

# BNA Insights

## PESTICIDES

### DATA COMPENSATION

The European Union in recent years has promulgated new regulations to set forth the procedures by which pesticides (called biocides and plant protectants in the EU) are registered and how companies can address issues related to the citation and compensation of data submitted that support those pesticide registrations. Canada also recently issued regulations setting forth new requirements on how data used to support a pesticide registration are protected. This article provides a broad overview of these regulations, the new procedures by which biocides and plant protectants will be registered in the EU, and the new ways that data citation and compensation will be addressed in the EU and Canada.

## Pesticide Data Compensation in the EU and Canada

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### EU Data Citation and Compensation Scheme for Biocides

**O**n May 22, 2012, the European Union (EU) adopted the Biocidal Product Regulation (BPR) (Regulation (EU) 528/2012).<sup>1</sup> The BPR replaces and repeals the Biocidal Products Directive (BPD) (98/8/EC) for regulating biocidal active substances and biocidal products. The BPR entered into force on July 17, 2012, with many new provisions going into effect on Sept. 1, 2013, with a transitional period for certain provisions.<sup>2</sup> The BPR only affects “biocidal products” (the EU term for antimicrobial pesticides) and the active substances

<sup>1</sup> See 92 DEN A-4, 5/14/12.

<sup>2</sup> The BPR is available at <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2012:167:SOM:EN:HTML>.

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*This article does not represent the opinions of Bloomberg BNA, which welcomes other points of view.*

contained therein. Specifically, the BPR defines active substances and biocidal products as follows:

- “Active substance” is defined as “a substance or a micro-organism that has an action on or against harmful organisms.”
- “Biocidal product” is defined as:
  - ▶ any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,
  - ▶ any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

A treated article that has a primary biocidal function shall be considered a biocidal product.<sup>3</sup> The inclusion of the term “treated article” (defined as “any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products” (BPR Article 3(l)(a))) in the definition of biocidal product is significant as it extends the scope of products subject to the BPR to include articles and materials treated with biocidal products.

<sup>3</sup> BPR, Article 3(a), (c).

The European Chemicals Agency (ECHA) will provide the administrative duties concerned with community-level substance approvals, however, assessment and approval of active substances will still be completed by an EU Member State Competent Authority (CA). The European Commission (EC) makes the final decision based on the evaluation and opinions submitted by ECHA and the CA whether to adopt an implementing regulation approving an active substance.<sup>4</sup>

## Authorization Approval Types and Procedures

For active substances that have been approved at the EU level, companies must also seek approval for the biocidal products containing those active substances at the Member State level. Importantly, there are now possibilities for some biocidal products to be authorized at the EU level and thus gain direct access to the entire EU market. The key authorization procedures for biocidal products under the BPR are discussed below.

### *Simplified Authorization Procedure*

Biocidal products containing only active substances included in Annex I of the BPR are eligible for the simplified authorization procedure, provided that the product does not contain any “substance of concern” or nanomaterials, the product is “sufficiently effective,” and the “handling of the biocidal product and its intended use do not require personal protective equipment.”<sup>5</sup> Products subject to simplified authorizations must be evaluated within 90 days of receipt of the application.<sup>7</sup>

A biocidal product authorized in accordance with this simplified procedure may be marketed in all Member States without the need for mutual recognition. The authorization holder must notify “each Member State no later than 30 days before placing the biocidal product on the market within the territory of that Member State and shall use the official language or languages of that Member State in the product’s labeling, unless that Member State provides otherwise.”<sup>8</sup> Annex I of the BPR currently includes only 19 substances, so the use of this simplified authorization process will be limited, although the BPR does set forth the procedure to add substances to Annex I.

### *National Authorization of Biocidal Products and Mutual Recognition*

Biocidal products that are not yet subject to community level approval through ECHA must be authorized at the Member State level and then can be the subject of mutual recognition. The authorization of biocidal products at the Member State level is a lengthy process. A CA has 30 days, from receipt of delivery, to validate the application based on a determination that the relevant information has been submitted and “the applicant states that it has not applied to any other competent authority for a national authorization for the same biocidal product for the same use(s).”<sup>9</sup> The CA then has

365 days from the validation date to evaluate the application.<sup>10</sup>

After a Member State authorizes a biocidal product to be placed upon the market within its jurisdiction, there are two systems of mutual recognition available under the BPR. Mutual recognition can be sought from other Member States either while the initial application is being processed (mutual recognition in parallel) or after the initial Member State has granted an authorization (mutual recognition in sequence).<sup>11</sup> The mutual recognition system is complex under the BPR; each Member State must review the assessment report of the initial Member State, and reach its own conclusions as to whether the product should be authorized, and if restrictions should be put in place.

