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AND INVESTIGATION MECHANISM**

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**ASSESSMENT AND CONSULTATION PHASE REPORT
AGRIFOOD HEALTH AND QUALITY MANAGEMENT PROGRAM IN ARGENTINA**

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Assessment and Consultation Phase Report Agrifood Health and Quality Management Program in Argentina (AR-ICIM004-2012)



PROJECT OMBUDSPERSON

Contents

1.	Background	1
1.1	The Request	1
1.2	The Program.....	2
1.2.1	Loan operation and credit line	2
1.2.2	Modernization of institutional management component.....	3
1.2.3	Possible environmental and social impacts.....	5
1.2.4	Safeguards.....	5
2.	Assessment Methodology	6
3.	Stakeholder mapping.....	7
4.	Main findings of the Assessment	8
4.1	Regulatory Reorganization Program (PRN)	8
4.1.1	Standard-setting process: preparation, consultation, and entry into force	9
4.2	Registration of phytosanitary products	11
4.2.1	Responses to the Requester's concerns about the registration of phytosanitary products ..	12
4.3	Toxicological Classification of Phytosanitary Products	12
4.3.1	Previous system.....	12
4.3.2	Current system	13
4.3.3	Responses to the Requester's concerns about the toxicological classification of phytosanitary products	15
4.4	Public Consultation on Resolution 302/12.....	15
4.4.1	Responses to the Requester regarding the public consultation	16
4.5	Application of agrochemical products	16
4.5.1	Responses to the Requester on the application of agrochemicals.....	17
5.	Main outcomes of the Consultation Phase	17
6.	Conclusions	18

Assessment and Consultation Phase Report

1. Background

1.1 The Request

1. On 12 January 2012, the Independent Consultation and Investigation Mechanism (“the ICIM” or “the Mechanism”)¹ received a request from Dr. Graciela Gómez (Requester) concerning some components of the Agrifood Health and Quality Management Program (“the Program”) financed by the Inter-American Development Bank (IDB) in Argentina. The borrower of the Program is the Government of the Republic of Argentina and the Executing Agency is the National Agrifood Health and Quality Service (SENASA).
2. On 23 January 2012, the Office of the Executive Secretary forwarded the Request to the Project Ombudsperson. Pursuant to Section 40(h) of the Policy of the Mechanism (“the Policy”) and its guidelines, the Project Ombudsperson paused the Eligibility Analysis for a period of 45 days, as of the date received, to provide Bank Management the opportunity to address with the Requester directly the concerns raised in her Request. On 5 March 2012, the Requester and the IDB Project Team met in Buenos Aires to discuss the content of the Request and, subsequently, exchanged correspondence about the Program. When the period of time afforded to Management concluded, in March 2012 the Requester expressed her decision to continue pursuing the process with the ICIM because she considered that her concerns had not been addressed to her satisfaction.
3. On 23 April 2012, the Project Ombudsperson determined that the Request was eligible for the Consultation Phase. Accordingly, the Assessment Phase began for the purposes of examining and obtaining further information on the issues alleged by the Requester; identifying the primary and secondary stakeholders in the case; and assessing the concerns in the Request relative to the Bank’s Operational Policies and whether conditions existed for initiating a dialogue in order to address the Requester’s concerns. Given the particular nature of the case, the availability of the Requester and the Executing Agency, and in order to facilitate a more efficient process, the Project Ombudsperson initiated certain standard activities of the dialogue process during the Assessment Phase, including an information exchange session among the Parties to clarify the scope and discuss the concerns raised in the Request.
4. In her written documents and at the meetings held during the Assessment Phase, the Requester reaffirmed her complaints regarding the hazards to the environment and to human health posed by the use of agrochemicals which, in her opinion, would be perpetuated by the implementation of the Program, through the reforms to and use of SENASA’s regulatory digest financed by the Bank, among other things. In this connection, the Requester stated that the Program promotes the adoption of an

¹ The terms Mechanism, Management, Executive Secretary, Project Ombudsperson, Panel, Policies of the Mechanism, Eligibility, Consultation Phase, Assessment, and any other relevant term in this Report are defined in the Policy of the Independent Consultation and Investigation Mechanism (ICIM), approved on 17 February 2010, and available at: www.iadb.org/ICIM.

agrochemical classification methodology in Argentina that: (a) is based on obsolete criteria and studies; (b) does not take into account the effects of the non-lethal dose of these substances, as in the case of glyphosate; and (c) does not consider the synergy of two or more substances that may be registered separately as less harmful to human health and to the environment. Moreover, the Requester alleged that the outcomes of the public consultation on the proposed standards for the “Review of the criteria for the toxicological classification of phytosanitary products,” conducted between 30 June and 30 August 2011 by SENASA, had not been published to date. In her opinion, failure to disseminate the results of the consultation violated Argentina’s General Law on the Environment.² She also stated that some of the experts who issue the toxicological endorsements required for registering new phytosanitary products may have conflicts of interest when they also provide services to the agencies interested in registering the products. Finally, she noted that the Program component that includes preparation of a “Manual of Good Practices in the Use of Agrochemicals” is insufficient to address the impact of improper use of such products.

5. In accordance with the Determination of Eligibility, these concerns are related to the Bank’s Environment and Safeguards Compliance Policy (OP-703).

1.2 The Program

1.2.1 Loan operation and credit line

6. Conditional credit line AR-X1007 was approved by the IDB’s Board of Executive Directors on 9 January 2008, for an amount of up to US\$300 million over a 15-year period, to finance operations to implement a plan to modernize SENASA.³ On that date, as the “first program” under that credit line, the Board of Executive Directors approved

² Cf. Law 25,675 of 27 November 2002, General Law on the Environment, **Citizen participation** – Articles 19 to 21:

Art. 19. – All persons have the right to be consulted and to express their opinions regarding administrative procedures related to the preservation and protection of the environment, which are of general or specific impact, and of general scope.

Art. 20. – Authorities shall institutionalize consultation procedures or public hearings as mandatory procedures for the authorization of activities that may generate adverse and significant effects on the environment.

Participants’ opinions or objections will not be binding on the authorities holding the consultation; however, should their opinions be opposed to the outcomes of the public hearing or consultation, they should be justified and publicized.

