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GUIDING PRINCIPLES ON GOOD PRACTICES FOR THE AVAILABILITY/DISTRIBUTION OF PROTECTED ELEMENTS IN OECD TEST GUIDELINES

Series on Testing and Assessment
No.298

These Guiding Principles were slightly amended in 2021 to qualify the upfront payments in cases where they occur (see p.21).

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SERIES ON TESTING AND ASSESSMENT
NO. 298

GUIDING PRINCIPLES ON GOOD PRACTICES FOR THE AVAILABILITY/DISTRIBUTION OF PROTECTED ELEMENTS IN OECD TEST GUIDELINES

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among **FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD**

Environment Directorate
ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT
Paris 2019

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This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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FOREWORD

This document describes good practices for the licensing of protected elements included in OECD Test Guidelines (TGs) and specifies the information required from a test method developer when submitting a proposal for a new TG that contains protected elements. Following the workshop organised at OECD in September 2017 (OECD, 2018a), there was agreement that more guidance, transparency and communication are needed around protected elements resulting from innovation in sciences and techniques that are gradually integrated in OECD Test Guidelines (TGs). The aim of the present document is to serve as a guide for organisations (e.g. private companies, universities, etc.) having developed and claimed intellectual property (IP) on material and techniques that could be readily used to fulfil a regulatory need, if it was integrated in an OECD Test Guideline. By observing and following the guiding principles, test developers would join the Programme with increased awareness of expectations and requirements.

These Guiding Principles were elaborated in 2018 by a group of experts in intellectual property issues from various sectors ranging from biotechnology applications to standards development, and experts in anti-trust/competition law. Experts were nominated by their National Coordinators and are practitioners generally representing national patent offices, lawyers in private companies, or IP experts in regulatory agencies.

This document contains a broad overview of the intellectual property and similar protections that affect the OECD Test Guidelines Programme. Laws governing intellectual property and similar rights vary widely from jurisdiction to jurisdiction; anyone seeking to answer specific questions about the interpretation of the concepts in this paper in a specific jurisdiction must seek the advice of a specialised lawyer. Therefore, the OECD shall in no way be held liable for the content of this document, which is intended as a general overview only and should not be interpreted as legal advice.

This document was approved by the OECD Working Group of the National Coordinators of the Test Guidelines Programme in April 2019 and is declassified and published under the responsibility of the Joint Meeting of the Chemicals committee and Working Party on Chemicals, Pesticides and Biotechnology.

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GUIDING PRINCIPLES

ON GOOD PRACTICES FOR THE AVAILABILITY/DISTRIBUTION OF PROTECTED ELEMENTS IN OECD TEST GUIDELINES

Introduction – Setting the scene

The OECD Test Guidelines for the testing of chemicals are a collection of the most relevant internationally agreed testing methods used by governments, industry and independent laboratories to assess the safety of chemical products. They are primarily used in regulatory safety testing and subsequent chemical notifications and registrations. The set of Test Guidelines are updated on a regular basis to keep pace with progress in science and countries' regulatory needs.

With the development of new technologies, new ways of testing chemicals have emerged and will increasingly develop. These new methods generally include elements covered by intellectual property rights (IPR). IPR aim at stimulating innovation by enabling inventors to seek the returns on their investments. To date, many Test Guidelines for *in vitro* methods already include protected elements. This should not hamper their use for generating chemical safety data but should be accompanied by good practices for the distribution and availability of protected elements they contain, as encouraged by OECD. In September 2017, the OECD held a workshop to present and discuss issues of availability, distribution and transparency associated with access to protected elements in OECD Test Guidelines (TGs) (OECD, 2018a). The workshop report includes a number of recommendations for further activities, one of which is to develop guidance at the OECD level on best practices for licensing protected elements in OECD Test Guidelines.

The Guiding Principles described in this document explain the functioning of the OECD Test Guidelines Programme, specify the type of protected elements commonly encountered and the information to be provided to OECD when submitting a project proposal to develop a new Test Guideline. Finally, the Guiding Principles promote the terms and conditions that should be followed to guarantee accessibility of these elements to the end-users when such elements are integrated in OECD Test Guidelines. These Guiding Principles also apply to the licensing of protected elements used in the development of similar methods. A glossary of terms is available in Annex 1, as well as a model form for a licensor to commit to Fair, Reasonable and Non-Discriminatory conditions (see Annex 2).

The OECD Test Guidelines Programme: functioning principles

1.1. Purpose, Benefits of Harmonisation, Mutual Acceptance of Data

Accepted internationally as standard methods for safety testing, the OECD Test Guidelines are used by industry, academic and government professionals involved in the testing and assessment of chemicals (industrial chemicals, pesticides, personal care products, etc.). These Guidelines are regularly updated with the assistance of national experts from OECD member countries (see http://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm). OECD Test Guidelines are covered by the Mutual Acceptance of Data (MAD); data generated from the testing of chemicals in any OECD member or adherent country in accordance with the OECD Test Guidelines and Principles of Good Laboratory Practice (GLP) are accepted in all member and adherent countries in fulfilment of the same regulatory requirements.

Availability/Accessibility

One characteristic of the OECD Test Guidelines is their public availability, free of charge to the users' community. The OECD Test Guidelines are mainly intended to be used by laboratories performing the tests for regulatory purposes, at the request of authorities in member and adhering countries. The OECD i-library references all current Test Guidelines, and these can be downloaded as PDF without payment or any sort of privilege (https://www.oecd-ilibrary.org/books).

A number of supporting documents are also published free of charge in the Series on Testing and Assessment (validation reports, guidance documents, performance standards, workshop reports, review papers,…) (http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm).

Relevance (biological/mechanistic/predictive)

The relevance of a test method is indicated by the relationship of the test to the effect of concern and whether it is meaningful and useful for a particular purpose. It is the extent to which the test correctly measures or predicts the biological effect of interest. Relevance incorporates consideration of the accuracy (concordance) of a test method (OECD, 2005).