### *Union Authorization of Biocidal Products*

One of the new elements included in the BPR is the possibility of having certain biocidal products authorized at the EU level. Applicants may seek “Union Authorizations” for biocidal products that “have similar conditions of use across the Union,” although biocidal products containing certain active substances excluded from approval under Article 5 and certain other product types are not eligible for Union Authorization.<sup>12</sup> Union Authorization will be available in three different stages depending on the product type:

- From Sept. 1, 2013: Product types 1 (Human hygiene), 3 (Veterinary hygiene), 4 (Food and feed area), 5 (Drinking water), 18 (Insecticides, acaricides, and products to control other arthropods), and 19 (Repellents and attractants);
- From Jan. 1, 2017: Product types 2 (Disinfectants and algacides not intended for direct application to humans or animals), 6 (Preservatives for products during storage), and 13 (Working or cutting fluid preservatives); and
- From Jan. 1, 2020: All remaining product types except 14 (Rodenticides), 15 (Avicides), 17 (Piscicides), 20 (Control of other vertebrates), and 21 (Antifouling).<sup>13</sup>

While the EU-level application is submitted to ECHA, an EU Member State CA must agree to review and evaluate the application and forward its results to ECHA, which has 180 days to prepare an opinion. The EC makes the final decision based on the evaluation and opinions submitted by ECHA and the CA whether to adopt an implementing regulation granting the Union Authorization of the biocidal product.<sup>14</sup>

## Data Sharing and Protection

The BPR includes an important change in the legal obligations for the authorization of active substances and biocidal products relating to the procedure regarding the protection and sharing of data. Previously, under the BPD, if the active substance was already authorized for a particular product type, companies that did not own or share in the data supporting the authoriza-

<sup>4</sup> BPR, Article 9.

<sup>5</sup> BPR, Article 25.

<sup>7</sup> BPR, Article 26.

<sup>8</sup> BPR Article 27.

<sup>9</sup> BPR, Article 29.

<sup>10</sup> BPR, Article 30.

<sup>11</sup> BPR, Articles 33-34.

<sup>12</sup> BPR, Article 42.

<sup>13</sup> BPR, Article 42; Annex V.

<sup>14</sup> BPR Article 44(5).

tion of the active substance could market biocidal products of the type authorized that contain the active substance. This is no longer the case under the BPR. Instead, the BPR provides that:

[D]ata submitted for the purposes of the [BPD] or of this Regulation shall not be used by [CAs] or [ECHA] 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.<sup>15</sup>

#### **Compensability/Sharing Period**

The time period of data protection—during which third parties may not use data in support of their own applications without the express permission of the data owner—varies from five to 15 years depending on whether the data support a new, existing, renewal of, or amendment for an active substance or biocidal product.<sup>16</sup> Specifically:

- **Data Submitted for Approval of an Existing Active Substance:** Protection period ends ten 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;
- **Data Submitted for Approval of a New Active Substance:** Protection period ends 15 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;
- **Data Submitted for Approval of Renewal or Review of an Active Substance:** Protection period ends five years from the first day of the month following the date of adoption of a decision in accordance with Article 14(4) concerning the renewal or review;
- **Data Submitted for Authorization of a Biocidal Product Containing Existing Active Substance(s):** Protection period ends ten years from the first day of the month following the first decision concerning the authorization of the product taken in accordance with Articles 30(4), 34(6), or 44(4);
- **Data Submitted for Authorization of a Biocidal Product Containing a New Active Substance:** Protection period ends 15 years from the first day of the month following the first decision concerning the authorization of the product taken in accordance with Articles 30(4), 34(6), or 44(4); and
- **Data Submitted for Authorization of Renewal or Amendment of a Biocidal Product:** Protection period ends five years from the first day of the month following the first decision concerning the renewal or amendment of the authorization.<sup>17</sup>

<sup>15</sup> BPR, Article 59(1).

<sup>16</sup> BPR, Article 60.

<sup>17</sup> BPR, Article 60(2)-(3).

