BEST PRACTICE GUIDE FOR ACCESS AND PROTECTION OF PROPRIETARY RIGHTS TO NON-CLINICAL HEALTH, SAFETY AND ENVIRONMENTAL DATA AND INFORMATION ON CHEMICALS[1]

Foreword

This Best Practice Guide (BPG) was developed to support the implementation of the OECD Recommendation of the Council Concerning Access and Protection of Proprietary Rights to Non-Clinical Health, Safety and Environmental Data and Information on Chemicals. . This Recommendation aims to protect both the public and the data owners by keeping a balance between the access of the public to chemical safety data and the protection of the proprietary rights associated with these results. This BPG provides a collection of existing good approaches by governments and industry for disclosing health, safety and environmental data while protecting their proprietary rights.

[1] This document has been declassified by the Chemicals and Biotechnology Committee (CBC) on 15 April 2022.

Contents

A. Introduction

1. This Best Practice Guide (BPG) has been developed to complement the OECD Recommendation of the Council Concerning Access and Protection of Proprietary Rights to Non-Clinical Health, Safety and Environmental Data and Information on Chemicals (hereafter "the Recommendation") [OECD/LEGAL/0203]. The BPG is intended to serve as a reference tool for governments and industry based, among other things, on real-world examples, implementing guidance and examples of definitions of key terms. It applies to the ways governments provide access to and/or protect proprietary rights associated with non-clinical health, safety and environmental data, as those terms are interpreted by national governments. The OECD recognises that countries have different legal frameworks concerning public disclosure, transparency and protection of proprietary information and non-clinical health, safety and environmental data and that a single government may have differing statutory requirements for the protection and disclosure of different kinds of data. Thus, this BPG is not intended to be prescriptive; instead, it aims to describe the different ways governments and industry have addressed these issues. This will facilitate implementation of the Recommendation while providing flexibility for countries in identifying appropriate tools of implementation.

B. Background

2. In recent years, there has been a steady increase in the amount of health, safety and environmental data generated by or derived from industry sources that are used by governments to assess the safety of new and existing chemicals. This trend has raised two concerns: one, how can the review of industry-sponsored data by governments be done in an open and transparent fashion to assure the public that regulatory decisions are based on sound science; and two, how can making such data more available be done in a way which also protects confidential information and/or the intellectual property rights of companies and does not create disincentives to innovation?

3. Governments are under increasing pressure to strike a balance between releasing as much information as possible, but doing so in a way that does not compromise intellectual property. Balancing these needs can be difficult. For instance, in order to reduce duplicative animal testing, governments are trying to facilitate the creation of consortia where producers of the same chemical can share data. However, the establishment of such consortia and the transfer of test studies from one company (or groups of companies) to another company has proven difficult due to legal and administrative hurdles, as well as scepticism by the companies participating in the consortia that the data generated by one company will not be misused by a competitor.

4. In addition, governments have a moral or legal obligation to consider all available data when conducting a regulatory risk assessment. This may include data which is not available to some national producers/importers.

5. Thus, at times governments are caught between protecting the rights of different data owners and protecting the public's right to know about what the governments are deciding on their behalf with health and environmental consequences. Therefore, information on chemical safety data becoming more openly available may present the public with the possibility of being more involved in the decision-making processes.

6. This BPG has been developed to describe how governments and industry are addressing the issues mentioned above, and examples of best practices available.

C. Examples of Definitions

7. While the focus of the BPG is on “proprietary data” to support the Recommendation by providing examples of best-practises, the BPG also provides examples of definitions of other key terms used by governments and that are outside of the scope of the Recommendation, such as “intellectual property rights”, “data exclusivity” and “confidential business information”, and how they relate (or don’t relate) to “proprietary data”. Therefore, although concepts such as *confidential business information* are not covered by the Recommendation, examples of the definitions are added in the BPG for completeness sake. The OECD does not have agreed definitions for some of the key terms mentioned in this document, therefore *examples* of definitions of these terms as they appear in national regulatory or legislative text are provided in Table 1.

Table 1. Examples of definitions

Concepts	National regulatory text/legislation	Definition / Excerpt of legal text
Compensable data	Canada pesticides (Pest Control Products Act)	Compensable protection status is provided to data for a specified period of time during which an applicant can gain the right to rely on that data by entering into a negotiated commercial agreement that addresses the issue of data access and compensation of the data holder. The data holder of the compensable data is obliged to negotiate with an applicant and, if necessary, binding arbitration may be used for a final resolution of access and compensation issues. Compensable protection is provided when the chemical entity has already been registered and therefore does not involve the registration of a new chemical entity.
	U.S. pesticides (Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA) 7 USC 136a(c)(1)(F), see also FIFRA registration manual:	Data submitted to support or maintain registrations/re-registration other than exclusive use data.
	U.S. industrial chemicals (Toxic Substances Control Act, TSCA)	Data forming the basis for exemptions from certain testing requirements (e.g. test rule or order exemptions under TSCA section 4(c), 15 USC 2603).
Exclusive use study	U.S. pesticides 40 CFR 152.83	A study is an exclusive use study if it meets the conditions of either paragraph (a) or paragraph (b) of this section. I. *Initial exclusive use period*. A study submitted to support the registration of a product containing a new active ingredient (new chemical) or a new combination of active ingredients (new combination) is an exclusive use study if all the following conditions are met: a) The study pertains to a new active ingredient (new chemical) or new combination of active ingredients (new combination) first registered after September 30, 1978. b) The study was submitted in support of, or as a condition of approval of, the application resulting in the first registration of a

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		product containing such new chemical or new combination, or an application to amend such registration to add a new use. c) Less than 10 years have passed (or up to 13 years, if the period of exclusive use protection has been extended under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(1)(F)(ii)) since the issuance of the registration for which the data were submitted. d) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B). II. *Exclusive use period for certain minor use data.* A study submitted by an applicant or registrant to support an amendment adding a new minor use to an existing registration that does not retain any period of exclusive use under paragraph (b)(1) of this section is an exclusive study under FIFRA section 3(c)(1)(F)(vi) if all the following conditions are met: a) The study relates solely to a minor use of a pesticide. b) The applicant or registrant at the time the new use is requested has notified the Administrator that any exclusive use period for the pesticide has expired and that the study is eligible for exclusive use treatment. c) Less than 10 years have passed since the study was submitted to EPA. d) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B). e) The minor use supported by the data has not been voluntarily cancelled nor have such data been used to support a non-minor use.
Confidential business information	Canada pesticides (Pest Control Products Act)	*Confidential business information* means information to which access may be refused under access to information requests made under Canada's Access to Information Act and includes manufacturing or quality control processes, methods for determining

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		composition, monetary value of sales, and the identity and concentration of most formulants and contaminants.
	U.S. pesticides	Information contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential.
	U.S. industrial chemicals	Information not subject to disclosure under Exemption 4 of the Freedom of Information act and whose disclosure is likely to cause substantial harm to the competitive position of a business.
	Australian Industrial Chemicals Introduction Scheme	Under the Australian Industrial Chemicals Introduction Scheme, the following types of information can be protected as confidential business information following an application by the introducer for the information to be considered as CBI: • the chemical's identity • the chemical's introduction details (e.g. exact function of a chemical in a product (use), exact concentrations, exact introduction volumes, customers) • For approval of a CBI application, information that satisfies the statutory test (where we balance commercial prejudice and public interest) must be provided.
	EU Biocidal Products Regulation (BPR) No 528/2012, Article 66 (2)	According to the EU BPR Article 66 (2), certain details of the biocidal product or the people associated are to be treated as confidential business information by all competent authorities. Article 66 (2) reads as follows: The Agency and the competent authorities shall refuse access to information where disclosure would undermine the protection of the commercial interests or the privacy or safety of the persons concerned.

