastructure	GFC / regulators	R14
WS-1	Address the structural reasons risk management can fail to protect, including	Academia / regulators	R4; links safe and just spaces

	legal but harmful waste flows to low and middle-income countries (LMICs)		
Long term (5+ years) structural transformation and framework maturity			
WS-6	Identify non-regrettable substitutes; adapt sustainable production, mitigation and management options and current and future consumption patterns scenarios	Industry / academia / regulators	WS-6; essential-use concept
WS-6	Advance the essential-use concept, SSbD, chemical simplification, and standardisation	Regulators / industry	WS-6
WS-2	Advance mixture toxicity and multiple-stressor assessment; mature towards biodiversity-based pollution metrics	Academia	Table 1; long-term target
WS-4	Advance footprint methods to account for exposure and impacts on marginalised groups	Academia	R15
WS-5	Connect the novel-entities boundary to IPBES and Nature-Positive initiatives; mainstream PB into innovation pathways, finance and insurance	Task Force / regulators	cross-boundary integration
WS-6	Continuously improve data, regulation, and policy through iterated PDCA cycles	All	anchor framework engine

6. Governance and alignment

This report is intended as a working basis for a standing ECETOC Task Force and as a feeder document into a wider architecture of work now in motion.

Alignment: Four external destinations are structurally connected to the workshop's outputs, among others. The Global Framework on Chemicals provides strategic objectives and the indicator process, with its first International Conference as the immediate decision point at which the GFC outputs should be available. The Stockholm Resilience Centre maintains the planetary-boundary assessment and the Planetary Health Check, to which the workshop community has undertaken to communicate its activities and to channel data for an updated novel-entities assessment. Earth Commission 2.0 is continuing the development of safe and just boundaries, explicitly including the improvement of the novel-entities boundary and the setting of actionable transformation pathways.

Audience: The division of roles follows Plan-Do-Check-Act logic. At the level of an individual firm, a single organisation may execute the entire cycle to evaluate its own policies and measures. At sectoral and global scale, the roles divide: academia and civil-society organisations contribute to planning and checking, through boundary science and indicator development, among others; industry implements mitigating technologies and evaluates their effectiveness in the do-and-check-phases; and regulators

improve legal frameworks in the Plan-Do-Check-Act phases. The task force's coordinating function is to foster coherence across these actors and to sustain the external channels above.

ECETOC task force: An expression of interest in joining the ECETOC Task Force was registered during the breakout sessions.

7. Conclusions and way forward

The workshop confirmed both the difficulty and the tractability of operationalising the planetary boundary for novel entities. The difficulty is intrinsic: the category is irreducibly heterogeneous; its effects are frequently detected late and distributed unjustly, and the most impact-proximal metrics are the least feasible to compute at present. The tractability follows from accepting that a perfect single boundary may not be feasible in the near term. A more viable boundary may be achievable now through a two-tier architecture as a comprehensive DPSIR-aligned indicator dashboard aggregated e.g. through chemical footprint approaches, into impact-proximal control variables, with (eco)toxic pressure as a near-term anchor for the aquatic compartment, complemented by persistence-based and equity-based metrics, and with uncertainty-aware in silico approaches supporting to provide a quantified, system-level picture of transgression despite pervasive data gaps.

The workshop's distinctive contributions are threefold. Firstly, it grounded an abstract boundary in implementable management logic including DPSIR for interpretation, PDCA for iteration, chemical footprints for integration already familiar to the regulators and industry actors. Secondly, it treated justice as a design constraint rather than an afterthought, with concrete implications for the measurement system and the data infrastructure. Thirdly, it refrained from a rhetorical dispute about whether the boundary is transgressed into producing an empirical research programme to operationalise a planetary boundary framework.

The expected deliverables of the task force follow directly: a more viable planetary boundary concept; a prioritised measurement system; a data and infrastructure blueprint; a set of actionable transition and innovation pathways; and the structured roadmap with owners and timelines set out above.

Realising the full framework will take years and will not resolve every challenge easily; in the interim, the precautionary principle, existing data, and more distal proxies can drive progress. But the central conclusion of the workshop is firm: with aligned metrics and control variables that can be measured, compared, tracked, aggregated, and acted upon, the novel-entities boundary can become a practical instrument for guiding chemicals management within a safe and just operating space.



6-7 May 2026 | Hotel The Standard, Brussels

PLANETARY BOUNDARY FOR NOVEL ENTITIES

DEFINING A SAFE OPERATING SPACE FOR CHEMICALS WITH ACTIONABLE TARGETS TO PROGRESS A TRANSITION TO A SUSTAINABLE FUTURE

This workshop is part of ECETOC's 2026 NEXUS WEEK

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Representatives and experts from the OECD, UNEP and Member State Competent Authorities participated in the workshop in their individual capacities. Their participation does not imply any official endorsement of, or agreement with, the views, interpretations, conclusions or positions expressed during the workshop or reflected in this report. This workshop report is intended to accurately reflect the workshop discussions and conclusions, but it is noted that not all workshop participants provided written input to the workshop report.

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