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**Discussion on “Harnessing rapid technological change for inclusive and  
sustainable development”**

Written statement submitted by

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Statement by Cruelty Free International

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### **PRIORITY THEME 1: Harnessing rapid technological change for inclusive and sustainable development**

As the American philosopher of science, Thomas S. Kuhn, wrote in his 1962 book *The Structure of Scientific Revolutions*, “Each of them necessitated the community’s rejection of one time-honored scientific theory in favor of another incompatible with it. Each produced a consequent shift in the problems available for scientific scrutiny and in the standards by which the profession determined what should count as an admissible problem or as a legitimate problem-solution. And each transformed the scientific imagination in ways that we shall ultimately need to describe as a transformation of the world within which scientific work was done”.

Cruelty Free International is of the view that there are actions that can be taken at national and international levels to champion a new model of animal-free science which can help deliver Agenda 2030 and more inclusive and sustainable development. .

In order to achieve the transformation desired by Agenda 2030 and the Sustainable Development Goals (SDGs) and harness rapid technological change for inclusive and sustainable development, the global community must move on from its default reliance on cruel and unreliable animal models to a scientific revolution centred on an in vitro and in silico approach to research, development and safety testing.

In vitro and in silico methods are often quicker, less expensive and more predictive than the in vivo methods they replace.

Toxicity tests on animals in laboratories are carried out to evaluate drugs, industrial, agricultural and consumer chemicals and food additives for their potential to cause adverse health and environmental effects. These animal test methods have been developed over the past 60 years. Millions of rats, mice, hamsters, guinea pigs, rabbits, dogs, cats, pigs, horses and monkeys suffer and die in these experiments. Extrapolating the results of animal tests to predict human health effects is based on a number of controversial assumptions and the tests have never been properly validated. Some 95% of drugs that are successful in animal preclinical trials go on to fail in humans.

#### **Alternatives are usually cheaper and faster than the animal test they replace**

The in vitro tests for skin and eye irritation can be conducted in a day, whereas the corresponding rabbit tests take two to three weeks. Similarly, one of the skin sensitisation

tests can be conducted in one day, whereas the corresponding test on mice takes at least six times that. These tests can already be conducted at a cost equivalent to the animal test, between 1,000 and 5,000 euros.

Methods that avoid the lengthier systemic toxicity tests are much cheaper and faster. For example, computer (QSAR) models can be run at very little cost, assuming some in-house expertise, saving thousands of euros. The cost of an expert to set out a Threshold of Toxicological Concern (TTC) approach or read across argument could typically be around 3,000 euros, compared to 300,000 euros for a two-generation reproductive toxicity test. The Cell Transformation Assay can cost as little as 500 euros and could avoid the cancer bioassay on rats which takes two years and costs approximately one million euros.

### **Alternatives are usually more reliable and accurate than the animal test they replace**

Modern alternative methods are required to go through a rigorous validation process to demonstrate they are as or more effective than the animal test they replace. The performance of the alternative is compared to human responses where they are already known, or the existing animal test where they are not. Validated alternative methods are published in the guidelines of international bodies that harmonise the most common methods to assess the safety of chemical substances. These bodies include the Organisation for Economic Cooperation and Development (OECD) which publishes Test Guidelines (TGs) relevant for safety testing of chemicals, including cosmetics. Alternatives will simply not be accepted at international levels by the OECD without sufficient evidence that they reliably detect toxic and non-toxic substances. By contrast, it is important to note that traditional animal tests have never been 'validated' for their use in reliably detecting safety. This means that there has not been an independent, controlled assessment of whether the animal test accurately and reliably predicts human reactions using a set of substances for which the human response is known. The validity of existing animal tests is assumed only, based on a history of their use. This is not adequate for today's high safety

Animal tests fail to provide the necessary information about the biological changes that lead to adverse health effects; they expose animals to doses far in excess of typical human exposure necessitating assumptions about the effects of lower doses; they do not take into account the differences between humans and animals and they are expensive, lengthy, cruel and unethical.

To meet today's health, environmental and sustainability challenges, deliver all the SDGs and meet the ethical demands of citizens and consumers, we need to do better.

We should be doing all we can to hasten the study of the impact of chemicals and drugs using human tissues and cells and computer models and developing truly international systems to share test data so that experiments must not be repeated and speed up the development and acceptance of non-animal methods.

**2. Can you provide examples of innovative initiatives in partnership with (or by) the private sector in/from your country that harnesses frontier technologies for inclusive and sustainable development? What are the innovations in terms of the use of technology?**

**What are the innovations in terms of business models?**

Following the European Union's prohibition on testing cosmetics and their ingredients on animals, government, the research community and industry have been spurred on to work together on research and development activities on methods alternative to animal testing.

The EUR 50 million SEURAT-1 research initiative, co-funded by the European Commission and industry and completed in 2015, developed a workflow to assess safety without relying on animal testing, designed for cosmetic ingredients but also applicable to other types of chemicals. The outcome was published in 2017 and is accessible online.

EU-ToxRisk15, the integrated European programme driving mechanism-based toxicity testing and risk assessment for the 21st century, is a major collaborative project funded by the EU framework programme for research and innovation, Horizon 2020. With a budget of over EUR 30 million, it was launched in January 2016 and will last for six years. The project, which builds on the results of SEURAT-1, aims to make progress towards animal-free safety assessments and tackles complex areas of toxicology, such as repeated dose and reproductive toxicity. The first eight case studies have progressed considerably, establishing collaborations with the US Tox2116 and the Commission, through EURL ECVAM.

Several other large Horizon 2020 research projects to assess chemical mixtures have begun in recent years, including EuroMix17 and EDC-MixRisk18. EuroMix aims to develop a strategy for the risk assessment of mixtures of chemicals from multiple sources, while EDC-MixRisk focuses on improving the risk assessment of exposure to mixtures of endocrine-disrupting compounds. Both explore mixture assessments including in vitro and in silico methods. The Commission collaborates on these projects through EURL ECVAM. The human biomonitoring project HBM4EU19, in which the Commission and several EU agencies are involved, includes one work package dedicated to mixtures.

**3. What are the actions that the international community, including the CSTD and STI Forum, can take to contribute to maximize the benefits associated to rapid technological change and mitigate the risk of these technologies widening or creating new inequalities within and across countries? Can you give any success stories in this regard?**

The international community, and particularly CSTD and STI Forum, should take a lead in recognising the importance of alternatives to animal testing to rapid technological change that is sustainable and inclusive. The CSTD and STI Forum could be excellent platforms for knowledge sharing in this area. and enabling that all economies are well placed to make use of this technology

**4. Could you suggest some contact persons responsible for policies related to rapid**

**technological change and its impact inequality as well as any experts from your Agency, academia, private sector, civil society or government dealing with projects in this area? We might contact them directly for further inputs or invite some of them as speakers for the CSTD inter-sessional panel and annual session.**

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