The trigger for all data protection periods in all cases is “when [the data] are submitted for the first time.”<sup>18</sup>

Interestingly, the BPR does not set forth any time periods for which data are subject to “exclusive use.” In contrast, for example, is Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(c)(1)(F)(i), which sets forth the criteria under which data submitters can receive a ten-year period of exclusive use for certain data submitted in support of a registration for a new pesticide chemical or new uses of an already registered pesticide.<sup>19</sup> Thus, during the ten-year exclusive use period, no other registrant can rely on data afforded exclusive use protection without the original registrant’s consent.<sup>20</sup> Without a similar provision, the BPR does not provide any patent-like protection for companies that develop data for new active substances, new biocidal products, or new uses for biocidal products.

#### **Mandatory Data Sharing**

The BPR includes a procedure to ensure that companies can no longer undertake tests that have already been performed on vertebrate animals. Instead, any applicant intending to perform a study involving vertebrates must submit a written request to ECHA to determine if such a study has already been submitted. Although not required, an applicant “may” also submit a written request to ECHA to determine if any studies not involving vertebrates have been submitted.<sup>21</sup> If such a study exists, ECHA must provide the applicant with information regarding the data submitter and owner. If the data are still protected, the prospective applicant “shall, in the case of data involving tests on vertebrates; and may, in the case of data not involving tests on vertebrates, request from the data owner all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications.”<sup>22</sup>

The prospective applicant and 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.”<sup>23</sup> The parties also “may” submit the matter to an arbitration body and commit to accept the arbitration order. Unlike FIFRA, the arbitration procedure appears to be a voluntary option available to parties instead of making every effort to negotiate and reach agreement. Although these procedures are not required for non-vertebrate studies, if an applicant chooses to ask ECHA whether any non-vertebrate studies have been submitted and such studies exist, the parties must make every effort to reach an agreement regarding non-vertebrate studies as well.

If an agreement is reached, the data owner will provide the applicant with copies of the data at issue or give permission to refer to the data as set forth in a letter of access (LOA). The LOA must include: (1) the name and contact details of the data owner and beneficiary; (2) the name of the active substance or biocidal product for which access to the data is authorized; (3)

<sup>18</sup> BPR, Article 60(1).

<sup>19</sup> 7 U.S.C. § 136a(c)(1)(F)(i).

<sup>20</sup> For a review of how data citation and compensation in FIFRA compares with the EU’s REACH (Regulation No. 1907/2006 on the registration, evaluation, and authorization of chemicals), see 105 DEN B-1, 6/1/11

<sup>21</sup> BPR, Article 62(2).

<sup>22</sup> BPR, Article 62(2).

<sup>23</sup> BPR Article 63(1).

the date on which the LOA takes effect; and (4) a list of the submitted data to which the LOA grants citation rights.<sup>24</sup> If an LOA is later revoked, such revocation “shall not affect the validity of the authorization issued on the basis of the letter of access in question.”<sup>25</sup> A revocation could limit the marketability of a product by limiting the ability of a company to rely upon data specified in the LOA for authorizations in multiple EU countries using mutual recognition.

If the parties do not voluntarily choose to use arbitration to determine compensation and no agreement is otherwise reached, the applicant must inform ECHA and, within 60 days of being so informed, can give the applicant “permission to refer” to the requested vertebrate studies, provided that the applicant “demonstrates that every effort has been made to reach an agreement and the prospective applicant has paid the data owner a share of the costs incurred.”<sup>26</sup> This is similar to FIFRA to the extent that EPA is likewise allowed to rely upon studies submitted to it even if no compensation agreement has been reached. Compensation for data sharing must be determined in a “fair, transparent and non-discriminatory manner,” which is the same standard for determining compensation under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation.<sup>27</sup> Although the data owner cannot “refuse to accept any payment” that is offered by the applicant, such acceptance is “without prejudice” to the data owner’s “right to have the proportionate share of the cost determined by a national court.”<sup>28</sup> Thus, the BPR provides for national courts, rather than arbitration bodies, to determine compensation when there is a dispute. Since the standard for determining compensation is the same under the BPR and REACH — a “fair, transparent, and non-discriminatory manner” — ECHA has also indicated that data sharing disputes will be handled in a similar manner to those occurring under REACH.

### EU Data Citation and Compensation Scheme for Plant Protectants

The EU adopted EC Regulation 1107/2009 to replace and repeal Directive 91/414/EC for regulating plant protection active substances and plant protection products. EC Regulation 1107/2009 entered into force on December 14, 2009<sup>29</sup>; most of the new provisions went into effect on June 14, 2011, with a transitional period for certain provisions.<sup>30</sup> EC Regulation 1107/2009 only affects “plant protection products” (the EU term for agricultural pesticides) and the active substances contained therein. Specifically, EC Regulation 1107/2009 defines active substances and plant protection products as follows:

- “Active substances” are defined as “[S]ubstances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products.”

