Environment & Energy

Data Citation and Compensation: How REACH Compares With the FIFRA Scheme

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The European Union's REACH regulation is a complex chemical management regulation intended to replace approximately 40 previously existing legal instruments with a single EU regulatory scheme for all chemical substances (both new and existing substances). [1]REACH (Regulation (EC) No 1907/2006) is available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF. It also creates a data compensation scheme for entities that must rely upon studies another entity generated to complete their registration for a particular chemical substance. This article provides background on REACH registration, data compensation and sharing procedures, and compares REACH's data compensation principles with how similar issues are addressed in the context of FIFRA data compensation arbitrations.

Registration

The core of REACH is its registration requirement. It mandates that all chemicals, unless regarded as registered [2]REACH arts. 2(5)(a)-(b), (6)(a), (6)(d); Annex IV and V. or otherwise exempt, [3]REACH arts. 2(1)-(3), 3(15)(a). manufactured or imported into the EU in quantities of one metric ton or more per year be registered by legal entities (certain manufacturers and importers) with the newly created ECHA. [4]*See* REACH arts. 5-7. Under Article 5, the non-registration of a substance that is required to be registered means that the substance cannot be manufactured, imported, or otherwise placed on the EU market. This REACH principle is often referred to as the "no data, no market" principle. Registration entails, in part, the generation of, or citation to, substance-specific health and safety data, whose results are set forth in a technical dossier.

For "phase-in substances," the term applied to existing chemicals, [5]The term "Phase-in substance" is defined in REACH Article 3(20). the registration process is proceeding in phases. To gain the benefit of extended "phased in" registration deadlines — $3^1/_2$, 6, and 11 years from June 1, 2007, depending on the annual volume and hazard of the substance — manufacturers and importers (and producers and importers of certain articles) were required to pre-register their substances between June 1, 2008, and December 1, 2008. [6]*See* REACH arts. 23, 28; *see generally Registration Guidance* at 46-49, 58. Once a legal entity pre-registered, it could continue manufacturing or importing the substance until the extended registration deadline. [7]*See* REACH arts. 21(1), 23(1)-(3); *see generally Registration Guidance* at 58; ECHA, *Guidance on Data Sharing* at 20 (Sept. 2007) (*Data Sharing Guidance*), available at http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.pdf (31 CRR 921, 10/1/07).

Non-phase-in substances can be broadly applied to new chemicals, including all substances that do not meet the definition of phase-in substances. [8]*Data Sharing Guidance* at 11. A non-phase-in substance, as well as a phase-in substance that is not pre-registered by a legal entity, does not benefit from an extended "phased in" registration period. An immediate registration is required in compliance with the REACH Article 26 process. A legal entity cannot manufacture and/or import the non-phase-in substance until three weeks after it submits a complete registration. [9]REACH art. 21(1); *Data Sharing Guidance* at 12 ("Non phase-in substances that are manufactured or imported in quantities of 1 tonne or more per year, will have to be registered by the company before the start of its activities involving these substances. The same applies to phase-in substances that have not been pre-registered").

Establishing SIEFs and Consortia for Data Development, Data Sharing, and Data Compensation

Once a substance is pre-registered, the legal entity is assigned to a Substance Information Exchange Forum (SIEF) with other pre-registrants of the same substance. The purpose of SIEFs is to facilitate the sharing of and compensation for existing data on the chemical, the collective identification of data gaps, and cost-sharing with respect to the generation of new data. [10]*See* REACH art. 29. *See generally* ECHA, "Data Sharing," available at http://echa.europa.eu/datasharing_en.asp(ECHA Data Sharing); ECHA, SIEF – Key Principles (Feb. 13, 2009), available at http://echa.europa.eu/doc/reachit/sief_key_principles.pdf (33 CRR 172, 2/23/09).

REACH and ECHA guidance require SIEF members to ask among themselves for the availability of tests on vertebrate animals before such testing is initiated. [11]REACH arts. 27(1), 30(1). While SIEF participation is mandatory for entities specified in REACH Article 29 (*i.e.,* registrants, certain downstream users, and third-parties that submitted information to ECHA), membership in a consortium or other form of cooperation agreement is entirely voluntary. Consortia are a more formal type of cooperation between registrants set up to provide practical help with SIEF data-sharing and compensation obligations and the preparation of registrations. While a SIEF is for a single substance, a consortium can incorporate different SIEFs of similar substances. [12]*See Data Sharing Guidance* at 95-102.