Art. 21. – Citizen participation should be ensured, primarily, in environmental impact assessments, and for environmental land-use plans and programs for the territory, especially in the planning and performance evaluation stages.

Available at: <http://www.ambiente.gov.ar/?aplicacion=normativa&IdNorma=85>. Last access: 23 July 2012.

³ Cf. IDB, *Loan Proposal, Agrifood Health and Quality Management Program (AR-L1032), CCLIP Line for the Agrifood Health and Quality Management Program (AR-X1007)*, 11 December 2007, pp. 1 and 12, paragraphs 1.1 and 1.41.

the Program (AR-L1032, Operation 1950/OC-AR) in the amount of US\$100 million. SENASA has executed the Program through the “Program Management Unit.”⁴

7. The loan contract was signed on 17 April 2008 and, at the closing date of this report, the Bank had disbursed US\$37,376,231.50 of the first loan⁵ and its corresponding credit line.

8. The aim of the Program and the credit line is “to help bring about a sustained increase in the domestic and international competitiveness of Argentina’s agricultural and agroindustrial sectors. The purpose is to strengthen and expand the country’s capacity to protect and improve agricultural, agrifood, and fisheries health and quality.”⁶ It provides financing for the following components: (a) modernization of institutional management; (b) strengthening of the animal health system; (c) strengthening of the phytosanitary system; (d) strengthening of the agrifood safety system, and (e) regional integration for agricultural health.

1.2.2 Modernization of institutional management component

9. Through the component “Modernization of Institutional Management”, the Program aims to contribute to “moving the organization toward a new management model for agricultural health and agrifood safety.”⁷ Under that component, the Bank has financed crosscutting, institution-wide actions in SENASA that involve: (a) the regulatory framework; (b) computer-based management system; (c) decentralization of operations to the regions; (d) environmental management; (e) institutional communications; (f) human resources training; and (g) laboratory services.

10. In accordance with the lines of action of SENASA’s strategic management plan, one of this component’s priority objectives is to standardize, adapt, update, and harmonize the regulatory framework for SENASA’s work. This includes the standards that regulate the classification and registration of phytosanitary products, including agrochemicals. In this context, SENASA adopted Resolution 466 on 12 June 2008, creating the Regulatory Reorganization Program (PRN). It brings together the Program’s Modernization of Institutional Management component, financed by the IDB, and the Institutional Support of SENASA component of the ALA/2006/18-398 EC-SENASA Agreement, financed by the European Communities.⁸ Thus, the Regulatory Reorganization Program is cofinanced by the IDB, the EC, and SENASA itself.

11. With regard to the PRN, the Bank has disbursed the resources earmarked for preparing SENASA’s Code of Standards (CNS), the aim of which is to “organize and facilitate access to current regulations through an integrated set of regulations prepared

⁴ Id., p. 18, paragraph 3.3.

⁵ Cf. IDB, *Finance Data Mart*. Last access: 23 July 2012.

⁶ Loan proposal, *supra* note 3, p. 1.

⁷ Id., p. 13, paragraph 2.3.

⁸ Cf. SENASA, Resolution 466 dated 12 June 2008.

Available at: <http://www.senasa.gov.ar/contenido.php?to=n&in=1334&ino=1334&io=8011>. Last access: 23 July 2012. SENASA, Presentations at the information exchange session, 17 July 2012.

on the basis of previously established standards, registries, and procedures, in order to ensure reliability by making the resulting information available.”⁹ To carry out these activities, the Executing Agency hired specialized consultants whose activities include, among other things, the analysis and interpretation of national regulations in force in its areas of competence; the drafting of new standards for SENASA; participation in the commissions that analyze, discuss, and draft the texts of administrative regulations; and preparation of the draft administrative procedures submitted to their consideration.

12. Within the framework of the PRN, SENASA began the process to prepare and approve a standard for updating the chapter on Toxicological Classification of Phytosanitary Products, under Resolution 350/99 of the former Secretariat of Agriculture, Livestock, Fisheries, and Food (SAGPyA), which establishes the “Manual of Procedures, Criteria, and Scope for the Registration of Phytosanitary Products in Argentina.” As stipulated in Resolution 466/08, SENASA conducted a national public consultation, between 30 June and 30 August 2011, on the draft resolution to reform SAGPyA Resolution 350/99. On 5 September 2011 a report was published that compiled the inputs received through the consultation, which included the Requester’s statement. However, no report was published on the outcomes of the consultation, and no reasons were given for accepting (totally or partially) or rejecting participants’ suggestions. Based on the draft regulations submitted to public consultation, SENASA adopted Resolution 302 on 19 June 2012, using as its criterion the World Health Organization’s Toxicological Classification of Phytosanitary Products, updated in 2009.

13. The Program’s “Modernization of Institutional Management” component, in its item on environmental management, also provides for the preparation and publication of procedural manuals for environmental management and for final disposal of agrochemicals.¹⁰ These manuals include “good agricultural practices for topics relevant to SENASA and where there is insufficient information and dissemination to ensure proper environmental management,” based on instruments of recognized international organizations (i.e., United Nations Food and Agriculture Organization–FAO; the United States Environmental Protection Agency–EPA, among others).¹¹ One of the publications will be the Manual on Good Practices in the Use of Agrochemicals, which “will include all recommended practices with regard to the use, transportation, storage, and disposal of phytosanitary product waste, in order to minimize the risk of contamination of food for human consumption as prevention measures for public health and environmental care.”¹² The text of the manual, based on the inputs of the different technical departments and recognized international guidelines, has been approved by SENASA, and was at press at the time this report was completed.

⁹ Resolution SENASA 466/08, *supra* note 8, Annex I – Objectives.

¹⁰ Cf. Loan proposal, *supra* note 3, p. 13, paragraph 2.4.

¹¹ Cf. IDB, Environmental and Social Management Report (ESMR), *Proposed Conditional Credit Line (CCLIP) and Individual Loan for the Agrifood Health and Quality Program (AR-L1032)*, 31 July 2007, part two, section 6.5.2.3.

¹² *Id.*, Sección 6.5.2.3.