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		Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests or the privacy or safety of the persons concerned: (a) details of the full composition of a biocidal product; (b) the precise tonnage of the active substance or biocidal product manufactured or made available on the market (c) links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product; (d) names and addresses of persons involved in testing on vertebrates. However, where urgent action is essential to protect human health, animal health, safety or the environment or for other reasons of overriding public interest, the Agency or the competent authorities shall disclose the information referred to in this paragraph.
Confidential test data	Canada (Pest Control Products Act)	Confidential test data means scientific or technical information respecting health or environmental risks or value of a product that access may be refused under access to information requests made under Canada's Access to Information Act. Confidential test data can be inspected by persons under certain conditions, including that they sign an affidavit stating their purpose and that they do not intend to make the test data available to others in order to register or amend a product in Canada or elsewhere
Data exclusivity	Canada (Pest Control Products Act)	Exclusive protection status is provided for a specified period during which it cannot be used by an applicant without written consent from the data holder. During the exclusive protection period, the data holder can voluntarily, but is not obliged to, enter into negotiation with an applicant for access to and compensation for data under exclusive protection. Data exclusivity is provided when a new chemical entity is registered in Canada, at that point it receives a 10 year exclusive use protection period. This 10 year exclusive use period can be extended up to 15 years through the addition of

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		significant minor uses to the chemical's registration (the exclusive use period is extended by one year for every three minor uses that are added).
	EU Biocidal Products Regulation No: 528/2012	Data protection and data sharing are covered by Articles 59-64. Data provided to the competent authorities (or the European Chemicals Agency, ECHA) are protected for a period of 10 years for data submitted for an active. After the data protection period has expired, if the subsequent applicant can prove that their active substance is technically equivalent to the previously protected substance, competent authority or the Agency may allow referal to data provided by the first applicant. Provisions are also in place to encourage data sharing to avoid animal testing. Articles 59 to 64 read as follows: Article 59 (Protection of data held by competent authorities or the Agency): Without prejudice to Articles 62 and 63, data submitted for the purposes of Directive 98/8/EC or of this Regulation shall not be used by competent authorities or the Agency for the benefit of a subsequent applicant, except where: (a) the subsequent applicant submits a letter of access; or (b) the relevant time limit for data protection has expired. Article 60 (Data protection periods): Data submitted for the purposes of Directive 98/8/EC or of this Regulation shall benefit from data protection under the conditions laid down in this Article. The protection period for the data shall start when they are submitted for the first time. Data protected under this Article or for which the protection period under this Article has expired shall not be protected again. The protection period for data submitted with a view to the approval of an existing active substance shall end 10 years from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.

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		The protection period for new data submitted with a view to the renewal or review of the approval of an active substance shall end five years from the first day of the month following the date of the adoption of a decision in accordance with Article 14(4) concerning the renewal or the review. Article 61 (Letter of access) A letter of access shall contain at least the following information: (a) the name and contact details of the data owner and the beneficiary; (b) the name of the active substance or biocidal product for which access to the data is authorised; (c) the date on which the letter of access takes effect; (d) a list of the submitted data to which the letter of access grants citation rights. Article 62 (Data sharing) In order to avoid animal testing, testing on vertebrates for the purposes of this Regulation shall be undertaken only as a last resort. Testing on vertebrates shall not be repeated for the purposes of this Regulation. 2. Any person intending to perform tests or studies ('the prospective applicant') (a) shall, in the case of data involving tests on vertebrates; and (b) may, in the case of data not involving tests on vertebrates, submit a written request to the Agency to determine whether such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application under this Regulation or Directive 98/8/EC. The Agency shall verify whether such tests or studies have already been submitted. Where such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application, under this Regulation or Directive 98/8/EC, the Agency shall, without delay, communicate the name and contact details of the data submitter and data owner to the prospective applicant. The data submitter shall, where relevant, facilitate contacts between the prospective applicant and the data owner. Where the data acquired under those tests or studies are still protected under Article 60, the prospective applicant: (a) shall, in the case of data involving tests on vertebrates; and (b) may, in the case of data not involving tests on vertebrates, request from the data owner all the scientific and technical data related

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		to the tests and studies concerned as well as the right to refer to these data when submitting applications under this Regulation. Article 63 (Compensation for data sharing) Where a request has been made in accordance with Article 62(2), the prospective applicant and the data owner shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order. Article 64 (Use of data for subsequent applications) Where the relevant data protection period according to Article 60 has expired in relation to an active substance, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the active substance is technically equivalent to the active substance for which the data protection period has expired, including the degree of purity and the nature of any relevant impurities.
	EU REACH Regulation (EC) No 1907/2006	Any manufacturer or importer of a substance that is subject to this regulation, in mixtures or in articles in quantities of one tonne or more per year and intended to be released under normal or reasonably foreseeable conditions of use need to be registered in accordance with the relevant provisions of this regulation to the ECHA. Data protection are covered by this regulation as outlined below: Article 10 (1) subparagraph 2 (Information to be submitted for general registration purposes): Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (vi) and (vii) for the purpose of registration;

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		Data sharing and avoiding uncessary testing: Article 25 (3): Any study summaries or robust study summaries of studies submitted in the frame-work of a registration under this Regulation at least 12 years previously can be used for the purposes of registration by another manufacturer or importer. Article 27 (6) (Sharing of existing data in the case of registered substances) Within one month from the receipt of the information referred to in paragraph 5, the Agency shall give the potential registrant permission to refer to the information re-quested by him in his registration dossier, subject to the potential registrant providing, upon request by the Agency, proof that he has paid the previous registrant(s) for that information a share of cost incurred. The previous registrant(s) shall have a claim on the potential registrant for a proportionate share of the cost incurred by him. Calculation of the proportionate share may be facilitated by the guidance adopted by the Agency in accordance with Article 77 (2) (g). Provided he makes the full study report available to the potential registrant, the previous registrant(s) shall have a claim on the potential registrant for an equal share of the cost incurred by him, which shall be enforceable in the national courts. Article 30 (3) (Sharing of data involving tests): If the owner of a study as referred to in paragraph 1 which involves testing on vertebrate animals refuses to provide either proof of the cost of that study or the study it-self to (an) other participant(s), he shall not be able to proceed with registration until he provides the information to the other participants(s). The other participant(s) shall proceed with registration without fulfilling the relevant information requirement, ex-plaining the reason for this in the registration dossier. The study shall not be repeated unless within 12 months of the date of registration of the other participant(s), the owner of this information has not provided it to them and the Agency decides that the test should be repeated by them. However, if a registration containing this information has already been submitted by another registrant, the Agency shall give the other

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		participant(s) permission to refer to the information in his registration dossier(s). The other registrant shall have a claim on the other participant(s) for an equal share of the cost, provided he makes the full study report available to the other participant(s), which shall be enforceable in the national courts.
	EU Food Law: Feed additives: Article 20 of Regulation (EC) No 1831/2003	Article 20 of Regulation (EC) No 1831/2003 provides data protection to any applicant for authorisation of a feed additive automatically (without a separate application and Commission decision to that effect) and for a period of 10 years, where a feed additive is authorised. During that period, European Food Safety Authority (EFSA) may not use the scientific data and other information in the relevant application dossier for the benefit of a subsequent applicant, unless the latter has agreed with the authorisation-holder that such data and information may be used. A further exemption is foreseen: the Commission may 'disclose', under certain conditions, information necessary to avoid repeating toxicological tests on vertebrate even if an agreement between applicants (prior and subsequent) is lacking). The 10-year protection period may also be further extended under certain conditions. Upon expiry of the 10-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information at issue may be used by EFSA for the benefit of another applicant. Article 20 of Regulation (EC) No 1831/2003, titled 'Data protection', reads as follows: *"1. The scientific data and other information in the application dossier required under Article 7 may not be used for the benefit of another applicant for a period of 10 years from the date of authorisation, unless the other applicant has agreed with the previous applicant that such data and information may be used.* *2. In order to stimulate efforts to obtain authorisations for minor species for additives whose use is authorised for other species, the 10-year data protection period shall be extended by one year for each minor species for which a use extension authorisation is granted.* *3. The applicant and the previous applicant shall take all necessary steps to reach agreement on sharing the use of information, in order not to repeat toxicological tests*

