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U.S. Department of Health and Human Services
U.S. Department of Agriculture
U.S. Environmental Protection Agency

MEMORANDUM OF UNDERSTANDING

AMONG

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

AND

DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
BIOTECHNOLOGY REGULATORY SERVICES

AND

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS

Purpose: Information sharing between the Environmental Protection Agency (EPA), Food and Drug Administration (FDA) of the Department of Health and Human Services, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service/Biotechnology Regulatory Services (USDA/APHIS/BRS or USDA), in the regulatory oversight over genetically-engineered plants and the foods derived from such plants.

Background: EPA, FDA, and USDA/APHIS/BRS, along with several other Federal agencies, are responsible for implementing the 1986 Coordinated Framework for Regulation of Biotechnology (the Coordinated Framework) (51 Fed. Reg. 23302; June 26, 1986). The Coordinated Framework ensures that federal agencies provide coordinated regulatory oversight over products of biotechnology to protect the environment and public health.

USDA/APHIS/BRS regulates the importation, interstate movement, and release into the environment of genetically-engineered organisms which includes plants and plant products that are undergoing confined experimental development in field trials. Under the Coordinated Framework, it is USDA's role to ensure that genetically engineered organisms, including genetically engineered plants and plants used for food, do not pose a plant pest risk pursuant to its Plant Protection Act authority, 7 USC § 7701 *et seq.*

FDA enforces, among other laws, the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §201 *et seq.*, which governs the safety and labeling of foods[1], including foods derived from genetically-engineered plants.

EPA regulates pesticides, and in particular plant-incorporated protectants (PIPs). PIPs are pesticidal substances (such as *Bt* protein) produced in plants and the genetic material necessary for their production in plants (such as *cry* genes). EPA grants experimental use permits for field testing and registrations that permit the sale and use of pesticides, including PIPs, in commerce under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.* EPA also issues tolerances or tolerance exemptions that permit pesticide chemical residues in food under section 408 of the FFDCA.

This memorandum of understanding (MOU) will support and encourage cooperation and communication between USDA, FDA, and EPA in the regulatory oversight over genetically-engineered plants and the foods derived from such plants. Under this MOU, USDA/APHIS/BRS, FDA, and EPA agree to share with each other information about genetically-engineered plants and the foods derived from such plants, including non-public information exempt from public disclosure usually referred to as "confidential business information" and/or "trade secrets" (also referred to as "non-public information" in this MOU).

Substance of MOU: USDA/APHIS/BRS, FDA, and EPA enter into this MOU to share, on a reciprocal and as-needed basis, non-public information related to the three agencies' respective programs regulating genetically-engineered plants and foods derived from genetically-engineered plants. USDA/APHIS/BRS, FDA, and EPA also agree to protect the confidentiality of the non-public information that they receive from each other pursuant to this MOU. To ensure appropriate protection of non-public information, each agency agrees to identify non-public information shared under this MOU. Disclosure of confidential and other non-public information to USDA/APHIS/BRS, EPA, and FDA employees pursuant to this MOU is provided with the understanding that those employees are not considered members of the public for purposes of disclosure of such designated information and thus such disclosure does not constitute a waiver of any FOIA exemption protection.

Subject to Paragraphs A., B., and C. below, an agency shall not further disclose non-public information received under this MOU except with the written permission of the agency from which the non-public information originated. An agency in receipt of a judicial or legislative mandate ordering disclosure of non-public information provided by another agency will promptly notify the agency that provided this information and will take all appropriate legal measures in accordance with its regulations to advise the requesting authority of the need to protect the information from public disclosure. If an agency that has received non-public information under this MOU receives a Freedom of Information Act (FOIA) request for which there are responsive records of such non-public information that originated with the other agency, it will refer that request to the other agency for it to respond directly to the requestor regarding the release of the non-public information. In such cases, the agency making the referral will notify the requestor that a referral has been made to the agency from which the non-public information originated and that a response will issue directly from that other agency.

A. Non-public information provided by USDA/APHIS/BRS

Under this MOU, USDA/APHIS/BRS would share non-public information, including confidential business information[2] that it receives from private entities pursuant to its Part 340 biotechnology regulations only as described below.

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[1] Under 21 U.S.C. 321(f), "food" means "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." Thus, this MOU includes animal feeds that are derived from genetically engineered plants.

