



Report on nano-specific gender differences to direct future ERA approaches

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Abstract

Implementation of sex and gender dimensions and analysis in risk assessment of nanomaterials means to recognise and analyse different aspects of sex/gender-related differences including anatomical, physiological, biological, functional, psychological and social parameters. European Commission (EC) has well recognised the wide-ranging importance of sex/gender analysis in more than 100 subfields where data show that gender analysis can benefit research, including medicine, IT sector, architecture, oceanography, geosciences, biodiversity, ecology, among others, but also nanotechnology. This deliverable provides main definition and components of sex/gender analysis, as well as its impacts on the soundness of environmental risk assessment of nanomaterials and nanotechnology. It also outlines clear needs for considering the biological, social and cultural features, behaviours and needs of both women and men in achieving sustainable development of nanotechnologies and the Sustainable Development Goals (SDGs).



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List of Abbreviations

AOP – Adverse outcome pathway

CEDAW - Convention on the Elimination of All Forms of Discrimination Against Women

EC - European Commission

ENMs – Engineered nanomaterials

ERA - European Research Area

EU - European Union

KE - Key Event

MIE - Molecular Initiating Event

OECD – Organisation for Economic Corporation and Development

RA – Risk Assessment

R&I – Research and Innovation

RG - Risk Governance

SDG - Sustainable Development Goal

SOP(s) – Standard Operating Procedure(s)

WoE - Weight of evidence



1. Introduction

Following the policy of the European Commission (EC) on the integration of the gender dimension into research,¹ RiskGONE has integrated sex and gender analysis, where relevant. From a scientific point of view, sex and gender are specifically considered in the tasks of WP6 and WP5 to direct future risk assessment (RA) approaches.

According to the report “Gendered Innovations: How gender analysis contributes to research” published by the EC in 2013,² the implementation of gender dimension in the Research and Innovation (R&I) activities brings multiple benefits to the citizen of European Union (EU) by

- increasing the excellence, creativity and business opportunities,
- improving the current status of gender norms and stereotypes, standards and reference models,
- enhancing the understanding of diverse gender needs, behaviours and attitudes,
- enhancement of the societal relevance of the knowledge, technologies and innovations produced,
- production of goods and services better suited to new markets.

This deliverable is therefore focused on gendered innovations for nanotechnology by providing recommendation for future RA of engineered nanomaterials (ENMs).

Target audience

This deliverable provides information and recommendation on implementing gender dimension and analysis for the research scientists (academia to industry), regulators, nanosafety-, nanotoxicology-, genetic toxicology-, human health-related industry sectors which regularly assess ENMs by toxicology-based assays and biological testing, governmental bodies, non-governmental bodies, scientific community outside EU projects (PhD students, Research students), other EU projects and their respective partners, EU NanoSafety Cluster.

¹ https://ec.europa.eu/info/research-and-innovation/strategy/strategy-2020-2024/democracy-and-rights/gender-equality-research-and-innovation_en

² <http://bookshop.europa.eu/en/gendered-innovations-pbKINA25848/>



2. Technical & Scientific progress

Summary of progress

The technical and scientific progress made at this stage has primarily been focused towards regulatory and policy guidelines and recommendations related to implementation of gender dimension in RA of ENMs. The most relevant policy-oriented documents provided by the EC and OECD are briefly presented.

WP6 partners implemented specifically sex/gender analysis as part of the work within Task 6.3. The case study “Development of an adverse outcome pathway for chronic /multi-generational impacts of nanomaterials in *D. magna*” was carried out focusing on development of an adverse outcome pathway (AOP) for ENMs-induced impairment of daphnia reproduction and male induction by ENMs. The identified key events (KEs) and the suggested molecular initiating event (MIE) are currently being evaluated on the basis of the weight of evidence (WoE) supporting them and the resulting confidence in them, following the guidance described in the OECD “Users' Handbook supplement to the Guidance Document for AOP”.

Finally, we have summarized recommendations from all regulatory and policy relevant projects and initiatives for efficient and timely implementation of gender dimension and analysis in current and future RA of ENMs.

Objectives

The aim of WP6 is to support risk governance (RG) of ENMs by delivering a more efficient, reliable and user-friendly environmental RA testing strategy through development of an improved, robust nano-specific predictive framework of harmonised and pre-validated regulatory-oriented RA tools. However, gender dimension and analysis should be implemented during evaluation of applicability of these tools as recommended by RA-related policy and regulations. Following this, regulatory and policy guidelines and recommendations related to gender-oriented RA was performed.