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		on vertebrates. If, however, no such agreement is reached on sharing the information, the Commission may decide to disclose information necessary to avoid repeating toxicological tests on vertebrates, while ensuring a reasonable balance between the interests of the parties concerned. "
	EU Food Law: *Smoke* flavourings: Article 16 of Regulation (EC) No 2065/2003	Article 16 of Regulation (EC) No 2065/2003 provides an automatic and unlimited in time data protection to the authorisation holder of a smoke flavouring. The information contained in the application dossier of the first applicant may not be used for the benefit of another applicant, unless the subsequent applicant has agreed with the authorisation holder that such information may be used (consent). Article 16 of Regulation (EC) No 2065/2003, titled 'data protection', reads as follows: *"The information in the application submitted according to Article 7 may not be used for the benefit of another applicant, unless the other applicant has agreed with the authorisation holder that such information may be used."another applicant, unless the other applicant has agreed with the authorisation holder that such information may be used."*
	EU Food Law: *Food* contact materials: Article 21 of Regulation (EC) No 1935/2004	Article 21 of Regulation (EC) No 1935/2004 on food contact materials provides an automatic and unlimited in time data protection to the first applicant for the authorisation of a substance. EFSA may only use information given by the first applicant for the benefit of a subsequent applicant, provided that (a) EFSA considers that the substance is the same as the one for which the original application was submitted, including the degree of purity and the nature of impurities, and (b) that the subsequent applicant has agreed with the first applicant that such information may be used (consent). Article 21 of Regulation (EC) No 1935/2004, titled 'Sharing of existing data', reads as follows: *"Information given in an application submitted in accordance with Articles 9(1), 10(2) and 12(2) may be used for the benefit of another applicant, provided that the Authority considered that the substance is the same as the one for which the original application was submitted, including the degree of purity and the nature of impurities, and that the*

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		other applicant has agreed with the original applicant that such information may be used." The rationale of this provision is provided in recital (22) of Regulation (EC) No 1935/2004: "*It is appropriate to protect the investment made by innovators in gathering the information and data supporting an application made under this Regulation. In order to avoid unnecessary repetition of studies and in particular animal testing, however, sharing of data should be permitted provided there is an agreement between the interested parties."*
	EU Food Law: *Novel* Foods Regulation: Article 26 of Regulation 2015/2283	Article 26 of Regulation (EU) 2015/2283 on novel foods is modelled on the data protection regime set out in the Health Claims Regulation: newly developed scientific evidence or scientific data supporting the application for the authorisation of a novel food may not be used for the benefit of a subsequent application for a period of five years from the date of authorisation of the novel food without the consent of the prior applicant. The protection is granted upon request by the prior applicant and by the Commission where certain specific conditions are met (proprietary data). Article 26 of Regulation (EU) 2015/2283 reads as follows: *"1. On request by the applicant, and where supported by appropriate and verifiable information included in the application provided for in Article 10(1)[of the same Regulation], newly developed scientific evidence or scientific data supporting the application shall not be used for the benefit of a subsequent application during a period of five years from the date of the authorisation of the novel food without the agreement of the initial applicant.* *2.The data protection shall be granted by the Commission under Article 27(1) where the following conditions are met: (a) the newly developed scientific evidence or scientific data was designated as proprietary by the initial applicant at the time the first application was made; (b) the initial applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made; and (c) the novel food could not have been assessed by the Authority and*

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		authorised without the submission of the proprietary scientific evidence or scientific data by the initial applicant. *However, the initial applicant may agree with a subsequent applicant that such scientific evidence and scientific data may be used."* The rationale of this provision is set out in recital (30) of the same Regulation: *"Under specific circumstances, in order to stimulate research and development within the agri-food industry, and thus innovation, it is appropriate to protect the investment made by the applicants in gathering the information and data provided in support of an application for a novel food made in accordance with this Regulation. The newly developed scientific evidence and proprietary data provided in support of an application for inclusion of a novel food in the Union list should be protected. Those data and information should, for a limited period of time, not be used to the benefit of a subsequent applicant, without the agreement of the initial applicant. The protection of scientific data provided by an applicant should not prevent other applicants from seeking the inclusion of a novel food in the Union list on the basis of their own scientific data or by referring to the protected data with the agreement of the initial applicant. However, the overall five-year period of data protection which has been granted to the initial applicant should not be extended due to the granting of data protection to subsequent applicants."*
	EU Food Law: Plant Protection Products: Regulation (EC) No 1107/2009	Article 3 point (21) of Regulation (EC) No 1107/2009 defines 'data protection' as the "temporary right of the owner of a test or study report to prevent it being used for the benefit of another applicant". Articles 59, 61 and 62 of Regulation (EC) No 1107/2009 on plant protection products also provide data protection, but with respect to national procedures for the authorisation of plant protection products, which do not involve EFSA. Data protection is provided under the conditions of Article 59. During that period, the Member State that has received the relevant data cannot use them for the benefit of other applicants for the authorisation of plant protection products, unless with the consent of the first

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		applicant. However, the Regulation foresees obligatory data sharing with respect to studies involving vertebrate animals. Article 59 of Regulation (EC) No 1107/2009 reads as follows: *"1. Test and study reports shall benefit from data protection under the conditions laid down in this Article. The protection shall apply to test and study reports concerning the active substance, safener or synergist, adjuvants and the plant protection product as referred to in Article 8(2) when they are submitted to a Member State by an applicant for authorisation under this Regulation, (the first applicant), provided that those test and study reports were:* *(a) necessary for the authorisation or an amendment of an authorisation in order to allow the use on another crop; and* *(b) certified as compliant with the principles of good laboratory practice or of good experimental practice.* *Where a report is protected, it may not be used by the Member State which received it for the benefit of other applicants for authorisation of plant protection products, safeners or synergists and adjuvants, except as provided in paragraph 2 of this Article, in Article 62 or in Article 80. The period of data protection is 10 years starting at the date of first authorisation in that Member State, except as provided in paragraph 2 of this Article or in Article 62. That period is extended to 13 years for plant protection products covered by Article 47. Those periods shall be extended by 3 months for each extension of authorisation for minor uses as defined in Article 51(1), except where the extension of authorisation is based on extrapolation, if the applications for such authorisations are made by the authorisation holder at the latest 5 years after the date of the first authorisation in that Member State. The total period of data protection may in no case exceed 13 years. For plant protection products covered by Article 47 the total period of data protection may in no case exceed 15 years. The same data protection rules as for the first authorisation shall also apply to test and study reports submitted by third parties for the purpose of extension of authorisation for minor uses as referred to in Article 51(1). A study shall also be protected if it was necessary for*

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		the renewal or review of an authorisation. The period for data protection shall be 30 months. The first to fourth subparagraphs shall apply mutatis mutandis. *2. Paragraph 1 shall not apply:* *(a) to test and study reports for which the applicant has submitted a letter of access; or* *(b) where any period of data protection granted for the test and study reports concerned in relation to another plant protection product has expired.* *3. Data protection under paragraph 1 shall only be granted where the first applicant has claimed data protection for test and study reports concerning the active substance, safener or synergist, adjuvant and the plant protection product at the time of submitting the dossier and has provided to the Member State concerned for each test or study report the information referred to in point (f) of Article 8(1) and in point (d) of Article 33(3) as well as confirmation that a period of data protection has never been granted for the test or study report or that any period granted has not expired."* Article 62 reads as follows: *"1. Testing on vertebrate animals for the purposes of this Regulation shall be undertaken only where no other methods are available. Duplication of tests and studies on vertebrates undertaken for the purposes of this Regulation shall be avoided in accordance with paragraphs 2 to 6.* *2. Member States shall not accept duplication of tests and studies on vertebrate animals or those initiated where conventional methods described in Annex II to Directive 1999/45/EC could reasonably have been used, in support of applications for authorisations. Any person intending to perform tests and studies involving vertebrate animals shall take the necessary measures to verify that those tests and studies have not already been performed or initiated.* *3. The prospective applicant and the holder or holders of the relevant authorisations shall make every effort to ensure that they share tests and studies involving vertebrate animals. The costs of sharing the test and study reports shall be determined in a fair, transparent and non-discriminatory way. The prospective applicant is only required to*