<sup>24</sup> BPR, Article 61(1).

<sup>25</sup> BPR, Article 61(2).

<sup>26</sup> BPR Article 63(3).

<sup>27</sup> BPR, Article 63(4).

<sup>28</sup> BPR, Article 63(3).

<sup>29</sup> See 225 DEN A-8, 11/25/09

<sup>30</sup> EC Regulation 1107/2009, Article 80.

- “Plant protection products” are:

[P]roducts, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses:

- (a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products;
- (b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient;
- (c) preserving plant products, in so far as such substances or products are not subject to special Community provisions on preservatives;
- (d) destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants;
- (e) checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants.<sup>31</sup>

EC Regulation 1107/2009 also applies to the following:

- (a) substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants, referred to as ‘safeners’;
- (b) substances or preparations which, while showing no or only weak activity as referred to in paragraph 1, can give enhanced activity to the active substance(s) in a plant protection product, referred to as ‘synergists’;
- (c) substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists, referred to as ‘co-formulants’;
- (d) substances or preparations which consist of co-formulants or preparations containing one or more co-formulants, in the form in which they are supplied to the user and placed on the market to be mixed by the user with a plant protection product and which enhance its effectiveness or other pesticidal properties, referred to as ‘adjuvants.’<sup>32</sup>

### Authorization Procedures

As with the BPR, there is a two step process under which active substances for plant protection products are approved at the Community level, while plant protection products are authorized by Member States. The regulation sets forth the hazard-based, cut-off criteria for active substance approvals.<sup>33</sup> These criteria relate to the efficacy of the substance, its composition, its char-

<sup>31</sup> EC Regulation 1107/2009, Article 2(1)-(2).

<sup>32</sup> EC Regulation 1107/2009, Article 2(3).

<sup>33</sup> EC Regulation 1107/2009, Article 4; Annex II.

acteristics, the methods of analysis available, the impact on human health and the environment, ecotoxicology, and the relevance of metabolites and residues. If a substance meets one of the criteria, it will not be approved. Thus, an active substance cannot be approved if it is classified as Category 1A or 1B mutagenic, carcinogenic, or toxic for reproduction, or is considered to have endocrine disrupting properties.<sup>34</sup> In addition, an active substance cannot be approved if it is considered to be a persistent organic pollutant, persistent, bioaccumulative, and toxic, or a very persistent and very bioaccumulative substance.

EC Regulation 1107/2009 sets forth the procedures by which applicants prepare applications and dossiers. The procedure includes:

- Member States preparing (within 12 months of the date that the Member State determines the admissibility of the application and starts assessing the active substance) draft assessment reports;

- The European Food Safety Authority (Authority) adopting a conclusion on whether the active substance meets approval criteria; and

- The Commission (within six months of receiving the conclusion from the Authority) adopting a regulation providing that either the active substance is approved, subject to any conditions or restrictions, the active substance is not approved, or the conditions of the approval are amended.<sup>35</sup>

The Authority thus performs the risk assessment while the Commission performs a risk management role and makes the final decision on an active substance.

The first approval is valid for a period that cannot exceed ten years,<sup>36</sup> but can be eligible for renewal.<sup>37</sup> An approval may be subject to certain conditions or restrictions regarding, for example, the degree of purity of the active substance, the designation of categories of users (e.g., professional or non-professional), designation of areas where the use may be authorized, and the need to impose risk mitigation measures and monitoring after use.<sup>38</sup>

The authorization of a plant protection product is an administrative act by which the CA of a Member State authorizes the placing on the market of a plant protection product in its territory. Applications are submitted to the Member State where the product is intended to be placed on the market for the first time. Applications shall be accompanied by two dossiers containing all the information available to enable the assessment of the potential effects of the plant protection product on human and animal health, and the possible impact on the environment. The information provided may be protected by a confidentiality clause if it constitutes an industrial or trade secret, provided certain conditions are satisfied (e.g., making the claim when submitting the application, separating the confidential information

<sup>34</sup> There is no agreed upon definition of an endocrine disruptor and the Commission has been tasked to come forward with proposals by December 14, 2013. EC Regulation 1107/2009, Annex II, Section 3.6.5.

<sup>35</sup> EC Regulation 1107/2009, Article 7-13.

