ge^2p^2 global

governance, ethics, evidence, policy, practice

Public Consultations Watch :: Global Calls for Input/Public Comment/RFIs 22 May 2025 - Issue 31

GE2P2 Global is an integrated non-profit foundation and public benefit corporation formed to advance scientific rigor, ethical resilience, and integrity in research and evidence generation, informing responsible governance, policy, and practice.

In the context of this mission, GE2P2 Global monitors public consultations/calls for input/RFIs and similar opportunities across its focus areas of global health, human rights, humanitarian action, education/literacy, heritage, climate/environment, peace, and sustainable development.

Monitoring this span of sectors yields a broad variety of public comment opportunities, even though this modality is not employed in any uniform way across the UN system, multilateral agencies, INGOs, member states or their ministerial/regulatory bodies. As we are still exploring this monitoring approach and broadening the range of calls included, we stress that this is an indicative and not an exhaustive digest.

In parallel, GE2P2 Global is striving to respond to public consultation opportunities where the experience and expertise of members of our growing community of practice suggest that a meaningful contribution can be developed. The GE2P2 Global Foundation also functions as the secretariat for the Global Forum for Research Ethics and Integrity — a global group of individuals from over 30 countries who collaborate on analysis and action, including response to selected public consultations.

We welcome information about calls for public consultation – at global or country level – to help enrich this digest. Equally, individuals and organizations/institutions interested in collaborating on joint responses to any of the opportunities listed below are welcome to contact us [David R Curry, GE2P2 Global Foundation, david.r.curry@ge2p2global.org].

Acknowledgements: We appreciate the support of Foundation Senior Fellow Gerald Schatz, JD for his continuing support in helping identify calls included in this digest, and Associate Fellow Sedem Adiabu, MPH, for her critical role in the secretariat function which supports development of submissions to selected calls.

Digest content is organized in three sections:

- [1] Title and source of all calls organized by due date [p.2 ff]
- [2] All calls, listed with more comprehensive information [i.e., objective, scope] organized by due date under thematic areas: Biomedical Research; Environment/Climate; Human Rights+ [p.5 ff]
- [3] <u>Selected Supplementary Content</u> including Final, Published Guidances/Regulations/Laws Employing Calls for Public Consultation [p.15 ff]

We expect to add thematic areas as our digest evolves and becomes more comprehensive.

Call for Public Consultation: Title/Source/Sorted by Due Date

<u>Visiting Committee on Advanced Technology</u>

A Notice by the National Institute of Standards and Technology on 04/22/2025

Request to make oral comments are due no later than Tuesday, May 27, 2025, 5:00 p.m. Eastern Time. There is no specified date by which written comments must be submitted.

ICC Office of the Prosecutor launches public consultation on policy on cyber-enabled crimes under the Rome Statute

Statement 7 March 2025 Office of the Prosecutor Comments due by 30 May 2025.

<u>Climate Finance: Vulnerability and Responsibility - Thematic study by the Expert Mechanism</u> on the Right to Development

UNHCHR Ongoing studies **Deadline: 30 May 2025**

Key information section in package leaflet of centrally authorised medicinal products: Public consultation

EMA Draft: consultation open Consultation dates: 14/04/2025 to 31/05/2025

Concept paper on the development of a Guideline on assessment and reporting of mechanistic models used in the context of model informed drug development

EMA Draft: consultation open Consultation dates: 14/02/2025 to 31/05/2025

NEW - Fogarty International Center; Notice of Meeting

A Notice by the National Institutes of Health on 05/12/2025

Fogarty International Center Advisory Board. Date: June 2-3, 2025

<u>Interested Parties Meeting: Implementation of the Best Pharmaceuticals for Children Act and Pediatric Research Equity Act</u>

A Notice by the Food and Drug Administration on 01/03/2025. **Comments by June 13, 2025.**

NEW - WTO opens online registration for 2025 Public Forum, launches call for proposals World Trade Organization, Geneva, 17 to 18 September 2025. Call for event proposals must be

submitted by 13 June 2025

NEW - Call for input for the UNGA-80th thematic report on "Freedom of assembly and association rights, collective action and human solidarity facing existential threat: preserving the fundamental principles"

UNHCHR, Special Procedures Deadline: 16 June 2025

NEW - Regulatory Reform

US Interior Department on 05/20/2025. Request for Information (RFI). **Comment period ends 06/20/2025**

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<u>Call for submissions on the draft of general comment No. 27 on children's right to access to justice and to an effective remedy</u>

Issued by CRC **Deadline: 30 June 2025**

Call for inputs: Biodiversity and human rights

Issued by OHCHR Deadline: 30 June 2025

Digital Product Passport:

EC 09 April 2025 Interested parties are invited to provide their feedback to the public consultation through the Have Your Say Portal **by 1 July 2025.**

NEW - Concept paper on the revision of Part IV guidelines on good manufacturing practice specific to advanced therapy medicinal products

EMA/INS/GMP/48771/2025 GMP/GDP Inspectors Working Group (GMP/GDP IWG) 11 March 2025 End of Consultation – 08 July 2025

NEW - <u>Public Inspection: Request for Information: Ensuring Lawful Regulation and Unleashing Innovation to Make American Healthy Again</u>

A Notice by HHS on 05/14/2025. **Comment period ends 07/14/2025.**

NEW - Submissions of information on synthetic biology to support the preparation of the thematic action plan in the context of synthetic biology and the work of the Ad Hoc Technical Expert Group on Synthetic Biology

Convention on Biological Diversity Notification 2025-065 Responses no later than 18 July 2025

Draft guideline on the quality aspects of mRNA vaccines

Draft: consultation open Consultation dates: 31/03/2025 to 30/09/2025

Reference Number: EMA/CHMP/BWP/82416/2025

Concept paper for the development of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a veterinary medicinal product

Draft: consultation open Consultation dates: 16/04/2025 to 31/10/2025

ISO/AWI 14155 - Biological and clinical evaluation of medical devices

ISO/TC 194 Stage 20.00

Due: Ongoing at national standards bodies level

Contribute a tool - Catalogue of Tools & Metrics for Trustworthy Al

OECD-AI Policy Observatory

Contribute your tools and metrics to our catalogue. No deadline date identified.

