



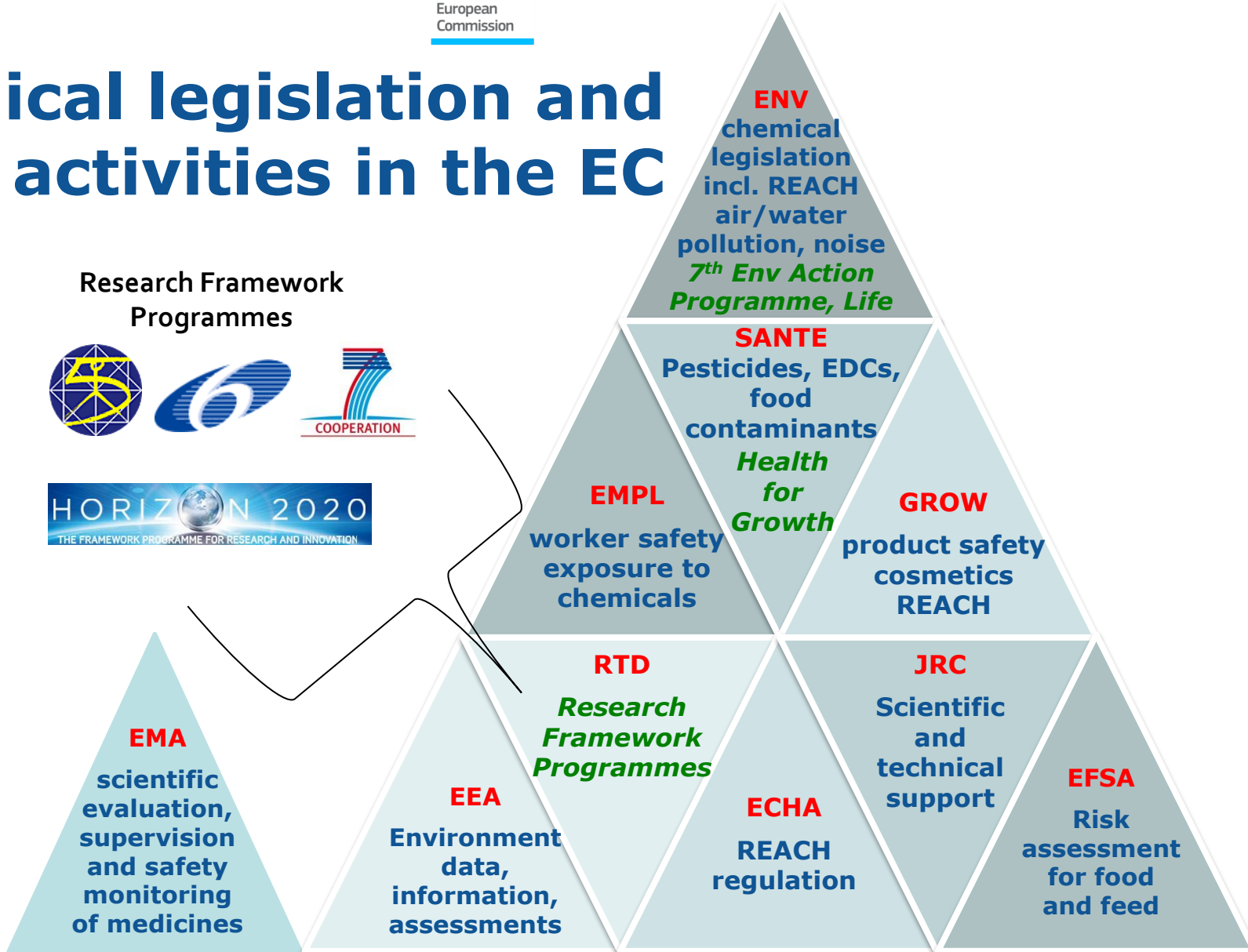
# EU Research and Innovation in support to chemical safety

Dr Christian Desaintes  
DG RTD Health

**ECHA topical workshop, Helsinki, 19 April 2016**

# Chemical legislation and activities in the EC

Research Framework  
Programmes



## Contribution to Commission and 3 Os priorities

- ***Juncker 1*** - A new boost for jobs, growth and investment
- ***Juncker 2*** - A connected digital single market
- ***Juncker 6*** - EU as a stronger global actor
- ***Juncker 7*** - Towards a new policy on migration



**Open Innovation**

**Open Science**

**Open to the World**





## **What will we achieve?**

- **Better health for all**
- **A more competitive EU health industry and care sector**
- **Maximising the digital potential**
- **European leadership on European/global challenges**

## **How do we achieve it?**

- **Personalised Medicine Initiative**
- **EU-ToxRisk and other EC/IMI projects**
- **European Human Biomonitoring Initiative**
- **Health "Big Data"**
- **Leverage public investment**
- **Strategy coordination and global initiatives**