1.2.3 Possible environmental and social impacts

14. The Project was classified as a Category B operation in accordance with Operational Policy OP-703.¹³ The loan proposal classifies the project's environmental impacts as follows:

(a) The Project's Environmental and Social Management Report (ESMR) of 31 July 2007 identified three types of activities that could have environmental and social impacts: (i) construction works for offices, laboratories, border quarantine control posts, animal quarantine station; (ii) operation of laboratories, border control posts, and quarantine stations, and (iii) phytosanitary pest control campaigns, because of the use of pesticides in the initial stages.¹⁴

(b) "The proposed Program will mainly have a positive socioenvironmental impact, since the purpose of its activities is to improve the country's capacity to protect agricultural health and quality. No significant adverse impacts attributable to the construction of infrastructure, or to the operation of laboratories, checkpoints, or the animal quarantine station, were identified. The impact of construction can be easily mitigated by using good practices."¹⁵

(c) "What potential adverse environmental impacts were identified are related to some of the initial components of the phytosanitary control programs for the fruit fly and the codling moth. The program calls for mitigation measures for the application of agrochemicals to ensure they are used in accordance with international and national standards, and to ensure that containers are handled appropriately."¹⁶

1.2.4 Safeguards

15. The Project Ombudsperson Team verified that, in order to prevent and/or mitigate the aforementioned impacts (paragraph 14 above), the IDB Project Team included in the ESMR the findings of the Program's environmental and social impact assessment; SENASA's institutional capacity assessment; and the Program's preliminary Environmental and Social Management Plan (ESMP).

16. As a safeguard, the IDB required that the Executing Agency conduct an environmental assessment for each project under the Program that could cause "environmental or social harm," and SENASA's Environmental Unit was given the responsibility of conducting a preliminary assessment of each project, preparing their terms of reference, and reviewing each one. It was also charged with conducting environmental impact assessments for projects under the IDB-financed Program that could have "significant and lasting"¹⁷ impacts. Pursuant to OP-703, projects requiring an environmental impact assessment also require public consultation.¹⁸

¹³ Pursuant to OP-703, Category B operations are those that are "likely to cause mostly local and short-term negative environmental and associated social impacts and for which effective mitigation measures are readily available." Although according to policy OP-703 the credit line operation did not require environmental classification, some matters relevant to environmental management were identified.

¹⁴ Cf. ESMR, *supra* note 11, p. 12.

¹⁵ Propuesta de Préstamo, *supra* note 3, p. 24, paragraph 4.13.

¹⁶ *Ibid*, paragraph, p. 28, 4.14.

¹⁷ ESMR, *supra* note 11, p. 31.

¹⁸ Cf. ESMR, *supra* nota 11, p. 32, and section 7.2.

17. Furthermore, the credit line agreement provides that:

During the execution of individual programs, the borrower or the executing agency and the Bank will exchange technical information of mutual interest. The progress of the programs will be discussed, taking into account: (a) the use of the credit line of this agreement; (b) the exchange and dissemination of experiences of mutual interest related to the fulfillment of: (i) the targets, objectives, and outcomes from the framework of indicators agreed upon by the parties; and (ii) the environmental requirements stipulated in the Argentina's legislation and the Bank's policies that are applicable to the programs in progress; and (c) the desirability of introducing any substantial change in the individual programs. Should it be determined that the individual programs are not achieving the expected objectives, the parties will adopt appropriate measures to correct the deficiencies.¹⁹

18. Similarly, the Program establishes that the Borrower should submit for the Bank's approval, among other documents, a midterm report and a final report for the Program, which are to cover, among other information, "the level of compliance with the Program's environmental and social management plan."²⁰

2. Assessment Methodology

19. In order to assess the Request, the Consultation Phase Team carried out the following activities, among others: (a) technical analysis of the documents and information submitted by the Requester, the Executing Agency, and the Bank's Project Team, as well as documents obtained from other public sources, and (b) two missions to Buenos Aires, in May and July 2012, during which Assessment and Dialogue meetings were held with the stakeholders of the case, both jointly and separately.

20. During the meetings, the Consultation Phase Team explained to the parties the ICIM procedure and its different stages. The Project Ombudsperson pointed out that the Request contained matters related to a wide range of goods and interests, and called into question a country's public policies. She explained that there would therefore be limitations on the sphere of action of the Bank and the ICIM to address the issue of agrochemicals in Argentina.

21. The Project Ombudsperson also explained to the parties that the Bank's policy OP-703 and its Implementation Guidelines recognize as valid a number of international instruments on the use and application of agrochemical products and other hazardous materials, including: (a) the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal; (b) the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade; (c) the Stockholm Convention on Persistent Organic Pollutants; (d) the FAO Guidelines on Good Labeling Practices for Pesticides; (e) the FAO Guidelines for Packaging and Storage of Pesticides; (f) the WHO Recommended Classification of Pesticides by Hazard; and (g) the WHO list of banned pesticides, among others.

¹⁹ IDB, *Conditional Credit Line Agreement, Agrifood Health and Quality Management Program (AR-X1007)*, 28 April 2008, Section 13.

²⁰ IDB, *Contrato de Préstamo No. 1950/OC-AR, Programa de Gestión de la Sanidad y Calidad Agroalimentaria*, 17 April 2008, Clause 4.05.

22. On 17 July 2012 the Information Exchange Session was held, following an agenda that reflected the topics identified earlier as being the key issues in this process, and agreed upon by the parties: (a) SENASA's standard-setting program; (b) the classification and registration of agrochemical products; (c) the application of agrochemical products, and (d) the procedures for consultation with the general public and, specifically, the public consultation process on the proposed standards on the review of criteria for the toxicological classification of phytosanitary products. These topics made up the agenda for the Dialogue.



