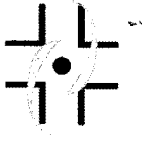


Risiken erkennen – Gesundheit schützen



**ANVISA**  
Agência Nacional de Vigilância Sanitária

**Federal Institute for Risk Assessment**

**(Bundesinstitut für Risikobewertung / BfR)**

**Brazilian Health Surveillance Agency**

**(Agência Nacional de Vigilância / ANVISA)**

## **Working Plan I**

### **Technical Cooperation on Toxicology**

**The Participants reaffirm their interest in cooperate in areas of toxicology.**

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**This Action Plan will cover six activities, as following:**

Proposed Cooperation Themes	Partner Organizations (Brazil and Germany)	Contact Person(s) (ANVISA and BfR)	Description of Activities	Timelines	Expected Results
<p>1. <i>Challenges for hazard and risk assessment from the new legislation for pesticides and biocides in Europe and Brazil, especially cut off criteria</i></p>	<p>BfR ANVISA</p>	<p>Focal points in each agency BfR: t.b.d. ANVISA: t.b.d.</p>	<p>1.1 Establishment of a mechanism for exchange information in order to narrow the practical work based on the Brazilian and EU/German legislations (especially cut-off criteria and CMR's classifications). 1.2. Definition of focal points in each agency until 05/2012 1.3. E- consultation (once per quarter) between BfR and ANVISA starting 05/2012 1.4. Videoconference in July of 2012 in order to decide further steps and the content of the Technical Meeting 1.5. Technical meeting at ANVISA in October of 2012 (to be discussed)</p>	<p>2012 - 2013</p>	<p>Improvement and convergence of toxicological evaluations and human health risk assessment of pesticides and biocides</p>

Proposed Cooperation Themes	Partner Organizations (Brazil and Germany)	Contact Person(s) (ANVISA and BfR)	Description of Activities	Timelines	Expected Results
2. Development of decision and evaluation criteria for endocrine disruptors	BfR ANVISA	Focal points in each agency	<p>2.1. Establishment of a mechanism for exchange information in order to narrow the evaluation of ED substances based on the Brazilian and European legislations, especially evaluation and decision criteria for ED's.</p> <p>2.2. Definition of focal points in each agency. until 01/2012</p> <p>2.3. E- consultation between BfR and ANVISA starting 05/2012</p> <p>2.4. Technical meeting at Anvisa in October of 2012 to decide on further steps</p> <p>2.5. Participation of ANVISA in the impact project for evaluation of ED substances</p>	2012 to 2014	To build a guidance establishing the decision and evaluation criteria for defining an endocrine disruptor pesticide to human health



Proposed Cooperation Themes	Partner Organizations (Brazil and Germany)	Contact Person(s) (ANVISA and BfR)	Description of Activities	Timelines	Expected Results
<p>3. Consequences of the revision of the data requirements for toxicological evaluation in Europe and Brazil for risk assessment</p>	<p>BfR ANVISA</p>	<p>Focal points in each agency</p>	<p>3.1. Establishment of a mechanism for exchange information considering which studies are required as core data and which ones are additionally required in specific cases – e.g. ED's studies. 3.2. Definition of focal points in each agency. until 05/2012 3.3. E- consultation (once per quarter) between BfR and ANVISA starting 05/2012 3.4. Videoconference in July of 2012 in order to decide further steps and the content of the Technical Meeting 3.4. Technical meeting at ANVISA in October of 2012</p>	<p>2012 to 2014</p>	<p>Improvement of toxicological evaluation and human health risk assessment based on comparable data requirements and guidance for waving of animal studies</p>

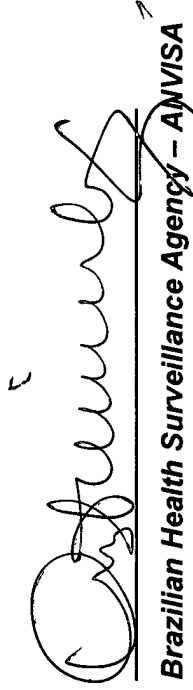
Proposed Cooperation Themes	Partner Organizations (Brazil and Germany)	Contact Person(s) (ANVISA and BFR)	Description of Activities	Timelines	Expected Results
<p>4. Discussion on the toxicological evaluation of pesticides of interest in Germany and Brazil.</p>	<p>BFR ANVISA</p>	<p>Focal points in each agency</p>	<p>4.1. Establishment of a mechanism in order to exchange experiences and difficulties during the toxicological evaluation;  4.2. Definition of focal points in each agency.  4.3. Videoconference in October of 2012 in order to decide further steps and the content of the Training  4.4. Training focusing on the CMR's classifications and risk assessment's criteria/defaults in e-consultation (once per quarter)  4.4.1. Number of meetings and place: one meeting in Berlin 2013 (to be discussed);  4.4.2. Period: from 2012 to 2015;</p>	<p>2012 to 2015</p>	<p>Establishment of a mechanism for routinely exchange information of toxicological evaluations in order to support regulatory decisions</p>

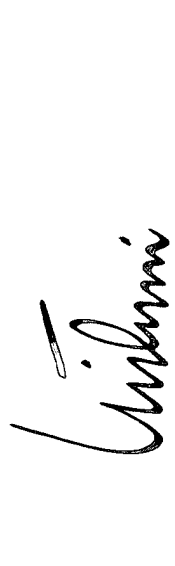


Proposed Cooperation Themes	Partner Organizations (Brazil and Germany)	Contact Person(s) (ANVISA and BfR)	Description of Activities	Timelines	Expected Results
5. <i>Data on poisoning with pesticides and medical surveillance</i>	BfR ANVISA	Focal points in each agency	<p>5.1. Establishment of a mechanism for routinely exchange information of Pesticides Poisoning Database and also about the strategies of assisting healthcare professionals with caring.</p> <p>5.2. Videoconference in October of 2012 in order to decide further steps</p> <p>5.3. Definition of focal points in each agency.</p>	2012 to 2015	Exchange information/experience on Pesticides Poisoning



Proposed Cooperation Themes	Partner Organizations (Brazil and Germany)	Contact Person(s) (ANVISA and BfR)	Description of Activities	Timelines	Expected Results
6. Discussion of criteria for classification and labeling according to the Globalized Harmonized System (GHS) and the European legislation (CLP), especially CMR properties	BfR ANVISA	Focal points in each agency ANVISA: Ana Maria Vekic, Fabiane Resende Gomes and Ricardo Augusto Velloso	6.1. Establishment of a mechanism for routinely exchange information. 6.2. Definition of focal points in each agency. 6.3. Technical meeting at ANVISA in October of 2012 to decide on further steps	2012 to 2015	Exchange information/ experience on classification and labelling

  
 Brazilian Health Surveillance Agency – ANVISA  
 Federal Republic of Brazil

  
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