<sup>36</sup> EC Regulation 1107/2009, Article 5.

<sup>37</sup> See EC Regulation 1107/2009, Articles 14-21.

<sup>38</sup> EC Regulation 1107/2009, Article 6.

from the rest of the application).<sup>39</sup> The time required to examine the application for authorization to place a plant protection product on the market is limited to a period of 12 months, commencing on the date that the Member State receives the application. During this period, the Member State shall check whether the product concerned satisfies the authorization conditions.

Under the principle of “mutual recognition,” the holder of an authorization in one Member State can apply for an authorization for the same plant protection product in another Member State for the same use and under comparable agricultural practices. Although there are no “Union Authorizations” as there are under the BPR, mutual recognition by Member States can be more feasible due to zonal authorizations.

Under this procedure, simultaneous applications for product authorization must be made to several Member States in the same zone for mutual recognition of authorizations.<sup>40</sup> The EC is divided into three zones: (1) Zone A (North): Denmark, Estonia, Latvia, Lithuania, Finland, Sweden; (2) Zone B (Center): Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, the Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom; and (3) Zone C (South): Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal.<sup>41</sup> In these cases, the Member States evaluate the application and dossier “as appropriate with regard to the circumstances in its territory,” and grant authorizations under the same conditions as the Member State that first examined the application, unless alternative conditions or refusal of authorization is justified.<sup>42</sup>

For products containing new active substances, Regulation 1107/2009 requires the Member States evaluating the applications for the zone to start the evaluation as soon as it has received the Authority’s draft assessment report.<sup>43</sup> In addition, the Member States must decide within 12 months whether requirements for authorization are met, and the other Member States in the zone must decide on the application within 120 days of receipt of the assessment report from the Member States examining the application.<sup>44</sup> These provisions all help ensure timely authorizations.

## Data Sharing and Protection

EC Regulation 1107/2009 includes important changes from its predecessor (Directive 91/414) regarding the procedures for the protection and sharing of data. Data protection is defined under the regulation as “the temporary right of the owner of a test or study report to prevent it being used for the benefit of another applicant.”<sup>45</sup> In real terms this means the period for which data compensation can be sought from another applicant for the use of existing data in an authorization (see below). The regulation provides that test and study reports “shall benefit from data protection” and “may not be used by the Member State which received it for the benefit of other applications for authorization of plant protection products, safeners or synergists and adju-

<sup>39</sup> EC Regulation 1107/2009, Articles 7(3), 33(4), 63.

<sup>40</sup> EC Regulation 1107/2009, Article 40.

<sup>41</sup> EC Regulation 1107/2009, Annex I.

<sup>42</sup> EC Regulation 1107/2009, Article 36(3), 41.

<sup>43</sup> EC Regulation 1107/2009, Article 37(3).

<sup>44</sup> EC Regulation 1107/2009, Article 37(1), (4).

<sup>45</sup> EC Regulation 1107/2009, Article 3(21).

vants,” except when the applicant has submitted an LOA or when the data protection period has expired.<sup>46</sup>

### **Compensability/Sharing Period**

The period of protection for data required for product authorizations is ten years starting on the date of the first authorization in a Member State.<sup>47</sup> There are provisions to extend the period to 13 years for plant protection products that satisfy the criteria in Article 47 for “low-risk” plant protection products and provisions to extend data protection periods by three months for each authorization for minor uses as defined in Article 51(1) in certain circumstances.<sup>48</sup> The total period of data protection cannot exceed 13 years for minor uses, or 15 years when protection is extended for minor uses of “low-risk” plant protection products. Data necessary for the renewal or review of an authorization shall be protected for 30 months. To avail itself of data protection, the data owner/applicant must claim data protection when it submits its dossier and confirm that a data protection period has never been granted or expired.<sup>49</sup> Tests and study reports are eligible for protection provided the reports were necessary for the authorization or amendment of an authorization and are compliant with the principles of good laboratory practice or good experimental practice.<sup>50</sup>

As with the BPR, and in contrast to FIFRA, EC Regulation 1107/2009 does not set forth any time periods for which data are subject to “exclusive use.” Data protection applies only when Member States are asked to grant individual plant protection product authorizations, and not during the EU-level review for the approval of active substances. Since an applicant must provide 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 to claim data protection, this means that the data protection period starts when the first applicant makes the application in the first EU Member State and runs concurrently across the EU, even in those Member States where an application has not yet been made.