Photo 1: Presentation by the Requester during the Information Exchange Session

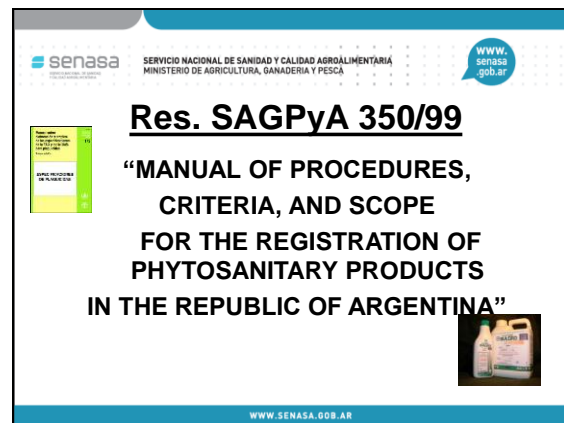


Figure 1: SENASA presentation during the Information Exchange Session

23. The outcomes of the Assessment activities include: (a) the stakeholders in this case were mapped, including their roles and positions; (b) the concerns raised in the Request were identified, clarified, and prioritized; (c) the jurisdictional limits of the Executing Agency was clarified, as was the scope, content, and current status of the Program components; and (d) the Requester's concerns were analyzed, considering their possible connection with the Program and with the Bank's Operational Policies. The findings of the Assessment Phase are described in more detail below, and the outcomes of the Consultation Phase are set out in Section 5 of this report.

3. Stakeholder mapping

24. In identifying stakeholders and their positions, they are classified either as primary or secondary stakeholders. Primary stakeholders are those directly affected by the Program or who have a direct influence on decision-making on the issues raised, and/or on Program design, implementation, and/or operation, in addition to their legitimate representatives. Secondary stakeholders are not directly affected, but have influenced or can influence the setting and/or decision-making of the Program, and/or the solution to the conflict.

25. In this case, the Consultation Team only identified primary stakeholders, whose roles, interests, and positions are summarized below.

26. **Requester.** The Requester is the environmental attorney Dr. Graciela Gómez, who represents presumed victims and/or their family members in various criminal lawsuits filed in domestic courts due to the health damages said to have been caused by the wrongful application of agrochemicals. The Requester confirmed that she has not filed lawsuits that are similar or related to the Request submitted to the ICIM. In addition, she expressed her willingness to participate in the dialogue with SENASA, under the auspices of the Mechanism.

27. **Executing Agency.** The Executing Agency is the National Agrifood Health and Quality Service (SENASA), a decentralized agency and the lead institution for agricultural health in the Republic of Argentina; it operates under the jurisdiction of the Ministry of Agriculture, Livestock, and Fisheries (MAGP).²¹ SENASA's functions include to: "inspect and certify animal and plant products and by-products, agricultural chemicals, and veterinary drugs; and to prevent, eradicate, and control animal diseases, including those communicable to humans, and plant pests that adversely affect the country's agricultural production."²² From the outset, the Executing Agency was very open and cooperative with the Assessment activities of this case, providing all the information needed by the Requester and the Consultation Phase Team. SENASA expressed its willingness to enter into dialogue with the Requester through the process facilitated by the ICIM.

4. Main findings of the Assessment

4.1 Regulatory Reorganization Program (PRN)

28. As mentioned earlier, Resolution 466/08 established SENASA's Regulatory Reorganization Program for the purpose of:

a. Standardizing, adapting, updating, and harmonizing the current regulatory framework for which SENASA serves as the enforcing agency, to increase the familiarity of its staff members and those it administers with the regulatory framework and its use, establishing mechanisms for updating it on an ongoing basis, to include the incorporation of domestic regulations and the harmonization of the standards with international agreements that have been signed, adapting itself to the new reality of Argentinian agribusiness and international trade.

b. Redesigning the current SENASA Code of Standards (CNS) in order to organize and facilitate access to current regulations through an integrated set of regulations prepared on the basis of previously established standards, registries, and procedures, in order to ensure reliability by making the resulting information available.²³

29. The resolution establishes the procedure for developing the PRN, including stages to: (a) define the methodology; (b) review and update the standard, which includes, among other things, reviewing the content of the existing standard and the reformulation

²¹ Cf. SENASA, "*Estrategia Federal, Acción Regional*" [Federal Strategy, Regional Action], 4 May 2007. Available at: <http://www.senasa.gov.ar/contenido.php?to=n&in=126&io=6418>. Last access: 23 July 2012.

²² Loan Proposal, *supra* note 3, paragraph 1.14.

²³ SENASA Resolution 466/2008, *supra* note 8, Annex I.

of standards, and (c) preparation of the new digest –the SENASA Regulatory Code– which includes activities for updating of regulations on an ongoing basis. In addition, Resolution 466/08 defines June 2008 to December 2012 as the execution period for the program.

30. By Resolution 401, dated 14 June 2010, SENASA declared that the first stage of the PRN was complete, meaning that the methodology had been defined and the thematic content of the CNS approved.²⁴

31. According to SENASA, during the PRN process a total of 2237 standards were examined and systematized, and 306 were annulled. In addition, as part of the exercise, from the time the PRN was adopted to the date this report was concluded, SENASA had worked on and issued 136 proposed amendments of standards.

4.1.1 Standard-setting process: preparation, consultation, and entry into force

32. Resolution 466/08 spells out specific procedures and a number of elements that should be contained in the files of SENASA's proposals to amend and adopt new

²⁴ The SENASA Regulatory Code is composed of four books:

(a) Book One – Multilateral and Regional Standards, the contents of which were adopted by SENASA Resolution 242/12. These standards include the Stockholm, Basel, and Rotterdam Conventions (*supra* paragraph 21), which have been ratified by the Argentinian State.

(b) Book Two – National Standards, the contents of which were adopted by SENASA Resolution 234/12.

(c) Book Three – Agrifood Regulations, which is divided into five parts, the contents of which were adopted by different SENASA resolutions: (i) Part One – Agrifood Safety and Quality (Resolution 800/10); (ii) Part Two – Plant Protection (Resolution 31/11); (iii) Part Three – Animal Health (Resolution 738/11); (iv) Part Four – Agrochemicals, Pharmacological, and Veterinary Products (Resolution 913/10); and (v) Part Five – Laboratory and Technical Control (Resolution 325/11).

(d) Book Four – Standards of Procedure, the contents of which were adopted by SENASA Resolution 121/12.

