Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

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September 28, 2009

Lucy Sharratt
Canadian Biotechnology Action Network (CBAN)
431 Gilmour Street, Second Floor
Ottawa, Ontario K2P 0R6

Éric Darier
Réseau Québécois contre les Organismes Génétiquement Modifiés (RQcOGM)
c/o Yossi Cadan,
Greenpeace Canada,
33 Cecil Street
Toronto, Ontario M5T 1N1

RE : Conditional authorization of 'SmartStax™' corn by the Canadian Food Inspection Agency (CFIA)

Dear Ms. Sharratt and Mr. Darier,

Thank you for your letter dated August 3, 2009 regarding the CFIA's conditional authorization of 'SmartStax™' corn. Additionally, I would like to thank Lucy Sharratt (CBAN), Terry Boehm (National Farmers Union) and Peter Andrée (Carleton University) for taking the time to participate in a subsequent teleconference with myself and several of my CFIA colleagues, to discuss this product.

Our discussions to date have allowed my colleagues and I to better appreciate your concerns about the CFIA's regulatory process regarding this product specifically, and for new stacked products in general. We would like to continue to engage with your respective groups, and opportunities to do so will hopefully arise in the coming months.

Please find enclosed responses to specific concerns that you outlined in your letter of August 3, 2009. Also, as I indicated during our teleconference, I would like to assure you that the Plant Biosafety Office will be making information publicly available on all of the stacked events that it has reviewed. This process will be completed on or before December 1st, 2009.

If you have further questions, please feel free address them to either myself or Krista Thomas, National Manager of the Plant Biosafety Office.

Sincerely,

Glyn Chancey
Executive Director,
Plant Health and Biosecurity Directorate
CFIA

Responses to questions posed by CBAN and RQcOGM dated August 3rd, 2009.

1. *Did the CFIA perform an environmental safety assessment for 'SmartStax'? Which Regulations did 'SmartStax' trigger? Is 'SmartStax' classified as a 'Plant with Novel Traits' by CFIA?*

Under the authority of Part V of the *Seeds Regulations*, all new plants with novel traits (PNTs) are subject to science-based environmental safety assessments before they can be grown in Canada. Once a PNT is authorized for unconfined environmental release, it can then be used in breeding programs to develop new varieties. A condition of authorization of any PNT is that the use of traditional cross-breeding to produce a "stacked product" such as SmartStax™ corn requires notification to the CFIA. The PBO reviews these notifications to ensure that any conditions of authorization which apply to the "parent PNTs" are also applicable to the stacked product derived from them. As with SmartStax™ corn, these conditions may be altered based on new information. Conditions will only be adjusted if sufficient scientific evidence is available to the CFIA upon which to base a decision. Entomologists and other experts in the CFIA's Science Branch conducted a very thorough evaluation of the science supporting the change in conditions to allow the use of a 5 per cent refuge for SmartStax™ corn.

2. *Did Monsano and Dow AgroSciences submit data packages specific to 'SmartStax' to the CFIA for evaluation? What kind of data did they provide and what questions did this data address? Was any of this data peer reviewed? Is any of this data available to the public?*

5. *What studies did the CFIA conduct or review that specifically evaluate the potential impacts of stacking insect resistant traits (there are 6 such traits in the case of 'SmartStax') on development of insect resistance? Please provide the list of relevant literature reviewed by the CFIA.*

Monsanto Canada Inc. and Dow AgroSciences Canada Inc. submitted a data package including an insect resistance management plan for SmartStax™ corn that was reviewed by scientists in the CFIA's Plant and Biotechnology Risk Assessment Unit (PBRA) over the course of approximately nine months. Scientists in the PBRA unit also consulted peer-reviewed literature on a variety of relevant topics. The list of publicly available literature reviewed by the PBRA unit is provided at the end of this document.

4. *What is the CFIA's rationale for cutting the environmental stewardship requirement of refuge from 20% to 5% for 'SmarStax'? Upon what analysis was this decision based?*

6. *What was the decision-making process to reduce the refuge requirement for 'SmartStax' and which parties were consulted?*

The CFIA's rationale for reducing the refuge requirement from 20 per cent to 5 per cent for SmartStax™ corn is based on an analysis of both peer-reviewed studies and scientific

information provided to the CFIA by Monsanto Canada Inc. and Dow AgroSciences Canada Inc. The scientific data reviewed supports the conclusion that SmartStax™ corn, when grown with an appropriately designed 5 per cent refuge, will be equally or more effective at delaying the development of resistance in insect pests than older Bt corn lines grown with a 20 per cent refuge.

At the request of the CFIA, Monsanto Canada Inc. and Dow AgroSciences Canada Inc. allowed the Canadian Corn Pest Coalition[1] (CCPC) to review the data package. As a result of its review, the CCPC provided CFIA with recommendations that were taken into account by the CFIA when making the decision to authorize the environmental release of SmartStax™ corn with the modified refuge requirement.