### **Mandatory Data Sharing**

To avoid duplicating tests carried out on vertebrate animals, Member States cannot 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. EC Regulation 1107/2009 states: “Any person intending to perform tests and studies involving vertebrate studies shall take the necessary measures to verify that those tests and studies have not already been performed or initiated.”<sup>51</sup>

Initially, Member States are required to prepare a list of the test and study reports necessary to support the first approval, amendment of approval conditions, or renewal of that approval for an active substance or a plant protection product, as well as a list of those tests or study reports for which the applicant has claimed data protection.<sup>52</sup> Prospective applicants are required

to consult information made publicly available by Member States regarding authorized products and, where the proposed product contains the same active substance, safener, or synergist as an authorized product, applicants must request from the Member State(s) a list of test and study reports such as those required to be prepared by the Member State(s).<sup>53</sup>

When submitting an application, prospective applicants must provide to the Member State(s) all data regarding the identity and impurities of the active substance(s) and evidence that an application for authorization is intended. The Member State CA must then provide the applicant with the name and address of the previous relevant authorization holders who in turn would receive the name and address of the applicant.

With language very similar to REACH, Regulation 1107/2009 provides that the prospective applicant and the authorization holder “shall make every effort” to ensure that they share tests and studies involving vertebrate animals.<sup>54</sup> Unlike the BPR, the regulation makes no mention of procedures regarding non-vertebrate animal studies. The question of whether the parties have made “every effort” to negotiate a settlement can be difficult, and the regulation does not provide how that determination is to be made. Although there are no guidance documents or cases defining these terms under the BPR, ECHA states with regard to REACH, which also requires parties to “make every effort” to negotiate, that: “[m]aking every effort requires everyone involved to find alternative solutions when necessary and suggest approaches which are justified and not discriminatory.”<sup>55</sup> REACH guidance also states that “Data sharing dispute procedures must be initiated as a last resort, i.e. only after all the possible efforts and arguments have been exhausted and the negotiations have eventually failed.”<sup>56</sup> Interestingly, the United Kingdom’s Chemicals Regulation Directorate has stated that it is “not in a position to adjudicate in their negotiations and will not become involved in considering whether ‘every effort’ has been made or in determining the costs payable to the data owners.”<sup>57</sup>

EC Regulation 1107/2009 does not set forth the procedure if a data sharing and compensation agreement is reached, but as noted above it does state that a Member State can review a test or study report when the applicant submits an LOA. If no agreement is reached, the applicant must inform the Member State’s CA. Member States are allowed to rely upon vertebrate studies for the purpose of the application of a prospective applicant even when the applicant and data owner have not reached a data sharing agreement.<sup>58</sup> A Member State

<sup>53</sup> EC Regulation 1107/2009, Article 61(1).

<sup>54</sup> EC Regulation 1107/2009, Article 62(3).

<sup>55</sup> ECHA, Data Sharing in a Nutshell (July 2012) at Section 5.3, available at: [http://echa.europa.eu/documents/10162/13631/nutshell\\_guidance\\_data\\_sharing\\_en.pdf](http://echa.europa.eu/documents/10162/13631/nutshell_guidance_data_sharing_en.pdf).

<sup>56</sup> ECHA, Questions and Answers on Data Sharing and Related Disputes (July 30, 2010) at 1, available at: [http://echa.europa.eu/documents/10162/13631/datasharing\\_q\\_a\\_en.pdf](http://echa.europa.eu/documents/10162/13631/datasharing_q_a_en.pdf).

<sup>57</sup> UK Health and Safety Executive, Chemicals Regulation Directorate, *Data sharing (including vertebrate data) under Regulation (EC) No 1107/2009* (June 12, 2012), available at <http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-the-protection-of-data>.

<sup>58</sup> EC Regulation 1107/2009, Article 62(4).

<sup>46</sup> EC Regulation 1107/2009, Article 59(1)(b).

<sup>47</sup> EC Regulation 1107/2009, Article 59(1).

<sup>48</sup> EC Regulation 1107/2009, Article 59(1).

<sup>49</sup> EC Regulation 1107/2009, Article 59(2).

<sup>50</sup> EC Regulation 1107/2009, Article 59(1).

<sup>51</sup> EC Regulation 1107/2009, Article 62(2).