Confidential information provided by USDA/APHIS/BRS may only be shared with FDA and EPA personnel who have been granted access to non-public information by the Director of USDA/APHIS/BRS's Regulatory Operations Division or his/her designate via the APHIS Access Authorization Agreement for Trade Secrets and Confidential Business Information form. The FDA and EPA liaison officers listed in this MOU will provide to the USDA Liaison Officer annually by October 30th and during the year as these needs change due to the nature of a specific regulatory issue being considered and due to personnel actions (such as retirements, transfers, or resignations) updated lists of FDA and EPA personnel who have a need for access to USDA/APHIS/BRS non-public information. The USDA Liaison Officer will provide the FDA and EPA liaison officers updated lists of FDA and EPA personnel who have been granted access to non-public information annually by November 15th and as personnel lose or gain access during the year. Documents provided by USDA/APHIS/BRS that contain non-public information must not be further disclosed to anyone not on the list of either FDA or EPA staff that have been given access to confidential information provided by USDA/APHIS/BRS.

B. Non-public information provided by FDA

FDA may share non-public information that is related to its program for foods derived from genetically-engineered plants. FDA may share non-public information with USDA or EPA, upon written request, in a manner consistent with the requirements of 21 CFR 20.85 regarding the disclosure of information by FDA to other Federal government departments and agencies. Specifically, the FDA contact persons designated in this MOU are authorized to share with USDA/APHIS/BRS and EPA and their staff non-public information in response to a written request and agreement not to disclose further the information without FDA's written permission. Consistent with the requirements of 21 CFR 20.85, FDA may share with USDA/APHIS/BRS or EPA confidential commercial information[3] related to its program for foods derived from genetically-engineered plants to the extent such sharing is not prohibited under 21 U.S.C. § 331(j) or other applicable law. Under 21 U.S.C. § 331(j), FDA is prohibited from sharing certain trade secrets[4] outside of the Department of Health and Human Services except in very limited circumstances. Nonetheless, upon request by EPA or USDA/APHIS/BRS for specific information identified by a company as trade secret, FDA will assess whether the information is in fact trade secret under § 331(j), and if so will ascertain whether a masked or aggregated form of the information may be provided whose disclosure is not prohibited by § 331(j) or whether the company will provide written consent to the sharing of the specific trade secret information with EPA and USDA.

EPA will share confidential information provided by FDA only with EPA personnel who have been designated by the Director of EPA/OPP's Biopesticide and Pollution Prevention Division and identified to FDA by the EPA Liaison Officer as having a need for access to such information. USDA/APHIS/BRS will share confidential information provided by FDA only with USDA/APHIS/BRS personnel designated by the Deputy Administrator of USDA/APHIS/BRS and identified to FDA by the USDA Liaison Officer as having a need for access to such information. Each year, not later than October 30th and during the year as needs change due to the

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[2] USDA/APHIS/BRS Confidential Business Information is information that would be protected from disclosure under Section (b)(4) of the Freedom of Information Act, 5 U.S.C. § 552(b)(4), such as trade secrets and commercial and financial information claimed or designated as privileged or confidential.

[3] Confidential commercial information is commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs. 21 CFR 20.61(b)

[4] A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process. 21 CFR 20.61(a).

nature of a specific regulatory issue being considered and due to personnel actions (such as retirements, transfers, or resignations), the USDA and EPA liaison officers will provide the FDA Liaison Officer an updated list of personnel from their respective agencies who have a need for access to FDA non-public information. Each year, not later than November 15th and during the year as needs change due to personnel actions such as retirements, transfers, or resignations, the FDA Liaison Officer will provide to the USDA/APHIS/BRS and EPA liaison officers updated lists of personnel from their respective agencies who have been granted access to FDA confidential information. EPA and USDA/APHIS/BRS staff designated for access to non-public information provided by FDA must first be authorized access to non-public information relevant to the requirements of their respective statutes and regulations, as appropriate, within their respective organizations.

C. Non-public information provided by EPA

EPA may share non-public information, including sensitive[5] and/or confidential business information[6] relevant to the requirements of FIFRA and FFDCA. EPA may share confidential business information with other Federal agencies in accordance with 40 CFR 2.209(c).