Becoming a Data Holder and Protecting Rights in SIEFs

ECHA provides that data sharing is "one of the core principles" of REACH. [13]ECHA Data Sharing, available at http://echa.europa.eu/datasharing_en.asp. Procedures are established to encourage data owners to participate in SIEFs "to prevent the unnecessary duplication of existing data." [14]European Commission, Environmental Directorate General, *Reach In Brief* at 10 (Oct. 2007), available at http://ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf (REACH in Brief). A Data Holder is any person or legal entity holding information/data relevant to a phase-in substance and willing to share the data within a SIEF. Some Data Holders may be other than a manufacturer/importer of substances into the European Union at > 1 metric ton or have an interest in placing a substance within the EU market place. As a result, these entities may not have pre-registered or intend to register relevant substances in which it is a Data Holder under REACH. When a substance is pre-registered by other entities that intend to place the substance on the market in the EU and ultimately perform a registration, a SIEF is formed. Once a SIEF is formed, a Data Holder can identify itself as such within the SIEF via REACH-IT, [15]REACH-IT is the main tool for companies to submit data and dossiers on chemical substances. *See* http://echa.europa.eu/reachit_en.asp
. so they can assert and protect their rights within the relevant SIEF. [16]*Data Sharing Guidance* at 29-30 and 32-33 (discussing how Data Holders can join a SIEF); REACH art. 29(1). Data Holders do not have an active role within any SIEF in determining those data to include in a joint submission dossier; instead Data Holders provide data to support the registration of a substance to the SIEF or Consortium for SIEF members' use and request compensation for data relied upon.

Obtaining a Letter of Access

In practice, activities related to granting data access occur at two levels. First, "permission to refer to the previous registrant's full study report" is granted by the Data Holder to the Lead registrant, or SIEF members (some of which may be part of a Consortium). [17]REACH art. 27(4); *see also* REACH art. 30(1). This right, referred to as a "Letter of Access" (LOA), permits a Data Holder to make relevant study data available by granting access to it. Typically, the Data Holder will not provide a hard copy of the study but instead provide a robust study summary with the right to reference the full study report. The Data Holder will grant an LOA as a commercial transaction, which will typically take place after the access recipient pays an agreed sum of money. In the case of consortia or joint data ownership, data sharing and compensation is a little more complex, but the intent is that the registrants have access to the key endpoints in the lead dossier that are appropriate for their tonnage band.

Data Holders may also grant the Lead Registrant or SIEF members (some of which may be part of a Consortium), Consortium Members and/or SIEF members the right to "sub-license" data citation rights to other legal entities that do not currently, but may in the future, need data citation rights for REACH registration purposes. Those include a Lead Registrant sub-licensing to the remaining SIEF members; a Consortium, organized as a separate legal entity, sub-licensing to the Lead Registrant and remaining SIEF members; and a SIEF member with a later registration deadline based on the substance's classification and tonnage band. Data Holders also may grant the right to sub-license to members of other SIEFs needing data access to certain studies.

DATA SHARING, COMPENSATION, AND DEVELOPMENT PROCEDURES

Data Sharing and Compensation Procedures for Non-Phase-In Substances and Phase-In Substances That Were Not Pre-Registered

REACH Article 27 sets forth the data sharing principles for non-phase-in substances and phase-in substances not pre-registered under REACH. A potential registrant of a non-phase-in substance or a phase-in substance that was not pre-registered is required to make an inquiry, also known as an Article 26 Inquiry, with ECHA as to whether a SIEF was formed or a registration was submitted for the substance. [18]REACH art. 26(1). Since SIEFs are active until June 1, 2018, the potential registrant making an Article 26 Inquiry will be placed in contact with the existing registrants to facilitate data sharing. ECHA is required to inform the potential registrant of any previous registrants, and inform previous registrants of the potential registrant's inquiry. [19]REACH art. 26(3). If there are several potential registrants, ECHA also will inform those potential registrants of each other. REACH art. 26(4). The Article 26 Inquiry includes certain mandatory information that ECHA requires to identify the substance. ECHA will then provide the potential registrant with a list of available robust summaries submitted within 12 years of the inquiry date, and can provide copies of available data submitted more than 12 years prior to the inquiry date. [20]REACH art. 26(3); ECHA, Questions and Answers on Data Sharing and Related Disputes (July 2010) at 5-8, available at http://echa.europa.eu/doc/datasharing/datasharing_q_a.pdf (Data Sharing Q&A); *Data Sharing Guidance* at 64-65.

