



Federal Institute for Risk Assessment
(Bundesinstitut für Risikobewertung / BfR)

Brazilian Health Surveillance Agency
(Agência Nacional de Vigilância / ANVISA)

Memorandum of Understanding on Cooperation

Made by and entered into as of the 22nd of May 2012, between Federal Institute for Risk Assessment (herein after referred to as “BfR”) and The Brazilian Health Surveillance Agency (herein after referred to as “ANVISA”).

For the purpose of the Protocol and the implementation of the provisions, representative of ANVISA is Dirceu Brás Aparecido Barbano, while representative of the BfR Institute is Professor Dr. Dr. Andreas Hensel.

BfR is the independent scientific agency of Federal Republic of Germany which is responsible for preparing expert reports and opinions on food and feed safety as well as on the safety of substances and products. BfR reports to the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV).

ANVISA, the Brazilian Health Surveillance Agency, is an autonomous agency operating under a special regime. Within the structure of Federal Public Administration, the Agency is linked to the Brazilian Ministry of Health, under a Management Contract.

Both parties agree that a wide-scope and further collaboration between BfR and ANVISA – in accordance with the respectively applicable legal regulation - will contribute to intensifying scientific research strengths of both parties. It is also agreed that the collaboration will help protect people’s health and safety of both countries. Hence, following the meeting, through friendly consultation, in line with the principle of equality and mutual benefit, shared the intent to cooperate.

Collaboration in other fields will be elaborated on and realised in special technical agreements in different fields of interest.

Both Parties agree that the information exchanged among them may be confidential and not of public domain on the territory of the Participant that originated the information. At the moment of exchanging the information, the participant will inform of the confidentiality of this information. In this case each participant understands that confidential information will be shared under a secure basis and in accordance to the applicable laws as well as policies and procedures allowed on each country. Each participant will make the best efforts to avoid:

- (a) Public disclosure of confidential information that has been exchanged under the present Memorandum; and
- (b) Any other disclosure of information for purposes that are not established by this Memorandum.

The cost of implementing the Protocol will be covered by either funded Research Programs or by the regular budgets of the two parties based on the principles of reciprocity and equality unless the representatives of the contracting parties agree otherwise on specific issues or activities.

The protocol is subject to approval by the relevant constitutional or statutory provisions applicable to each party.

The implementation date is that on which the exchange of notifications between the Contracting Parties confirming the approval of each party to this protocol is completed.

This memorandum begins on 22.05.2012. Any variations require notice and agreement of both parties.

Any additional legal matters not covered by this agreement will be discussed by the ANVISA and the BfR. This agreement will be subject to revision upon request of either of the two participating parties or in case of an extension of the scope of this agreement.

Both sides can terminate this agreement with 12 month period of notice without giving reasons.



This Memorandum of Understanding on Cooperation was signed in Berlin on the 22nd of May 2012 made in duplicity; each party has two copies, written in English and Portuguese.

**Agência Nacional de Vigilância
Sanitária – ANVISA
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for the president



Professor Dr. Dr. Andreas Hensel
President