



Agribusiness: Compensable Pest Control Product Registrations

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The regulation of pesticides in Canada is shared between the federal and provincial levels of government. The federal government is responsible for pre-market assessment, approval, and registration while the provincial governments deal with the sale, use and distribution of approved pesticides. The federal Pest Control Products Act ("PCPA") is supplemented by the Pest Control Product Regulations ("the Regulations"), which outline the criteria for assessment and registration of pest control products. Federal regulation is under the ambit of the Minister of Health and the Pest Management Regulatory Authority ("PMRA"). This pest control legislation is intended to create a fair process for data protection while encouraging the registration of new pesticides and facilitating the timely entry of competitively priced generic pesticides. To this end, section 17.7 of the Regulations requires new applicants to compensate prior registrants for using or relying on the data that has been submitted by those registrants. This is beneficial for companies spending time and resources developing new pesticide products, as it ensures that the data they collect and disclose when applying for registration attracts compensation from other parties who subsequently use or rely on their data.

One area of concern for many agricultural companies researching and registering pest control products is whether or not all data and studies submitted to the Minister in support of an application are compensable, even if the data requirements have been met by an earlier submission and irrespective of whether or not they are formally reviewed. Section 17.7(2) clearly states that (a) test data that supports an application to register a pest control product whose active ingredient is already registered and (b) test data that supports an application to amend a registration are "compensable data" if submitted to or considered by the Minister for the first time, and remain compensable for 12 years after the date of the application. Furthermore, Section 17.8 requires that the Minister provide applicants with "a list of the compensable data that they may use or rely on and in respect of which they will need to enter an agreement with the registrant." A plain reading of Section 17.8

indicates that new applicants will have a choice as to which prior "compensable data" to rely on and can then enter into negotiations on that basis.

What happens when, for example, Company B submits a study in support of its application, but the data requirements have been previously met by an earlier submission from Company A? In the past, the PMRA has taken the position that in such a situation, Company B's studies would not constitute compensable data, only Company A's would. So where new applicant Company C wishes to use and rely on Company B's submissions, it would not be able to negotiate with company B to do so. Not only does the PMRA's interpretation remove compensation from Company B, it also necessarily prevents Company C from using Company B's data despite the fact that it might be more relevant to Company C's objectives than the data submitted by Company A.

The plain language of the Regulations does not support this interpretation. The Regulations clearly indicate that data supporting an application to register or amend the registration of a pest control product that is submitted to or considered by the Minister is compensable. To this end, if Company B has submitted studies and data in support of an application, it is compensable even if Company A has already done so. If this were not the case, a company who submits data that is already included in another applicant or registrant's submission will never be eligible for compensation by a new applicant who uses or relies on that data. Such an interpretation goes against the spirit and intention of the Regulations.

The crux of Section 17 of the Regulations is to ensure that all data that has been submitted or reviewed is considered compensable data and to mandate the negotiation of that compensation. This leaves it to the applicants involved to choose which data to rely on and enter into negotiations for compensation based on that choice. This process fosters innovation and encourages fair competition, while a contrary interpretation would only serve to constrain choice



and ultimately diminish the market. While the Regulations are relatively new, it will be interesting to see how the PMRA chooses to interpret them, and the effects of such interpretation on the pest control sector.

About the Author

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