The potential registrant is required to request from prior registrants any information involving tests of vertebrate animals. A registrant may also request information for tests not involving vertebrate animals, but is not obligated to do so. [21]REACH art. 27(1). Once a request for information for studies submitted less than 12 years from the inquiry is made, the potential and prior registrants must make every effort to reach an agreement on the costs for data sharing and reliance. [22]REACH art. 27(2); Data Sharing Q&A at 8; *Data Sharing Guidance* at 66. It is anticipated that as registrations are completed, ECHA will engage more in the practice of sharing lists of submitted data while also providing the potential registrant with data submitted after the 12-year compensability period expires.

ECHA states that it "aims at guaranteeing that registrants and/or potential registrants make every effort to ensure that the costs of sharing information required for registration are determined in a fair, transparent, and non-discriminatory way." [23]Data Sharing Q&A at 3. Examples ECHA provided where sharing is considered unfair, non-transparent, or discriminatory are:

Not fair, if the Data Holder requests the full cost of the study be paid where there are several other registrants;

Not transparent, if the Data Holder requests that payment of a generic fee for the data contained in the joint registration dossier, without providing detailed information on the costs; or

Discriminatory, if the costs of the same study would be different for EU manufacturers and importers or Only Representatives (*i.e.,* a natural or legal person appointed by a non-European Community natural or legal person that manufactures a substance that is imported into the Community to fulfill REACH importer obligations). [24]Data Sharing Q&A at 3.

If an agreement for costs cannot be reached, ECHA established a procedure, required under REACH, for potential registrants to seek ECHA's permission to refer to the data. The previous registrant shall have a claim against the potential registrant for an equal share of the cost incurred by the existing registrant, which is enforceable in national courts [25]REACH art. 27(5)-(7); Data Sharing Q&A at 9-10; *Data Sharing Guidance* at 66; ECHA, *Information to ECHA indicating the failure to reach an agreement on data sharing*, available at https://comments.echa.europa.eu/comments/article275.aspx. Any ECHA decision granting permission to refer to data is an appealable decision. [26]REACH arts. 27(7), 91.

Data Sharing and Compensation Procedures for Phase-In Substances

Article 30 sets forth the data sharing principles for phase-in substances. SIEF participants must ask among themselves whether any tests are available involving or not involving vertebrate animals. [27]REACH art. 30(1). A SIEF participant is required to request from other SIEF participants any information involving tests of vertebrate animals, before undertaking new tests. A participant may also request information for tests not involving vertebrate animals, but is not obligated to do so. [28]REACH art. 30(1). A data owner must provide proof of a study's cost within one month of the request. [29]REACH art. 30(1). ECHA guidance states: "If a requested study is available to one member of that SIEF, he is obliged to make that study available to the other potential registrants, subject to the sharing of the cost." [30]Data Sharing Q&A at 12. The data owner and other SIEF participants "shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way." [31]REACH art. 30(1).

Although REACH does not specify a method for sharing costs, it provides that if companies cannot reach an agreement regarding appropriate costs, "the cost shall be shared equally." [32]REACH art. 30(1). If a data owner of a study that involves testing on vertebrate testing "refuses to provide either proof of the cost of that study or the study itself to (an)other participant(s), he shall not be able to proceed with registration until he provides the information to the other participant(s)." [33]REACH art. 30(3). REACH provides that in this case, the other SIEF participants should be allowed to proceed with registration without fulfilling the relevant data endpoint by providing an explanation of the data owner's refusal to provide information on that data endpoint. [34]*Id*.; Data Sharing Q&A at 15 ("[T]he other participant(s) shall proceed with registration without fulfilling the relevant information requirement, provided that they have received permission from ECHA to do so."). *See also* Data Sharing Q&A at 16.