The biological relevance and scientific basis of test methods that are candidates for OECD Test Guidelines need to be established and documented, usually in peer-reviewed scientific literature. The Programme on the development of Adverse Outcome Pathways (http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm) also provides a basis for describing the underlying biologic and mechanistic basis that should be modelled by assays. Scientific articles explaining the basis and mechanistic relevance of an assay are published, generally preceding experimental validation of test methods. The number of articles usually increases after the validation process with any new findings on the applicability and predictive capacity of the method to different categories or classes of chemicals.

Transferability and reliability

The transferability of a test method is demonstrated by the reproducibility of results expected when the test is repeated, outside of the laboratory that initially developed the test. The reliability is a measure of the extent that a test method can be performed reproducibly within and between laboratories over time, using the same protocol. It is assessed by calculating within- and between-laboratory reproducibility and within-laboratory repeatability (OECD, 2005).

For a test method to be considered valid and fit for Test Guideline development, its relevance and reliability need to be demonstrated experimentally and results made available for an independent review.

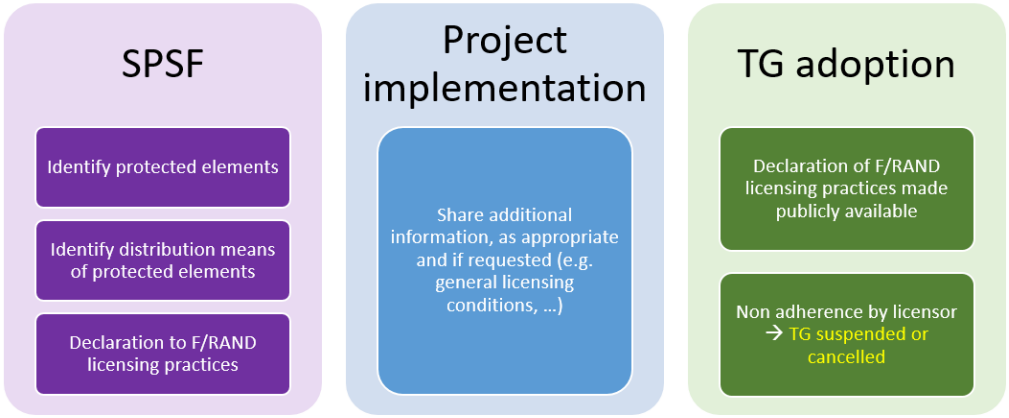
Transparency

All documentation establishing the validity of a test method is made available for review prior to the method gaining acceptance by the OECD member countries. The documentation is published when the method becomes an OECD Test Guideline. If a test method contains protected elements (see following section), the developer of the method is explicitly required to be transparent and indicate at the stage of the initial proposal to the Test Guidelines Programme what these elements are and how the user can access these elements.

Protection and secrecy are distinct concepts. While protection of test method elements is not a problem in itself, the secrecy that some intellectual property rights (IPR) owners will claim under the label of confidential business information/trade secrets/confidential know-how may impede the transparency that regulators want and need to understand the functioning, relevance, reliability of a key element of a test system they endorse.

Transparency is required from the moment a project proposal is submitted to the Test Guidelines Programme. Not disclosing information and claiming confidentiality or trade secret is against the principle of transparency and there is a risk that the project will not be taken up in the Programme. Any changes to protected element in a TG or changes to access rights to protected element during the course of Test Guideline development, or after adoption of a Test Guideline, should be reported to the OECD. Hiding or restricting access rights to protected elements is contrary to the principles of the TG programme described above, and will result in suspension of the project or cancellation of the Test Guideline (see Figure 1 below).

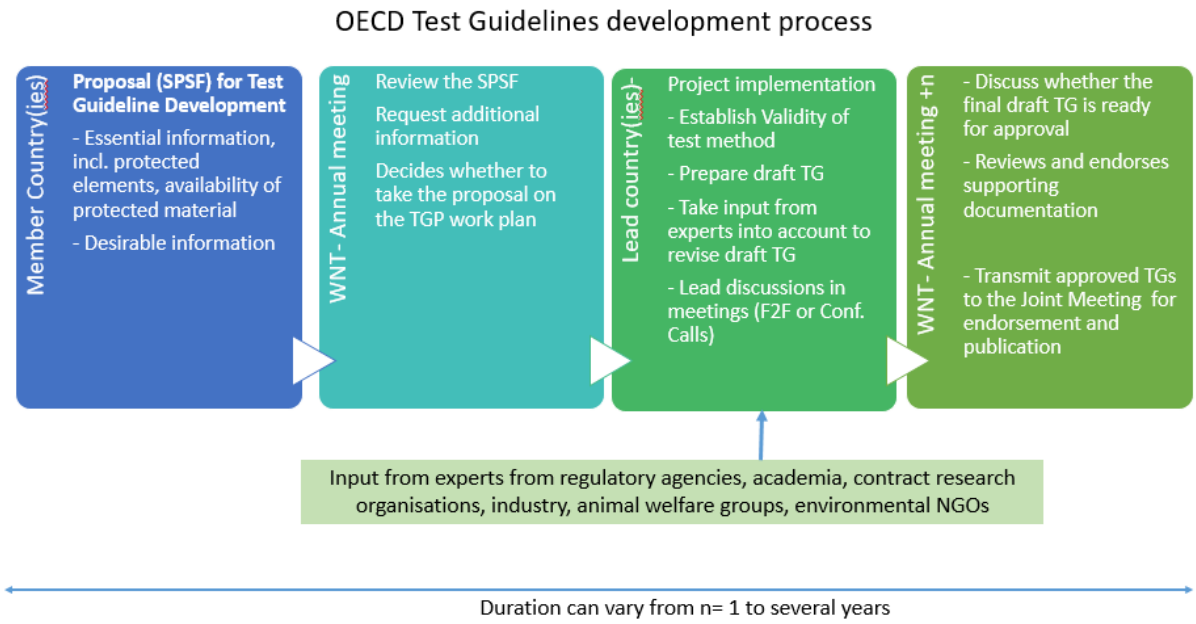
Figure 1. Documentation and Transparency



Overview of the Test Guidelines development process from proposal to adoption

The following Figure 2 illustrates the process for Test Guidelines development and publication, following an annual cycle, at the OECD. The initial proposal always comes from a National Coordinator, representing the regulatory authority in his/her country. The content of the proposal can be jointly prepared with the developer of a test method, but the National Coordinator has the responsibility for the Standard Project Submission Form. The initial proposal should be accompanied by all relevant information available and timelines for the project implementation.