Cf. SENASA, Resolution 401 of 14 June 2012. Available at:

http://www.senasa.gov.ar/Archivos/File/File4815-Res_401_2010.pdf. Last access: 23 July 2012; SENASA, Presentations in the Information Exchange Session, 17 July 2012.

standards.²⁵ In this process, SENASA's technical area (National Directorate of Agrochemicals, Veterinary Products, and Food (DNAPVA)) identifies a problem that requires an updating of a standard, or a new standard. It collects the information stipulated in Resolution 466/08 and requests the Unit of the Office of the President (UP) for authorization to proceed. Once authorization has been received, the internal technical-administrative process begins, including consultation with the sectors that will be regulated by the proposed standard, as well as the relevant areas within SENASA and the MAGP. Based on these consultations, a draft of the standard is arrived at by consensus, then examined by SENASA's Legal Affairs Department to determine its legality, legal consistency, legislative technique, and the relevance of citizen participation. The consultants hired with IDB financing participate in this stage.

33. If the standard creates obligations for third parties, it should be submitted to public consultation. According to Resolution 466/08, there are two exceptions to the requirement of a public consultation: (a) in sanitary emergencies, and (b) when the aim of the proposal is to consolidate an existing standard without substantively changing its content. Since the PRN was adopted, 105 of the 136 standards reformed were submitted to public consultation.

34. If a public consultation is necessary, the Unit of the Office of the President determines whether, in addition to a national consultation, the proposed standard should be submitted to international consultation through the competent mechanisms of the World Trade Organization (WTO). For national consultations, the proposed standard is posted on the SENASA Web site for a period of 30 to 60 days, depending on its complexity. Once the consultation period is over, all inputs received are attached to the project file –from the Web site or in writing at SENASA headquarters– and then forwarded to the Unit of the Office of the President. The file is then forwarded to the technical area that proposed the standard so it can examine the inputs. The technical area may accept –totally or partially– or reject the suggestions from participants, recording in the file the circumstances and reasons for its decision. The technical area then prepares a

²⁵ According to the resolution: The following elements should be contained in the file of a standard being prepared: Clear identification of the activity to be regulated or of the standard to be updated and/or amended. Communication to the President's Unit to facilitate consideration of the measure being advanced, duly set up. National and international background on the subject. Executive summary that specifically states the reasons and/or motives for the proposal and its purpose [...]. Technical and economic rationale of the methodology proposed for regulating the activity [...]. Identification and characterization of the total universe and of the segment targeted by the proposed regulation. Identification of the segments that would not be covered by the proposal, and justification thereof. Identification of the feasibility of implementing it within the agency, including operational, budgetary, human resources considerations, etc.[...]. Proposal of how to implement the measure over time, indicating the possible and/or necessary time periods for implementing it totally or partially. Identification of the geographical area covered by the measure and, if need be, of the entities and/or agencies that will need to participate in executing it. Outcomes of consultations with the agencies, entities, sectors, commissions, and/or working groups involved in the topic addressed by the proposal, duly documented with a copy of the corresponding background information. Copy of the regulatory background information of the measure. Proposed standard [...]. If the proposed standard modifies and/or expands the terms of another standard or other preexisting standards, consideration should be given to drafting a new comprehensive and consolidated text of all the regulations governing the matter. SENASA Resolution 466/2008, *supra* notes 8, Annex II.

final draft of the standard and forwards it to the Unit of the Office of the President, which continues with the process to adopt the standard and, if appropriate, to give legal force to the standard in due course, based on considerations of timeliness, merit, and advisability. Once signed, the standard is sent to the Official Bulletin for publication.

35. At present, citizens can access the outcomes of a consultation by the following means: (a) reviewing the inputs from all the participants on the SENASA Web site and then checking if the inputs were or were not included in the standard approved and published in the Official Bulletin, or (b) requesting to see and/or receive a copy of the standard's processing file, which will contain the inputs, the technical area's analysis of same, and the approved standard.

4.2 Registration of phytosanitary products

36. SAGPyA Resolution 350 of 1999 establishes the "Manual of Procedures, Criteria and Scope for the Registration of Phytosanitary Products in the Republic of Argentina" (hereinafter "the Registration Manual") for the purpose of "approving their sale and use [including agrochemicals] after evaluating sufficient scientific data that demonstrate that the product is effective for its proposed purpose and does not involve undue risks to health and to the environment."²⁶ This instrument is based on the "Manual on Development and Use of FAO Specifications for Pesticides" of 1995.

37. SENASA is the competent authority for the registration of phytosanitary products in Argentina, through the Registro Nacional de Terapéutica Vegetal [National Registry of Plant Treatment] (RNTV). To register a product, SENASA examines "the physical and chemical properties of the product, its effectiveness, its potential capacity to produce toxic effects on human health and the environment, labeling, and packaging."²⁷ The registration procedure and requirements will depend on the type of substance or product to be registered in the RNTV, classified as follows: (a) registration of new active chemical and biochemical substances, on an experimental or definitive basis; (b) registration of active chemical and biochemical substances equivalent to others already registered; (c) registration of formulated products with new active chemical or biochemical substances; and (d) registration of formulated products with active substances equivalent to others already registered. In any of these cases, SENASA analyzes the composition of the product in the form it will be commercialized. It therefore takes into account for purposes of registration –and toxicological classification– the product's active ingredient, adjuvants, and inert components, as well as the effects of this combination in the end product.

38. Among other requirements for registering new substances, SENASA requires a toxicological endorsement by a group of experts accredited with SENASA, which is to report on the toxic effects of the substance or product on mammal species. Final

²⁶ Secretariat of Agriculture, Livestock, Fisheries, and Food (SAGPyA), Resolution 350 of 30 September 1999, "Manual de Procedimientos, Criterios y Alcances para el Registro de Productos fitosanitarios en la República Argentina," Annex, paragraph 1. Available at: <http://www.senasa.gov.ar/contenido.php?to=n&in=1043&io=4375>. Last access: 23 July 2012.

²⁷ SENASA, presentations at the Information Exchange Session, 17 July 2012.

registration of the new substance or product will also require an ecotoxicological endorsement, by which the endorsing group will report on toxic effects on the abiotic environment and on other species. The purpose of these endorsements is to review and, if need be, to validate the studies submitted by the party seeking to register the product, which come from domestic and/or foreign laboratories accredited by SENASA.