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		share in the costs of information he is required to submit to meet the authorisation requirements. *4. Where the prospective applicant and the holder or holders of the relevant authorisations of plant protection products containing the same active substance, safener or synergist, or of adjuvants cannot reach agreement on the sharing of test and study reports involving vertebrate animals, the prospective applicant shall inform the competent authority of the Member State referred to in Article 61(1).* *The failure to reach agreement, as provided in paragraph 3, shall not prevent the competent authority of that Member State from using the test and study reports involving vertebrate animals for the purpose of the application of the prospective applicant. […]".* The rationale of these provisions is set out in recitals (39) and (40) as follows: *"(39) Studies represent a major investment. This investment should be protected in order to stimulate research. For this reason, tests and studies, other than those involving vertebrate animals, which will be subject to obligatory data sharing, lodged by one applicant with a Member State should be protected against use by another applicant. This protection should, however, be limited in time in order to allow competition. It should also be limited to studies which are genuinely necessary for regulatory purposes, to avoid applicants artificially extending the period of protection by submitting new studies which are not necessary. Business operators, in particular small and medium sized enterprises, should have the same opportunities in respect of market access.* *(40) The use of non-animal test methods and other risk assessment strategies should be promoted. Animal testing for the purposes of this Regulation should be minimised and tests on vertebrates should be undertaken as a last resort. In accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes, tests on vertebrate animals must be replaced, restricted or refined. Therefore, rules should be laid down to avoid duplicative testing and duplication of tests and studies on*

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		vertebrates should be prohibited. For the purpose of developing new plant protection products, there should be an obligation to allow access to studies on vertebrates on reasonable terms and the results and the costs of tests and studies on animals should be shared. In order to allow operators to know what studies have been carried out by others, Member States should keep a list of such studies even where they are not covered by the above system of compulsory access."
Intellectual property rights	Peer –reviewed article. Singh R. Vol. 1. New Delhi: Universal Law Publishing Co. Pvt. Ltd; 2004. Law relating to intellectual property (A complete comprehensive material on intellectual property covering acts, rules, conventions, treaties, agreements, case-Law and much more)	Intellectual property rights (IPR) refers to the legal rights given to the inventor or creator to protect his invention or creation for a certain period of time. Types of intellectual property protection to be afforded should be defined i.e. exactly what is to be protected and what is the overall aim of doing so. For example, is protection aimed at: • preventing use, reproduction or exploitation of data in breach of the protection foreseen; and/or; • preventing illegitimate submission of data for registration/notification purposes; and/or • concealing the specific identity of a substance, for example by substituting a generic identity – this is anticipated under exceptional circumstances only.
Copyright	US Federal Government definitions - US Copyright Office	A form of protection provided by the laws of the United States for "original works of authorship", including literary, dramatic, musical, architectural, cartographic, choreographic, pantomimic, pictorial, graphic, sculptural, and audiovisual creations. "Copyright" literally means the right to copy but has come to mean that body of exclusive rights granted by law to copyright owners for protection of their work. Copyright protection does not extend to any idea, procedure, process, system, title, principle, or discovery. Similarly, names, titles, short phrases, slogans, familiar symbols, mere variations of typographic ornamentation, lettering, coloring, and listings of contents or ingredients are not subject to copyright.
Patent	US-Federal Government definitions - USPTO	A patent is a limited duration property right relating to an invention, granted by the United States Patent and Trademark Office in exchange for public disclosure of the

Concepts	National regulatory text/legislation	Definition / Excerpt of legal text
		invention. Patentable materials include machines, manufactured articles, industrial processes, and chemical compositions.
Trade secret	US-Federal Government definitions - USC 18 USC 1839 [For context, this is a section of the US federal criminal code.]	The term "trade secret" means all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if – • the owner thereof has taken reasonable measures to keep such information secret; and • the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information.
	EU Trade secrets directive EU Regulation (2016/943)	A definition is provided in Article 2 of the trade secrets directive: 'trade secret' means information, which meets all of the following requirements: a it is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; b it has commercial value because it is secret; c it has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret. When placed in the public domain, the information loses its protection. Article 2 – Definitions reads as follows:

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Concepts	National regulatory text/legislation	Definition / Excerpt of legal text
		(1) 'trade secret' means information which meets all of the following requirements: *a. it is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;* *b. it has commercial value because it is secret;* *c. it has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret;* *(2) 'trade secret holder' means any natural or legal person lawfully controlling a trade secret;* *(3) 'infringer' means any natural or legal person who has unlawfully acquired, used or disclosed a trade secret;* *(4) 'infringing goods' means goods, the design, characteristics, functioning, production process or marketing of which significantly benefits from trade secrets unlawfully acquired, used or disclosed.*

D. Scope of the Recommendation

8. The scope of the recommendation covers both new and existing chemicals. The Recommendation states:

"**AGREES** that, for the purpose of this Recommendation, the word "chemicals" covers new and existing chemicals;"

9. The types of chemicals covered by the Recommendation are purposely not defined to provide Adherents with flexibility for implementing it. It is understood that implementation efforts should focus on the types of chemicals that are covered by the OECD Environment, Health and Safety Programme, i.e. new and existing industrial and consumer chemicals (including nanomaterials), pesticides and biocides. Adherents may of course implement the Recommendation for other types of chemicals, e.g. food additives.

10. The Recommendation focuses on non-clinical health, safety and environmental data. In principle, this would cover any non-clinical data that is used for an assessment of the risks to human health and the environment, such as physical chemical properties, fate and behaviour, (eco)toxicity. Adherents may also consider applying the provisions of the Recommendation to efficacy data.

Elements of Best Practices

11. This section is organised in six topics. Each topic includes an overview of the issue, the relevant provisions of the Council Recommendation and examples of good practises by both governments and industry. The BPG outlines how governments have addressed these issues in different ways and thereby provides guidance and support to Adherents in their efforts to implement the Recommendation. The BPG is meant to be a living document and therefore, as Adherents implement the Recommendation, further best practises will be included.

1. Disclosing health, safety and environmental data to the maximum extent possible, and takes measures, that such disclosure does not breach proprietary rights or data exclusivity rules

1.1. Overview of the Issue

12. For the public, a fundamental component which underlies many chemical management programmes in OECD member countries is the principle that individuals have the *right to know* about the chemicals to which they may be exposed in their daily lives. Further, governments recognise the importance of the availability of health, safety and environmental data and information regarding chemicals, to ensure that the public has access to such data and information, can take informed decisions about their use as well as have confidence in regulatory decisions regarding chemicals. In response, governments – as well as academia and the media - are increasingly adding such data into the public domain via on-line databases, posting regulatory assessments on the Internet, etc. However, not all scientific information which might be relevant for the assessment of chemicals can be posted due to existing legislation and regulations in some countries regarding proprietary rights. Recognising that the data available to the public may not reflect all of the significant and relevant data possessed by governments when assessing a chemical, has led some to question whether final regulatory decisions do in fact reflect all of the relevant data. This is exacerbated by the fact that many test results generated by research labs and published in peer-reviewed literature are difficult to interpret and may not be used by governments when drawing conclusions in regulatory risk assessments. As a result, the public may have the perception that regulatory decisions are in some cases based on “secret” industry-generated data.

1.2. Relevant provisions of the Council Recommendation

“RECOMMENDS that Adherents facilitate transparency and maximum possible disclosure of health, safety and environmental data. To that effect, Adherents should:

- respect applicable confidentiality protections and limitations;
- make clear to the public that:
  - this disclosure by the Adherent is not intended as an explicit or implicit permission or licence for the relevant data and information and their content to be used, reproduced, or otherwise exploited in breach of any proprietary right or data exclusivity rules or as an explicit or tacit statement as to whether and what proprietary rights do or do not apply to the data disclosed;
  - the public authority making the disclosure shall not be responsible for its use by third parties.

NOTE: Confidentiality protections also cover aspects of the protection of personal data.

