

Position Paper to

Support safe and sustainable innovation - Help overcome trade barriers - Make legislation enforceable

Internationally harmonised and standardised characterisation and test methods are essential for the protection of human health and the environment. They guarantee that the safety assessment of chemicals and materials over the whole life cycle is based on valid data. [OECD Test Guidelines](#) (TGs) are internationally accepted standards for the safety testing of chemicals, support the implementation and enforcement of legislation, and are essential for safe and sustainable innovation and the competitiveness of industry. Developing and validating TGs to keep pace with innovation is a challenge that is often underestimated. It is time to put the importance of developing TGs into focus at international and European level.

The undersigned, therefore, advocate a European Test Methods Strategy that ensures continuous financial support for the systematic (further) development of OECD TGs. This strategy should also consider and promote international cooperation in the spirit and context of the OECD collaborative effort.

OECD TGs support innovation and reduce trade barriers

The [OECD Mutual Acceptance of Data](#) (MAD) agreement ensures that test results generated in accordance with OECD TGs and the OECD Principles of Good Laboratory Practice are accepted in all OECD and adherent countries. Data generated according to OECD TGs are internationally comparable for research and development as well as regulation. This facilitates innovation, international trade and the reduction of non-tariff barriers to trade.

Innovation is a key driver in overcoming the challenges that humanity encounters. OECD TGs allow reliable and reproducible characterisation and prediction of possible effects to human health and environment. The MAD agreement ensures acceptance by relevant authorities, thus supporting innovation and long-term investments, as these guidelines are used by industry in both the innovation process and to fulfil regulatory requirements in various regions of the world. The lack of adequate TGs hinders innovation and the achievement of broader policy ambitions for a more sustainable society as pursued by the UN Sustainable Development Goals (SDG) and, for example, the European Green Deal.

In addition, the MAD agreement gives rise to considerable cost savings for industry and government, and prevents many unnecessary (animal) tests being carried out. Moreover, it reduces non-tariff trade barriers by keeping additional costs within limits when placing a chemical, material or product on the international market.

OECD TGs support sustainable innovation and thus strengthen the UN SDG

Continuous commitment to method validation and harmonisation supports accelerated TG development. Furthermore, it allows methods for endpoints to be addressed that are related to safety and sustainability assessments that are required to implement policy ambitions like the UN SDGs. SDG implementation is supported in the EU for example, by the Green Deal and the zero pollution ambition: moving towards a non-toxic environment.

The TGs enable the generation and subsequent sharing of reliable and reproducible information, thus making them essential for:

- safe and sustainable innovation, manufacturing, use and reuse of (new) chemicals and materials;
- the knowledge base required to support continuous innovation;
- fostering end-users' trust in chemicals and materials, which is essential for the market to thrive.

In contrast, the lack of adequate TGs will slow down the process to achieve broad policy ambitions along with market developments.

OECD TGs are essential for legislation and its enforceability

Legislation has to keep pace with innovation to ensure safe and trustworthy development of new technologies and materials. It has to be enforceable in order to maintain stakeholders' trust in legislation and the regulatory authority. To ensure clear and enforceable chemicals' legislation, OECD TGs are essential as they form the basis of the vast majority of recognised methods in, for example, the European Test Methods Regulation ([Regulation \(EC\) 440/2008](#)) that lays down test methods pursuant to the European REACH Regulation ([Regulation \(EC\) 1907/2006](#)). Comparable legislation exists in other OECD member countries. Having OECD TGs that address all regulatory endpoints ensures that all relevant aspects of chemicals and materials can be reliably and reproducibly measured, and subsequently assessed and managed.

OECD TGs need to be continuously amended and developed

In the case of nanomaterials, it was shown that existing TGs were not always applicable and TGs for some endpoints were missing, while legislation required information on such endpoints for nanomaterials to enter the market.

To raise awareness of this regulatory need, the Malta Initiative was launched in 2017 to support the amendment and development of TGs for nanomaterials. Despite the major progress achieved, method development for nanomaterials is still incomplete, as it is likely that innovative materials will require further method developments.

Work on amending and developing TGs needs to be continued and sustained. To ensure that TGs are ready for existing as well as possible future regulatory needs, they need to cover new (advanced and/or particulate) materials. They also need to address new method developments, for example, new approach methodologies (NAMs) to further reduce animal testing. Methods need to be validated to demonstrate that they are relevant and can be reliably applied to such new materials. This is a recurring challenge that cannot be met by individual EU or other OECD member countries or stakeholders.

Constant funding is needed within a European Test Methods Strategy

The experiences of the Malta Initiative show that a coordinated effort leads to successful and efficient TG development. This should be continued and expanded in a European Test Method Strategy which includes:

- (a) funding of researchers for the development, validation and harmonisation of test methods, and
- (b) an international platform for collaboration and exchange between stakeholders to:
 - identify relevant/concerning endpoints, methodological gaps and related methods ready for validation and harmonisation;
 - support international collaboration between researchers, regulators and industry in TG development;
 - ensure the development of test methods that have a sound scientific basis are operable and useful in (pre-) regulatory and scientific testing;
 - increase the likelihood of (effective) adoption and implementation by the OECD Member countries.

Experience has also shown that adaptation and development of test methods require intensive effort (in terms of time, human and financial resources), which individual researchers, industrial actors or EU Member States cannot undertake alone. Furthermore, a coordinated approach can be more effective and help avoiding duplication of work.

To sustain and continue these coordinated efforts, we strongly encourage the European Commission to strengthen also the financial support for the validation and harmonisation of test methods and coordination of efforts towards OECD TG development. Such support will lead to the availability of the currently missing tools required for implementing the UN SDGs – a goal that is also reflected in EU policy ambitions regarding safe and sustainable chemicals and materials.

<https://malta-initiative.org/>

Signatories