If a data owner of a study that involves testing on invertebrate animals refuses to provide either proof of the cost of that study or the study itself to (an)other participant(s), the other SIEF participants shall proceed with registration as if no relevant study was available in the SIEF." [35]REACH art. 30(4). Thus, the SIEF participants (sometimes including the Lead registrant) must ensure that the invertebrate data are presented in their registration dossier, which will likely require that a new invertebrate study be commissioned. [36]REACH art. 30(4); Data Sharing Q&A at 15 (in data sharing disputes for studies not involving vertebrate animals, the SIEF participants "will have to perform individually such studies, prior to submitting a complete registration dossier"). This is different from the requirements associated with obtaining and submitting vertebrate data.

Any ECHA decision to require a particular registrant to carry out a test not available within the SIEF, to allow other participants to refer to another's data, or to prevent a data owner from proceeding with registration until it provides the requested information to the other participants, are decisions subject to appeal. [37]REACH arts. 30(5), 91.

Data Development Procedures

There are registration circumstances when data must be developed. For example, a potential registrant may determine that the studies previously submitted to support an endpoint are not sufficiently characterized. [38]Data Sharing Q&A at 6-7. Similarly, a SIEF may determine that a new test is needed to complete the registration dossier. In the latter case, REACH provides that SIEF participants "shall take all reasonable steps to reach an agreement within a deadline set by the Agency as to who is to carry out the test on behalf of the other participants and to submit a summary or robust study summary to the Agency." [39]REACH art. 30(2). If no agreement is reached, ECHA established a website for registrants to submit required information regarding any data development disputes. [40]ECHA, Information to ECHA indicating the failure to reach an agreement on who shall perform a test, available at https://comments.echa.europa.eu/comments/article302.aspx. Upon review, ECHA will "select the registrant who will perform the study on the basis of objective criteria, including active participation on the preparation of the dossier and the deadline applicable to the respective registrations of the SIEF members." [41]Data Sharing Q&A at 13.

DATA COMPENSATION UNDER REACH

REACH calls for participants in a SIEF to determine the costs of sharing information "in a fair, transparent, and non-discriminatory way." [42]REACH arts. 27(3), 30(1). ECHA issued guidance on data sharing under REACH. [43]*Data Sharing Guidance* at Section 7 and Annex 5. For comparative purposes, outlined below is how certain of these data compensation issues were addressed in the context of FIFRA data compensation arbitrations. It is important to note that while FIFRA provides for arbitration of data disputes when agreement cannot be reached, REACH's procedures for resolving data disputes can be quite different. As discussed above, ECHA is charged with resolving disputes between: (1) potential and prior registrants for compensation of studies supporting non-phase-in substances; and (2) SIEF participants and Data Holders of phase-in substances when SIEF participants believe the Data Holder is precluding SIEF participants from registering their products by not sharing certain data or providing proof of costs for such data. This, however, does not preclude the resolution of data disputes outside this framework (*i.e.,* agreed upon third-party mediator) as long as there is no imminent impact on a REACH registration obligation.

Compensability

Compensability of Publicly Available Studies

Under REACH Article 10, registrants must "be in legitimate possession of or have permission to refer to the full study report summarized [in a study summary or a robust study summary] for the purpose of registration." [44]REACH art. 10(a). When a full study report (*e.g.*, a scientific paper) is publicly available, there is some question whether the public availability constitutes "legitimate possession" or "permission to refer." In its *Data Sharing Guidance*, ECHA directs potential registrants to first gather all existing available information, including "data in the public domain that can be identified through a literature search." [45]*Data Sharing Guidance* at 47. ECHA does not seem to assert, however, that public availability is consistent with legitimate possession or permission vis-à-vis the full study report. Indeed, ECHA acknowledges that when publication has occurred, "generally, such publication will be subject to copyright rights." [46]*Data Sharing Guidance* at 54. ECHA also states the following when discussing when a company has "legitimate possession of the full study report" and the "right to refer to the full study report":

(b) REACH refers to **legitimate possession of the full study report** for Registration purposes. This term, however, is not defined. It does not mean ownership, although the owner of the data clearly is also in legitimate possession of that data. In the absence of definition in the legal text, it is for national courts to interpret this term under the control of the European Court of Justice (ECJ). In most legal systems, legitimate possession is defined by the holding of a good and right to use it, although the right to use could also be limited. A possible definition of legitimate possession would be to have a copy (in electronic or paper form) of the full study report, with the right to use the data for REACH registration purposes. By having the right to use to register under REACH, the entity having legitimate possession will not infringe the rights of other parties, such as copyrights. This right to use a study for REACH registration can be granted by the owner(s) of the full study report.