1.3. Examples of good practice

1.3.1. Governments

- **European Union – European Medicines Agency (EMA)**

13. The EMA's public website contains clinical data submitted by pharmaceutical companies. Users are required to register and agree to terms of use, information is made available in a "view-on-screen-only" mode, a watermark is applied to the information to emphasise the prohibition of its use for commercial purposes, and the user is not permitted to download, save, edit, photograph, print, distribute or transfer the Clinical Reports.

- **European Union - European Food Safety Authority (EFSA)**

14. The EFSA's website, which as of 27 March 2021 (after entry into force of the new Transparency Regulation) will publicly disclose scientific data, studies and other information supporting any request for a scientific output addressed to EFSA, including applications as well as any supplementary information supplied by applicants, taking into account the protection of confidential information and the protection of personal data. Information shall be made public without delay once an application has been considered valid or admissible.

15. The information shall be made public in a dedicated section of EFSA's website that shall be publicly available and easily accessible. The information shall be available to be downloaded, printed and searched through an electronic format.

16. Closed lists of clearly defined information items for which confidentiality may be claimed, with the exception of safety relevant information are set out in the General Food Law and seven sectoral acts. When an applicant submits a request for authorisation accompanied by scientific studies, it may request certain parts of the submitted studies and other information to be kept confidential. This request must be duly justified (proof of "potential harm to a significant degree" in case of public disclosure). The applicant should submit a non-confidential version and a confidential version of the submitted studies and other information. Without delay and once an application is found valid or admissible, EFSA would make the non-confidential version of those studies, as submitted by the applicant, public. In parallel, EFSA would assess the confidentiality claim within 10 weeks. Once the assessment is completed, any additional data and information for which confidentiality requests has been considered as unjustified would also be made public (final non-confidential version as assessed by EFSA). Upon receipt of the confidentiality decision by EFSA, applicants would have the right to make a confirmatory application asking EFSA to reconsider its decision.

17. The disclosure of information shall be without prejudice to any existing rules concerning Intellectual Property Rights (which may set out limitations on certain uses of the disclosed documents on their content), and 'data exclusivity rules'. The disclosure to the public shall not be considered as an explicit or implicit permission or licence for the relevant data and information and their content to be used. EFSA shall ensure that clear undertakings or signed statements are given to that effect by those accessing the relevant documents, prior to their disclosure.

- **European Union - European Chemicals Agency (ECHA)**

18. The ECHA's website includes, by way of example, information disseminated in accordance with Regulation (EC) No 1907/2006 (REACH).

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19. Visitors of the website are informed through a legal notice (https://echa.europa.eu/legal-notice) of the possible proprietary rights attached to the featured data/information originating from third parties – and the need to obtain permission from the right holders, where applicable. Additional measures might also be taken by the Agency in some cases.

20. ECHA's information desk is available to answer specific questions pertaining to data/information featured on the website, as well as the terms of its notices.

- **US – EPA FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act):**

21. The provisions restricting or prohibiting disclosure of information routinely contained in records maintained by the US EPA's Office of Pesticide Programs (OPP) are found in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Freedom of Information Act (FOIA), and the Federal Food, Drug, and Cosmetic Act (FFDCA)[2]. OPP records contain much information that may qualify for confidential treatment under FIFRA section 10(b) or which may be otherwise protected under FIFRA section 10(g). FFDCA section 408(i) protects business confidentiality "to the same extent" as FIFRA section 10.

22. FIFRA section 10(b) protects from disclosure of "trade secrets or commercial or financial information obtained from a person and privileged or confidential," except that product formula information may be revealed to other federal agencies consulted by EPA and at public hearings or findings of fact issued by EPA. Certain annual production data is also confidential under FIFRA section 7(d).

23. However, FIFRA section 10(d)(1) limits the types of data that may be protected as confidential. Safety and efficacy data on registered or previously registered pesticides are not confidential business information and must be made available to the public, though three types of safety and efficacy data are removed from this mandatory availability requirement, except where EPA first determines that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment. The following information are considered confidential:

a. information that discloses manufacturing or quality control processes;

b. information that discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide; and

c. information that discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide.

24. Additionally, FIFRA section 10(g) provides that pesticide studies, regardless of confidentiality, may not be disclosed by EPA other than to requesters who sign the Affirmation of Non-Multinational Status. Congress imposed this limitation in the 1978 amendments to FIFRA to protect registrants of pesticides in the United States against unauthorized use of their health and safety data by competitors to obtain pesticide registrations in foreign countries. The Affirmation of Non-Multinational Status requires each person who seeks to obtain this information to affirm that they are not a foreign or multinational pesticide producer, and do not intend to and will not purposefully or negligently deliver (or cause delivery of) such information to a foreign or multinational pesticide producer [3]. Providing a false or misleading Affirmation of Non-Multinational Status is unlawful under FIFRA section 12(a)(2)(M).

[2] FFDCA section 408(i) governs confidential business information in tolerance data.

[3] For purposes of FIFRA section 10(g), a foreign or multinational pesticide producer is a business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States.

- **Health Canada's Inspection of Confidential Test Data Supporting Pesticide Registration Decisions**

25. Canada's *Pest Control Products Act* (PCPA) provides the public with the opportunity to inspect the scientific confidential test data supporting pesticide registration decisions. Companies who want to register a pesticide in Canada must provide test data to Health Canada's Pest Management Regulatory Agency (PMRA) for the evaluation of potential risks to human health and the environment as well as to demonstrate the product's value. The data are evaluated by PMRA scientists, who conduct risk and value assessments leading to decisions on whether or not the pesticide can be used in Canada and under what conditions. Data requirements cover a number of areas, such as: toxicology related to human health, bystander and occupational exposure, food residue trials, environmental toxicology and fate, as well as information supporting the efficacy, crop tolerance and benefits of the pesticide.

26. After a pesticide is registered, the public is invited to review the published evaluation report and decision document made available on the PMRA website. These documents explain the risk and value assessments supporting a registration decision, along with a summary of the information considered. In addition, however, members of the public may inspect the confidential test data supporting a registration decision in the "Reading Room", located at the PMRA's National Head Office in Ottawa, Ontario. This includes decisions after a final decision is made, to amend or to continue a registration after a post-market review (such as, a re-evaluation or a special review) is completed, as well as at the proposed decision stage for post-market reviews initiated as of January 1, 2022. Anyone wishing to inspect the confidential test data must submit an application form to identify the data to be inspected as well as an affidavit/statutory declaration stating the purpose of the inspection and attesting that the data will not be used or made available to others to register or amend a product in Canada or elsewhere. There are no fees associated with the inspection of confidential test data.

1.3.2. Industry

27. Some Companies have taken initiatives to make their health and safety information available to the public. Syngenta publishes data using Creative Commons copyright licenses. Bayer has a database that includes health and environmental safety studies for their active substances that have been evaluated by EFSA. In addition, on-demand, stakeholders can have the full study reports behind these summaries.

2. Take measures that requirements concerning health, safety and environmental data and information on chemicals provide protection of proprietary rights

2.1. Overview of the Issue

28. It is important to note that costs to a chemical company of generating data for the regulatory review of a new or existing chemical can be significant, and thus the unauthorized use of such data by a competitor puts the generator of such data at a competitive disadvantage. The impacts to the generator of the data are not limited to the loss of compensation for costs associated with generating the data (e.g., if the competitor submits the same data to another regulatory authority), but the data may also provide a competitor with information regarding the chemical product that could be used for product development.

2.2. Relevant provisions of the Council Recommendation

"RECOMMENDS that Adherents take measures to protect proprietary rights concerning required health, safety and environmental data and information on chemicals. To that effect, Adherents should:

a. require each data submitter to provide certification or other evidence of the right to use the data and information, and

b. not accept non-clinical health, safety, and environmental data and information if:

i. it requires the generation and submission of such data or information to fulfil a particular data requirement, and

ii. the submitter cannot provide certification or other evidence of the right of use"

NOTE: Certification or other evidence of right to use the data and information could be in the form of a letter of access from the original data owner or in the form of a formal declaration of the rights to use the data (see Australia below).

