

~~June 12, 2009~~
1-18-2010

MATERIALS TRANSFER AGREEMENT

U.S. Environmental Protection Agency (EPA)
Office of Research and Development (ORD)
National Center for Computational Toxicology (NCCT)

Recipient Organization's Legal/Official Name:

BioDetection Systems B.V. (BDS)

1. EPA agrees to transfer to Recipient's Investigator named below the following Research Material (please check box to select all that apply):

- A copy of the ToxCast™ chemical library consisting of chemical samples prepared as solutions in dimethyl sulfoxide at a concentration of 20 millimolar.
- In vitro assay data derived from the ToxCast™ Program on chemicals which were analyzed using a variety of high throughput assay techniques. Below, this is referred to as the "ToxCast™ Data".
- In vivo whole animal toxicology summary data derived from the EPA Toxicology Reference Database (ToxRefDB). Below, this is referred to as the "ToxRefDB Data."
- Summary descriptions of the individual data sets.
- Individual subsets of this data will be delivered to the recipient after they have been prepared for use at the EPA and cleared for release to the Recipient.

2. EPA's Research Material may not be used in human subjects. The Research Material will be used only for research purposes by Recipient's investigator in his/her laboratory, for the research project described below, under suitable containment conditions. Recipient

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agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

3. The EPA Research Material does not include specimens or data derived or collected from human subjects.

4. The EPA Research Material will be used by Recipient's investigator solely in connection with the following research projects described with specificity as follows (*use space below or an attachment page if necessary*):

Testing of the chemicals: stable assays including the AR- and ERalpha CALUX assays, as well as about 15 additional stable CALUX assays for nuclear hormone receptor/genotoxicity/stress-related pathways. For these tests protocols for agonist and antagonist testing are available.

Selection of high priority chemicals for testing will be carried out in collaboration. BDS will carry out part of the testing of chemicals using externally funded research projects (i.e. ChemScreen and The Netherlands Toxicogenomics Centre), and BDS/NCCT will seek other opportunities to test the remainder. Capacity building at BDS through installation of HTS technologies will form a part of this. Also here, a collaboration with NCCT is envisioned.

Protocols and prevalidation data on the ER/AR assays were generated in the ReProTect project, and have recently been submitted to ECVAM to initiate formal validation. Since ER reporter gene assays from different origin are currently being used in a variety of screening and testing programs, including ToxCast and now ChemScreen, and in some cases validated by different organizations such as OECD and EPA, our goal will be to harmonize and avoid duplication of efforts. A more harmonized approach to validate reporter gene assays will be explored within this collaboration with NCCT. We will work with NCCT to determine priorities as to which compounds to test first, how many concentrations, etc.

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5. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge EPA's contribution of this Research Material, if used, unless requested otherwise. To the extent permitted by law, Recipient agrees to treat as confidential, any of EPA's written information about this Research Material that is stamped "CONFIDENTIAL." The foregoing shall not apply to information that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Any oral disclosures from EPA to Recipient which EPA wishes to be treated as confidential shall be identified as being Confidential at the time of the disclosure and by written notice delivered to Recipient within thirty (30) days after the date of the oral disclosure. Recipient may publish or otherwise publicly disclose the results of the Research Project, but if EPA has given Confidential information to Recipient, such public disclosure may be made only after EPA has had thirty (30) days to review the proposed disclosure to determine if it includes any Confidential information, except when the shortened time period is pursuant to a court order or to the extent such review period is permitted by law.

6. The Recipient will provide to the EPA all Testing Results obtained by the Recipient using the Research Material. EPA acknowledges that Recipient owns all Testing Results and Recipient acknowledges that the EPA will make such Testing Results freely available to the public upon review and approval by the Recipient.

7. Are Testing Results being provided back to EPA that include specimens or data derived or collected from human subjects?

Yes – Go to item #7(a).

No – Skip to item #8.

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7(a). Do these Testing Results include specimens or data derived or collected from fetuses, children, pregnant women, or nursing women?

Yes

No

7(b). Were these Testing Results obtained under a protocol that was reviewed and approved by an Institutional Review Board (IRB) that operated in accordance with the requirements of EPA Regulation 40 CFR 26, HHS Regulation 45 CFR 46, or any other Federal Regulation for the protection of human research subjects?