39. In issuing these endorsements, toxicology and ecotoxicology experts must be registered with the “Registry of Independent Professionals Specialized in Toxicology and Ecotoxicology.” To be so registered, they must meet a series of requirements, including a minimum ten years of professional service, and a minimum of five years professional experience in the relevant subject areas. Registered professionals may not issue endorsements for their employers, social contacts, or relatives.²⁸

40. Taking into account these studies, SENASA classifies the product in accordance with its hazard and indicates what information must be stated on the product label and the instructions for use.

4.2.1 Responses to the Requester’s concerns about the registration of phytosanitary products

41. From the information provided by the Parties it follows that the registration –and toxicological classification– of agrochemical products is performed on the end product sold on the market (paragraph 37). Accordingly, SENASA not only considers the active ingredient, but also the coadjuvants, the inert components, and the synergies created among them.

42. With regard to possible conflicts of interest of the toxicology and ecotoxicology specialists, the Project Team and the Consultation Phase Team explained to the Requester that that issue is not related to the Program’s components. This notwithstanding, SENASA stated that, in addition to the guarantee provided for in the standard creating the Registry of Professionals, it will seek other ways to ensure that the specialists meet those requirements.

4.3 Toxicological Classification of Phytosanitary Products

4.3.1 Previous system

43. SAGPyA Resolution 350/99 adopted the 1995 toxicological classification of the World Health Organization (WHO-95), which uses the product’s acute toxicity as the reference, for the purpose of the registration of phytosanitary products.

²⁸ Cf. Argentinian Institute of Plant Health and Quality, Resolution 359 of 10 September 1996, *Registro de Profesionales Independientes Especializados en Toxicología y Ecotoxicología* [Registry of Independent Professionals Specialized in Toxicology and Ecotoxicology], Articles 2 and 15.

44. The WHO-95 classification is based on the median lethal dose (LD50) and the median lethal concentration (LC50);²⁹ it divides products according to whether they are solids or liquids; and has five toxicological categories, characterized by color and by phrase, as shown in Table 1.

4.3.2 Current system

45. As part of its Regulatory Reorganization Program, SENASA resolved to amend Chapter 20 (Protocols and Tables) of SAGPyA Resolution 350/99, specifically the criteria for establishing the toxicological classification of products to be registered in the Phytosanitary Product Registry (paragraph 43). By Resolution 302 of 22 June 2012, SENASA adopted the most recent version of the WHO-recommended Toxicological Classification, revised in 2009 (WHO-09), adding to it the colors corresponding to the WHO-95 classification.³⁰

46. This updated classification is based on the hazard of the product, and its criterion for analysis is the acute median lethal dose (LD50), oral or dermal toxicity in rats, depending on whether the product is commercialized as a solid or a liquid.³¹ As updated, products with 5000 mg/kg test limits will be classified as Band IV (green) (“normally harmless”), and products with a 2000 mg/kg test limit will be classified as Band III (blue) (“slightly hazardous”). Thus, the new classification is stricter than the previous one (see Table 2).

²⁹ LD50 represents the individual dose of a substance that causes the death of 50% of a group of test animals due to exposure by any means other than inhalation. This dose is usually expressed in milligrams (mg) of material per kilogram (kg) of weight of the test animal. For its part, LC50 represents the concentration, statistically calculated, of a substance that can be expected to cause the death, during exposure or within a specified period of time after exposure, of 50% of the tested animals during a given period of time. It is usually expressed in milligrams (mg) of the substance per liter (L) of normal air. Cf. SENASA, presentation at the Information Exchange Session, 17 July 2012.

³⁰ Cf. SENASA, Resolution 302 of 22 June 2012, that amends Resolution 350/99, related to the “Manual de Procedimientos, Criterios y Alcances para el Registro de Productos Fitosanitarios en la República Argentina” [Manual of Procedures, Criteria, and Scope for the Registration of Phytosanitary Products in the Republic of Argentina]. Available at: <http://www.senasa.gov.ar/contenido.php?to=n&in=1526&io=20687>. Last access: 23 July 2012.

³¹ SENASA Resolution 302/12 also contains provisions on the following: common criteria to be considered for laboratory studies submitted in relation to the registration of plant health products, based on the EPA’s provisions, and (b) criteria for laboratory studies submitted for the purpose of registration, taking into account the guidelines of the Organization for Economic Cooperation and Development (OECD) on acute oral toxicity, acute dermal toxicity, inhalation toxicity classification, dermal irritation, ocular irritation, and cutaneous sensitization. Cf. SENASA Resolution 302/12, *supra* note 29, Articles 3 and 4.

Table 1. WHO-95 Toxicological Classification. Source: SENASA

CATEGORY (WHO)	HAZARD CLASSIFICATION		ORAL	LIQUID mg/kg	DERMAL	LIQUID mg/kg
			SOLIDO mg/kg		SOLIDO mg/kg	
Ia Extremely hazardous (red band)	Very Toxic 		5 or less than 5	20 or less than 20	10 or less than 10	40 or less than 40
Ib Highly hazardous (redband)	Toxic 		More than 5 to 50	More than 20 to 200	More than 10 to 100	More than 40 to 400
II Moderately hazardous (yellow bank)		Harmful (black)	More than 50 to 500	More than 200 to 2000	More than 100 to 1000	More than 400 to 4000
III Slightly hazardous (blue band)	Caution		More than 500 to 2000	More than 2000 to 3000	More than 1000	More than 4000
IV Products not normally hazardous (Green band)	Caution (black)		More than 2000	More than 3000	-----	-----

Table 2. WHO-09 Toxicological classification with color-coding. Source: SENASA

		ORAL	DERMAL
Ia	Extremely hazardous	<5	< 50
Ib	Highly hazardous	5 to 50	50 to 200
II	Moderately hazardous	50 to 2000	200 to 2000
III	Slightly hazardous	More than 2000	More than 2000
IV	Unlikely to present acute hazard	5000 or more	5000 or more

47. In addition, Resolution 302/12 provides that the DNAPVA must consider all updates or changes introduced by WHO for improving safety, reducing hazard, and protecting applicators' safety.