(c) REACH also refers to the **right to refer to the full study report**. This is mainly when the owner of the data provides a 'letter of access' to another party that is limited to the use of the data for one or more specific purposes, such as for Registration under REACH (and/or for other regulatory purposes) but without passing on to that party a copy of the full study report.

(d) By contrast, a mere copy of the full study report, with no letter of access or right to use the data, is not sufficient for Registration purposes, unless the full study report itself is publicly available and not protected under copyrights or other relevant intellectual property rights. [47]*Data Sharing Guidance* at 55 (footnotes omitted; emphasis in original).

It thus appears that if copyright protection applies to a study, even if publicly available (*i.e.,* key details discussed in a published article), arguments supporting the position that compensation is due exist. How that compensation is paid remains unresolved. Data owners can be expected to argue that payment must be made to the data owner while others may seek only to pay a copyright fee if sufficient data from the full study are publicly available to prepare a robust study summary.

ECHA also provides the following "warning" regarding the legitimate possession of data:

Warning: Please note that except [for] specific cases enumerated in Art. 10(a) last paragraph, the registrant must be in legitimate possession or have permission (*e.g,.* a letter of access) to refer to the full study report. This also applies to cases where robust study summaries or study summaries can be found on the internet (for example summaries published in the framework of the OECD SIDS/ICCA HPV Program, or the US HPV Chemical Challenge Program). In addition, any party downloading studies that are publicly available should carefully check whether certain uses of those studies infringe copyrights of the owner(s). This also applies to cases where access is given to full study reports by Government agencies (for example through the US Freedom of Information Act or similar legislation). [48]*Data Sharing Guidance* at 55 (emphasis in original).

Compensability Period

Under REACH, studies are compensable for 12 years after initial registration. [49]REACH arts. 25(3), 27. Specifically, the rule establishes a data compensation period for study summaries and robust study summaries of 12 years, but the period runs from when the data were "submitted in the framework of a registration under [REACH]." [50]REACH art. 25(3). ECHA states when a substance is already registered and relevant data were submitted over 12 years earlier, a new registrant "is not required to request the information from the previous registrants …, [but] [i]f he decides to use the older studies, he is not required to pay any financial compensation … ." [51]*Data Sharing Guidance* at 65. Note that for substances covered under REACH Article 24 (*i.e.*, notified substances), the 12-year rule serves to extend the 10-year data compensation period set forth in the Notification of New Substances Directive by an additional two years. *Data Sharing Guidance* at 65-66. Since the earliest that a REACH registration dossier for a phase-in substance could be submitted was June 1, 2008, this so-called "12-year rule" should not come into play for non-pre-registered "phase-in substances" until June 1, 2020, at the earliest. Thus, the age of a particular study is irrelevant. Rather, the key issue is when the first registration dossier containing the data was submitted.

This compensability scheme is different from that established under FIFRA. Under FIFRA, studies are compensable for the 15-year period following the registration application date. [52]FIFRA §3(c)(1)(F), 7 U.S.C. §136a(c)(1)(F). Publicly available FIFRA arbitration decisions generally have not explicitly reduced the value owed for compensable studies due to their age. While FIFRA establishes a 10-year period of exclusive use (for pesticides initially registered after 1978), REACH has no comparable restriction.

Study Quality

ECHA advises taking the quality of each study into account. ECHA specifically discusses two methods for establishing the scientific quality of a study: (1) the Klimisch, *et al.* (1997) data scoring system; and (2) the U.S. Environmental Protection Agency's approach developed as part of its High Production Volume (HPV) Challenge Program. Generally, under the REACH framework, it appears that the Klimisch system is more commonly used to evaluate studies. Under the Klimisch scoring system, all studies are evaluated regarding their reliability, relevance, and adequacy, and categorized as either 1=reliable without restrictions; 2=reliable with restrictions; 3=not reliable; or 4=not assignable. [53]*Data Sharing Guidance* at 70-71.