This catalogue is a platform where AI practitioners from all over the world can share and compare tools and metrics to help make AI trustworthy, build upon each other's efforts to create global good practices, and speed up the process of implementing the OECD AI Principles. This catalogue can only

exist with your contributions and those of AI practitioners from all sectors. You can also share your experience using a tool or metric by submitting a use case.

:: Contribute a tool

:: Share your experience using a tool

<u>A framework for evaluating rapidly developing digital and related technologies: AI, large language models and beyond</u> - <u>International Science Council Discussion Paper: Invitation to Comment</u>

International Science Council [ISC]

No submission deadline date identified.

Global consultation on the Copenhagen Framework on Citizen Data

Collaborative on Citizen Data - 2 February 2024

Year-long global consultation spanning over 2024.

The <u>Collaborative</u> will aim to finalize the "Copenhagen Framework on Citizen Data" based on this global consultation and other country piloting studies, and submit to the 56th session of the United Nations Statistical Commission in March 2025.

Public Consultation Calls: Purpose/Objective/Scope/Background Information – Sorted by Thematic Area

Biomedical Research/Regulation/Governance

NEW - Request of Nominations: Experts to the EPA's Human Studies Review Board Advisory Committee

EPA 04/30/202r **Comment period ends 05/30/2025.**

SUMMARY:

Pursuant to the Federal Advisory Committee Act (FACA), the Environmental Protection Agency (EPA) invites nominations from a diverse range of qualified candidates with expertise in the areas of toxicology, bioethics, and statistics to be considered for appointment to its Human Studies Review Board (HSRB). The HSRB is a statutory Federal advisory committee required by <u>Public Law 109-54</u> and <u>40 CFR part 26</u> to review and comment on all proposed and completed research involving intentional human subject exposure that is subject to the coverage of EPA's regulations (see subparts K-L). Submission of nominations will be made via the HSRB website at: https://www.epa.gov/osa/human-studies-review-board.

<u>Key information section in package leaflet of centrally authorised medicinal products: Public</u> consultation

EMA Draft: consultation open **Consultation dates: 14/04/2025 to 31/05/2025** *Summary:*

The European Medicines Agency (EMA) and the Quality Review of Documents (QRD) Working Group are currently working on the revision of the QRD template for centrally authorised medicinal products for human use, with the aim of improving the content and structure of the package leaflet and making it more understandable and relevant to patients, while still complying with the current legislative framework. The draft revised QRD template has been released for public consultation until 31 August 2025.

Separate from the public consultation of the QRD template, EMA would like to gather the views of stakeholders on the potential usefulness and added value of a new "key information section" in the package leaflet. The addition of this new section addresses one of the recommendations in the Report from the Commission to the European Parliament and the Council in accordance with Article 59(4) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, and it would allow patients, users and healthcare professionals to rapidly identify key safety messages, balanced with information on the benefit-risk profile of the medicine.

As concluded in the report, the evidence and views collected may help inform the decision on whether such a key information section in the package leaflet is needed and, if so, what type of information should be provided therein.

EMA would like to invite all interested stakeholders to respond to the following survey by 31 May 2025: <u>EU Survey</u>: Potential inclusion of key information section in package leaflet of centrally authorised medicines - public consultation

More information is available: Product-information (QRD) templates - Human.

Concept paper on the development of a Guideline on assessment and reporting of mechanistic models used in the context of model informed drug development

EMA Draft: consultation open Consultation dates: 14/02/2025 to 31/05/2025

Reference Number: EMA/5875/2025

Introduction

Mechanistic models, i.e. mathematical or computer models that integrate biopharmaceutical, physico-13 mechanical, (patho)physiological and pharmacological processes, along with population characteristics, 14 are frequently and increasingly used in all phases of the drug research and development life cycle. 15 Mechanistic models covered by this new guideline include, but are not limited to, Physiologically Based 16 Pharmacokinetic (PBPK), Physiologically Based Biopharmaceutics (PBBM) and Quantitative Systems 17 Pharmacology (QSP) models...

Problem statement

Regulators should be able to confidently assess and quantify the potential risks associated with decisions based on mechanistic models, ensuring informed and accurate outcomes. However, due to the nature of these models, this is a non-trivial task and methods for uncertainty quantification are not well established within the current regulatory assessment framework. Moreover, key metrics and components for technical assessment and related acceptance criteria for mechanistic models, given the context of use and regulatory impact are not always clear which leads to their underuse or inappropriate use in drug development or/and poor communication between developers and regulators...

NEW - Fogarty International Center; Notice of Meeting

A Notice by the National Institutes of Health on 05/12/2025

Fogarty International Center Advisory Board. Date: June 2-3, 2025.

Closed: June 2, 2025, 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate the second level of grant applications.

Open: June 3, 2025, 9:00 a.m. to 3:00 p.m.

Agenda: Update and discussion of current and planned Fogarty International Center activities.