Yes (Please indicate the applicable Regulation here and provide copies of the protocol and IRB approval documents.)

No (Please provide explanation with documentary support as appropriate.)

7(c). Can the Provider of the Testing Results identify the subjects directly or through identifiers (codes) linked to the subjects?

Yes – EPA's use of the Research Material may be human subjects research subject to 40 CFR 26. Go to item #7(d).

No – EPA's use of the Research Material is not human subjects research subject to 40 CFR 26. Skip to item #8.

7(d). Is the Provider of the Testing Results prohibited by this agreement from releasing information to the EPA that might allow the identification of any of the subjects, including but not limited to the key to any existing code?

Yes – EPA's use of the Research Material is not human subjects research subject to 40 CFR 26. Skip to item #8.

No – EPA's use of the Research Material may be human subjects research subject to 40 CFR 26. Go to item #7(e).

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7(e). Is the Research Material publicly available?

Yes – EPA’s use of the Research Material is human subjects research that is exempt from 40 CFR 26.

No – EPA’s use of the Research Material is human subjects research that may be subject to 40 CFR 26 and must be further evaluated accordingly by the EPA Human Subjects Review Official.

8. This Research Material represents a significant investment on the part of EPA and is considered proprietary to EPA. Recipient’s investigator therefore agrees to retain control over this Research Material and further agrees not to transfer the Research Material to other people not under his/her direct supervision without advance written approval of EPA. EPA reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Project is completed, the Research Material will be returned to the EPA or disposed, if directed by EPA.

9. This Research Material is provided as a service to the research community. It is being supplied to Recipient with no warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. EPA makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.

10. Recipient shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. However, if said inventions contain any portion of the Research Material, are derived from the Research Material, or could not have been produced but for the use of the Research Material,

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Recipient agrees to contact the EPA to determine what ownership interests, if any, the EPA may have, and, where applicable, to negotiate in good faith the terms of a commercial license. Inventorship for a patent application or a commercialized product based on said inventions shall be determined according to United States patent law.

11. Recipient agrees not to claim, infer, or imply endorsement by the Government of the United States of America (hereinafter referred to as "Government") of the Research Project, the institution or personnel conducting the Research Project or any resulting product(s). Recipient agrees to hold the Government harmless against all liabilities, demands, damages, expenses and losses arising out of Recipient's use of the Research Material in the Research Project.

12. When EPA receives Testing Results in accordance with Section 3 and 7, from the partner, the partner will not be liable to EPA for any claims or damages arising from EPA's use of the Testing Results.

13. This Agreement shall begin on the date of its execution and continue for twelve (12) months thereafter, and shall automatically renew for successive year long periods (a) unless one party notifies the other party no sooner than thirty (30) days prior to such renewal date that it elects not to renew the Agreement, or (b) unless earlier terminated as provided in the next sentence. The EPA shall have the right to terminate this Agreement at any time if Recipient breaches any of the terms of this Agreement. Upon termination, Recipient shall return to the EPA all unused portions of the Research Materials upon written request of the EPA. Recipient may retain one copy of the Confidential Information solely for the purpose of monitoring its obligations under this Agreement.

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14. All notices pertaining to or required by this Agreement shall be in writing and shall be signed by an authorized representative and shall be sent by mail or commercial courier addressed as follows:

EPA's Contact Information

Monica R. Linnenbrink
National Center for Computational Toxicology (NCCT)
US EPA (MD-B-205-01)
4930 Old Page Rd.
Research Triangle Park, NC 27711
Ph. 919-541-1522; fax 919-541-1194
Linnenbrink.monica@epa.gov

Recipient's Contact Information

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13. Paragraphs 2, 8, 11 and 12 shall survive termination.

MTA Template—EPA Provider#1

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negotiation of this Agreement are subject to all applicable civil and criminal statutes including 31 U.S.C. ' ' 3801-3812 (civil liability), 18 U.S.C. ' 1001 (criminal liability), and 31 U.S.C. ' ' 3729-33 (False Claims Act).