Under REACH, registrants "are only required to share in the costs of information that they are required to submit to satisfy their registration requirements." [54]REACH art. 30(1). With this principle, ECHA has stated: "[C]ompanies cannot be forced to pay for studies that they do not need and they also cannot be forced to pay before they actually need them in their respective tonnage band." [55]ECHA, *Frequently Asked Questions Regarding REACH,* Data Sharing Q.8, available at http://echa.europa.eu/reach/reach_faq_en.asp?topic=datasharing&#datasharing. One area of potential dispute within SIEFs and with data owners is whether more than one study for any given endpoint should be part of the dossier. While some argue that only one study per endpoint is needed, there could be circumstances when all available data should be included in the dossier to assess adequately the hazard of a substance, which therefore means that compensation for any additional data would need to be considered. ECHA has noted, for example, that while only one study per endpoint is needed, "there will be some cases in which several studies — some of which may not have passed the initial screen, may be collectively used to address an endpoint." [56]*Data Sharing Guidance* at 71, 77. By using the Klimisch coding system, companies can choose studies of higher quality (Klimisch code 1 or 2) over those that fail to meet essential criteria for reliability, relevance, and/or adequacy.

ECHA states that only studies with a reliability rating of 1 or 2 "should normally qualify for financial compensation," although an exception may arise if a Klimisch 3 study can satisfy an endpoint via the weight-of-evidence approach and no higher ranked studies were available. [57]*Data Sharing Guidance* at 73, 79. ECHA further states that, generally, robust study summaries would only be prepared for the highest quality or "key" studies. [58]*Data Sharing Guidance* at 71. For example, if reports from both Klimisch categories 1 and 2 are available for the same endpoint, "the report with the higher rating will be used as the key study for cost allocation purposes." [59]*Data Sharing Guidance* at 77.

FIFRA arbitration decisions generally declined to award compensation for studies that EPA determined inadequate. The FIFRA arbitration decisions allowed compensation for data classified as "supplementary" or "core supplemental."

Historic Versus Replacement Costs

ECHA states the following regarding the use of historical or replacement costs:

Article 30.1 requires the owner of a study to provide proof of its costs within one month of a request for a study. However, nothing prevents Potential Registrants to agree on other valuation methods, such as the replacement value," *i.e.,* the price that would be paid today to obtain the same study. Which of these two methods (historic costs or replacement costs) is more appropriate is a matter for discussion within the SIEF. [60]*Data Sharing Guidance* at 73.

When historic costs are relied upon, ECHA guidance identifies certain circumstances that could "justify an increase or decrease of the value of a study for cost sharing purpose." Factors ECHA cites as reasons why the value of a study could increase include:

preliminary testing for determining test concentrations;

substance testing according to the standard protocol;

development of suitable analytical methods;

supplementary analyses (*e.g.*, substance characterization, stability of test medium, concentration in test medium);

administrative and travel expenses;

processing and professional support by the commissioning party (may include study design and/or preparation of test material); or

preparation of International Uniform Chemical Information Database (IUCLID) data set and robust study summary. [61]*Data Sharing Guidance* at 74.

The value of a study could decrease because a study is not a Good Laboratory Practice (GLP) study or because of "other possible study deficiencies to be determined on a case by case basis." [62]*Data Sharing Guidance* at 74.

FIFRA arbitration decisions favor using original study costs, finding cost estimates (such as replacement costs) less reliable. Some arbitration decisions discounted cost estimates.

Overhead

ECHA guidance allows compensation for administrative expenses, including "processing and professional support by the commissioning party, travel expenses, archival of the test substance and raw data." [63]*Data Sharing Guidance* at 75. It advises that the amount not be fixed, but rather be related to the value of the study concerned. [64]*Data Sharing Guidance* at 75. In two examples provided in guidance, ECHA derived a value for the administrative costs "using a model that establishes administrative costs as a percentage of the experimental cost. The higher the experimental cost, the lower the percentage." [65]*Data Sharing Guidance* at 124, n. 20. In the context of compensating for preparing robust study summaries as a percentage of the administrative costs, ECHA notes that International Council of Chemical Associations (ICCA) HPV experience "supports a maximum value of up to 30% of the administrative costs." [66]*Data Sharing Guidance* at 75.

FIFRA arbitration decisions also allowed overhead or administrative expenses. The amount awarded was redacted in certain cases of publicly available arbitrations; for those arbitration decisions where the amount of overhead is not redacted, the amount of overhead awarded is usually between 15% and 20%.