<u>Interested Parties Meeting: Implementation of the Best Pharmaceuticals for Children Act and</u> Pediatric Research Equity Act

A Notice by the Food and Drug Administration on 01/03/2025. **Comments by June 13, 2025.** *SUMMARY:*

The Food and Drug Administration's (FDA, Agency, or we) Office of Pediatric Therapeutics, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research are announcing a public meeting entitled "Interested Parties Meeting: Implementation of the Best Pharmaceuticals for Children Act and Pediatric Research Equity Act." The purpose of the public meeting is to seek input from interested parties, including patient/parent/caregiver groups, consumer groups, regulated industry, academia, and others. This input will enable FDA to obtain any recommendations or information relevant to the report to Congress that FDA is required to submit concerning pediatric drug and biologic development and labeling, as outlined in section 508 of the Food and Drug Administration Safety and Innovation Act (FDASIA).

The public meeting will be held on May 15, 2025, from 9 a.m. to 4:30 p.m. Eastern Time. Regardless of attendance at the public meeting, you can submit electronic or written comments to the public docket.

NEW - Concept paper on the revision of Part IV guidelines on good manufacturing practice specific to advanced therapy medicinal products

EMA/INS/GMP/48771/2025 GMP/GDP Inspectors Working Group (GMP/GDP IWG) 11 March 2025 End of Consultation – 08 July 2025

This concept paper aims to outline the rationale, objectives, and proposed changes for updating Part IV – GMP specific to ATMP of the good manufacturing practice (GMP) guide Eudralex Volume 4 following the revision of Annex 1 which came into operation in August 2023. As the Part IV is an EU standalone guideline and that the sector is to abide solely for reference, it should be revised independently to address recent developments in the manufacture of sterile medicinal products.

English (EN) (113.06 KB - PDF) https://www.ema.europa.eu/en/documents/scientific-guidelines-good-manufacturing-practice-specific-advanced-therapy-medicinal-products en.pdf

NEW - <u>Public Inspection: Request for Information: Ensuring Lawful Regulation and Unleashing</u> Innovation to Make American Healthy Again

A Notice by HHS on 05/14/2025. **Comment period ends 07/14/2025.** *SUMMARY:*

To implement the President's Deregulatory Initiatives, including Department of Government Efficiency Deregulatory Agenda, and to better promote the health and well-being of the American people, the U.S. Department of Health and Human Services (HHS) is planning the largest deregulatory effort in the history of the Department. To facilitate this effort, HHS seeks input from all interested parties on how to dramatically deregulate across all areas the Department touches. HHS also welcomes other submissions explaining how regulations, guidance, paperwork requirements, and other regulatory obligations can be repealed.

NEW - Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again

Health and Human Services Department on 05/14/2025. **Comment period ends 07/14/2025.** *SUMMARY:*

To implement the President's Deregulatory Initiatives, including Department of Government Efficiency Deregulatory Agenda, and to better promote the health and well-being of the American people, the U.S. Department of Health and Human Services (HHS) is planning the largest deregulatory effort in the history of the Department. To facilitate this effort, HHS seeks input from all interested parties on how to dramatically deregulate across all areas the Department touches. HHS also welcomes other submissions explaining how regulations, guidance, paperwork requirements, and other regulatory obligations can be repealed.

NEW - Submissions of information on synthetic biology to support the preparation of the thematic action plan in the context of synthetic biology and the work of the Ad Hoc Technical Expert Group on Synthetic Biology

Convention on Biological Diversity Notification 2025-065 **Responses no later than 18 July 2025**In its decision <u>16/21</u>, the Conference of the Parties to the Convention on Biological Diversity decided to develop a thematic action plan to support capacity-building and development, access to and transfer of technology and knowledge-sharing in the context of synthetic biology for the implementation of the three objectives of the Convention on Biological Diversity and the Kunming-Montreal Global Biodiversity Framework, in line with the long-term strategic framework for capacity-building and development (also see decision <u>15/8</u>, annex I). To support the preparation of this thematic action plan, the Conference of the Parties invited Parties, other Governments, indigenous peoples and local communities, women, youth, academia, research institutions, the business sector and relevant organizations to submit

information on their experiences, needs and priorities with regard to synthetic biology, in addition to other relevant processes and initiatives on capacity-building and development, access to and transfer of technology and knowledge-sharing related to synthetic biology.

Draft guideline on the quality aspects of mRNA vaccines

Draft: consultation open Consultation dates: 31/03/2025 to 30/09/2025

Reference Number: EMA/CHMP/BWP/82416/2025

Summary:

This guideline addresses the quality aspects of mRNA vaccines. It addresses specific aspects regarding the manufacturing process, characterisation, specifications and analytical control of mRNA vaccines, as well as the definition of starting materials, active substance and finished product for mRNA vaccines. Additional regulatory considerations are provided for changes in existing mRNA vaccine strains, bivalent and multivalent vaccines, self-amplifying mRNA vaccines, other delivery systems and use of platform technology/prior knowledge. The scope of this guideline is applicable to mRNA vaccines against infectious diseases. Other mRNA-based medicinal products are out of scope of this guideline, although relevant parts of this guideline may be applicable to those. It is not intended to address specific requirements for mRNA vaccines to be used in clinical trials, however the scientific principles described may also be applicable during pharmaceutical development.

Concept paper for the development of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a veterinary medicinal product

Draft: consultation open Consultation dates: 16/04/2025 to 31/10/2025

Reference Number: EMA/CVMP/ERA/75412/2023

Summary:

This concept paper provides background to the intended development of a scientific approach for use in the evaluation of the risk for humans exposed to antimicrobial resistance via the environment, originating from use of veterinary medicinal products. It is intended to provide advice on how relevant dossier requirements outlined in Regulation (EU) 2019/6 (e.g., Article 8(2)) may be fulfilled.