<sup>52</sup> EC Regulation 1107/2009, Article 60.

may direct the parties to resolve the matter by formal and binding arbitration administered under national law.<sup>59</sup> Otherwise, the parties may resolve the matter through litigation in the courts of the Member States. As with REACH and the BPR, compensation for data sharing shall be determined in a “fair, transparent and non-discriminatory way.”<sup>60</sup> The Commission is required, by December 14, 2016, to report on the effects of the provisions regarding data protection of tests and studies involving vertebrate animals.<sup>61</sup>

## Canadian Pesticide Data Citation and Compensation Scheme

On June 23, 2010, Health Canada issued final regulations to set forth new “rules on how the scientific data used to support a pesticide registration is protected from reliance by another applicant or registrant.”<sup>62,63</sup> Health Canada states: “These Regulations are designed to provide a legally enforceable and fair process of pesticide data protection. They are intended to benefit pesticide users, particularly in the agricultural sector, by . . . facilitating the timely and predictable entry of competitively priced generic pesticides via a clear negotiation and arbitration process.”<sup>64</sup> The regulations “apply to an application to register a pest control product or to amend a registration made on or after Aug. 1, 2007, and before the day on which these Regulations come into force, if the applicant wishes to use or rely on compensable data of a registrant and the Minister has requested in writing that the parties negotiate the amount of compensation payable for that use or reliance.”<sup>65</sup>

## Data Compensation Protection

Data that support registrations and amendments to registrations, but that do not qualify for exclusive use protection, receive a 12-year compensatory protection status. This is less than the 15-year compensatory protection provided in the U.S. During the compensatory period, a follow-on applicant can use or rely on previously submitted data provided the applicant complies with the regulatory requirement to compensate the registrant.

- **Compensable Data:** Unlike EPA, which does not generally assist companies in determining the scope of compensable data, Health Canada will be

<sup>59</sup> EC Regulation 1107/2009, Article 62(6).

<sup>60</sup> EC Regulation 1107/2009, Articles 61(3), 62(3).

<sup>61</sup> EC Regulation 1107/2009, Article 62(5).

<sup>62</sup> See 122 DEN A-2, 6/28/10

<sup>63</sup> The regulations are available at <http://www.gazette.gc.ca/rp-pr/p2/2010/2010-06-23/html/sor-dors119-eng.html>. See also [http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/\\_cg-gc1-reg-nov2009/quest-ans-rep-eng.php](http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/_cg-gc1-reg-nov2009/quest-ans-rep-eng.php) (Questions and Answers on the Proposed Data Protection Regulations under the Pest Control Products Act) (last updated Mar. 1, 2010). Health Canada notes on its website that the Q&As comments and suggestions received during the public consultation period regarding the Q&As are being considered and a final report will “be made available as soon as possible.”

<sup>64</sup> Regulations Amending the Pest Control Products Regulations (PCPR), Regulatory Impact Analysis Statement, Executive Summary.

<sup>65</sup> PCPR, Regulatory Impact Analysis Statement, Executive Summary (Transitional 3.(1)).

involved in determining the compensable data as the regulations provide that “the Minister must provide the applicant with a list of the compensable data that they may use or rely on and in respect of which they will need to enter into an agreement with the registrant.”<sup>66</sup> The regulations define “compensable data” as test data other than the following: (1) test data that were submitted to support the registration of a new active ingredient and the pest control products associated with that ingredient, including any test data that were part of the additional information reported under Pest Control Products Act (PCPA) Section 12 in relation to that ingredient and those products; (2) test data that are included in a scientific study that has been published; and (3) test data that are generated by a scientific study that is fully funded by a government or one of its institutions.<sup>67</sup>

- **Exclusive Use Protection:** Health Canada’s regulations now provide ten years of exclusive use protection for data used to support the Canadian registration of a new pesticide that contains a new active ingredient (*i.e.*, a substance that has never been an ingredient in a registered pest control product). Test data that are subject to exclusive use protection include: (a) test data that were provided in support of the initial application to register the active ingredient; (b) test data that were provided in support of a concurrent application to register a pest control product that contains that active ingredient; and (c) test data that were included in any additional information that was reported to the Minister under PCPA Section 12 in relation to those applications.<sup>68</sup> The exclusive use period begins at the time of registration. During this exclusive use period, an applicant may use or rely on test data of a registrant in an application to register a pest control product or amend a registration only if the registrant provides the applicant with an LOA.<sup>69</sup>
- **Compensable Periods:** For data that support an application to register a pest control product whose active ingredient is already registered and for data that support an application to amend a registration, the compensable protection period begins at the time of application. For data submitted in response to a notice delivered to the registrant under PCPA Sections 16(3), 18(1), or 19(1) (*e.g.*, re-evaluation, special review), the compensable protection period begins after the date on which the Minister receives the data. For foreign test data considered by the Minister in the course of a re-evaluation or special review, the compensable protection period begins after the date on which the Minister initiates the re-evaluation or special review.<sup>70</sup> These regulations potentially avoid the dispute that is part of some arbitrations in the U.S. whether the compensation period be-

<sup>66</sup> PCPR § 17.8(1).

