

# NORTH DAKOTA LEGISLATIVE COUNCIL

## Minutes of the

### CROP HARMONIZATION COMMITTEE

Thursday, March 9, 2000

American Crop Protection Association Office  
1156 15th Street NW, Suite 400  
Washington, DC

Representative Eugene Nicholas, Chairman, called the meeting to order at 9:00 a.m. (EST).

**Members present:** Representatives Eugene Nicholas, Michael D. Brandenburg; Senators Meyer Kinnoin, Terry M. Wanzek; Citizen Member Brett Oemichen

**Others present:** See attached appendix

**It was moved by Senator Kinnoin, seconded by Senator Wanzek, and carried on a voice vote that the minutes of the October 27, 1999, meeting be approved as distributed.**

Chairman Nicholas expressed his gratitude to the American Crop Protection Association for helping organize and sponsor this meeting. He said the dialogue with the crop protection industry, commodity groups, and federal agencies is important in addressing the problems facing North Dakota farmers.

Chairman Nicholas called on Mr. Tim Galvin, Administrator, Foreign Agricultural Service, United States Department of Agriculture, for comments regarding USDA efforts toward harmonization. He said pursuant to the December 3, 1998, US-Canada Record of Understanding, progress has been made regarding border trade concerns. He said there is a program in place which allows American grain to be transshipped through Canada. In addition, he said, problems have been addressed regarding shipping of feed cattle to Canada. He said Canadian and American officials meet quarterly to discuss trade issues regarding grains and to receive estimates of amounts of grain that is shipped to the United States.

Mr. Galvin said there has been a significant increase in trade between Canada and the United States. He said last year the amount of United States commodities exported to Canada approximated \$7 billion and the amount of Canadian commodities exported to the United States approximated \$7.8 billion.

Mr. Galvin said a year ago few people understood the problem facing farmers with respect to the use of pesticides. However, he said, during the last year the issue has gained prominence, and the North American Pesticide Summit held last spring attempted to develop a framework to identify gaps in registrations and differences in regulatory approaches. He

said there has been much progress in developing registration priorities, joint registration, and harmonized residue chemistry data requirements. He said a good example of the cooperation between the two countries is the joint approval of Helix-treated canola seed. He said that product is now available in both countries. In addition to the Helix registration, he said, there were other joint registrations in 1999, and there are a number of joint registration reviews in progress.

Mr. Galvin said the second meeting of the North American Market for Pesticides will be held on April 14, 2000, in Ottawa. He said there must be better communication regarding informing producers regarding what is being done with respect to harmonization. He said there have been joint efforts between provincial and state governments, and a formal advisory committee has been formed that can make recommendations for federal solutions. He said much can be resolved in discussion at the state and provincial levels.

In response to a question from Representative Nicholas, Mr. Galvin said progress has been made with the Environmental Protection Agency (EPA) and the Canadian Pesticide Management Regulatory Agency. He said those agencies are cooperating well and a common approach for registrations will expedite matters. He said it is important that grower groups identify needs and bring those needs to the attention of the EPA. He said the United States Canola Association has been a leader in that respect.

Representative Nicholas said North Dakota has had a good response from the Denver office of the EPA with respect to addressing producer priorities.

In response to a question from Representative Brandenburg, Mr. Galvin said priority setting is the key. He said there must be an effort to identify issues and problems so that the EPA and the Canadian Pesticide Management Regulatory Agency can address those problems.

In response to a question from Senator Wanzek, Mr. Galvin said the voice of North Dakota farmers is being heard. He said the activities undertaken by the Legislative Assembly during the 1999 legislative session were noticed at the federal level.

Chairman Nicholas called on Mr. Jay Vroom, President, American Crop Protection Association, for comments regarding harmonization. Mr. Vroom thanked the committee for holding this meeting and facilitating discussions between the committee, industry, and federal officials. He said the work undertaken by North Dakota officials is having an impact. He said the American Crop Protection Association is committed to harmonization and will support the proposal to make joint reviews an EPA priority. He said there has been a positive movement to help get new products to market. He said regulatory solutions will affect the marketplace, and industry's fate is tied to the fate of farmers. Because of the plight of farmers, he said, the crop protection industry lost over \$1 billion in sales last year. He said the crop protection industry backs the efforts to restore a sound economic profile for American farmers.

Representative Nicholas said the members of this committee have discussed the farm problems with members of Congress. He said American farmers are at a serious competitive disadvantage with farmers in Europe. He said it is clear the conservation reserve program substantially affects the economic fate of the crop protection industry.

Senator Wanzek said the committee is looking for solutions that will be advantageous to producers as well as industry. He said the committee recognizes the fate of agriculture is important to everyone attending this meeting.