Comments should be provided using this template

The completed comments form should be sent to vet-guidelines@ema.europa.eu

ISO/AWI 14155 - Biological and clinical evaluation of medical devices

ISO/TC 194 Stage 20.00

Due: Ongoing at level of national standards bodies

Scope

Standardization of the approach to biological and clinical evaluation of medical and dental materials and devices together with standardization of biological test methods applicable to those materials and devices as well as good clinical practice principles to clinical investigations in humans of those devices. *Abstract*

This document addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the clinical performance or effectiveness and safety of medical devices.

For post-market clinical investigations, the principles set forth in this document are intended to be followed as far as relevant, considering the nature of the clinical investigation (see Annex I).

This document specifies general requirements intended to

— protect the rights, safety and well-being of human subjects,

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- ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results,
- define the responsibilities of the sponsor and principal investigator, and
- assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

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Genetics/Genomics	
No new calls identified.	
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Emerging/Disruptive Technologies

ICC Office of the Prosecutor launches public consultation on policy on cyber-enabled crimes under the Rome Statute

Statement 7 March 2025 Office of the Prosecutor Comments due by 30 May 2025.

The Office of the Prosecutor of the International Criminal Court is pleased to invite public comments on its draft policy on cyber-enabled crimes under the Rome Statute.

The Office welcomes the engagement of all stakeholders in this new initiative to advance accountability for crimes under the Rome Statute enabled by conduct in cyberspace. The Office encourages comments from all partners, especially from States Parties, civil society, interested private sector corporations, and other organisations with particular expertise in this area.

This collective work will culminate in a final policy paper that will guide the Office in addressing the increasing importance of cyberspace to the exercise of the ICC's jurisdiction at all stages of its work, including investigations and prosecutions.

The current draft is available to download <u>HERE</u>. Comments should be sent to <u>otp.cyber.policy@icc-cpi.int</u> no later than 23:59 (CET) on 30 May 2025. All input received by this date will be carefully considered in the internal review and revision process.

Visiting Committee on Advanced Technology

A Notice by the National Institute of Standards and Technology on 04/22/2025

Request to make oral comments are due no later than Tuesday, May 27, 2025, 5:00 p.m. Eastern Time. There is no specified date by which written comments must be submitted. SUMMARY:

The National Institute of Standards and Technology (NIST) Visiting Committee on Advanced Technology (VCAT or Committee) will hold an open in-person meeting on Tuesday, June 10, 2025, from 9 a.m. to 5 p.m. Eastern Time, and Wednesday, June 11, 2020, from 9 a.m. to 1 p.m. Eastern Time with a virtual option for VCAT members only to ensure the ability to meet quorum. SUPPLEMENTARY INFORMATION:

... The meeting will be open to the public. The VCAT is composed of not fewer than nine members appointed by the NIST Director and selected to provide representation of a cross-section of the traditional and emerging United States industries. The primary purpose of this meeting is for the VCAT to review and make recommendations regarding general policy for NIST, its organization, its budget, and its programs within the framework of applicable national policies as set forth by the President and the Congress. The agenda will include an update on major programs at NIST. It will also include a session on

the changes within the organization, budget considerations, as well as alignment of NIST programs with Administration priorities. The agenda is subject to change if needed to accommodate Committee business. The final agenda will be posted on the NIST website at https://www.nist.gov/director/vcat/agenda-minutes.

Individuals and representatives of organizations who would like to offer comments and suggestions related to the Committee's business are invited to request a place on the agenda by no later than 5:00 p.m. Eastern Time, Tuesday, May 27, 2025, by contacting Stephanie Shaw at stephanie.shaw@nist.gov... Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements to Stephanie Shaw at stephanie.shaw@nist.gov.

Digital Product Passport:

EC 09 April 2025 Interested parties are invited to provide their feedback to the public consultation through the Have Your Say Portal **by 1 July 2025.**

The European Commission launched a public consultation on the future Digital Product Passport. The objective is to gather stakeholders' views on how data should be stored and managed by service providers and on the need for a certification scheme for such service providers. The feedback gathered through the public consultation will inform the development of an effective functioning of the Digital Product Passport system.

The Digital Product Passport is a key innovation under the 2024 <u>Ecodesign for Sustainable Products Regulation</u> to store and share relevant data about a product's sustainability, durability and other environmental aspects. The Digital Product Passport will be available to consumers, businesses and relevant public authorities. It will help to make informed decisions and increase the demand for sustainable products. The Digital Product Passport could also host additional information, for instance product instructions or conformity documents.

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Biodiversity/Environment/Climate/Disaster Mitigation

Human Studies Review Board (HSRB) Meetings for 2025

A Notice by the Environmental Protection Agency on 11/29/2024 *Public Participation*

The HSRB encourages the public's input. You may participate in these meetings via oral comments or written comments.

SUMMARY:

The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of its public meetings of the Human Studies Review Board (HSRB) for 2025. The HSRB provides advice, information, and recommendations on issues related to scientific and ethical aspects of third-party human subjects' research that are submitted to the Office of Pesticide Programs (OPP) to be used for regulatory purposes.

Four three-day virtual public meetings will be held on:

- 1. January 29-31, 2025;
- 2. April 2-4, 2025;
- 3. July 22-24, 2025;
- 4. October 14-16, 2025.

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Science Integrity/Evidence to Policy/ Open Science

:: Call for Public Consultation

The Right to Participate in and Benefit from Science – Call for Feedback

ISC / International Science Council

21 November 2024

The ISC's interpretation of 'the right to participate in and benefit from science' provides a clear framework for understanding the right to science, emphasizing its application in research, policy, and global access to scientific knowledge. It clarifies the obligations, opportunities, and responsibilities in ensuring universal access to science, fostering global dialogue to shape a more inclusive and sustainable future.

