RISK GONE **RiskGONE final event** Madrid, 15-16 June 2023 NILU **NILU - Main activities and outcomes**

The Horizon 2020 project RiskGONE has been on a journey of almost 5 years, defining a risk governance (RG) process for engineered nanomaterials, based on the revision, adaptation and pre-validation of existing risk assessment and RG frameworks and tools for conventional chemicals.

The Climate and Environmental Research Institute NILU acted as project coordinator and partner involved in all the WPs of the project. Some of NILU's main activities and outcomes are here reported.

WP1 - SCIENTIFIC COORDINATION AND MANAGEMENT

As project coordinator, NILU thanks all the 22 partners for the scientific effort and fruitful and pleasant collaboration, which resulted in numerous publications, reports, Standard Operating Procedures and pre-validated Test Guidelines related to environmental and human health, and social, economic, and ethical aspects. It was a pleasure to coordinate such a great project and Consortium.

WP2 - RISK GOVERNANCE

- Support to the development of the RiskGONE cloud platform and the NMBP-13 portal
- Development of data collection templates for the methods:
 - Comet assay
 - CFE
 - Alamar Blue
 - HPRT
 - Endotoxin detection

<u>Riskgone</u>	IN-VITRO Test D	ata Recording Fo	orm (TDRF)			
Please complete all applicable fields below as fa	r as possible. Aim to fami	iliarise yourself with th	he Introductory Gui	dance and Examp	le Filled Templat	es.
While aiming to standardise data recording as fa	ar as we can, flexibility ma	y still be needed for s	ome Test/Assay typ	es and their resu	lts:	
Thus it may be necessary to add additional iter	ms e.g. for further replica	- tes, concentrations, til	mepoints, or other	variations on inpu	ts, results outpu	ts, etc.
If so, please highlight changes & alterations e.	g. using colour, and/or co	mments in notes, or a	djacent to data/tabl	es to flag items, f	luctuations from	norm, etc
IN-VITRO TEST CONDITIONS	Please ensure you	also complete a Test	Method Descript	ion Form (TMDF) for this test tvr	e*.
Project Work Packa	ge: WP5-HUMAN HAZARD A	SSESSMENT				
Partner conducting test/as	say: NILU					
Test facility - Laboratory na	me: HEL					
Lead Scientist & contact for	test: Espen Mariussen	E-mail address:				
Assay/Test work conducted	by: Eleonora Longhin	E-mail address:				
Full name of test/assay (add OECD Test ref-ID if a	pp.): COMET					
Short name or acronym for test/as	say: COMET					
Type or class of experimental test as used h	ere: Genotox					
End-Point being investigated/assessed by the	test: DNA damage					
Metric(s) used to assess End-Point outcome/respo	nse: Scored single cells (% tai	l intensity)				
SOP(s) for test - ref. project or other doc Title	COMET					
th/link to sop/protocol on proj. server/web where app	lic.: TBD					
Test start date (YYYY-MM-	DD): 22.01.2020					
Test end date (YYYY-MM-	DD): 02.07.2020					

WP4 - CHARACTERISATION

• Pre-validated guidance on the determination of ENMs endotoxins content – D4.4

		Particles concentration		Difference	Acceptance	
		tested (ug/ml) +/-		with EU	requisite: +/-	Validity
	ENM identifier	endotoxin (E)	EU/ml	spiked=1	25%	
	ERM0000085	10	2,75	-0,09	-109,42	Invalid
	ERM0000085	10+E	2,66			
	ERM0000086	10	2,72	0,67	-32,51	Invalid
	ERM0000086	10+E	3,39			
[ERM0000083	10	4,47	-0,80	-179,68	Invalid
	ERM0000083	10+E	3,67			
	ERM0000063	100	-0,01	0,17	-82,84	Invalid
	ERM0000063	100+E	0,16			
	ERM0000063	10	-0,04	0,30	-70,02	Invalid
	ERM0000063	10+E	0,26			
	ERM0000065	100	-0,03	0,61	-38,53	Invalid
	ERM0000065	100+E	0,58			
	ERM0000065	10	0,05	1,06	5,75	Valid
	ERM0000065	10+E	1,10			
	ERM0000062	100	0,02	1,11	11,47	Valid
	ERM0000062	100+E	1,14			