Chairman Nicholas called on Mr. Jim Aidala, Associate Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency, for comments regarding harmonization. Mr. Aidala said the EPA is working closely with North Dakota and the regional office in Denver to address the concerns of producers. He said the availability of crop protection products and the pricing of those products is an important issue for farmers and the farm economy. He said the EPA has been working with grower groups and the United States Department of Agriculture to address producers' concerns. Because communication with growers is important, he said, the EPA has been devoting time to working with growers in the plains area. In addition, he said, the EPA is working with the Canadian Pesticide Management Regulatory Agency to harmonize requirements. Because the EPA must examine data to address registration, it needs cooperation from the crop protection industry to get access to that data. He said the data is expensive, and there are issues that must be addressed with respect to rights and responsibilities connected with the data.

In response to a question from Representative Brandenburg, Mr. Aidala said because the United States has the toughest environmental standards, commodities produced in this country have an international badge that is helpful to the sale of the commodities in international trade. Meeting EPA

standards is difficult, he said, but once the standards are met the public knows a product is safe. He said the EPA is conducting joint reviews with Canada for registration of crop protection products. He said the results of cooperation with the Canadian Pesticide Management Regulatory Agency are visible, and the EPA is trying to use the example of that cooperation with the European community as well.

Ms. Anne Lindsay, Director, Field and External Affairs Division, Office of Pesticide Programs, Environmental Protection Agency, said in the years since approval of the North American Free Trade Agreement (NAFTA), North American regulatory agencies are working toward the same goals to protect the public health and help growers. She said the EPA and the Canadian Pesticide Management Regulatory Agency are attempting to eliminate duplication and are willing to accept field data regardless of which country the data is collected. She said the EPA and the Canadian Pesticide Management Regulatory Agency are jointly working on the review of five new active ingredients. She said the work is divided, results are shared, and each agency makes its decisions based upon that work. However, she said, the decisions of each agency are generally the same. She said a joint application is generally completed in about one year compared to three years when the application is not handled jointly.

Mr. Rick Keigwin, Chief, Registration Support Branch, Office of Pesticide Programs, Environmental Protection Agency, said the EPA and the Canadian Pesticide Management Regulatory Agency can only handle a limited number of joint reviews each year. However, he said, the agencies cooperate on other registrations. He said each agency is trying to use the other agency's basic reviews in the review process. He said the EPA provides quarterly updates through its Denver office to the North Dakota Agriculture Commissioner regarding the list of critical needs submitted by North Dakota. In addition, he said, grower groups that have identified needs receive regular updates.

In response to a question from Senator Kinnoin, Ms. Lindsay said because the cost of registration in a joint review is about the same in both countries, the price of a product should not be substantially different in the two countries.

Mr. Aidala said the regulatory agencies are attempting to avoid having a process that would affect the price of a product.

In response to a question from Representative Brandenburg, Mr. Aidala said although the concept of a joint NAFTA label on a protection product would allow use of the product within a geographical area not recognizing international boundaries, each country within the area must still recognize that label.

Ms. Lindsay said the laws of Canada and the United States limit what each regulatory agency can do. She said there are certain steps that both

regulatory agencies must take before registering a product, and there must be a submission for registration from the manufacturer of the product to both countries.

In response to a question from Senator Wanzek, Ms. Lindsay said the EPA is making an effort to ensure there is equal access to pesticides in the United States. She said if there are products imported from Canada which are produced using crop protection products that are prohibited from use in this country, the Food and Drug Administration (FDA) has the ability to enforce residue tolerances. She said the FDA has increased monitoring to ensure American laws are being enforced appropriately.

Mr. Aidala said requiring Canadian growers to make certain certifications that are not required for American growers could result in a complaint under NAFTA.

In response to a question from Citizen Member Oemichen, Ms. Lindsay said data requirements for the EPA and the Canadian Pesticide Management Regulatory Agency are substantially harmonized. She said the EPA encourages crop protection product manufacturers to conduct a preapplication discussion with the EPA to iron out any differences before submitting an application for a joint review. She said although the EPA and the Canadian Pesticide Management Regulatory Agency are using each other's review results, each entity must make an independent judgment regarding a registration.

Mr. Kerry Klough, Assistant Regional Administrator for Partnerships and Regulatory Assistance, Environmental Protection Agency, said the prioritized list submitted to the EPA helped identify what producers' concerns are. He said the EPA has provided a grant to the North Dakota Agriculture Commissioner to fund an employee for two years to work on registration issues.

Chairman Nicholas complimented Mr. Klough regarding his work with the state of North Dakota in the area of harmonization.

Representative Brandenburg emphasized that harmonization affects Canadian farmers as well as American farmers. He said it is vital the process be expedited to provide for full harmonization.

Mr. Shawn Pfaff, Legislative Assistant for Congressman Earl Pomeroy, said Congressman Pomeroy is supportive of the efforts of this committee and the efforts made by the EPA to effect harmonization.