ISC – The Right to Participate in and Benefit from Science

The International Science Council believes that there is a universal human right to participate in and enjoy the benefits of science, and that it is a responsibility of governments to create and sustain the opportunities of citizens to use this right.

A right to participate in science

This right presumes a right to basic scientific literacy, and a right to scientific education, training and mentoring.

- A right to participate in generating diverse forms of knowledge through the study of natural and social phenomena using theoretical, observational, experimental, and analytical approaches to introduce and test existing and new models, conjectures, hypotheses and ideas unconstrained by political agendas or belief systems.
- II. A right to challenge established knowledge about natural and social phenomena when generating and communicating new models, conjectures, hypotheses and ideas, and the uses to which this knowledge has been or may be put.
- III. A right to collaborate and engage in scientific dialogue and research across national, political, regional and other boundaries.
- IV. A right to communicate both positive and negative findings.
- V. A right to form professional societies and associations.
- VI. A right to advocate for the responsible use of science.

A right to enjoy the benefits of science

- I. A right not to be excluded from the benefits of science on the basis of unjust discrimination based on race, nationality, ethnic origin, language, sex, gender identity, reproductive ability, sexual orientation, age, disability, political opinion, or religious belief.
- II. A right to equitably access information, data, and other resources necessary to enhance scientific knowledge, teaching and research.
- III. A right to apply scientific knowledge for technological developments for the good of humanity and the planet.

:: Resources, Events	
No new resources identified.	

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Heritage/Cultural Assets

Governance, Trade, Global Finance

:: Call for Public Consultation

NEW - <u>WTO opens online registration for 2025 Public Forum, launches call for proposals</u> World Trade Organization, Geneva, 17 to 18 September 2025. **Call for event proposals must be submitted by 13 June 2025**

Participants interested in organizing a working session can find details on the application process in this <u>information note</u>, which includes access to the online application form. As in previous years, all Forum sessions are organized by participants.

Background

The Public Forum is the WTO's largest outreach event, providing a unique platform for interested stakeholders from around the world to discuss the latest developments in global trade and to propose ways of enhancing the multilateral trading system. The event attracts over 2,000 representatives each year from civil society, academia, business, government, international organizations and the media. See more information on previous Public Fora.

NEW - Regulatory Reform

US Interior Department on 05/20/2025. Request for Information (RFI). **Comment period ends 06/20/2025**

SUMMARY:

The U.S. Department of the Interior (DOI) seeks comments and information to assist DOI, including the Bureaus and Offices established within DOI, in identifying existing regulations that can be modified or repealed, consistent with applicable law, to ensure that DOI administrative actions do not undermine the national interest and that DOI achieves a meaningful reduction in regulatory burdens while continuing to meet statutory obligations, advance American energy independence, and ensure the responsible stewardship of the Nation's public lands and resources. This RFI is part of DOI's implementation of recent directives from the President, including Executive orders, which seek to deconstruct the regulatory burden that has been self-imposed on our Nation's interests and improve the relevant processes to establish a more efficient regulatory program at DOI.

:: Resources, Events

NEW - Information Report: Oversight Observations To Inform Department of State Realignment of U.S. Agency for International Development Functions

AUD-GEER-25-19 May 2025

Summary of Review

On March 28, 2025, the Department of State (Department) notified Congress of its intent to realign selected U.S. Agency for International Development (USAID) functions within the Department. The information report, which was developed as part of an Office of Inspector General (OIG) evaluation of the Department's initial realignment efforts, is designed to highlight OIG observations from its prior

work, and the work of other federal oversight bodies, that could help the Department more efficiently and effectively realign USAID functions.

OIG concluded that the Department is undertaking a significant and multi-faceted integration of select USAID functions concurrent with a reorganization of domestic offices and bureaus in the Department. Individually, these tasks would be daunting. But together, these initiatives could be overwhelming to the organization without a well thought out plan of action. During its work, OIG observed that senior Department leaders involved in the realignment are aware of the challenges that they face. Additionally, OIG recognizes that the Department's Assistance Transition Working Group has established workstreams related to many of the topics discussed in the OIG report.

Although OIG did not make formal recommendations in the report, OIG encourages the Department to consider how issues identified by OIG and other oversight organizations might impact the success of the Department's efforts. Considering previously identified issues will allow the Department to implement best practices.

Although the focus of the information report is the realignment of USAID functions within the Department, the information may also be applicable to the Department's efforts to implement its internal reorganization.

Strategic Foresight Toolkit for Resilient Public Policy

A Comprehensive Foresight Methodology to Support Sustainable and Future-Ready Public Policy **OECD Report** 21 January 2025

PDF: https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/01/foresight-toolkit-for-resilient-public-policy 9ad1cd60/bcdd9304-en.pdf

Abstract

By exploring 25 evidence-based potential disruptions across environmental, technological, economic, social, and geopolitical domains, the Strategic Foresight Toolkit for Resilient Public Policy helps anticipate challenges and opportunities that could reshape the policy landscape between 2030 and 2050. These disruptions are not predictions, but hypothetical future developments identified through extensive research, expert consultations, and workshops.

The Strategic Foresight Toolkit features a five-step foresight process, guiding users to challenge assumptions, create scenarios, stress-test strategies, and develop actionable plans. It includes facilitation guides and case studies to support effective implementation. Each disruption is accompanied by insights on emerging trends, potential future impacts, and both immediate and long-term policy options to ensure resilience and preparedness.