4.3.3 Responses to the Requester's concerns about the toxicological classification of phytosanitary products

48. From a reading of Resolution 302/12, it follows that the suggestions of the Requester (and of other people and citizens that participated in the consultation) were not taken into account at all by SENASA. In this connection, the Executing Agency explained to the Requester that the Government of Argentina decided to adopt the WHO-09 Toxicological Classification. The Executing Agency also pointed out that, although a great deal remains to be done in this area, the recent amendment of the relevant chapter of Resolution 350/99 marks progress toward greater protection of the environment and health. For its part, the Consultation Phase Team emphasized that the Bank's policy OP-703 and its Guidelines for Implementation mention WHO-09 as a valid instrument for toxicological classification. Thus, although the Program does finance legal consulting services and other activities that could have an impact on changes in and/or application of the aforementioned standard, international parameters are being followed, which means that noncompliance with OP-703 does not seem likely.

49. In addition, it was once again pointed out that the toxicological classification and registration of agrochemical products are based on the end product to be commercialized, and includes analysis of the active ingredient, coadjuvants, inert components, and the effects of the combination thereof (paragraph 37).

50. Regarding the Requester's concerns about: (i) the inappropriate application of a combination of two or more products that were registered separately with SENASA, and (ii) the non-lethal doses of agrochemical products that accumulate in humans and in the environment, it was discussed and agreed that these issues have more to do with the application of the products and not with their classification and registration (paragraphs 55 to 57).

4.4 Public Consultation on Resolution 302/12

51. Pursuant to the procedures stipulated in Resolution 466/08 on the PRN, the proposed standard that culminated in Resolution 302/12 was submitted to national public

consultation between 30 June and 30 August 2011. The public consultation in this case concerns the Program component “Modernization of Institutional Management.”

52. Of the total of responses, 261 stated they were against the proposed resolution, four were in favor of it, and the remaining five submitted specific and objective observations. Most of the inputs, including those submitted by the Requester, opposed the proposed standard, stating that: (a) substituting the toxicological classification of current pesticides by hazard and values with the WHO-09 toxicological classification uses the same DL50 method of the current classification; (b) the WHO itself does not guarantee the classification and indicates that its criteria only serve as a supplementary guide, and (c) the classification is based on outdated and biased research, and does not take into consideration important studies conducted by independent researchers in Argentina and other countries.

53. As indicated earlier (paragraph 12), the results of the consultation were not published; this notwithstanding, options do exist for the public to find out whether the suggestions were accepted or not by SENASA, namely: request to see the file of the standard-setting process, or check the final approved standard (paragraph 35).

4.4.1 Responses to the Requester regarding the public consultation

54. In the opinion of the Requester, failure to disseminate the results of the consultation is in noncompliance with Argentina’s environmental regulations (paragraph 4). The relationship between this and the Bank’s Operational Policies is found in Section B.2 of policy OP-703 that states that “[the] Bank will also require the borrower for that operation to ensure that it is designed and carried out in compliance with environmental laws and regulations of the country where the operation is being implemented.” However, the Executing Agency holds that its standards are of a sanitary nature, and are framed by the WTO Agreement on the Application of Sanitary and Phytosanitary Measures,³² and therefore “compliance with environmental laws is a separate issue.” In any case, SENASA will deliver the Requester a report summarizing the outcomes of the public consultation within the next 30 days, and will study a way to disseminate the outcomes to the other persons who participated in the consultation. In addition, the Executing Agency declared that as, a result of this process, it will analyze a new procedure for disseminating to the citizens the results of future public consultations.

4.5 Application of agrochemical products

55. The provinces are responsible for regulating the use of agrochemicals in their territories. Currently, standards for this are in place in 23 provinces. Although there is a National Registry of Applicators, it is not used by applicators and is therefore not implemented, since applicators can register with the Provincial Registries of Applicators. In general, provincial registries require the following for the registration of terrestrial and aerial applicators: description of the equipment to be used, training course, have the support of a responsible expert agricultural engineer; terrestrial applicators must also

³² The agreement was approved by national law when the Argentinian State approved the Marrakesh Agreement with the outcomes of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT).

submit reports on their applications. In addition, aerial applicators must be authorized by Argentina's Air Force for the equipment and for the pilot of the fumigator plane. Despite these requirements, it is difficult for the appropriate state bodies to supervise the applicators, primarily terrestrial applicators, because they work in various provinces.

56. For this reason, SENASA has proposed to the Phytosanitary Federal Commission (CFF) that a National Integrated Registry System be created to centralize, at the national level and through the DNAPVA, all registration information on applicators in each province. SENASA proposes that each province administer the information in its registry, which will make up a single data base administered at the federal level. This proposal is still under discussion at the CFF. Proposals have been added to it for joint activities between the Nation and the provinces to provide training on the correct use of agrochemicals; make available to the public basic information on applicators registered in the provinces; and the requirement that applicators use GPS.

4.5.1 Responses to the Requester on the application of agrochemicals

57. The Executing Agency and the Bank's Project Team agree with the Requester that the main risk is not the toxicological classification of agrochemical products but their application. They therefore decided to analyze possible activities in the area that could be incorporated into the Program, such as disseminating information, conducting sensitization campaigns, and offering training for applicators, provincial and municipal employees, and the general public.

5. Main outcomes of the Consultation Phase

58. As a result of the exchange of information and the dialogue process, the Parties signed an Agreement of Understanding on 18 July 2012 (Annex 1), the most salient parts of which indicate that:

(a) Recognizing that some of the concerns raised by the Requester are also institutional concerns of the highest order, SENASA ratified its intention to address, within the framework of its authority and current legal system, the issues raised by the Requester;

(b) The Requester expressed her satisfaction with the content of the agreement of understanding, considering that it addresses the concerns in her Request, given the jurisdictional limits of SENASA and the Bank, the international standards recognized by OP-703, and the content and scope of the Program's components;

(c) SENASA is studying a new procedure for reporting to the citizens on the outcomes of the public consultation held within the framework of the PRN;



Photos 2 and 3: Signing of the Agreement of Understanding

(d) The Executing Agency will consider new ways to ensure that the toxicology and ecotoxicology specialists that issue the necessary endorsements for the registration of phytosanitary products do not have potential conflicts of interest with the party interested in registering the product they have been asked to endorse; and

(e) The IDB Project Team and SENASA will consider new training and sensitization activities that can be incorporated into the Program in order to support the provinces and the municipios in promoting the correct use and application of agrochemicals.