European Commission policy for the integration of the gender dimension into research



The EC established the Gendered Innovations/Innovation through Gender Expert Group in 2011. This group published created report “Gendered Innovations: How gender analysis contributes to research”, published by the Commission in 2013.³ Under the Horizon Europe, the EC convened Horizon 2020 (H2020) Expert Group to update and expand Gendered Innovations/Innovation through Gender (Gendered Innovations 2)., which updated and expanded the previous work to support the integration of the gender dimension into EU R&I activities. Main output was the report “Gendered Innovations 2: How inclusive analysis contributes to research and innovation” published by the EC in 2020.⁴ This report provides terms and methodological tools for a successful gender integration into key R&I fields by performing 15 interdisciplinary case studies (Table 1). Terms “sex” and “gender” have been also clearly defined as briefly presented in Table 2.

Table 1. Case studies performed by the EC expert group Gendered Innovations 2.

R&I field	Case studies
Health	Prescription drugs: analysing sex and gender Systems biology: collecting sex- and gender-specific data Chronic pain: analysing how sex and gender interact
Climate change, energy and agriculture	Marine science: analysing sex Smart energy solutions: analysing intersectionality Agriculture: embedding gender norms in R&I
Urban planning, transport	Smart mobility: co-creation and participatory research Waste management: co-creation and participatory design High-quality urban spaces: gender impact assessment
Information and communication technology (artificial intelligence, machine learning, robotics)	Extended virtual reality: analysing gender Facial recognition: analysing gender and intersectionality in machine learning Virtual assistants and chatbots: analysing gender and intersectionality in social robots
Finance, taxation and economics	Fair tax: gender equality and taxation in the European Union Venture funding: analysing gender
Ad hoc case study: coronavirus	The impact of sex and gender in the COVID-19 pandemic

³ Directorate-General for Research and Innovation (2013), Gendered Innovations: How gender analysis contributes to research, European Commission (<https://op.europa.eu/en/publicationdetail/-/publication/d15a85d6-cd2d-4fbc-b998-42e53a73a449/language-en/format-PDF/source-139651854>).

⁴ <https://op.europa.eu/en/publication-detail/-/publication/33b4c99f-2e66-11eb-b27b-01aa75ed71a1/language-en>

Table 2. Definition of terms “sex” and “gender” by the EC expert group Gendered Innovations 2.

Sex	Gender
refers to biological characteristics	refers to sociocultural attitudes, behaviours and identities
<p>For biomedical research defined by genetic sex determination, gametes, secondary sex characteristics.</p> <p>For research in non-human animals defined by genetic sex determination, non-genetic sex determination (social and environmental) and gametes.</p> <p>For engineering and design defined by anatomical and physiological characteristics that may affect the design of products, systems and processes.</p>	<p>Dimensions:</p> <ol style="list-style-type: none"> 1) Gender norms produced through social institutions 2) Gender identities relate to how individuals or groups perceive and present themselves in relation to gender norms. 3) Gender relations relate to how person interacts with other people and institutions.

The methods developed by the Expert Group Gendered Innovations 2 are divided in subgroups as follows:

- General methods: analysing sex, analysing gender, intersectional approaches, co-creation and participatory research, asking about gender and sex in surveys
- Field-specific methods:
 - o health and biomedicine: analysing gender in health and biomedicine, analysing sex in tissues and cells, analysing sex in lab animal research, analysing sex in biomedicine
 - o Information and communication technologies: analysing gender and intersectionality in machine learning, analysing gender and intersectionality in social robotics
 - o Climate change: analysing sex in hermaphroditic species, urban planning/transportation, gender impact assessment
 - o Innovation: norm-critical innovation.

The case studies, terms, methods and policy recommendations address the global challenges, targeted impacts and key R&I orientations of the 6 clusters of Horizon Europe’s Pillar II, as

well as mission areas and foreseen European partnerships. Conclusion of the Expert Group is that *“Integrating sex and/or gender analysis into research and innovation:*

- ▶ *adds value to research in terms of excellence, creativity and business opportunities;*
- ▶ *helps researchers and innovators question gender norms and stereotypes, and rethink standards and reference models;*
- ▶ *leads to an in-depth understanding of diverse gender needs, behaviours and attitudes;*
- ▶ *addresses the diverse needs of citizens of the European Union and thereby enhances the societal relevance of the knowledge, technologies and innovations produced;*
- ▶ *contributes to the production of goods and services better suited to new markets.”*