Designed for policymakers, public administrators, and foresight practitioners, this publication is designed to promote holistic, strategic and evidence-informed decision-making. It aims to support countries and organisations in using strategic foresight to design and prepare robust and adaptable public policies for a range of possible futures. With its practical methodology and forward-looking approach, the Strategic Foresight Toolkit is a vital resource for building sustainable, resilient, and effective public policies.

Public Integrity Indicators

OECD - Datasetdata-explorer.oecd.org

14 February 2025

Interactive Graphic: OECD Public Integrity Indicators

Overview

Following the adoption of the <u>OECD Council Recommendation on Public Integrity</u> in 2017, the Public Governance Committee (PGC), via its Working Party of Senior Public Integrity Officials (SPIO) subsidiary body, developed the <u>OECD Public Integrity Indicators</u> (PII) to measure the implementation of the OECD

Council Recommendation on Public Integrity. The PII are complementary to the <u>OECD Public Integrity Handbook</u> and the <u>OECD Public Integrity Maturity Models</u>.

The OECD Public Integrity Indicators (PII) measure the quality and effectiveness of public integrity systems across six areas:

- Quality of Strategic Framework (data available)
- Accountability of Public Policymaking covering conflict-of-interest, political finance, lobbying, public information, open government, and public consultation (data available)
- Effectiveness of Internal Control and Risk Management (data available)
- Integrity and Effectiveness of the Justice System (to be launched in 2024)
- Strength of External Oversight and Control (to be launched in 2024)
- Meritocracy of the Public Sector (to be launched in 2025)

The OECD Public Integrity Indicators provide cross-country comparative data to help policy makers and practitioners strengthen the resilience of public integrity systems towards corruption risks and prevent the mismanagement and waste of public funds. The PIIs measure the strength of standard regulatory safeguards (*de jure*) and implementation of these safeguards in practice (*de facto*). The OECD Secretariat collaborates closely with national administrations to obtain primary data collected directly from a wide range of actors across the executive, legislative and judiciary branches.

Regulatory governance

OECD Datasetdata-explorer.oecd.org 14 February 2025 *Overview*

The OECD Dataset on the Indicators of Regulatory Policy and Governance (iREG) presents up-to-date evidence of regulatory policy and governance practices of the OECD member countries, the European Union as well as the five EU Member States that are not OECD member countries. It focuses on practices as described in the 2012 Recommendation of the Council on Regulatory Policy and Governance (Recommendation), the first international instrument to address regulatory policy as a whole-of-government activity. The data covers in detail three principles of the 2012 Recommendation: stakeholder engagement, regulatory impact assessment (RIA) and *ex post* evaluation. For each of these areas, the indicators present information in four categories:

- 1. Systematic adoption records formal requirements and how often these requirements are conducted in practice;
- 2. Methodology gathers information on the methods used in each area, e.g. the type of impacts assessed or how frequently different forms of consultation are used;
- 3. Oversight and quality control records the role of oversight bodies and publically available evaluations; and
- 4. Transparency records information that relates to the principles of open government, e.g. whether government decisions are made publically available.

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Human Rights

<u>Climate Finance: Vulnerability and Responsibility - Thematic study by the Expert Mechanism on the Right to Development</u>

UNHCHR Ongoing studies **Deadline: 30 May 2025** *Objectives*

This study complements the one on climate justice and just transition by further exploring and analyzing the various processes, initiatives, and practices that contribute to adequately financing climate transition and development at different levels. It shall systematically explore, track, and trace initiatives that have been decided upon and are currently under discussion and/or implementation. It will examine their specific objectives, stakeholders, and partners. Additionally, the study will also examine, through examples and best practices, the implementation of mechanisms enshrined in the Kyoto Protocol under the principle of "common but differentiated responsibilities." Special attention will be given to Article 6 of the Paris Agreement concerning the carbon market...

<u>Call for Input for the report on Corporations and International Solidarity</u>

UNHCHR — Issued by Independent Expert on human rights and international solidarity **Deadline: 10**June 2025

Purpose:

To inform the Independent Expert's report on corporations and international solidarity to be presented to the 80th session of the UN General Assembly in October 2025.

Background:

As noted by the UN Secretary General in <u>Our Common Agenda</u>, corporations can be important partners in promoting and implementing International Solidarity network actions and policies along with States and civil society actors. They can pursue sustainable development to support intergenerational solidarity by protecting the environment and show respect for the continuity of communal cultural traditions. The <u>Revised Draft Declaration on International Solidarity</u>, Article 6, calls upon corporations to provide transparent, accessible mechanisms for communication and response to solidarity demands presented to them by civil society, labor unions, Indigenous Peoples and other groups. The Independent Expert seeks input from States, civil society organizations, and corporations to understand the role of corporations and their scope of action in promoting and implementing International Solidarity. The Independent Expert welcomes as much information as possible including concrete examples relating to the issues highlighted in the questionnaire below in English French and Spanish. Inputs can be country-specific or of a general nature. Please feel free to respond to all or select questions depending on expertise, relevance or focus of work. Inputs may also address questions that are not listed here but which stakeholders would like to bring to the attention of the Independent Expert.

NEW - Call for input for the UNGA-80th thematic report on "Freedom of assembly and association rights, collective action and human solidarity facing existential threat: preserving the fundamental principles"

UNHCHR, Special Procedures Deadline: 16 June 2025

Purpose:

To inform the thematic report of the Special Rapporteur on freedom of peaceful assembly and of association, to be presented to the 80th session of the UN General Assembly in October 2025. *Background*

The Special Rapporteur on freedom of peaceful assembly and of association focus her next thematic report on analysing the existential threats to these rights due to the collapse of the international financial aid ecosystem, the weaponisation of financial assistance against rights-defending voices, and the radical and rapid backsliding on civic space and the defence of these rights.