WP3 - GUIDELINES FOR RISK-BENEFIT ASSESSMENT

- Draft Guidelines for ENMs on (NILU main author):
 - Risk Assessment (D3.1)
 - Life cycle assessment (D3.2)
 - Multi-Criteria Decision Analysis Framework (D3.7)
- Contributing to: - Risk transfer in insurance models (D3.4)
 - Societal acceptance and risk perception



ENMs characterization in stock and medium (NTA, DLS)

WP5 - HUMAN HAZARD ASSESSMENT

Evaluation and adaptation to ENMs of standard operating procedures (SOPs) for the assays: colony forming efficiency (CFE), Alamar Blue, Comet assay, mammalian gene mutation HPRT (TG476), micronucleus (TG487) – D5.1, D5.2



- Discussion with the national contact point to support SPSF submission to OECD
- Virtual and on-site courses, and



COMET ASSAY

INSTRUCTIONAL VIDEO

Online Comet Assay

workshop



WP7 - COMMUNICATION AND LIN TERNATIONAL BODIES

MDPI

- Set up and maintenance of the RiskGONE website at www.riskgone.eu
- Dissemination activities and scientific publications, e.g.:



Article

Check for updates

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Elijah Peterser

Christie Maria Sayes

National Institute of Standards and

Technology (NIST), United States

Antalya Bilim University, Turkey

National Center for Nanoscience and

Check for updates

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Hepato(Geno)Toxicity Assessment of Nanoparticles in a HepG2 Liver Spheroid Model

Elisabeth Elje^{1,2}, Espen Mariussen¹, Oscar H. Moriones^{3,4}, Neus G. Bastús³, Victor Puntes^{3,5,6}, Yvonne Kohl⁷, Maria Dusinska¹ and Elise Rundén-Pran^{1,*}

- The alamar blue assay in the context of safety testing of nanomaterials Baylor University, United States
 - Eleonora Marta Longhin*, Naouale El Yamani, Elise Rundén-Pran and Maria Dusinska
- The miniaturized enzyme-modified comet assay for genotoxicity testing of Independent Researcher, Icheon, South nanomaterials

N. El Yamani^{1*}, E. Rundén-Pran¹, A. R. Collins², E. M. Longhin¹



Lack of mutagenicity of TiO₂ nanoparticles in vitro despite cellular and nuclear uptake

Interpret results

Naouale El Yamani^{a, 1}, Laura Rubio^{b, 1}, Alba García-Rodríguez^b, Alena Kažimírová^c, Elise Rundén-Pran ^a, Barančoková Magdalena ^c, Ricard Marcos ^b 🙁 🖾, Maria Dusinska ^a 🔍 🖾

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1

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Hazard identification of nanomaterials: In silico unraveling of descriptors for cytotoxicity and genotoxicity

Naouale El Yamani^a, Espen Mariussen^{a, b}, Maciej Gromelski^c, Ewelina Wyrzykowska^c, Dawid Grabarek ^e, Tomasz Puzyn ^{e, d}, Speranta Tanasescu ^e, Maria Dusinska ^a, Elise Rundén-Pran ^a 😤 🖾

training materials for the assays Comet assay and CFE – D5.6

Video training available at <u>www.riskgone.eu</u>

WP6 - ECO-TOXICOLOGICAL HAZARD ASSESSMENT

-

 Considerations and adaptation of the Comet assay for ecotoxicity testing (fish cell lines): SOPs - in D6.1; data collection template – in D6.3; and training – in D6.7

^ ^ * * ***

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E. Elje¹, P. Hoet³, I. Vinković Vrček⁴, S. H. Doak⁵, V. Fessard⁶ and University of Milano-Bicocca, Italy

> The colony forming efficiency assay for toxicity testing of nanomaterials-Modifications for higher-throughput

Elise Rundén-Pran1*, Espen Mariussen1.2, Naouale El Yamani1, Elisabeth Elje^{1,3}, Eleonora Marta Longhin¹ and Maria Dusinska¹

Open Access Article

Advanced Respiratory Models for Hazard Assessment of Nanomaterials—Performance of Mono-, Co- and Tricultures

by 🙁 Laura Maria Azzurra Camassa 1.† 🖾 😳, 🙁 Elisabeth Elje 2.3.† 🗠, 🙁 Espen Mariussen 2.4 🖾 😳 😫 Eleonora Marta Longhin ² 🖂 😫 Maria Dusinska ² 🖂 😳 😫 Shan Zienolddiny-Narui ^{1,•} 🖂 💿 and 🚺 Elise Rundén-Pran ^{2,*} 🖂 💿

... and contribution to many other publications (published or in progress)

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