2.3. Examples of good practice

2.3.1. Governments

- **Australia**

29. Australia's domestic approaches to intellectual property and sharing confidential business information are outlined in the Industrial Chemicals Environmental Management (Register) Bill (ICEMR Bill), and the new *Industrial Chemicals Act 2019* (IC Act). The IC Act came into force on 1 July 2020.

30. Introducers of industrial chemicals will need to make a formal declaration that they have the rights to use all intellectual property on which they rely in meeting their regulatory obligations under the new *Industrial Chemicals Act 2019* (IC Act). Making a false declaration is an offence under Australian law.

31. An Explanatory Note on Information Use and Disclosure provides a plain-language summary of how this would operate under the ICEMR Bill, including how confidential business information may be shared.

- **Health Canada**

32. In Canada, the Pest Control Products Act (the Act) and the Regulations set out a data protection program, established in 2010 (see the Canada Gazette, Part II), applicable to both pre-market (applications) and post-market (special reviews and re-evaluations) reviews. These provisions intend to strike a balance between encouraging the registration of new innovative pest control products and the availability of generic pest control products by outlining the conditions that an applicant needs to follow to rely on an existing registrant's data to support their application. The program also allows Canada to meet its international trade agreement commitments. These agreements are the North American Free Trade Agreement, Agreement on Trade-related Aspects of Intellectual Property Rights of the World Trade Organization Agreement, and the Canada-European Union (EU) Comprehensive Economic and Trade Agreement (CETA).

33. Data generated by pest control product registrants to support registrations in Canada receive exclusive or compensable protection status for a period of time to encourage innovation. The Regulations give 10 years of exclusive use protection to data supporting a registration containing a new active ingredient never before registered in Canada. The exclusive protection period can be extended up to a maximum of 15 years total through the addition of approved minor uses of significance to Canada. This exclusive use period begins at the time of registration and registrants of pest control products under exclusive protection status can voluntarily allow other applicants (e.g. generic companies) to rely on their data. Data submitted that does not support the registration of a new active ingredient, but is used to amend a registration or register a new end-use product containing a registered active ingredient, is given a 12-year compensatory protection status. This compensable period begins

at the time of application and during this time other applicants may rely on such data, providing compensation is paid; this supports the registration of competing "generic" pest control products, thereby potentially lowering the price for pest control product users. Once either the exclusive use period or the compensable period has lapsed, the data becomes generic and can be relied upon without consent and without the payment of compensation.

34. Thus, the data protection program provides applicants and registrants with the flexibility to choose how to fulfil the data requirements during a pre-market or post-market review: they can provide their own data, or pay to rely on the data of another registrant (i.e. if it is not already "generic"), whichever suits their business needs best. For example, during pre-market reviews, a generic applicant seeking to register a pest control product, may choose to rely on the data supporting the previous registration of an equivalent pest control product (i.e. by paying compensation), or to provide their own data to demonstrate its safety and value. As well, during post-market reviews, Health Canada may issue a notice to all registrants of a particular active ingredient to submit specific studies needed to verify the continued acceptability and value of a pest control product. In this post-market situation, registrants can choose to either submit their own data in response to the notice or to rely on the data submitted by another registrant (e.g. by paying compensation).

35. The Regulations also set out provisions for mandatory negotiation and binding arbitration to determine the amount of compensation payable for reliance on a registrant's test data.

2.3.2. Industry

36. When the industry invested in the generation of studies for EU REACH, and subsequently engaged in data-sharing contracts with third parties to allow other companies to use those same studies for regulatory purposes, the contracts always included provisions on confidentiality. In some cases, only the right to refer to the studies was provided, but not access to the full study report to prevent unauthorized use.

3. Effective and efficient approaches that can be used by governments that require a third-party user to obtain prior consent, from the owner of data published on-line, before the third-party can re-use such data

3.1. Overview of the Issue

37. Some scientific data can – or must – be made publicly available over online platforms of the regulatory authorities that have received the information. However, the publication of data or material originating from third parties does not in itself entail an automatic licensing right to exploit the information. Therefore, attention should be drawn to prospective users of the possible proprietary rights vested in the data; and attempts should be made, where legally and practically possible, to promote or facilitate the re-use of such data.

3.2. Relevant provisions of the Council Recommendation

"RECOMMENDS that Adherents facilitate transparency and maximum possible disclosure of health, safety and environmental data. To that effect, Adherents should:

- respect applicable confidentiality protections and limitations;
- make clear to the public that:
  - this disclosure by the Adherent is not intended as an explicit or implicit permission or licence for the relevant data and information and their content to be used, reproduced, or otherwise exploited in breach of any proprietary right or

data exclusivity rules or as an explicit or tacit statement as to whether and what proprietary rights do or do not apply to the data disclosed;

- the public authority making the disclosure shall not be responsible for its use by third parties."

38. To implement these provisions, **Governments should aim to address** data sharing between industry and/or the regulatory bodies that house the data and 3rd parties wishing to access that data, including:

- researchers (e.g. academic as well as governmental human and environmental health institutes);
- stakeholders (e.g. consumer protection groups, environmental groups and animal protection groups);
- developers of new technology (e.g. next generation non-animal test methods);
- the general public; and
- industrial entities wishing to register substances that are similar to those that already have data available, providing any applicable data protection (exclusivity) period has passed.
- industrial entities wishing to register substances that are the same as those that already have data available (i.e., registrants of the same substance), providing any applicable data protection (exclusivity) period has passed.

39. **Governments should also aim to address** the release of data by the competent authorities where no agreement is reached amongst the industrial players and there is a need to avoid repetition of toxicological studies on vertebrates (e.g. Feed additives: Article 20 of Regulation (EC) No 1831/2003; Plant protection products: Articles 59, 61 and 62 of Regulation (EC) No 1109/2009, see section 3 above).

40. Others may take a different approach to confidentiality protections to health and safety data. Some countries limit the extent to which health and safety data may be withheld from public disclosure. However, while most such data cannot be withheld from public disclosure, there may be some exception for some portions of such data. These exceptions might include manufacturing or processing details, or specifics concerning mixture composition. Other information that may be included in the study report, but that is not of central relevance to the study, such as names of laboratory personnel or company-internal substance code names, may also be protected from disclosure in such jurisdictions (see for example here).

41. Intra-government data sharing: Some countries have legal provisions permitting the disclosure of otherwise confidential or proprietary information between and among government agencies, either at the federal level, or between federal and state/provincial, tribal, or local governments (see for example here).

3.3. Examples of good practice

3.3.1. Governments

- **European Union - ECHA**

42. Certain information in ECHA's possession must be made publicly available, free of charge, over the internet – for instance, non-confidential versions of study summaries and robust study summaries submitted as part of a registration dossier under Regulation (EC) No 1907/2006 (REACH). As a consequence, users of ECHA's website are informed of possible proprietary rights in the disseminated information originating from third parties through a legal notice (https://echa.europa.eu/legal-notice), as

well as through pop-up windows and tick-box facilities. This includes the possible application of sector specific data protection, like that recognised under REACH [4].

43. In promoting re-use, ECHA may take further measures in making certain data available to the public in a specific format/manner, while respecting the applicable legal requirements. A prime example of this is the 'REACH Study Results' dataset (a subset of data originating from the REACH registration dossiers that is made available for download in the IUCLID format (https://iuclid6.echa.europa.eu/reach-study-results), enabling its re-use for specified purposes (e.g. Safety Data Sheet compilation, or (Q)SAR development). ECHA has attempted to filter the data-set to information that is presumed to be non-proprietary, so as to avoid concerns over the potential infringement of proprietary rights. Nevertheless, as this is a new initiative, any prospective user of the data-set would need to subscribe and accept the dedicated terms and conditions of use before being able to download the content. It is possible that this approach might be re-visited in the future.