Call for inputs: Biodiversity and human rights

Issued by OHCHR Deadline: 30 June 2025

Purpose:

To inform the High Commissioner's global analytical study on the implementation of a human rights-based approach into the goals and targets of the Kunming-Montreal Global Biodiversity Framework, in line with the provisions of the Convention on Biological Diversity, consistent with the considerations set out in section C of the Framework and taking into consideration the outcomes of the sixteenth meeting of the Conference of the Parties to the Convention. The global analytical study is to be submitted to the Council at its sixty-first session.

Background

<u>Human Rights Council resolution 57/28</u> requested the United Nations High Commissioner for Human Rights to consult Member States and other relevant stakeholders in order to conduct a global analytical study on the implementation of a human rights-based approach into the goals and targets of the Kunming-Montreal Global Biodiversity Framework, in line with the provisions of the Convention on Biological Diversity, consistent with the considerations set out in section C of the Framework and taking into consideration the outcomes of the sixteenth meeting of the Conference of the Parties to the Convention.

<u>Call for submissions on the draft of general comment No. 27 on children's right to access to</u> justice and to an effective remedy

Issued by CRC Deadline: 30 June 2025

Purpose:

Call for submissions on the draft of general comment No. 27 on children's right to access to justice and to an effective remedy

Background

The Committee on the Rights of the Child now seeks contributions from all interested stakeholders on the draft of the general comment. The draft is available <u>here</u>.

Information for children by Child Rights Connect and UNICEF is available <u>here</u>. Background information about the general comment is available <u>here</u>.

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Selected Calls for Public Consultation of Global Interest but Limited to State Parties or Other Designated Entities

No new calls identified.		
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Selected Final, Published Guidances, Frameworks, Regulations, Meetings Employing Calls for Public Consultation

Children's Online Privacy Protection Rule

Final rule amendments. <u>Federal Trade Commission</u> 04/22/2025.

SUMMARY:

The Federal Trade Commission amends the Children's Online Privacy Protection Rule (the "Rule"), consistent with the requirements of the Children's Online Privacy Protection Act. The amendments to the Rule, which are based on the FTC's review of public comments and its enforcement experience, include one new definition and modifications to several others, as well as updates to key provisions to

respond to changes in technology and online practices. The amendments are intended to strengthen protection of personal information collected from children, and, where appropriate, to clarify and streamline the Rule since it was last amended in January 2013.

Final Scientific Integrity Policy of the U.S. Department of Health and Human Services

A Notice by the <u>Health and Human Services Department</u> on <u>12/30/2024</u>

Office of the Assistant Secretary for Planning and Evaluation, Office of the Secretary, HHS.

ACTION: Notice of final policy. The effective date of the Policy is October 16, 2024. *SUMMARY:*

The Department of Health and Human Services (HHS) is publishing its Scientific Integrity Policy to increase access to and raise awareness of the Policy.

SUPPLEMENTARY INFORMATION:

Scientific integrity plays a vital role in the mission of HHS. Ensuring integrity in science throughout the Department allows HHS to foster and produce high-quality science, communicate effectively with the public, and base critical policy decisions on trustworthy and rigorous scientific findings. HHS has adopted a Department-wide scientific integrity policy to further strengthen scientific integrity and evidence-based policymaking throughout the Department.

The Scientific Integrity Policy of the U.S. Department of Health and Human Services (Policy) was approved on September 16, 2024. The finalized Policy was announced to the HHS community and posted on the HHS scientific integrity website, at https://www.hhs.gov/programs/research/ scientificintegrity/index.html, on September 30, 2024.

Purpose

The purpose of this policy is to promote a continuing culture of scientific integrity at the U.S. Department of Health and Human Services (HHS). This policy aims to ensure the integrity of all aspects of HHS scientific activities, including proposing, conducting, reviewing, managing, and communicating about science and scientific activities, and using the results of science to inform policy and program decision-making.

Core Values That Support Scientific Integrity at HHS

The success of HHS's mission to enhance the health and well-being of all Americans depends on the development and use of accurate, complete, and timely scientific and technical information. Scientific integrity requires that such information be developed under and subjected to well-established scientific processes, free from inappropriate interference that undermines impartiality, nonpartisanship, or professional judgment. HHS agencies work to maximize the quality, accuracy, objectivity, utility, and timeliness of the scientific and technological information they produce, use, and disseminate. In turn, this information enables HHS to employ innovative approaches to effectively address the many public health and human services challenges that our work targets. These efforts allow accurate, complete, and timely scientific and technical information to improve the design, delivery, and impact of HHS policies and programs, and support equity, justice, and trust. Responsibility for upholding scientific integrity lies with the entire scientific ecosystem, including all HHS employees, its contractors and grantees, and those engaged in science and scientific activities outside HHS.

Final Scientific Integrity Policy of the National Institutes of Health

A Notice by the National Institutes of Health on 10/21/2024

ACTION: Notice of final policy. DATES: This Final Policy is effective on December 30, 2024. *SUMMARY:*

The National Institutes of Health (NIH) is issuing this Final NIH Scientific Integrity Policy to promote a continuing culture of scientific integrity at NIH. This Policy codifies NIH's long-standing expectations to preserve scientific integrity throughout all NIH activities, establishes key roles and responsibilities for

those who will lead the agency's scientific integrity program, and, as appropriate, establishes relevant reporting and evaluation mechanisms.