FDA will share non-public information provided by EPA only with FDA personnel, and USDA/APHIS/BRS will share non-public information provided by EPA only with USDA/APHIS/BRS personnel, who have been granted access to confidential information by the Director of EPA/OCSPP/OPP's Biopesticide and Pollution Prevention Division or her/his designate via the FIFRA Access Authorization Agreement form. Each year, not later than October 30th and during the year as needs change due to the nature of a specific regulatory issue being considered and due to personnel actions such as retirements, transfers, and resignations, FDA and USDA/APHIS/BRS staff who have a need for access to EPA non-public information will complete the FIFRA Access Authorization Agreement form in accordance with the FIFRA Information Security Manual. Each year, not later than November 15th and during the year as needs change due to personnel actions such as retirements, transfers, or resignations, the EPA Liaison Officer will provide the FDA and USDA liaison officers updated lists of personnel from their respective agencies who have been granted access to non-public information provided by EPA.

FDA and USDA/APHIS/BRS staff will protect all non-public information provided by EPA in accordance with 40 CFR 2.209(c)(5) and the FIFRA Information Security Manual.

Each individual who will be authorized access to non-public information provided by EPA will (1) read the required documentation annually; (2) sign the FIFRA Access Authorization Agreement annually; and (3) sign the Affirmation of Non-multinational Status. Annually is defined as 365 days after the person's last signature of these forms. The forms must be forwarded via EPA/OCSPP/OPP's Biopesticide and Pollution Prevention Division Document Security Officer to the FIFRA Security Officer.

No state, county, local official, or USDA/APHIS/BRS or FDA grantee or contractor will be permitted to have access to non-public information provided by EPA..

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[5] EPA Sensitive Information: Information whose release is limited or prohibited by FIFRA or FFDCA, or by another statute or regulation.

[6] Confidential Business Information (CBI): Any business information in any form received by EPA from any private source or public agency that has been claimed as confidential in accordance with 40 CFR 2.203 or other provision in 40 CFR regarding confidentiality or which may be claimed as confidential pursuant to 40 CFR 2.204(c)(2), and which has not been determined to be non-confidential under the procedures in 40 CFR part 2, subpart B.

Liaison Officers:

USDA, FDA and EPA liaison officers are designated in the appendix to this MOU.

Duration of MOU: This MOU will become effective when approved by the indicated signatories for EPA, USDA/APHIS/BRS, and FDA and will continue in effect for a ten year period and may be modified by mutual written consent at any time. Any party may terminate this MOU by providing written notice to the other parties. The MOU termination will be effective upon the sixtieth (60) calendar day following notice, unless a later date is set forth.

Source of Funding: This MOU does not constitute a fiscal or funds obligating document. Each Party to this MOU recognizes the other's responsibility to fund and carry out its own activities subject to, and to the extent made possible, by the availability of appropriated funds and no funds will be transferred under this MOU. Any specific collaborative activities arising from this MOU that require transfer of funds shall be the subject of a separate agreement.

No Private Right of Action: This MOU does not create any right or benefit, substantive or procedural, enforceable by law or equity. This MOU does not direct or apply to any person outside of FDA, EPA, and USDA/APHIS/BRS.

Congressional Restriction: Under 41 U.S.C. 22, no member of, or delegate to, Congress shall be admitted to any share or part of the MOU or to any benefit to arise therefrom.

Approved and Accepted for EPA's Office of Pesticide Programs Biopesticide and Pollution Division	**Approved and Accepted for USDA's Animal and Plant Health Inspection Service/Biotechnology Regulatory Services**	**Approved and Accepted for the Food and Drug Administration**
STEVEN BRADBURY, Ph.D., Director Office of Pesticide Programs Office of Chemical Safety and Pollution Prevention Environmental Protection Agency 2/2/11 Date	MICHAEL C. GREGOIRE Deputy Administrator Biotechnology Regulatory Services Animal Plant Health Inspection Services United States Department of Agriculture 1/10/2011 Date	LESLIE KUX Acting Assistant Commissioner for Policy Food and Drug Administration 12/20/10 Date

APPENDIX

Liaison Officers:

A. For USDA's Animal and Plant Health Inspection Service/Biotechnology Regulatory Services:

Cynthia A. Eck
Document Control Officer
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Director
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B. For FDA's Center for Food Safety and Applied Nutrition

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Office of Regulations, Policy, and Social Sciences
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For FDA's Center for Veterinary Medicine

Jeanette Murphy
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For FDA's Office of Regulatory Affairs

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C. For EPA's Office of Pesticide Programs:

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