44. REACH also expressly recognizes the importance of confidentiality protection. Article 118(2) of REACH creates a legislative presumption for a few classes of inherently confidential information, that ECHA can only grant access to in exceptional cases of emergency. For instance, the precise tonnage of the substance or preparation manufactured or placed on the market belongs to such class of inherently confidential information. Similarly, article 66 of the Biocidal Products Regulation establishes a list of information for which disclosure will be deemed to undermine the protection of the commercial interests or the privacy or safety of the persons concerned. Such information is related for example to the details of the full composition of a biocidal product.

4. Effective mechanisms for the sharing of health, safety and environmental data between the data owner and a prospective purchaser

NOTE: This topic and examples of best practices go beyond the provisions of the revised Council Recommendation. While they contribute to the overall objectives of the Recommendation, the text of the Recommendation takes precedence over the information in this section. This information is provided for clarity and completeness of the record of the development of the best practice guide, and should not be relied upon to interpret the Recommendation.

4.1. Overview of the Issue

45. Effective data-sharing mechanisms between data owners and prospective purchasers are an important tool to use test data under the OECD system of Mutual Acceptance of Data and hazard assessments effectively on a global level. Considerable efforts have been made by European registrants under EU-REACH to enable the effective data-sharing in the EU. For example, when Act on Registration and Evaluation of Chemical Substances (K-REACH) was adopted with its comparable information requirements, this presented a new challenge to industry. Data-sharing systems that worked quite effectively within the EU were not necessarily designed in a way that enabled effective data-sharing beyond the EU. Considerable further efforts were needed by data-owners to enable the data-sharing with Korean registrants and also with future other registrants under EU-REACH-like chemicals management systems (e.g. Turkish REACH KKDIK, UK-REACH etc.). Setting up these new systems coincided with the work done by Korean registrants preparing for compliance with K-REACH and hence wishing to obtain the data as soon as possible. Both the registrants and the authority were under time-pressure and this has led to difficulties and delays in global data-sharing. However, with

[4] The regulatory frameworks that are administered by ECHA, namely REACH and Regulation (EU) No 528/2012 (BPR), set-out data sharing mechanisms, enabling prospective users to obtain a right to refer to certain data under certain conditions. These mechanisms are only available for certain uses of the data; for instance, in the context of REACH, REACH registration.

increasing experience in global data-sharing and systems being set-up to enable this process to work more effectively, the difficulties encountered in this first phase may be expected to be overcome.

46. There may be instances when a company that needs to submit a non-clinical vertebrate animal study to the government may be forced to conduct a *new* study on a chemical, even if another company has already conducted the same study to fill the environmental and/or human health data gap on the same chemical. Similarly, there may be instances when a company elects to conduct a new study on a chemical, even though another company has data for a similar chemical which could be provided instead using grouping and read-across principles to meet the regulatory requirement. This may be because: (1) the data owner and the prospective purchasers cannot agree on an appropriate pricing, (2) the owner refuses to sell the study, or data-sharing requests may be too demanding for the data owner (e.g. the prospective purchaser may not be willing to accept the data-sharing approach set up by the owner), (3) the government that possesses the industry study may not share it with another company or government as the study is protected by the company that owns it, and the government cannot share the study without the permission of the owner, (4) the rules and procedures for sharing data are too complex and burdensome thus creating a hurdle for one company to purchase a study from another company or from a consortium (this can in particular be a challenge for smaller companies), (5) a company is not aware that relevant data already exists, whether that be data relating to the same substance, or similar substance(s); for substances of a complex or variable nature (like UVCB's and multi-constituent substances), deficiencies in substance identification and substance naming protocols may further hinder transparency on the existence of relevant data, or (6) the existing study may be of low or questionable quality (e.g. not according to OECD GLP and OECD Test Guidelines or with deviations from the Test Guideline, or old data etc.) and/or not compliant with the data requirements specific to the jurisdiction where the prospective purchaser of the study needs to submit the study to authorities. Also, some authorities may be less inclined to use alternative methods (QSAR, read-across, weight of evidence etc.) or the concepts may be applied following different principles.

47. It is advisable, that authorities create a regulatory environment conducive to data-sharing amongst industry, including mechanisms such as (1) providing a regulatory framework for fair, transparent and non-discriminatory data-sharing and (2) helping to avoid unnecessary duplication of (animal) testing.

4.2. General Principle(s)

48. Consideration should be given to the following:

- industry or other bodies (data owners), and related institutions that may house the data;
- regulatory bodies / other institutions which facilitate and/or control processes for data-sharing;
- 3rd parties wishing to access / purchase the data – this may include industrial entities wishing to register substances that are the same as substances with available data, or are similar (e.g. with respect to their structure, physico-chemical and (eco)toxicological properties) to substances with available data, and for which an applicable data protection (exclusivity) period has not yet passed.

49. Mechanisms should aim at:

- determining the costs of sharing the information in a fair, transparent and non-discriminatory way. Regulatory mechanisms ensuring and arbitrating the implementation of this principle for animal studies are recommendable;
- avoiding situations that prospective purchasers of data are not aware that relevant data exists; it is recommended that authorities provide Guidance giving advice on minimum

criteria where to check for availability of data (e.g. eChemPortal could be a good reference point);

- enhancing relevance of data of one jurisdiction to that in another jurisdiction, regulators can seek to align their information requirements with one another. This goes beyond identifying the same information requirements but also encompasses the handling of alternative ways of complying with these information requirements. For example, data can be more easily shared between two jurisdictions that have comparable principles on accepting alternatives to animal testing such as read-across approaches, weight-of-evidence arguments or (Q)SARs.

4.3. Examples of good practice

4.3.1. Governments

- **European Union - EFSA**

50. The Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market contains certain data exclusivity rules, the so-called 'data protection rules'. 'Data protection' is defined as the "temporary right of the owner of a test or study report to prevent it being used for the benefit of another applicant" (Article 3 point 21 of the Regulation). It is provided with respect to national procedures for the authorisation of plant protection products, which do not involve EFSA. Data protection is provided under the conditions of Article 59. During that period, the Member State that has received the relevant data cannot use them for the benefit of other applicants for the authorisation of plant protection products, unless with the consent of the first applicant. However, the Regulation foresees obligatory data sharing with respect to studies involving vertebrate animals. Therefore, rules are laid down to avoid duplicative testing and duplication of tests and studies on vertebrates should be prohibited. For the purpose of developing new plant protection products, there is an obligation to allow access to studies on vertebrates on reasonable terms and the results and the costs of tests and studies on animals are shared. In order to allow operators to know what studies have been carried out by others, Member States are required to keep a list of such studies even where they are not covered by the above system of compulsory access.

- **European Union - ECHA**

51. There are data sharing mechanisms under Regulation (EC) No 1907/2006 (REACH) and the Biocidal Products Regulation, which apply to private actors. The basic premise for these mechanisms is not different from the practices of a standard organisation in setting a technical standard, which involves the use of technology that is protected by a patent. In ensuring that a technical standard can be applied by parties involved in the concerned industry sector, the patent holder is required to license its standard-essential patents on fair, reasonable and non-discriminatory (FRAND) terms. In the context of REACH and the Biocidal Products Regulation, concerned parties are subject to a number of data submission obligations. In fulfilling these obligations, data sharing is often a prerequisite, due to restrictions imposed by the legislative framework, such as the prohibition on the duplication of vertebrate animal studies.

52. Under the Biocidal Products Regulation, by way of example, concerned parties are obliged to make an inquiry to the Agency before they can perform a test or study involving vertebrates. If such a study has already been submitted for the purposes of the Regulation, the Agency will give the contact details of the data submitter to the prospective applicant. These parties are then required to make every effort to reach an agreement on data sharing that is fair, transparent and non-discriminatory. In case of a collapse in negotiations, the prospective applicant can involve ECHA.

53. Based on a comprehensive assessment of all documented communications between the parties, ECHA will establish whether or not every effort to reach an agreement in a fair, transparent and

non-discriminatory manner was made. This allows ECHA to decide whether or not the prospective applicant should be granted permission to refer to the relevant data or not. Indeed, in certain cases, ECHA can grant a right to refer (a licence) to the benefit of the prospective applicant.