# FP7-H2020 research in safety assessment

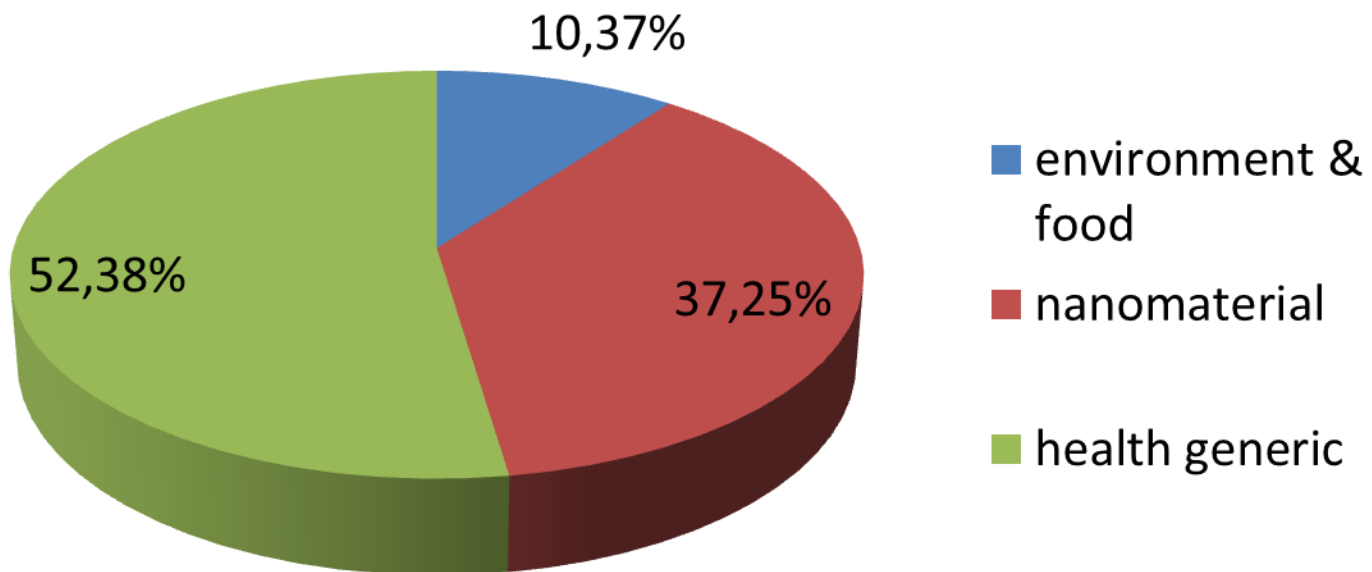
More than **€300 million** from RTD- and **IMI-**  
*funded research projects*#\*

- **SEURAT-1: repeated dose systemic toxicity**
- **HeCaToS: drug-induced liver and heart toxicity**
- **EU-ToxRisk: follow-up and extension of SEURAT-1**
- **e-Tox: *in silico* toxicology & database**
- **SAFE-T: new tests based on biomarkers**
- **MIP-DILI: iPSC & computer models for liver injury**

# excluding an estimated €100 million matching funds from the industrial associated partners (€25 million from Cosmetics Europe in SEURAT-1, and €75 million from EFPIA in IMI projects)

\* As up to April 2016

# Areas covered by FP7 research in safety assessment



# SEURAT-1 impact

## Open Science



- *Scientific knowledge*
  - on underlying mechanisms of adverse health effects
  - **>300 scientific publications**

## *New tools & techniques*

- **liver bioreactor, differentiated iPS cells, predictive biomarkers, *in silico* models, etc.**

## *Huge amount of -omics and toxicity data*

- **open access in Cosmos database and ToxBank**

## Open Innovation



## SEURAT-1 impact (2)

*Validation of the approach in cross-cluster case studies*

- *Oriented towards regulatory needs*
- *Sustainable partnership with industry*
- *Approach valid for all human safety assessment application sectors*
- *Leverage for innovation potential*



# SEURAT-1 impact (3)

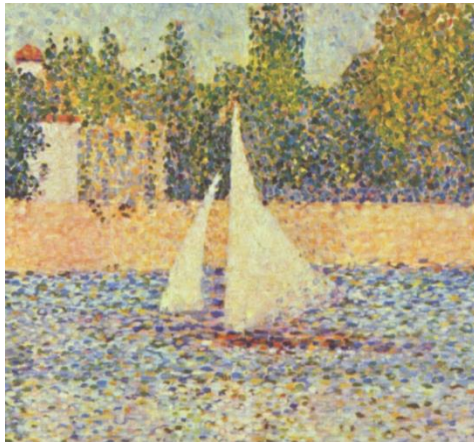
## Open to the World



- *International research collaboration*
  - **approach complementary to US programmes (ToxCast/Tox21)**

*Flagship EU initiative "an international driver"*

# From SEURAT-1 to EU-ToxRisk: expectations from the EC



**EU Flagship and international driver**

**building on open innovation within SEURAT-1**

**from continuity to more ambitious objectives, towards  
better prediction of risk & improved read-across**

€28 million

## EU-ToxRisk

*6 years: January 2016 – December 2020*

*Mechanism-based safety testing strategy*

- **Repeated dose toxicity in 4 organs (liver, lung, kidney and nervous system)**
- **Developmental and reproductive toxicity (incl. ED)**
- **200 compounds**

*Test systems - single cells to 4 organs-on-a-chip*

*Case studies to validate the approach*

*Participation of large industries, SMEs*

ROCHE, BASF, Unilever, L'Oreal, Cosmetics Europe, SimCyp, CAAT-EU

*Interaction with regulators and other initiatives*

ECHA, eTox, Tox21, JRC

# Expectation from the European Commission

*Improved toxicological knowledge and RAX*

*Better prediction of human risk*

*Meet regulatory needs*

*Commercial exploitation*

*International co-operation + JRC*

*Collaboration with IMI and other EU projects*

*Reduction of laboratory animals in safety testing*

*More exchange between different stakeholders*

*Public outreach*

# Political context at the start of EU-ToxRisk

## *Paradox*

- Higher demand for better safety assessment for humans
- Increasing pressure to ban **all** animal experiments

*EU-ToxRisk and other H2020 EC/IMI projects to address both concerns*

# We wish a safe® journey through chemicals



*Contact*

*Dr Christian Desaintes*

*[christian.desaintes@ec.europa.eu](mailto:christian.desaintes@ec.europa.eu)*