SUPPLEMENTARY INFORMATION:

Background

Scientific integrity aims to make sure that science is conducted, managed, communicated, and used in ways that preserve its accuracy and objectivity and protect it from suppression, manipulation, and inappropriate influence (https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting the Integrity of Government Science.pdf). In support of our mission, NIH has always sought to incorporate robust scientific integrity principles and practices throughout every level of its scientific enterprise. In fostering scientific integrity, NIH aims to ensure that (1) scientific findings are objective, credible, and readily available to the public, and (2) the development and implementation of policies and programs is transparent, accountable, and evidence-based. NIH has numerous policies and procedures to ensure the Nation's investment in biomedical research is scientifically robust and rigorous and that our workforce maintains the highest standards of integrity. In supporting the NIH mission, all NIH researchers and staff are expected to:

- Foster an organizational culture of scientific integrity,
- Protect the integrity of the research process,
- Communicate science with integrity, and
- Safeguard scientific integrity.

Food and Drug Administration Report and Plan on Best Practices for Guidance; Availability

A Notice by the Food and Drug Administration on 12/03/2024 *SUMMARY:*

The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled "Food and Drug Administration Report and Plan on Best Practices for Guidance" (Report and Plan). FDA is publishing this Report and Plan in response to the Consolidated Appropriations Act, 2023, which directs FDA to issue a report identifying best practices for the efficient prioritization, development, issuance, and use of guidance documents and a plan for implementation of such best practices. *Background*

Clear, concise, and timely communication through guidance documents is essential to the public health mission of FDA. FDA guidance documents are prepared for FDA staff, industry, and the public to describe the Agency's interpretation of, or policy on, a regulatory issue. (21 CFR 10.115(b)). Specifically, FDA uses guidance documents to assist regulated industry, FDA staff, and the public in understanding the Agency's current thinking on policy, scientific, medical, and regulatory issues, such as: the design, manufacturing, and testing of regulated products; content and evaluation of applications for product approvals; and inspection and enforcement policies...

LOC Biosecurity laws: Argentina, Australia, Brazil, Canada, China, France, Germany, India, Indonesia, Italy, Japan, Mexico, Russian Federation, Saudi Arabia, South Africa, South Korea, Turkey, United Kingdom, United States

Library of Congress, September 2024

LL File No. 2024-023388 LRA-D-PUB-002658 (corrected 10/2024)

Introduction

This report explores various approaches to defining "biosafety" and "biosecurity" in legislation and regulations in the following jurisdictions: Argentina, Australia, Brazil, Canada, China, France, Germany, India, Indonesia, Italy, Japan, Mexico, Russia, Saudi Arabia, South Africa, South Korea, Turkey, the United Kingdom, and the United States. These jurisdictions have been chosen because they are members of the Group of Twenty (G20).

Individual country reports are included after the comparative analysis. These reports discuss definitions of "biosafety," "biosecurity," and related terms, when available, as well as information about legislation, regulations, guidelines, and secondary sources discussing subjects related to those topics. Additionally, most G20 nations are signatories to multinational treaties addressing matters of biosecurity and biosafety. The table below at page 5 identifies G20 nations and indicates whether each has signed key multilateral treaties connected to biosafety: the Biological Weapons Convention, the Convention on Biological Diversity, the Cartegena Protocol, and the Nagoya Protocol. As indicated in the table, all G20 nations have either ratified or acceded to the Biological Weapons Convention. All listed nations, apart from the United States, participate in the Convention on Biological Diversity. The Cartagena Protocol and the Nagoya Protocol supplement the Convention on Biological Diversity; most G20 countries have ratified one or both of these treaties...

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Selected Peer-reviewed Journal Literature/Gray Lit Integrating Public Consultation

OECD Guidelines for Citizen Participation Processes

Paris: OECD Publishing. 2022

https://www.oecd-ilibrary.org/governance/oecd-guidelines-for-citizen-participation-processes f765caf6-en [Accessed 10 Nov 2023]

The OECD Guidelines for Citizen Participation Processes are intended for any public official or public institution interested in carrying out a citizen participation process. The guidelines describe ten steps for designing, planning, implementing and evaluating a citizen participation process, and discuss eight different methods for involving citizens: information and data, open meetings, public consultations, open innovation, citizen science, civic monitoring, participatory budgeting and representative deliberative processes. The guidelines are illustrated with examples as well as practical guidance built on evidence gathered by the OECD. Finally, nine guiding principles are presented to help ensure the quality of these processes.

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Selected Resources for Public Consultation Notices, Calls, Processes

UNHCHR UN High Commissioner for Human Rights – Calls for Input

https://www.ohchr.org/en/calls-for-input-listing

UNESCO - Consultations

https://www.unesco.org/en/search?category=UNESCO&text=consultation&category=UNESCO&sort_by =unesco_date#toggle-facets

WHO - Public Consultations

 $\frac{https://www.who.int/home/search?indexCatalogue=genericsearchindex1\&searchQuery=public\%20consultation\&wordsMode=AnyWord$

OECD - Consultations and calls for contributions

https://www.oecd.org/about/civil-society/consultations-and-calls-for-contributions.htm

GE2P2 Global

IFAD Public Consultations

https://webapps.ifad.org/members/executive-board-public-consultation

European Medicines Agency's (EMA) open public consultations

https://www.ema.europ_a.eu/en/news-events/open-consultations

U.S. Federal Register - "Public Comment" or RFI

https://www.federalregister.gov/documents/search?conditions%5Bpublication_date%5D%5Bgte%5D=0 9%2F13%2F2023&conditions%5Bterm%5D=%22public+comment%22+or+RFI#

U.S. HHS – Open Requests for Comments

https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html

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