7. *Has the CFIA reviewed the agronomic need for the use of insecticidal traits included in 'SmartStax' relative to actual and current pest infestations in Canada?*

The CFIA assesses PNTs to determine their impact on environmental safety. Once authorized, the actual commercial use of a product will be dependent on a number of different factors, including pest pressure. The responsible deployment and management of all corn pest technologies is supported by the CFIA through active participation in the CCPC.

9. *Is this the first such conditional authorization granted to a Bt Crop?*

Dow AgroSciences Canada Inc. and Pioneer Hi-Bred Production Inc.'s insect resistant and glufosinate-ammonium herbicide tolerant corn event DAS-59122-7 has been conditionally authorized (see Decision Document DD2005-55). Monsanto Canada Inc.'s glyphosate-tolerant, insect resistant corn event MON-88017-3 was also initially authorized conditionally (see Decision Document DD2006-57). Decision Documents can be accessed on the CFIA website at
http://www.inspection.gc.ca/english/plaveg/bio/dde.shtml

3. *What documentation did the CFIA provide to Monsanto and Dow AgroSciences to authorize unconfined environmental release of 'SmartStax'?*

8. *What are the Terms of conditions for authorization for 'SmartStax'? Please provide the text of the CFIA authorization that includes this conditionality.*

10. *In email correspondence from the CFIA, CBAN was told that "Renewal would be condition on satisfactory results of the additional research studies requested." What are the specified research questions that Monsanto and Dow AgroSciences*

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[1] The Canadian Corn Pest Coalition (CCPC) is a collaborative group of corn experts promoting the proper stewardship of corn pest management technologies. The CCPC brings together representatives from federal and provincial governments, university researchers, producer organizations, provincial agronomists and technology developers. Included are experts in entomology, corn breeding, insect resistance management, pathology, agronomy and regulatory bodies.

will answer when they report to the CFIA on December 31, 2012 and what are the methodologies by which these questions will be investigated?

Such documentation contains both personal information and confidential business information. As such, it can be accessed by making a separate request to the CFIA's Access to Information and Privacy Unit (ATIP). The contact information for the manager of this unit is provided below, and I would encourage you to contact her for advice on submitting an ATIP request.

Andree Delisle
Manager, Access to Information and Privacy
613-773-5554
andree.delisle@inspection.gc.ca

Publicly available research reviewed by the CFIA in its analysis of the proposed change to the refuge area for SmartStax™ Corn

Bravo, A.. and Soberón, M. 2008. How to cope with insect resistance to Bt toxins? Trends in Biotech. 26(10): 573-578.

Caprio, M. 1998. Evaluating resistance management strategies for multiple toxins in the presence of external refuges. J. Econ. Entomol. 91: 1021-1031.

Christou, P., Capell, T., Kohli, A., Gatehouse, J.A. and Gatehouse, A.M.R. 2006. Recent developments and future prospects in insect pest control in transgenic crops. Trends in Plant Science 111(6): 302-308.

Crowder, D.W., Onstad, D.W., Gray, M.E., Pierce, C.M.F., Hager, A.G., Ratcliffe, S.T. and Steffey, K.L. 2005. Analysis of the dynamics of adaptation to transgenic corn and crop rotation by western corn rootworm (Coleoptera: Chrysomelidae) using a daily time-step model. J. Econ. Entomol. 98(2): 534-551.

Crowder, D.W., Onstad, D.W., Gray, M.E., Mitchell, P.D., Spencer, J.L. and Brazee, R.J. 2005. Economic analysis of dynamic management strategies utilizing transgenic corn for control of western corn rootworm (Coleoptera: Chrysomelidae). J. Econ. Entomol. 98(3): 961-975.

Gould, F., Anderson, A,. Reynolds, A., Bumgarner, L. and Moar, W. 1995. Selection and genetic analysis of a *Heliothis virescens* (Lepidoptera: Noctuidae) strain with high levels of resistance to *Bacillus thuringiensis* toxins. J. Econ. Entomol. 88: 1545-1559.

Gould, F. 2003. *Bt*-resistance management – theory meets data. Nature Biotech. 21(12): 1450-1451.

Gray, M.E., Sappington, T.W., Miller, N.J., Moeser, J. and Martin, O.B. 2009. Adaptation and invasiveness of western corn rootworm: intensifying research on a worsening pest. Annu. Rev. Entomol. 54: 303-321.

Halpin, C. 2005. Gene stacking in transgenic plants – the challenge for 21st century plant biotechnology. Plant Biotech. J. 3: 141-155.

Liu, Y.-B., Tabashnik, B.E., Dennehy, T.J., Patin, A.L. and Bartlett, A.C. 1999. Development time and resistance to *B.t.* crops. Nature 400: 519.

Ma, B.L., Meloche, F. and Wei, L. 2009. Agronomic assessment of Bt trait and seed or soil-applied insecticides on the control of corn rootworm and yield. Field Crops Research 111: 189-196.