Figure 2



If the proposed test method contains protected elements, the initial proposal is explicitly required to indicate this, as well as the means foreseen to make these protected elements available to users if the method becomes a Test Guideline. Further detail on the specific information requested on protected elements is described in paragraph 50.

Depending on the validation status of the test method when initially proposed to the Test Guidelines Programme, additional experimental work, data retrieval or analysis may be necessary. Following experimental work to establish the validity of the test method, a draft Test Guideline is prepared by the lead country(ies). Several rounds of review and commenting on the draft Test Guideline are organised, during which experts and regulators provide input for the improvement of the final product. The Test Guideline is also expected to describe how and where end users can obtain the material, equipment or reagents required to execute the test method, including any protected element.

Protected elements in OECD Test Guidelines

Concepts

Access to innovation is critical to progress in toxicology testing, where alternative methods and techniques to animal testing are needed for the generation of relevant, reliable and humanely generated chemical safety data for the protection of human health and the environment. Innovative techniques are increasingly integrated in testing methods as they offer insight into more mechanistic and biologically relevant effects compared to the traditional apical endpoints such as organ weight and anatomo-pathology; these techniques may offer humane alternatives to the less ethical animal testing. These new techniques and technologies result from costly investments. Intellectual property rights, such as patents and trademarks, are an important driver of innovation in many fields, including the development of new test methods. They represent a key asset with which companies are able to attract investment and recoup the significant costs incurred to develop and validate new tests. However, if used in OECD Test Guidelines, it is in the common interest to set-up reasonable conditions so that users can access and benefit from innovations, and regulators can base their decisions on best available techniques and reliable data.

In the context of OECD Test Guidelines, a "protected element" may be regarded as any feature or aspect of a test method which use is protected by intellectual property (IP) rights, e.g. patents, such that it is not available to the public without the consent of the holder of the IP rights. Such protected elements exist particularly within *in vitro* and *in silico* methods, but also in *in vivo* test methods (see examples: http://www.oecd.org/chemicalsafety/testing/protected-elements-in-test-guidelines.htm).

In the last few years, toxicology testing methods have progressively integrated techniques and products such as e.g. *in vitro* cell culturing wherein engineered cell lines are often protected (OECD, 2018b). Likewise, *in vivo* methods have been developed comprising the use of transgenic animals having knocked-out genes that make them attractive models for e.g. genotoxicity testing, wherein the transgenic animals themselves constitute protected IP. In addition, in more recent developments *in vitro* test methods have been protected by patents (and/or other IP) rights that comprise measurement of the expression of a set of genes (*i.e.* a biomarker signature) in a specified cell system. The increasing use by innovator companies of IP rights such as patents to protect investments in the research and development of such new methods can complicate the accessibility of such new methods. Consequently, there is a pressing need to find a way of allowing accessibility to new and

improved testing methods whilst, at the same time, protecting and encouraging investment in R&D by innovator companies.

The use of these techniques and products are made possible when there is a reasonable agreement between the rights owner, any intermediate player, and the end user in the laboratory. As these techniques are progressively penetrating regulatory safety testing, it becomes important to be more explicit about the so-called 'reasonable' conditions alluded to earlier. Indeed, in the absence of agreed guiding principles and good practices, there is a risk that IP rights owners could be tempted to take major advantage of the incorporation of their invention in a standard-setting program such as the Test Guidelines Programme; they may want to apply conditions to the use of their intangible asset that would prevent or restrict potential users from using the Test Guideline.

The disclosure of essential information, through a patent protection for example, is important to guaranteeing transparency and gaining acceptance of the invention's application in the regulatory domain.

Types of protection and restriction

An invention or a product can be protected in different ways. The types of IP protection underlying a "protected element" of an assay, test or model include but are not limited to the following:

- Patents – provide protection for technical inventions (products, processes, apparatus or uses), such as new chemical reagents, cell lines, process for performing a test, and depending on the jurisdiction, computer software associated with a technical effect, medical and laboratory devices, etc.
- Registered (and unregistered) designs – provide protection for the shapes of objects, such as medical devices and laboratory equipment;
- Trademarks – provide protection for the names and logos associated with products and companies;
- Copyright – provide protection for written and artistic work, including marketing material, computer programs/software, website layout and the like;
- Database rights – provide protection for collections and compilations of data.
- Commercial use restriction- any restriction to the use of a protected element for a commercial purpose (i.e. with income generation).

Trade Secrets provide protection to information such as confidential business information (CBI) and confidential know-how. Such protection is very limited because a trade secret holder is only protected from unauthorised disclosure and use, which is referred to as misappropriation. Obstructive secrecy and claiming exceptions based on secrecy are not compatible with the OECD TG Programme (see paragraphs 11-13 on transparency).

Some forms of IP protection, such as patents, registered trademarks and designs, may require a formal application to be filed and an examination process to be conducted by the relevant national or regional authority. Other IP rights, such as copyright and unregistered trademarks and designs, may subsist automatically upon the creation and/or use of the article, with or without registration with an authority. However, these practices vary from jurisdiction to jurisdiction.

IP rights are territorial in the sense that they must be obtained and enforced on a country-by-country basis (or, in some cases, on a region-by-region basis). In the case of patents, for example, a singular worldwide patent as such does not exist. Thus, it is incumbent upon the test developer to apply for patent rights at the national IP office in each country/region in which protection is desired (although this process may be commenced by filing a single international, or PCT, patent application). Thereafter, the national/regional IP office will examine the merits of the application and, if satisfied, may allow it to proceed to grant as a patent. Once the patent has been granted, and the scope of protection defined therein, it is possible for those IP rights to be enforced against other parties (although certain rights to damages for infringement may also accrue prior to grant of a patent upon publication of the application, *i.e.* provisional protection). The conclusions of the examination process by each of the national/regional IP offices may differ, not least because there are differences in the patents systems across regions. Consequently, the scope of protection can vary between jurisdictions.