Chairman Nicholas called on Mr. Rick Holt, Manager, North American Registration and Regulatory Affairs, DuPont, for comments regarding harmonization. Mr. Holt said the Organization for Economic Cooperation and Developments consists of over 25 countries working together on trade issues. He said the Organization for Economic Cooperation and Developments environmental program is a pesticide working group that meets approximately every

nine months to develop tools for chemical testing and assessment that promote international harmonization. He said the goal of NAFTA was to create a North American market. With respect to crop protection product harmonization, he said, a goal of NAFTA was to provide for a single submission for registration and routine joint reviews and work sharing. He said the North American initiative between the EPA and the Canadian Pesticide Management Regulatory Agency has established a completion target date of 2002 or 2003 with respect to regulatory decisionmaking.

Mr. Holt said to achieve cross-border availability of crop protection products, the regulatory process must be harmonized. He said there must be an incentive for industry to register cross border. A concern of industry, he said, is that additional costs be minimized and most conservative risk assessments be combined. He said the incentive for industry is faster registration.

Mr. Holt said several joint pilot projects have been completed and the EPA and the Canadian Pesticide Management Regulatory Agency are learning how to cooperate. He said the crop protection industry has concerns with respect to the fact that two separate submissions are required and guidelines are not yet harmonized. He said there is no list of nonharmonized guidelines and harmonized guidelines. However, he said, that will be addressed in April. He said there must be some identification of a core data set. He said another concern of industry is that a delay in registration in one country could delay registration in the other country. Another concern, he said, is the insistence by the Canadian Pesticide Management Regulatory Agency on an identical label for use in both countries. He said the lack of mutual acceptance of reviews is also a concern of industry. However, he said, the biggest concern is related to workload and budget concerns of the EPA and the Canadian Pesticide Management Regulatory Agency. He said if multiple submissions were submitted, the EPA will not likely be able to achieve faster registration due to a heavy workload.

Mr. Holt said there must be harmonization of guidelines and of core data sets in the future. In addition, he said, streamlining of the EPA registration process is necessary. He said harmonization will work and it is moving in the right direction.

In response to a question from Citizen Member Oemichen, Mr. Holt said uniform-use labels advocated by the Canadian Pesticide Management Regulatory Agency may not be practical due to language barriers and the differences in units of measurement in the United States and Canada. In addition, he said, some products have different inert ingredients in the United States and Canada which require different labels.

Chairman Nicholas called on Ms. Megan Marquet, United States Canola Association, for comments regarding harmonization. Ms. Marquet said canola

growers have been working on the harmonization issue for years and are currently undergoing strategic planning with Canadian growers. She said the Canola Association has been reaching out to other grower groups in the United States to organize a grower technical working group. She said it is important to work more closely with the EPA, the United States Department of Agriculture, and the crop protection product industry to show there is a North American market so that registrants will register in both countries. She said canola growers have received special attention from the EPA in addressing their needs.

Mr. Daryn McBeth, National Barley Growers Association, said the trade associations for canola, barley, and soybeans have worked closely with wheat growers on the issue of harmonization. He said the commodity group boards have worked to develop priorities as well as to work with the EPA and state agriculture departments. He said the commodity groups also work with the crop protection product industry to keep abreast of new products. Although availability of crop protection products and economics of the availability of the products is important, he said, public and consumer protection issues are also of great concern to the commodity groups. He said an important issue for American growers is the fact that many Canadian commodities that have been treated with crop protection products not available in this country are processed in this country.

Ms. Marquet said there has been much encouraging progress in achieving harmonization during the last few years. She said she is confident joint submissions are the way of the future. However, she said, there is concern with older chemistries that are available in Canada but not in this country. She said the Canola Association is looking for solutions to trade irritants and to set some criteria for prioritizing trade irritants. She said it is important that registrants support registration in both countries.

In response to a question from Representative Nicholas, Ms. Marquet said the Canola Association is not pursuing registration of all 30 products that are available in Canada but not available in this country.

She said the association would like to see the registration of 8 to 10 of those products. She said of the Section 18 requests submitted by North Dakota, only two have not yet been approved. She said everyone is well aware of the critical need to get the products to market.

In response to a question from Senator Wanzek, Mr. Vroom said almost all registration data submitted for a registration is generated by the registrant. He said the IR-4 project is used to conduct some minor use data for projects that are not economically feasible. He said land grant universities do much of the research under the IR-4 project.

Citizen Member Oemichen said the North Dakota minor use fund also assists in the registration of certain products.

Representative Brandenburg said the Canadian Pesticide Management Regulatory Agency, Canadian farmers, and the Canadian crop protection product industry should be involved in future meetings of this committee.

Ms. Lindsay said the April summit in Ottawa will provide a forum at which Canadian and American regulatory agencies, producers, and industry can address harmonization issues.

Chairman Nicholas said the committee has received a great deal of input at this meeting. He said the committee will hold at least one more meeting, and he would like to have the committee receive updates regarding the harmonization process from a number of sources, including an update from the Canola Association. There being no further business, Chairman Nicholas adjourned the meeting at 11:35 a.m.

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John D. Bjornson  
Committee Counsel

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