<sup>67</sup> PCPR § 17.1

<sup>68</sup> PCPR § 17.5(1).

<sup>69</sup> PCPR § 17.6. The exclusive use period can be extended by up to five years (*i.e.*, to a maximum of 15 years) if a minor use of significance is added to the original registration. See PCPR § 17.1, 17.5(3).

<sup>70</sup> PCPR § 17.7(2).

gins from the time the application is submitted or the time the registration is granted.

- **Negotiation and Arbitration:** Health Canada states that the “companies will be expected to determine the amount of data compensation owed through time-limited negotiation (and, if necessary, time-limited binding arbitration) without Health Canada being involved in determining the value of the data.”<sup>71</sup> The regulations provide that the negotiation period will be limited to 120 days, unless the parties agree to extend the period.<sup>72</sup> If the parties are unable to reach an agreement through negotiations, the applicant can initiate binding, final-offer arbitration. An arbitrator will have 120 days from the commencement of the arbitration period to issue an award unless the parties agree to extend the timeframe.<sup>73</sup> Once the amount of compensation has been determined, through a negotiated settlement or arbitration award, the registrant that generated the data is required to provide an LOA to the data granting the follow-on applicant the right to rely upon the data as determined by the settlement or award.<sup>74</sup> If the registrant that generated the data fails to provide an LOA despite the follow-on applicant’s compliance with the terms of the settlement or award, that applicant may use or rely on the compensable data without having to comply further with the negotiated settlement or arbitral award.<sup>75</sup>
- **Timing of Applicant’s Registration:** If the settlement or award provides for a schedule of compensation payments, the follow-on registrant will be granted a one-year registration, with the validity of this registration determined at renewal. A follow-on applicant can receive its registration before an LOA is received if the applicant enters into an escrow agreement, and deposits with a third-party, funds sufficient to meet the registrant’s last

<sup>71</sup> PCPR, Regulatory Impact Analysis Statement, Executive Summary.

<sup>72</sup> PCPR § 17.9(2)-(3).

<sup>73</sup> PCPR § 17.91(4).

<sup>74</sup> PCPR § 17.94(1).

<sup>75</sup> PCPR § 17.94(2).

offer made at the end of the negotiation period.<sup>76</sup> If the registrant does not put its last offer in writing, the applicant may make the request to register its product in the absence of an LOA without establishing an escrow account. Health Canada states that it selected this procedure “since it provides flexibility and balance by guaranteeing payment while facilitating the timely market entry of competitively priced generic pesticides.”<sup>77</sup> These procedures are quite different from those in the U.S., where an applicant can receive its registration before any negotiations are concluded or any financial assurances are provided.

Health Canada has posted a template of an agreement to be used between parties when an applicant intends to follow the formal process specified in the *Pest Control Products Regulations* to rely on a registrant’s compensable data to register a generic product.<sup>78</sup>

### Formulator’s Exemption

The regulations provide that the exclusive use and data compensation regulations do not apply when an applicant wishes to use or rely on test data of a registrant to register a pest control product that is equivalent to the registrant’s product, “using a pest control product provided by that registrant” (i.e., purchasing a registrant’s active ingredient supported by the test data) and (1) the registrant provides the Minister with a “letter of confirmation of source,” defined as “a document that is signed by a registrant in which the registrant confirms that they have agreed to provide an identified registered pest control product to a named person”;<sup>78</sup> and (2) the only pest control product used in the manufacture of the applicant’s product is the one provided by that registrant.<sup>79</sup>

<sup>76</sup> PCPR § 17.93.

<sup>77</sup> PCPR, Regulatory Impact Analysis Statement, Regulatory and Non-Regulatory Options Considered.

<sup>78</sup> See Health Canada, *Ministerial Agreement for Data Protection under the Pest Control Products Act*, available at <http://www.hc-sc.gc.ca/cps-spc/legislation/acts-lois/pest/pcpa-agreement-entente-lpa-eng.php> (last updated June 21, 2010).

<sup>78</sup> PCPR § 17.1.

<sup>79</sup> PCPR § 17.4.