One of the legal requirements for obtaining patent protection is that the patent application must contain enough information to enable a skilled person to put the invention into effect (i.e. the disclosure of the invention must be "enabled" or "sufficient"). Consequently, if the gene combination and/or algorithm is essential for putting the invention into effect, then these aspects must be fully disclosed in the patent application.

Other types of protection identified above do not come automatically with the same level of transparency to the public.

Examples of protected elements in Test Guidelines

The following are typical examples of protected elements:

- A method of measuring a biological marker which is indicative of a property of a compound, e.g. toxicity, biocidal efficacy, etc.,
- A cell line or a composite tissue model for use in a test method,
- A chemical or biological reagent for use in test method,
- A device or instrument for use in test method,
- A computer algorithm (e.g. for use in the interpretation of data obtained using a test method.

The list of adopted OECD Test Guidelines that contain protected elements, including the nature of the protected elements and their accessibility, is available from the OECD public website (http://www.oecd.org/chemicalsafety/testing/protected-elements-in-test-guidelines.htm). Please note that the information is provided to the OECD on a voluntary basis by the relevant rights holders (or test method developers) and the OECD makes no guarantees as to its accuracy or completeness, which the OECD is unable to independently verify. Users should verify the information independently before taking any actions in relation to the below.

Existing distribution, release and dissemination models

For a protected invention to be used by a third party, the rights owner will have to develop means, define conditions and establish contractual agreement(s) so that potential users can

access the innovative material, by agreeing to the conditions. The most common types of means and models that exist in the area of science are the material transfer agreement (MTA), licence agreement, open source and patent pools in the area of drug development (i.e. an agreement between two or more patent owners to license one or more of their patents to one another or to third parties, often associated with complex technologies that require complementary patents in order to provide efficient technical solutions).

Key players

There can be multiple entities claiming IP rights on a protected material in a test method (e.g. cell line owner, developer of the commercial kit that includes a cell line, etc.). In relation to OECD Test Guidelines, the following key players exist:

- IP rights owner – often, this will be the test method developer, but it is conceivable that the IP rights have been assigned (i.e. transferred) to or from another legal entity, or that third parties hold additional relevant IP rights;
- Commercial rights holder (e.g. anyone who commercialises a cell line, any company selling reagents and who may restrict access)
- Test method developer – this may be, for example a small or medium enterprise (SME), established in order to develop or based upon the development and commercialisation of a new test method;
- Test method provider – sometimes, this will be the test method developer but often the methods will be offered under licence by distribution agents such as contract research organisations (CROs);
- End user –this can be a manufacturer (or possibly a research company) seeking to identify and/or characterise an element within their products, such as chemicals or cosmetic formulations, or it can also be a CRO (who may conduct tests on behalf of the chemical manufacturer for example);
- Regulatory authorities implementing chemicals regulations in member countries, and setting the data requirements determining the use of the Test Guidelines;
- Working Group of the National Coordinators of the Test Guidelines Programme (WNT), who oversees the development of OECD Test Guidelines, from proposal to approval (see Figure 2 above).

The owner of IP rights on protected elements included in a test method may not always be dealing with users of the OECD Test Guideline directly, as the owner of IP rights may not be the test method developer or test method provider.

The test method developer may not be the original IP rights or licensing rights holder, but may be an intermediate player who assembled the protected elements into a test method in such a way that it can be useful in a regulatory context. It will be important for the end user of a Test Guideline (e.g. a contract research organisation) to know what type of agreement, under what conditions and with whom s/he has to sign, regardless of who is the original inventor or IP owner. Test method developers are encouraged to liaise with cell banks (see list in OECD, 2018b, p. 37) to identify any cell line usage restrictions, when drafting a proposal that is going forward for WNT consideration for inclusion in the OECD Test Guidelines Programme work plan.

Where possible, it will be good to agree commercial use rights up-front with the cell bank, and to also develop a workflow for deposit and distribution of derived cell lines

The test method provider or the provider of the protected elements may be identified as the entity distributing/selling/commercialising the test method or the protected elements of the test method. This entity should have conducted its due diligence to obtain the rights to do so directly or indirectly from the owner of IP or licensing rights holder, or from the test method developer. This entity must ensure that the protected elements of a test method are available to the user via a registered entity (e.g. a cell bank or repository), and not block any request to use the protected element, if requested. It can act as a repository, e.g. a cell bank in the case of cell lines or a biological resources centre for any biological material, or a company who has the legal rights to exploit the protected material for commercial purposes and to distribute the commercial product containing the protected element(s).

The end user is the entity applying the test method described in an OECD Test Guideline for generating chemical safety data for submitting them to a regulatory authority.

The regulatory authorities define the standard (e.g. Test Guideline) to use to satisfy a data requirement set in their chemical regulatory frameworks. The regulatory authorities also have responsibility in accepting and using the data generated to evaluate the risk and take measures to protect human health and the environment from the unwanted hazards of chemicals.

The Working Group of the National Coordinators of the Test Guidelines Programme (WNT) is composed of National Coordinators (countries' representatives) who make decisions on the approval of new or revised Test Guidelines, or their deletion; the WNT also reviews and decides on project proposals. The WNT is also composed of industry representatives, animal welfare and environmental non-governmental organisations, and has a Secretariat at the OECD.

Current and intended distribution, dissemination, and release model for protected elements when a test method becomes an OECD Test Guideline

Licensing agreement

A licensing agreement is a legal contract between at least two parties, known as the licensor and the licensee. In a typical licensing agreement, the licensor grants the licensee the right to produce and sell goods, apply a brand name or trademark, or use patented technology owned by the licensor. In exchange, the licensee usually submits to a series of conditions regarding the use of the licensor's property, which may include the obligation to make payments known as royalties.

Due to the legal ground it must cover, licensing agreements can be lengthy and complex documents. Most such agreements cover the same basic points. These include, but are not limited to, the scope of the agreement, including exclusivity or territorial restrictions, financial aspects including required advances, royalty rates, and how royalties are calculated, guarantees of minimum sales, time schedules involving "to market" dates, length of contract, and renewal options, the licensor's rights of monitoring and quality control, including procedures to be followed, minimum inventories required to be maintained, limitation of liabilities, escrow agreement for source codes, dispute resolution and finally, returns and allowances.