Overview of the OECD recommendation

The Sustainable Development Goal (SDG) 5 in the United Nations’ Agenda 2030 for Sustainable Development Gender equality, the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW), and the 1995 Beijing Declaration and Platform for Action explicitly set that “the empowerment of all women and girls are universal goals in their own right”. The OECD has issued two recommendations on gender: the 2013 Recommendation of the Council on Gender Equality in Education, Employment, and Entrepreneurship,⁵ and the 2015 Recommendation of the Council on Gender Equality in Public Life⁶. The Recommendation on Gender Equality in Education, Employment, and Entrepreneurship, adopted in May 2013, sets out a number of measures that Adherents should consider implementing in order to address gender inequalities in education, employment and entrepreneurship. It recommends that Adherents should “through appropriate legislation, policies, monitoring, and campaigning – ensure equal access to education; better enable female labour force participation, promote family-friendly policies; foster greater male uptake of unpaid work; work toward better gender balance in positions of public and private sector leadership; and promote entrepreneurship among women”. The Recommendation on Gender Equality in Public Life, adopted by the OECD Council in 2015, is focused on effective governance and the implementation of gender equality objectives and

⁵ <https://www.oecd.org/els/2013-oecd-recommendation-of-the-council-on-gender-equality-in-education-employment-and-entrepreneurship-9789264279391-en.htm>

⁶ <https://www.oecd.org/gov/2015-oecd-recommendation-of-the-council-on-gender-equality-in-public-life-9789264252820-en.htm>

gender mainstreaming measures (i.e. gender budgeting, inclusive public procurement and regulatory cycles). It recommends that Adherents “strengthen accountability and oversight mechanisms for gender equality and mainstream initiatives across and within government bodies”.

In 2021, the OECD published the report “Gender and the Environment: BUILDING EVIDENCE AND POLICIES TO ACHIEVE THE SDGS”⁷ following a call from the OECD Member countries. Based on the SDG framework, the OECD has explored links between gender equality and environmental sustainability in the nine environment-related SDGs (2, 6, 7, 9, 11, 12, 13, 14 and 15) and provided evidence and rationale for the need to embed gender equality in economic, social, and environmental goals, by identifying trade-offs and complementarities among different policies in the context of Agenda 2030. This work was focused on integration of gender mainstreaming into all OECD policy areas aiming to “bring together, for the first time, all the existing evidence from OECD countries on the differential impacts of environmental factors on men and women’s health, such as air pollution, water and soil contamination, exposure to chemicals, climate change and natural disasters”. The report has demonstrated the critical importance of implementing gender dimension and analysis in achieving sustainable development and the SDGs. Regarding ERA approaches and methodologies, this OECD report concluded that “the synergies between gender equality and environmental goals translate into positive economic and wellbeing outcomes across a number of dimensions”. Gender dimension and analysis may significantly advance nine environment-related SDGs such as SDG 1 by chasing no poverty conditions, SDG 3 by reaching good health and well-being around the world, SDG 4 by increasing quality of education, SDG 8 by promoting and fostering decent work and economic growth and SDG 10 by reducing inequalities. All these ambitions may be significantly reached by improving gender equality and women’s economic empowerment.

RiskGONE WP6 case study on male induction in *Daphia magna* after exposure to ENMs

As a part of the WP6 work within Task 6.3, we identified daphnia-related AOPs with a focus on endocrine disruption and oxidative stress. Two daphnia-related AOPs are currently under

⁷ OECD (2021), *Gender and the Environment: Building Evidence and Policies to Achieve the SDGs*, OECD Publishing, Paris, <https://doi.org/10.1787/3d32ca39-en>

development in the AOPWiki: AOP 201 “Juvenile hormone receptor agonism leading to male offspring induction associated population decline” and AOP216 “Excessive reactive oxygen species production leading to population decline via follicular atresia”. Building on these, and an extensive literature search based on chronic daphnia exposure to ENMs was performed and finally provided a starting point for AOP developmental approach and identified the specific genes involved in juvenile hormone receptor induction leading to male induction (AOP 201) and excessive oxidative stress leading to oocyte apoptosis associated reproduction decline (AOP 216). The whole work is described in the Deliverable D6.4, while deliverable D6.5 will present the final version of the AOP and the changes resulting from these consultations and discussions.

Current work of WP6 to integrate gender/sex dimension in European Research Area (ERA) of ENMs is related to meta-analysis of existing scientific data on the sex differences in ENMs ecotoxicity which is targeted towards preparation of review paper on the topic of sex differences in nano-specific ecotoxicity.

3. Conclusions

This deliverable describes the current and future work of WP6 to implement gender/sex dimension and analysis in ERA of ENMs.

According to the EC and OECD recommendations, successful implementation of gender dimension and analysis for RA of ENMs should encompass following activities:

- Creation of awareness on including the sex/related dimension in research funding, design, implementation and application of research results.
- Identification and encouragement of work of gender experts.
- Communication and dissemination of sex/gender-related requirements of regulatory and funding agencies.
- Integration of the sex/gender analysis in the national research and innovation agenda, research policies and programmes, as well as in the education and teaching curriculum for more efficient RA approaches.
- Development and adoption of tools and methods for understanding the sex/related dimension during RA activities.
- Setting standards and harmonization of approaches to include information on the sex/gender dimension in RA of ENMs.



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