



**NGTX - 21st Century Toxicology  
for Next Generation Tobacco  
and Nicotine Products (NGPs)  
Task Force 2021 Report**

**Virtual CORESTA SSPT Conference  
October 2021**



## ❖ Sub Group Composition

- Coordinator : Marianna Gaca (BAT)
- Secretary : Liam Simms (ITG)

## ❖ Objectives

To review, assess, apply and harmonize 21st century toxicology approaches to tobacco and nicotine products, including but not limited to screening approaches, AOP development, organs on a chip and systems biology to support quantitative risk assessment.

- To review emerging technologies and application to NGP testing- review document to be prepared (NWIP#221)
- To identify appropriate approaches and application of emerging technologies to NGP testing
- To provide guidance documents to support assay application for NGP testing using TT21C relevant assays

## ❖ Priorities:

- “Good *In Vitro* Method Practices ” (GIVIMP: OECD Guidance Document) guidance: review of document for NGP testing
- High Content Screening (HCS) working group method standardisation
- 3D models guidance on how to use them (a new item to be confirmed)
- External publication on 21st century toxicology approaches for NGP testing and presentation at future CORESTA meeting

## ❖ On going projects:

Project No.	Project Name: Activity	Leader	Status
NWIP#221	Review emerging technologies and application to NGP testing- review document	M. Gaca	TR expected end of Q4 2021 External publication Q1 2022

## ❖ Which approaches to take forward (practical)?

### ➤ Use and application of high content screening

- common test systems (cells),
- common endpoints (cell health, oxidative stress, DNA damage),
- applied to tobacco and nicotine products

## ❖ Use and application of high content screening (HCS)- potential outcomes (TBC)

- Explore HCS data variance across the companies and how HCS can be accepted for NGP testing.
- Review the data already held by individual companies for reference cigarettes, controls etc,
- Develop guidance how HCS can be used for NGP testing to be placed on the CORESTA website.
- To be further discussed at Autumn 2021 virtual meeting



**Chemical Research in Toxicology**

**In Vitro Systems Toxicology Assessment of a Candidate Modified Risk Tobacco Product Shows Reduced Toxicity Compared to That of a Conventional Cigarette**

Ignacio Gonzalez-Suarez,<sup>1</sup> Florian Martin, Diego Marescotti, Emmanuel Guodj, Stefano Acali, Stephanie Johns, Remi Dulze, Karine Baumer, Darine Peric, Didier Goodertier, Stefan Frenzel, Nikolai V. Ivanov, Carole Mathis, Julia Hoeng, and Manuel C. Frutkin

Philip Morris International R&D, Philip Morris Products S.A., Quart Jonsson 5, 2000 Nunchli, Switzerland

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Contents lists available at [ScienceDirect](#)

**Toxicology in Vitro**

journal homepage: [www.elsevier.com/locate/toxinvit](http://www.elsevier.com/locate/toxinvit)

High Content Screening in NHBE cells shows significantly reduced biological activity of flavoured e-liquids, when compared to cigarette smoke condensate

Lukasz Czekala<sup>a,\*</sup>, Liam Simms<sup>a</sup>, Matthew Stevenson<sup>a</sup>, Edgar Trellis-Sticken<sup>a</sup>, Paul Walker<sup>a</sup>, Tawfir Walele<sup>a</sup>

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Contents lists available at [ScienceDirect](#)

**Regulatory Toxicology and Pharmacology**

journal homepage: [www.elsevier.com/locate/yrtph](http://www.elsevier.com/locate/yrtph)

Assessment of novel tobacco heating product THPL0. Part 6: A comparative in vitro study using contemporary screening approaches

Mark Taylor<sup>a</sup>, David Thorne<sup>a,\*</sup>, Tony Carr<sup>a</sup>, Damien Brebrey<sup>a</sup>, Paul Walker<sup>a</sup>, Christopher Proctor<sup>a</sup>, Marianna Gaça<sup>a</sup>

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Risk Assessment of a novel tobacco vapour product using ToxTracker® assay and highcontent screening in vitro

Munakata S, Erami K, Hashizume T

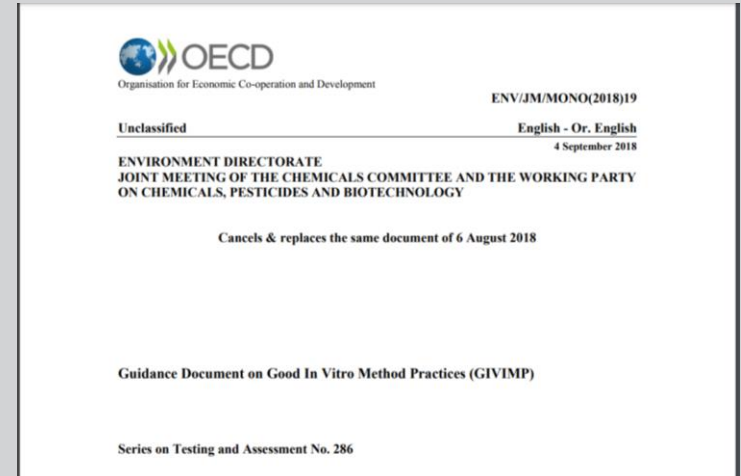
Japan Tobacco Inc, R&D Group, Scientific Product Assessment Centre, Japan



# Good *In Vitro* Method Practices (GIVIMP)

## ❖ Guidance documents

- **OECD Guidance Document** on Good *In Vitro* Method Practices (GIVIMP)
- Team assembled: Vitrocell, CRL, BAT, JTI Oekolab, Covance, PMI, JT, Altria, JUUL
- Majority of sections in the guidance document have been reviewed
- A guidance document recommending the principles of GIVIMP for non-regulatory assays will be compiled and will be placed on the CORESTA website
- Autumn 2021 virtual meeting to review document progress, and guest presentation, “How a GIVIMP certification program can increase confidence of *in vitro* methods”





### ❖ Further suggested working groups:

- Standardisation of *in vitro* whole aerosol exposure
- Alignment of current methods
- Reference products for NGPs
- Standardization of high content screening
- Screening technologies for whole aerosols
- Translation of data to human exposures
- Dosimetry
- New TOX 21 assays
- Oral models (absorption, permeation)
- Regulatory acceptance
- AOPs (Adverse Outcome Pathways)
- Adaptation of models for CROs

### ❖ Meetings

- **Last: November 2020, virtual**
- **Next: November 2021, virtual meeting, to include a working session to define TT21C inputs into the CORESTA “Strategy House”, 2 year and 5 year plans**