One of the most important elements of a licensing agreement covers the financial arrangement. Payments from the licensee to the licensor usually take the form of guaranteed minimum payments and royalties on sales. Not all licensors require guarantees, although some experts recommend that licensors get as much compensation up front as possible. In some cases, licensors use guarantees as the basis for renewing a licensing agreement. If the licensee meets the minimum sales figures, the licence is renewed; otherwise, the licensor has the option of discontinuing the relationship.

Another important element of a licence agreement establishes the timeframe of the deal. Many licensors insist upon a strict market release date for products licensed to outside manufacturers or use. After all, it is not in the licensor's best interest to grant a license to a company that never markets or use the product. The licensing agreement will also include provisions about the duration of the contract, renewal options, and termination conditions.

Most licensing agreements also address the issue of quality. The best form of quality control is usually achieved before the fact—by carefully checking the reputation of the licensee.

Another common element of licensing agreement covers which party maintains control of copyrights, patents, or trademarks. Many licences also include a provision about territorial rights, or who manages distribution in various parts of the country or the world. In addition to the various clauses inserted into agreements to protect the licensor, some licensees may add their own requirements. They may insist on a guarantee that the licensor owns the rights to the property, for example, or they may insert a clause prohibiting the licensor from competing directly with the licensed property in certain markets.

Material Transfer Agreement

A Material Transfer Agreement (MTA) is a contract that governs the transfer of tangible research materials between two organisations, whether the recipient intends to use it for his or her own research purposes or not. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives. Biological materials, such as

reagents, cell lines, plasmids, and vectors, are the most frequently transferred materials, but MTAs may also be used for other types of materials, such as chemical compounds and even some types of software.

The types of MTAs that are most common are MTAs concerning, e.g. transfer between academic or research institutions, transfer from academia to industry, transfer from industry to academia and transfer from industry to industry. Each calls for different terms and conditions.

Material Transfer Agreements (MTAs) are contractual documents used for the acquisition of various biological and research materials, and occasionally, data, developed by non-profit, government and private industry. Often these materials are a necessary component of a research project and are available only from a sole source, often industry. Industry may view their materials as important proprietary resources and may want to assert ownership of any inventions made with those materials or restrict publication of unfavourable results. Universities will want to ensure that MTA terms permit full dissemination of research results, and do not conflict with other university policies. Because of these differing views, the negotiations necessary to accommodate the needs of both parties can be time consuming. The usual areas of negotiation relate to publications, use of the research results, the ownership of the technology generated by the research, and regulations of how the generation and ownership of any new IPR should be handled.

The main element of a typical MTA cover, e.g. the scope of the agreement and use of the material, including whether or not the MTA shall be exclusive, confidentiality, warranties, financial aspects, length of contract, and renewal options, limitation of liabilities, escrow agreement for source codes, dispute resolution, the parties' option of discontinuing the relationship and finally, returns and allowances.

One of the most important elements of an MTA concerns research restrictions and directives, reporting requirements, handling of results, publishing of results and the parties right to purchase the other party's results.

Another common element of MTA covers which party maintains control of copyrights, patents, or trademarks and the prohibiting of either party from competing directly with the other party's business or activities.

The OECD has developed a template MTA with the typical conditions for the transfer of protected material. Although this MTA is not an obligation, it can be used as a reference or starting point for parties willing to sign an agreement (http://www.oecd.org/env/ehs/testing/Example_TG_Material_Transfer_Agreement_(MTA)_Template.pdf).

Supporting documentation requested at the proposal submission stage

Although it is not an absolute obligation to share the licensing agreement when submitting a project proposal to the OECD, test method developers will have to commit to adhere to F/RAND terms and conditions through a declaration (see Annex 2). When such declaration is submitted, it will be shared with the Working Group of the National coordinators of the Test Guidelines Programme, and its availability made publicly available upon request on the OECD Internet site (see Table : http://www.oecd.org/chemicalsafety/testing/protected-elements-in-test-guidelines.htm). Any other signed agreement(s) needed to perform the future OECD Test Guideline, for instance an MTA or license agreement with a cell bank for commercial use, should be identified at the stage of the project proposal.

Cost model for the distribution (including cost range)

General or specific information related to the cost model envisaged should preferably be shared with the WNT for information and transparency purposes. Such information provides an indication of the accessibility of the test method to potential end users at reasonable conditions.

Overview of conditions often applied to protected elements present in standards

F/RAND conditions applied in other regulated sectors

Reasonable and non-discriminatory ("RAND") terms, known in the European Union as fair, reasonable, and non-discriminatory ("FRAND") terms, denote a voluntary licensing commitment from the owner of an intellectual property right (a patent or a different type of IPR) participating in a standards organisation in case his/her IPRs are or may become, essential to practice a technical standard. The view of courts in several jurisdictions is that, in appropriate circumstances, the licensee of a standard that is, a company or entity that uses a standard to render a service or manufacture a product is an intended third-party beneficiary of the F/RAND agreement, and, as such, is entitled to certain rights conferred by that agreement. The principle of F/RAND licensing is well-established in other technical fields in which standard essential IPRs and in particular standard essential patents (SEPs) are utilised, most notably within the mobile telecommunication sector.

A patent, under most countries' legal regimes, grants its owner an exclusive right to prevent others from using the covered technology. A standard setting organisation will generally request that a patent holder clarifies its willingness to offer a licence to its standard essential patents on F/RAND terms. If the patent holder refuses upon request to give a commitment to license a standard essential patent on F/RAND terms, then the standard setting organisation may exclude that technology. When viewed in this light, the F/RAND commitment serves to harmonise the private interests of patent holders with those of users of the standard in the public interest.

Standard setting organisations commonly adopt policies that govern the conditions under which IPR holders must disclose their IPR and give commitments for their IPRs to be included in the standards they adopt (the IPR policy).

