



February 11, 2008

Ms. Jennifer Choe Groves
Director for Intellectual Property and Innovation &
Chair of the Special 301 Committee
Office of the United States Trade Representative
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Re.: Comments related to Section 182 of the Trade Act of 1974 Special 301 Review

Dear Ms. Groves:

CropLife America (CLA) welcomes the opportunity to comment on the Federal Register notice, dated January 16, 2008, requesting to identify countries under Section 182 of the Trade Act of 1974 (Special 301). CLA is a national trade association representing the developers, manufactures, formulators, and distributors of plant science solutions for agriculture and pest management in the United States. Our member companies spend hundreds of millions of dollars every year in research and development of new crop protection products and developing health and environmental safety data in support of registering and marketing these products in the U.S. and around the world. I am pleased to submit our comments concerning the identification of certain foreign countries' acts, policies and practices that are relevant to the decision whether particular trading partners should be identified under Section 182 of the Trade Act of 1974, or non-statutory categories of Priority Watch List in regards to the degree to which these countries fail to provide adequate and effective intellectual property rights and fair market access to our products:

MEXICO.

Mexico's Law 604, Article 86bis grants five years of data protection for agricultural chemical products. It is desirable that Mexican legislation is leveraged with U.S. and Canadian law to grant ten years of data protection for consistency within the NAFTA countries.

In addition, rights holders are impeded from enforcing their rights in violation of a due process. Mexico's pesticide regulatory authority, COFEPRIS, disallows rights holders from reviewing second application dossiers to gather evidence needed to prosecute registrants of copy products. Rights holders are therefore unable to challenge applications that unfairly rely on their regulatory data.

Finally, Mexican Federal Legislation on Transparency and Access to Government Public Information (as amended 6 July 2006) enabled access and disclosure of confidential business information contained in regulatory dossiers.

CAFTA-MEMBER COUNTRIES.

• Representing the Plant Science Industry •

All CAFTA member countries, except Costa Rica, have enacted legislation requiring 10 years of data protection for agricultural chemical products. However, the need for regulations to require competent agencies to enforce the laws is a common denominator in the region. Regulations are non-existent in all countries, except Guatemala.

In the case of Costa Rica, Law 7975 is not only vague, as to protection of regulatory data against disclosure, but is silent in relation to the amount of years of protection. Costa Rica has published a draft regulation to amend this section. However, the draft regulation contains additional issues:

1. Enables second applicants to obtain approvals by using protected data without the consent of the titleholder. DR-CAFTA Art. 15.5 only allows use of patent protected subject matter to obtain approvals, not protected data.
2. Inclusion of a "use clause" that requires approved products to be marketed in the country within twelve months from the date of the marketing approval to maintain protection. This limitation to protection goes beyond DR-CAFTA commitments.
3. Inclusion of a "novelty bar" requiring marketing approvals to be prosecuted in Costa Rica within six months from the first approval in a foreign country to be eligible for protection. DR-CAFTA's provision requires to file an application for regulatory clearance in the country within five years of the first approval overseas, not twelve months.

Lax enforcement also erodes proprietary rights in all DR-CAFTA member countries because few -or no controls- to examine the source and quality of second applicants' data often allows reliance on proprietary's data.

ANDEAN COUNTRIES.

In Peru, there is no legislation for protection of regulatory data for agricultural chemical products.

In Colombia, Decree 502 is insufficient because it only grants five years of protection for agricultural chemical products data.

CropLife America urges USTR to assure that both countries will enact domestic laws and will promote consistent amendments to the norms of Andean Community of Nations in order to implement IPR provisions of the Free Trade Agreement with the United States.

ARGENTINA.

In Argentina, titleholders cannot effectively enforce their rights because Argentine Law 24.766 does not grant a term of protection. Furthermore, regulatory authorities interpret that any form of disclosure of data places it in the public domain and therefore protection is not an issue.

A regulation is needed, not only to establish the term of protection, but also to prevent expedited secondary marketing approvals by using of rights holders' data.

CHILE.

In Chile, Law N° 19.996 (amending Law N° 19.039), Article 89 provides ten years of data protection for new agricultural chemical entities in compliance with the Free Trade Agreement with the U.S. However, protection is hindered by Article 91 (paragraph e) that denies protection if applications for marketing approval are submitted after twelve months from the first foreign marketing approval for the product. The provision conflicts with Chilean regulations for agricultural chemical product assessment. For instance, the 'Servicio Agrícola Ganadero' (SAG) requires experimental authorizations and results of local seasonal efficacy trials that take at least twenty four months in developing. Therefore, to comply with Chilean regulatory requirements, applicants will inevitably miss the time bars provided to be eligible for data protection.

In addition, SAG is granting marketing approvals to second parties by partially relying on titleholders' dossiers. The rationale is that certain studies contained in the dossiers were not required by law and therefore not eligible for protection.

Sincerely,



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