Meihls, L.N., Higdon, M.L., Siegfried, B.D., Miller, N.J., Sappington, T.W., Ellersieck, M.R., Spencer, T.A. and Hibbard, B.E. 2008. Increased survival of western corn rootworm on transgenic corn within three generations of on-plant greenhouse selection. P.N.A.S. 105(49): 19177-19182.

Meinke, L.J., Sappington, T.W., Onstad, D.W., Guillemaud, T., Miller, N.J., Komáromi, J., Levay, N., Furlan, L., Kiss, J. and Toth, F. 2009. Western corn rootworm (*Diabrotica virgifera virgifera* LeConte) population dynamics. Agricultural and Forest Entomology 11: 29-46.

Meloche, F., Rhainds, M., Roy, M. and Brodeur, J. 2005. Distribution of western and northern corn rootworms (Coleoptera: Chrysomelidae) in Quebec, Canada. Can. Entomol. 137: 226-229.

Mitchell, P.D. and Onstad, D.W. 2005. Effect of extended diapause on evolution of resistance to transgenic *Bacillus thuringiensis* corn by northern corn rootworm (Coleoptera: Chrysomelidae). J. Econ. Entomol. 98(6): 2220-2234.

Moar, W., Roush, R., Shelton, A., Ferré, J., MacIntosh, S., Leonard, B.R. and Abel, C. 2008. Field-evolved resistance to *Bt* toxins. Nature Biotech. 26(10): 1072-1076.

Moellenbeck, D.J., Peters, M.L., Bing, J.W., Rouse, J.R., Higgins, L.S., Sims, L., Nevshemal, T., Marshall, L., Ellis, R.T., Bystrak, P.G., Lang, B.A., Stewart, J.L., Kouba, K., Sondag, V., Gustafson, V., Nour, K., Xu, Deping, Swenson, J., Zhang, J., Czapla, T., Schwab, G., Jayne, S., Stockhoff, B.A., Narva, K., Schnepf, H.E., Stelman, S.J., Poutre, C., Koziel, M. and Duck, N. 2001. Insecticidal proteins from *Bacillus thuringiensis* protect corn from corn rootworms. Nature Biotech. 19: 668-672.

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Pereira, E.J.G., Lang, B.A., Storer, N.P. and Siegfried, B.D. 2008. Selection for Cry1F resistance in the European corn borer and cross-resistance to other Cry toxins. Entomologica Experimentalis et Applicata 126: 115-121.

Roush, R.T. 1994. Managing pests and their resistance to *Bacillus thuringiensis*: Can transgenic crops be better than sprays? Biocontrol Science and Technology 4: 501-516.

Roush, R.T. 1998. Two-toxin strategies for management of insecticidal transgenic crops: can pyramiding succeed where pesticide mixtures have not? Phil. Trans. R. Soc. Lond. B 353: 1777-1786.

Storer, N.P. 2003. A spatially explicit model simulating western corn rootworm (Coleoptera: Chrysomelidae) adaptation to insect-resistant maize. J. Econ. Entomol. 96(5): 1530-1547.

Storer, N.P. 2006. Field measures of western corn rootworm (Coleoptera: Chrysomelidae) mortality caused by Cry34/35Ab1 proteins expressed in maize event 59122 and implications for trait durability. J. Econ. Entomol. 99(4): 1381-1387.

Tabashnik, B.E. 1989. Managing resistance with multiple pesticide tactics: theory, evidence, and recommendations. J. Econ. Entomol. 82: 1263-1269.

Tabashnik, B.E., Liu, Y.-B., Malvar, T., Heckel, D.G., Masson, L., Ballester, V., Granero, F., Mensua, J.L. and Ferre, J. 1997. Global variation in the genetic and biochemical basis of diamondback moth resistance to *Bacillus thuringiensis*. P.N.A.S. 94: 12780-12785.

Tabashnik, B.E., Carrière, Y., Dennehy T.J., Morin, S., Sisterson M.S., Roush, R.T., Shelton A.M., Zhao J. 2003. Insect resistance to transgenic Bt crops: lessons from the laboratory and field. J. Econ. Entomol. 96: 1031-1038.

Tabashnik, B.E., Gassmann, A.J., Crowder, D.W. and Carrière, Y. 2008. Insect resistance to *Bt* crops: evidence versus theory. Nature Biotech. 26(2): 199-202.

Zhao, J.Z., Cao, J., Li, H., Collins, H.L., Roush, R.T., Earle, E.D. and Shelton, A.M. 2003. Transgenic plants expressing two *Bacillus thuringiensis* toxins delay insect resistance evolution. Nature Biotech. 21(12): 1493-1497.

Zhao, J.-Z., Cao, J., Collins, H..L., Bates, S.L., Roush, R.T. and Earle, E.D. 2005. Concurrent use of transgenic plants expressing a single and two *Bacillus thuringiensis* genes speeds insect adaptation to pyramided plants. P.N.A.S. 102(4): 8426-8430.