54. However, the data sharing mechanisms under ECHA's remit have inherent limitations. In the majority of cases, the dispute mechanism is confined to vertebrate animal studies. Additionally, the data sharing mechanisms can only be relied on for cases specific to the concerned legislative act – they cannot be used as a vehicle for obtaining data for other purposes.

4.3.2. Industry

- **Example from the inorganics sector – Nickel Institute**

55. Nickel and nickel compounds are data-rich substances. The Nickel Institute's science department owns some of the data, which it renders available for global data-sharing. But its data-sharing goes beyond the licensing of the studies that it owns. It also encompasses the sharing of the science department's hazard assessments prepared on the basis of its own data and other studies. These assessments have been used for compliance with EU-REACH and have also been made available for compliance with Korea-REACH / ARECS.

56. The Nickel Institute's data-sharing system was originally set up with EU-REACH in mind and therefore organised through the EU-REACH Nickel Consortia. The Nickel Institute serves as Secretariat for the EU Nickel Consortia and manages all licenses to use and letters of access individually. With Korea-REACH and other REACH systems upcoming, this system was not applicable: The Nickel Institute is not in a position to serve as Secretariat for nickel registrations in multiple jurisdictions. Therefore, the Nickel Institute needed to develop a new system able to address global data-sharing in a way that is more efficient.

57. The Nickel Institute's system functions on the basis of the following:

  - The Nickel Institute is ready to enter into one data-sharing agreement per each nickel substance (nickel metal, nickel compound etc.) for each jurisdiction. In this data-sharing agreement, it grants the licensee the right to give sub-licenses to any registrant of that substance in that jurisdiction. The Nickel Institute is not ready to engage in data-sharing with all the individual registrants, as this would be unmanageable for it.
  - The Nickel Institute's science division has data packages for global data-sharing (consisting of studies it owns as well as of hazard assessments that are based on its own and other studies) for nickel metal and nickel compounds. When there is a request from a jurisdiction for entering into a data-sharing agreement, the Nickel Institute updates the data package. This is facilitated by the fact that the Nickel Institute's science division monitors new studies for nickel and nickel compounds and contributes to annual updates of the EU-REACH dossiers. This updated data package is then rendered available for assessment under a Non-Disclosure Agreement. When the potential licensee confirms their interest in obtaining the license of the data-package and also guarantees that they will stand ready to ensure the access to this data package for registrants of the substance in the jurisdiction, the data-sharing agreement is entered into.
  - Rather than tailor-making the data package depending on the data requirements, the Nickel Institute provides the entire data package for each substance. It, however, limits the right to use the data based on regulatory data requirements. For example, if a substance is only registered at a tonnage level of between 100 and 1000 t/y in Korea, the licensee will obtain the full data package, but the data-sharing agreement will limit their right to use and sub-license only the data that Korea-REACH requires at that tonnage level. The fee for the data-package license is reduced accordingly. Should there be a tonnage update, the additional rights can be granted after payment of the cost of the higher tier of the data package.

- Finally, the Nickel Institute has made it a practice to help licensees – to the extent its resources permit – in their understanding and use of the data. It considers that the direct exchange with the licensees during the data-sharing process contributes to the quality of future registrations and therefore the safe use of nickel and nickel compounds.

5. Effective mechanisms for the sharing of health and safety test data between a government that possesses an industry study and another government, provided prior consent by the data owner has been secured

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5.1. Overview of the Issue

58. In some instances, countries have developed bilateral agreements to share proprietary business information with one another (perhaps in the context of performing a joint review or risk assessment for a particular chemical substances or group of substances).

5.2. General Principle(s)

59. Governments should aim to

- Obtain consent from the affected business for this data sharing between governments

5.3. Examples of good practice

5.3.1. Governments

- **European Union - European Parliament (EP), ECHA and EFSA**

60. Data sharing between different regulatory bodies within the same jurisdiction (e.g. within the EU, the European Parliament (EP) proposed an EP Pilot project under the 2019 EU budget entitled "Feasibility study on a common open platform on chemical safety data" involving ECHA and EFSA (the European Medicines Agency will currently not actively participate in the pilot). This project has been financed by the European Commission (Directorate-General of Environment). A tender for this study has been launched a with a submission deadline of 20 November 2019. The aim of the study is to explore the opportunities to set up a common platform on chemical safety data, with two main objectives: (i) information gathering: map existing database(s), systems and platforms, define and validate use cases in the area of access, sharing and use of chemical safety data requiring or benefiting from a common platform; and (ii) feasibility analysis: propose options/solutions for the provision of a platform and develop recommendations to achieve them.

6. Promoting transparency and access to data by third parties, without infringing proprietary rights, for the other

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6.1. Overview of the Issue

61. While data on the properties of chemical substances may be protected against use for certain purposes by third parties that are in competition with the data owners (e.g. inclusion or reference to that data within a regulatory registration dossier), there may be other uses or ways of accessing that data by third parties who are not in competition with the data owner(s). Examples of such third parties could include research groups, academia, government institutes, NGOs, and the public. There may be various reasons why access to existing data could be useful, including: it may support the development of new technology (e.g. new non-animal testing methods); it may allow insight into real-world chemical space and associated hazards and/or other properties; and it may allow for the scrutiny of regulations and their implementation, in the context of when and how data for chemical substance is generated.

6.2. General Principle(s)

62. Consideration should be made clear for which uses, by which parties, are protected against and which are not.

6.3. Examples of good practice

6.3.1. Governments

- OECD QSAR Toolbox drawing on ECHA's safety data and others set to support chemical safety predictions

63. The OECD QSAR Toolbox (Toolbox) is software developed in close collaboration with the European Chemicals Agency (ECHA) designed to fill gaps in data needed for environmental and human health hazard assessment. The Toolbox promotes the use of alternatives assessment methods and reduces the need for animal testing, while aiming to protect human health and environment. Different estimation techniques such as chemical grouping and read across, trend analysis, and Quantitative Structure Activity Relationships (QSAR) can be used to fill data gaps and predict experimental toxicity values.

64. The Toolbox can also serve as a source of or link to experimental data. In Toolbox version 4.4, donated databases contain more than 2.6 million data points for over 90,000 chemicals and provide information on physical-chemical properties, environmental fate and transport, ecotoxicological information, and human health hazards. In addition, the Toolbox supports the import of data from the International Uniform Chemical Information Database (IUCLID), and the export of Toolbox predictions to IUCLID. The Toolbox links to regulatory metadata from ECHA REACH studies, which include details on experimental conditions, results, and references, and are aligned with downloadable results from the IUCLID website.

6.3.2. Industry

- AMBIT, CEFIC LRI's open software drawing on ECHA's safety data set to support chemical safety predictions

65. The AMBIT software, funded initially within the CEFIC LRI programme, provides a web service and user friendly web interface to a chemical database, various chemical structure search facilities and toxicity prediction models. The AMBIT data model supports substances with complex compositions and substances experimental data which allows importing data from the International Uniform Chemical Information Database (IUCLID6) as well as other sources. The chemical structures already contained in AMBIT are automatically linked to constituents/impurities/additives of the imported substances. The flexible data storage and visualization allows for user friendly presentation of study data (physicochemical properties, environmental fate, ecotoxicological and toxicological information) and

composition. Comprehensive assessment workflows are developed for read-across and category formation based on all the data available in AMBIT. The assessment workflow facilitates the search for target and source structures through multiple similarity methods, generating data matrices, gap filling and generating assessment reports with predefined formats automatically. The enhanced AMBIT facilitates drafting and improves quality for read-across and category formation and will be a useful tool for experts responsible for substance assessments.

66. The current landscape of chemical databases is in order of many thousands, distributed under different licenses, and are being continuously updated and may be of interest in different use cases. In addition to REACH study results https://iuclid6.echa.europa.eu/reach-study-results and OpenFoodToxv2, AMBIT3 will follow stakeholder's recommendation and integrate additional sources as e.g. ECHA's REACH 2018 dataset, US EPA CompTox Dashboard, EFSA's OpenFoodTox 2 dataset and the RepDose database.