The goal of F/RAND commitments is, on the one hand, to make sure that standard essential technology protected by IPRs is accessible to the users on F/RAND terms and thus facilitate the diffusion of the standard. They are intended to prevent IPR holding members from refusing to give access to the technology or grant access only under unfair or unreasonable licensing terms and conditions, if and once their protected technology is included in a standard. As the term F/RAND suggests, IPR holders are required to offer that licence under fair, reasonable and non-discriminatory terms.

On the other hand, the F/RAND commitment also serves to ensure that the holder of standard essential IPRs will receive royalties from users of the standard that adequately compensate the IPR holder for the added value that his/her protected technology contributes to the products/services which implement the standard. The development of a patented technology typically requires significant investment in research, and contributing that technology to a standard may not be the only option by which a patent holder can recoup that investment. By agreeing to contribute its technology to the standard, the IPR holder

forgoes the exclusive use or the exclusive licensing of its technology, in exchange for adequate compensation on fair and reasonable terms.

The individual terms are often defined as follow:

- Fair and reasonable refers mainly to the licensing rates. According to some, this is a rate charged to licensees which would not result in an unreasonable aggregate rate if all licensors charged a similar rate for their respective IPRs that are essential to the standard. According to this view, aggregate rates that would significantly increase the cost to the industry and make the industry uncompetitive are unreasonable. Similarly, such rate must reward the licensor with adequate compensation for contributing its essential patents to a standard. Compensation is adequate if it provides the licensor with the incentive to continue investing and contributing to the standard in future time periods.
- Non-discriminatory relates to both the terms and the rates included in licensing agreements. The non-discrimination element of F/RAND indicates that the IPR holders cannot discriminate between implementers that are "similarly situated[1]". F/RAND compatible solutions can differ from sector to sector and depend on specific arrangements. In sectors where cross-licencing practices are widespread, efficiency gains related to such practices should be taken into account.

Transposing the F/RAND conditions to the OECD Test Guidelines Programme

The main concept of F/RAND as described in the Communication from the Commission on Setting out the EU approach to Standard Essential Patents envisages that both parties must be willing to engage in good faith negotiations, with the view to establishing licensing conditions that are fair, reasonable and non-discriminatory.

The parties to the negotiations are in the best position to establish what F/RAND conditions will be in a specific situation. In the specific context of the OECD Test Guidelines, the following IP valuation principles should be taken into account when determining the Fair and Reasonable elements of a licence fee:

- Determining a F/RAND value should require taking into account the present value added by the protected element. That value should be irrespective of the market success of the product which is unrelated to the protected element;
- In this approach the value should not in principle include any element resulting from the decision to include the protected element into the Test Guideline;
- In cases where the protected element is developed mainly for the purpose of being included in the Test Guideline and has little market value outside of it, alternative evaluation methods, such as the relative importance of the protected element in the Test Guideline compared to other contributions to the Guideline, should be considered;
- F/RAND value obtained should insure that it constitutes a further incentive for the developers of protected elements;

[1] Unwired Planet v. Huaweï [2017] EWHC 711 (Pat).

- the Non-Discriminatory element of F/RAND provides for non-discrimination between parties that are "similarly situated";
- to avoid entry barriers for small enterprises or laboratories, licensing conditions should not include large base-fees and not large upfront payments for setting up the technology, but rather be based on turn-over and/or cost per test.

In the context of the OECD Guidelines, F/RAND commitment should be applied in order to ensure effective access to the protected elements, and therefore a wide access to the Test Guideline. The IPR policy will require participants wishing to have their protected elements included in the Test Guideline to provide an irrevocable commitment in writing to give access to all third parties and to license their protected elements on fair, reasonable and non-discriminatory terms ('F/RAND Commitment') for the use of the Test Guideline. Moreover, it will require all members that have given such a commitment to ensure that any acquirer to which the IPR owner transfers its IPR (including the right to license that IPR) is bound by that commitment, for example through a contractual clause between buyer and seller.

The non-commitment of the test method developer to license under F/RAND terms or the non-compliance during the course of Test Guideline implementation will be reported to the National Coordinator and/or the OECD Secretariat and addressed under the Programme and result in the possible cancellation of the Test Guideline if it cannot be used on F/RAND terms and conditions.

Information on protected elements to be provided by a developer when submitting a project proposal for the development of a Test Guideline at OECD

The Test Guidelines Programme (TGP) is fed annually by proposals to develop new or updated Test Guidelines or supporting documents. These proposals can be submitted by the National Coordinators to the TGP. Test developers may contact their National Coordinator (list publicly available: http://www.oecd.org/env/ehs/testing/national-coordinators-test-guidelines-programme.htm) with a proposal, and address the following requirements in the Standard Project Submission Form:

- Identify components (e.g. test system, reagent, etc.), equipment or other scientific procedures that are covered (or pending) by Intellectual Property Rights (IPR) (e.g., patents, patent applications, industrial designs and trademarks, copyright on protected software or prediction model, etc.). Information should be provided on the overall availability of the IPR-protected components including whether they are commercially available or require a Material Transfer Agreement (MTA) or other licensing agreements. In addition, a description of the IPR-covered component/test system should be disclosed, and it should be indicated whether Performance Standards have been developed for the test method.
- In particular, in section 8 of the SPSF, the following is requested:
  - 8.1 Nature of protected elements (e.g. reagent identity, cell line identity, specific process, etc.), providing as much detail as needed depending on the element;
  - 8.2 Form of protection (e.g. trade mark, patent, etc.) for each protected element, or any known use restrictions on e.g. cell lines deposited in cell banks,

- 8.3 For users to access protected elements, please tick the relevant box(es): MTA/ License requirement/ other/No agreement required,
- 8.4 Are you providing the agreement document(s) referred to in 8.3 with the Standard Project Submission Form (SPSF):
- 8.5 How and where can users get access to protected elements (organisation or company contact information)?
- 8.6 Has any search for existing patent(s) possibly associated with this test method been performed (e.g. through patent search or Freedom-To-Operate search). If yes, please provide a list of the relevant patents and if possible further related information and documents. ?
- 8.7 Have Performance Standards been developed?

A test method developer is encouraged to provide as much relevant information as possible. The National Coordinator can advise in case of doubt. Transparency is essential, as it helps the WNT to understand the relevance and reliability of the test method they are expected to endorse. In case where the proposed test method includes elements obtainable upon signature of a license agreement, a form will have to be filled-out by the test method developer declaring, among other things, that licensing conditions will be under F/RAND terms (see Annex II).