Cost Allocation

ECHA guidance identifies the following possible mechanisms for allocating costs, among others:

sharing data equally, based on the number of parties involved;

proportionality, based on production or sales volume; and

alternative mechanisms using part of the above models in different modes. [67]*Data Sharing Guidance* at 76.

As noted, REACH does not specify a cost sharing method. It provides that if companies cannot reach an agreement regarding appropriate costs, "the cost shall be shared equally." [68]REACH art. 30(1). Some FIFRA arbitration decisions debated whether the portion paid should be based on a per capita basis (dividing the total by the number of persons relying on the data) or on market share basis (dividing the total by each registrant's share of the market). Recent arbitration decisions have generally settled on the per capita basis, although they have sometimes modified it.

Some study owners may impose usage restrictions on their studies (*e.g.,* use for REACH only, not for general citation). ECHA guidance indicates that such limitations may be appropriate to consider in assigning study values. Some FIFRA arbitration cases assigned less than an equal share to a follow-on registrant because (1) the follow-on does not acquire full ownership rights in the data (hard copy rights), or (2) the data owner did not allow the follow-on to cite the data in California. Some of the allocations and conditions in FIFRA cases include:

25% reduction for some studies, 20% for others.

1/3 share and use in California required.

35% share and use in California required.

5% reduction.

2.5% reduction.

Reduction amount redacted.

Other arbitration decisions dismissed those considerations and assigned equal shares.

Inflation

ECHA guidance suggests that inflation be considered when historic costs are used to determine study costs. [69] *Data Sharing Guidance* at 74. If costs are determined on replacement costs, they are generally considered to be present-day costs and thus do not require the application of inflation to bring costs to the present day. Some FIFRA arbitration decisions have rejected an adjustment for inflation, but others have allowed it. To include inflation, a particular inflation index must be selected. Some of the decisions allowing an inflation adjustment were silent on the index, requiring only that the measure be "appropriate." Of those that discussed indices, the following were selected:

the GDP implicit price deflator.

the Producer Price Index - All Commodities.

the Producer Price Index 2842 #332 (an index for producer prices for specialty cleaning, polishing, and sanitation preparations/disinfectants; the case involved swimming pool algaecides and sanitizers).

When inflation is awarded in FIFRA arbitration decisions, it generally is allowed up to the date that the registration is submitted. After that time, interest can be applied, as discussed below.

Risk Premium

ECHA indicates that a risk premium may be appropriate, noting that "[t]he decision to conduct a study involves a risk for the initiator that the project may not be successful in generating the information desired (with no possibility then for any future recompensation)." [70] *Data Sharing Guidance* at 75. ECHA notes that the appropriateness of a risk premium may change depending on the type of study conducted, since certain studies do not carry the same degree of risk as others. Specifically, ECHA states:

When accessing an existing study with a known outcome, there is no exposure to this risk for a new part and accordingly, in certain circumstances, a certainty premium may be assigned to the study. This would only be applicable for toxicity or ecotoxicity studies where testing difficulties might reasonably be anticipated. In many other scenarios, there may be little justification for the application of this premium due to the nature of the testing and the inherent properties of the substance involved. [71] *Data Sharing Guidance* at 75.

FIFRA arbitration decisions are divided on whether a risk premium should be awarded at all. A risk premium high of 60 percent was awarded on a portion of total costs in one case, in other cases a 25 percent, 10 percent, or 5 percent premium was awarded, and in yet others, a risk premium was disallowed. A consistent theme in these decisions is that a risk premium, if allowed at all, must bear a reasonable relationship to the data costs.

Interest

Although ECHA guidance does not specifically mention interest, without interest, companies that owe compensation would have an incentive to delay payment. FIFRA arbitration decisions have awarded interest from the time that a company relies upon data by submitting an application until the date the compensation is paid. In the REACH context, a company relies upon data others own when it pre-registers a substance, which could be the specific date of pre-registration, if known, or Nov. 30, 2008, the last possible pre-registration date. Interest may apply at certain intervals (*i.e.,* quarterly, bi-annually) at the bank prime lending rate from the Federal Reserve Board or the prime rate plus one or two percentage points, depending on the company's credit status.

Conclusion

This brief overview is intended to highlight the similarities and differences between REACH and FIFRA data compensation schemes. As REACH matures, it will be important to monitor closely data compensation decisions to guide prudent business practices and ensure data development decisions are fully informed.