Sharing of relevant information:

Sharing with the WNT community

The SPSF and supporting information are shared with the Working Group of the National Coordinators of the Test Guidelines Programme, via a protected site.

Sharing with the public

Upon publication of a Test Guideline, limited but useful information on protected elements, type of protection and distribution means is published in the form of a table listing the same information for all Test Guidelines concerned (http://www.oecd.org/chemicalsafety/testing/protected-elements-in-test-guidelines.htm).

It is expected that if changes occur to the distribution means, it will only be under more favourable conditions for the users, and in line with F/RAND terms.

Conclusions and Recommendations

The following summarises the recommended best practices that must be taken into consideration when protected elements are included in a proposal to develop an OECD Test Guideline:

- The SPSF should identify the protected elements, the type of protection, and disclose the relevant information that enable the regulator to trust the relevance and reliability of the protected element; transparency over the protected elements and access to relevant information upon request should be enabled;
- The SPSF should describe the means to obtain the protected elements and the conditions at which these elements are obtainable;
- In the case of a licence, the SPSF should describe the licensing conditions;
- The test method developer should commit to licensing under F/RAND terms and conditions (see Annex 2 for the declaration), and not deviate during the course of the project and when the Test Guideline is implemented, or else report back to OECD;
- The test method provider should ensure that, in the case of third parties owned IP rights for certain protected elements, their use as part of the test method is similarly available under FRAND terms.

Glossary of terms and acronyms

Material Transfer Agreement (MTA): An MTA is an agreement between the cell bank (provider) owning the biological materials concerned and the recipient of such materials. It is used to document the transfer of protected materials and may include a number of terms and conditions.

Intellectual property rights (IPR): the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time.

Performance Standards (PS): The purpose of performance standards is to communicate the basis by which new test methods, in particular those containing protected elements (i.e., patented, copyrighted, trade marked, registered elements) can be determined to have sufficient accuracy and reliability for specific testing purposes. These performance standards, based on validated and accepted test methods, can be used to evaluate the accuracy and reliability of other analogous test methods that are based on similar scientific principles and measure or predict the same biological or toxic effect. Performance Standards currently include three elements: essential test method components, minimum list of reference chemicals, accuracy and reliability values. A patented test may be adopted as an OECD Test Guideline provided a detailed generic description of the method is provided as well as proper reference to the validated, patented version of the method, and usually together with a set of performance standards (OECD, 2005). [Note for the reader: in the last 15 years, many PS have been developed for several *in vitro* methods containing

protected elements; as more innovative methods develop and also contain more innovative IP protection means, there will be discussions to adapt PS, as appropriate, taking them to the level of the hazard endpoint to predict (i.e. less specific), and not the individual method itself.]

Standard project Submission Form (SPSF): format used by the National Coordinators of the Test Guideline Programme to describe and submit project proposals to develop new or revised Test Guidelines, Guidance or other supporting documents.

Working Group of the National Coordinators of the Test Guidelines Programme (WNT): Group of representatives from regulatory authorities in member countries, representatives from industry and from non-governmental organisations who take part in the oversight of the OECD Test Guidelines programme.

ANNEX 1 - Typical terms found in Licence contracts or Material Transfer Agreements

The following definitions are often found in licence contracts relevant to the Test Guidelines Programme. They are given by way of example and are not intended to serve as a model. Given the variations in laws governing intellectual property from jurisdiction to jurisdiction, in every case licensors and licencees must seek the advice of a specialised lawyer and should not rely on the below when drafting such agreements.

A selection of the definitions that are to be expected in a licence contract or when dealing with such contracts are:

- "[Trademark of the concerned] Assay" shall mean the [description of the Trademark of the assay that is concerned] assay.
- "[insert the trade mark of the concerned] Assay SOP" shall mean the latest and submitted version of Licensor's assay Standard Operating Procedure set out in Agreement. The version number on the [insert the trade mark of the concerned] Assay SOP will indicate which version that shall apply.
- "Cell Line" shall mean the biological material specified in the Handover Specification.
- "Confidential Information" shall include technical, financial and business information disclosed by either Party to the other in any form for the purpose of this Agreement, including without limitation, information pertaining to the [name of the referred to IPR, if any] Technology Platform, the Licensor Know How, the Licensor Software, the Cell Line and other information in relation to the Services such as documents, data or information relating to the Equipment, devices, methods, formulae, compositions, materials, apparatus, techniques, production methods, processes, designs, research, specifications and other technical and/or commercial data.
- "Equipment" shall mean the equipment for performing the Services presented in the Assay SOP (i.e. Standard Operation Procedure).

- "Escrow Agreement" means the escrow agreement that shall be entered into between the Parties and the Escrow Agent with regard to the retention of the Licensor Software source code.
- "Escrow Agent" means the mutually agreeable escrow agent that the Parties have appointed and with whom the Parties have entered into an Escrow Agreement.
- "Escrow Material" means the information and data to be subject to an escrow arrangement.
- "Handover Specification" shall mean the specification of the Licensor Know-how, the Licensor Software and the Cell Line to be handed over by Licensor to the Licensee on a date to be agreed upon in writing for the purpose of the License.
- "Improvement" shall mean any modification or development of the [insert the trade mark of the concerned] Technology Platform, the Licensor Know-how, the Licensor Software and the Cell Line as the case may be in the form of patentable or non-patentable inventions, improvements, ideas, technology, know-how or other Intellectual Property Rights.
- "Intellectual Property Rights" shall mean the rights to patents, patent applications, technology, techniques, designs, utility models, trade secrets, copyrights, trade marks, trade names, know how or the like.
- Licence (or IP rights)": A legal contract between two or more parties wherein the holder of IP rights grants to one or more other parties the right to exploit or use those IP rights in return for a consideration, e.g. a licence fee.
- "Licencing Fees": Fees payable to the IP rights holder under the terms of a licence in return for access to those IP rights. The fees may include one-off "milestone' payments and/or royalties based on sales.
- "Marketing Commitment" shall mean the marketing commitments and activities to be performed by the Licensee when marketing the Services during the term of this Agreement.
- "Licensor Know-how" shall mean Licensor's knowledge, experience, data, techniques, and other information relating to the Services, owned or controlled by Licensor at the time of execution of this Agreement and which Licensor is entitled to disclose and license to the Licensee, including [insert the trade mark of the concerned] Assay SOP as listed in the Handover Specification.
- "Licensor Software" shall mean the software developed and owned by Licensor used for the analysis in connection with the Services as further set out in the Handover Specification.
- "Price Adjustments" shall mean the price adjustments mechanism set out in Agreement
- "Price List" shall mean the price list of Licensor set out in the Agreement.
- "Services" shall mean the assessments and services, which the Licensee is entitled to perform by utilizing the [insert the trade mark of the concerned] Technology Platform, the Licensor Know-how, the Licensor Software and the Cell Line as described in the Handover Specification.

- “[Trade mark of the concerned] Technology Platform” shall mean a [insert description of the concerned method] method for safety assessment of chemicals, a patented technology developed and owned by Licensor.
- “Test Substance” shall mean each substance that is tested and invoiced by the Licensee to their customers.
- “Trademarks” shall mean the trade marks specified in the Agreement.

Typical definitions in a Material Transfer Agreements (MTA)

A selection of the definitions that are to be expected in a MTA or when dealing with such agreements are:

- "Materials" means (a) those materials listed in Schedule 1 hereto, in the aggregate quantities specified in the Agreement; (b) any substance or compound that is a derivative or modification thereof or is replicated therefrom, and any other compositions made using such substance or compound; and (c) any associated know-how and data that is transferred to Recipient by Provider.
- “Material Transfer Agreement” (MTA): A legal contract that governs the transfer of tangible research materials between two parties, typically when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.
- “Recipient's Technology" means the [insert the trade mark of the concerned] assay an animal free genomic testing for prediction and classification of chemical sensitizers, which is a proprietary technology of Recipient, including thereto related test services.
- "Research" means those tests, studies and other activities set forth in the Agreement carried out by Recipient.
- "Research Documentation" means any and all documents, records, accounts, notes, reports (including, without limitation, the progress reports and the final report prepared in accordance with the concerned provisions in the Agreement) and other data from the Research related to the Materials, whether in written, electronic, video or other tangible form created by or by a third party on behalf of Recipient.
- "Researchers" means all employees or agents of Recipient who are engaged in carrying out the Research.
- "Results" means any ideas, improvements, inventions, discoveries, know-how, data, documentation, reports, materials, writings, designs, computer software, processes, principles, methods, techniques and other information, recorded in any form, that are discovered, conceived, reduced to practice or otherwise generated as a result of or in connection with the Research or any other use of the Materials by, or by a third party on behalf of, Recipient (whether solely or jointly with others), and any patent, trade secret, copyright or other intellectual property rights pertaining to any of the foregoing; provided, however, that "Results" shall exclude any substance or structure that is a derivative, modification or replication of the Materials and any other compositions made using the Materials, which derivatives,

modifications, replications and compositions form part of the Materials pursuant to the Agreement and are owned by Provider.

ANNEX 2 – FRAND Terms Licensing Declaration Form

Intellectual and Industrial Property Rights (IPR) Licensing or sublicensing Declaration Form. This form is to be filled by test method developers proposing the development of a Test Guideline at the OECD that contains element(s) protected by intellectual property. The signed form is attached to the project proposal; the National Coordinator submits the proposal to the OECD. OECD will not perform an evaluation of compliance with FRAND terms; however, the signed declaration can be made publicly available upon request.

Any change to access and/or rights on protected elements will need to be reported to OECD (ehs.contact@oecd.org). Hiding or restricting access rights to protected elements is contrary to the principles of the TG programme described above, and will result in suspension of the project or cancellation of the Test Guideline.

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Test Method developer / Organisation ("Declarant"):

Legal name: _____

Contact details for Licensing information:

Title/position:_____

Department:_____

Address:_____

_____

Telephone:

_____

Email: _____

URL: _____

General IPR licensing declaration:

In accordance with the Guiding Principles on Good Licensing Practices for Protected Elements in OECD Test Guidelines ('Guiding Principles for Licensing') (OECD, 2019), the Declarant hereby declares that, with reference to the project proposal to develop a new test method for (insert title) (the "Test Guideline"):

_____

_____

The Declarant will ensure that (sub)licenses can be granted on a non-exclusive basis to any and all users for all uses of the protected material necessary for the execution of the future Test Guideline described above, including for commercial purpose by a service provider. The declarant will also ensure that (sub)licenses can be granted on a non-exclusive basis to developers of (e.g. similar) test methods using the protected material covered by Intellectual property. Such licences will be on terms and conditions that are in accordance with F/RAND as described in the Guiding Principles for Licensing. If the Declarant fails to comply with this declaration, the OECD may cancel the Test Guideline.

The Declarant will report to the OECD any changes to protected element or changes to access rights to protected elements that occur during the development of the Test Guideline or after its adoption.

The Declarant further declares that:

- it is aware that the implementation of an OECD Test Guideline for generating chemical safety data depends on the accessibility to all users of this Test Guideline and availability of all elements referenced in the Test Guideline, including elements protected by intellectual and industrial property law;
- they shall ensure that the protected elements are available and accessible to users in the long-term;
- the OECD will make this form publicly available to anyone requesting information about the Test Guideline.

Signature:

By signing this General IPR Licensing Declaration form, you represent that you have the authority to bind the Declarant to the representations and commitments provided in this form.

Name of authorised person:_____

Title of authorised person:_____

Place, Date:_____

Signature:

References

OECD (2005). Guidance Document on the Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment. Series on Testing and Assessment, No. 34. ENV Publications. OECD, Paris.

OECD (2018a). Report of the OECD Workshop on Intellectual Property Issues in OECD Test Guidelines. Series on Testing and Assessment, No. 278. ENV Publications. OECD, Paris.

OECD (2018b). Guidance on Good *In vitro* Methods Practices. Series on Testing and Assessment, No. 286. ENV Publications. OECD, Paris.