59. In view of the mutual trust rebuilt between the Parties as a result of the dialogue process, the Parties agreed that the commitments in the Agreement of Understanding will be monitored by the Bank's Project Team. The Project Team will send periodic information in writing to the Requester, with a copy to the ICIM, on the progress of the aforementioned commitments.

6. Conclusions

60. The parties expressed their satisfaction with the process and its outcomes, which are set out in the Agreement of Understanding. For her part, the Requester recognizes that her concerns exceed the scope of the Program and that the replies to same, given the scope of jurisdiction of SENASA, the IDB, and the Mechanism, have been satisfactory. In accordance with all of the above, the Project Ombudsperson closes the Consultation Phase and, pursuant to ICIM policy, will file the case with the Office of the Executive Secretary.

ANNEX 1 – AGREEMENT OF UNDERSTANDING

Independent Consultation and Investigation Mechanism

Consultation Phase

Agrifood Health and Quality Management Program (AR-MIC1004/2012)

AGREEMENT OF UNDERSTANDING

1. BACKGROUND

1. In January 2012, the Independent Consultation and Investigation Mechanism (ICIM) received a Request from Mrs. Graciela Gómez (Requester), regarding the Agrifood Health and Quality Management Program (“the Program”), financed by the Inter-American Development Bank in Argentina. The borrower of the Program is the Government of the Republic of Argentina, and the Executing Agency is the National Agrifood Quality and Health Service (SENASA).

2. Before the Determination of Eligibility, the Projects Ombudsperson applied Section 40(h) of the Policy of the MICI and paused the analysis to afford Bank Management the opportunity to directly contact the Requester regarding the concerns expressed in her Request in order to address them. Accordingly, the Requester and the IDB Project Team met in Buenos Aires to discuss the contents of the Request and, subsequently, exchanged correspondence regarding the Program. At the conclusion of the period granted to Management, in March 2012 the Requester expressed her decision to continue the process with the ICIM.

3. On 23 April 2012, the Ombudsperson determined that the Request was **Eligible for the Consultation Phase**. Consequently, the Assessment Phase was begun for the purpose of collecting more technical information as well as information on the Program vis-à-vis the different aspects of the Request; identify the stakeholders in the case; and assess whether conditions were suitable for initiating a dialogue on the impacts alleged by the Requester. During this stage, the Consultation Phase Team carried out the following activities, among others: (i) technical analysis of the information submitted by the Requester, the Executing Agency, and the Bank’s Project Team, as well as documents obtained by the Ombudsperson’s team, and (ii) two missions to Buenos Aires, in May and in July 2012, during which the Consultation Phase Team met with the parties (the Requester and the Executing Agency), both jointly and separately.

4. Given the particular nature of the case, the availability of the Executing Agency, the Requester and the Bank, and in order to facilitate a more efficient process, the Ombudsperson proposed to the parties to initiate certain activities typical of the dialogue process during the Assessment Phase. On 17 July 2012 the Information Exchange Session was held, in accordance with an agenda that reflected the topics identified earlier

as being the key issues in this process, and that were agreed upon by the parties: (a) SENASA's standard-setting program; (b) the classification and registration of agrochemical products; (c) the application of agrochemical products, and (d) the procedures for consultation with the general public and, specifically, the public consultation process on the proposed standards on the review of criteria for the toxicological classification of phytosanitary products.

5. The topics referred to in the above paragraph concern the Program component entitled "Modernization of Institutional Management," as well as the Bank's Environmental and Safeguards Compliance Policy (OP-703). Further details on the analysis of these topics and their possible relationship to the Program and to policy OP-703 can be found in the Assessment Report of this case.

2. UNDERSTANDINGS AND COMMITMENTS

6. Recognizing that some of the concerns raised by the Requester are also institutional concerns of the highest order, SENASA reaffirms its intention to address, within the framework of its jurisdiction and current legal system, the issues addressed by the Requester.

7. For her part, the Requester expresses her satisfaction with the contents of this agreement, considering that the concerns contained in her Request are being addressed within the framework of the jurisdictional limits of SENASA, the Bank, and the Mechanism; the international standards recognized by policy OP-703; and the content and scope of the Program's components.

8. **Toxicological classification of phytosanitary products.** The parties agreed that SENASA Resolution 302/2012, which updated the corresponding chapter of SAPGyA Resolution 350, of 30 August 1999, in accordance with the toxicological classification of pesticides established by the World Health Organization (WHO) in 2009, represents progress over the previous standard. In addition, they recognize that the WHO parameters are mentioned as valid criteria in IDB policy OP-703. For her part, the Requester reaffirmed her understanding that the WHO parameters are only guiding recommendations; that they are not based on the most recent studies of agrochemicals; and they do not consider non-lethal doses that are cumulative and that, in the long term, create serious health hazards for the environment and for human health.

9. **Registration of Agrochemical Products.** SENASA clarified that, in registering agrochemical products, an analysis is made of the active ingredients as well as the adjuvants and inert ingredients of formulated products. This notwithstanding, SENASA is not responsible for, nor is it authorized to, control the application and undue use of these products in quantities not recommended or combinations of different products registered separately. The parties shared concerns about the incorrect application of agrochemicals, and of the controls exercised during and after their application. As part of the discussion of the registration of agrochemical products, the Requester expressed her concern about possible conflicts of interest in the groups that perform the toxicological and ecotoxicological endorsements required by SENASA for the registration of phytosanitary products. In this regard, the parties agreed on the need to strengthen mechanisms to

prevent potential conflicts of interest for these professionals, to which end SENASA will take the necessary steps.

10. Application of Agrochemical Products. The parties agreed that the harm caused by agrochemicals usually result from incorrect use. They therefore underscored the need to give active support to the municipalities and the provinces, which are the bodies responsible for overseeing the use and application of agrochemicals. SENASA agreed, with Program support, to develop training and sensitization activities on the hazards related to the application and use of these products for municipal and provincial employees, farmers, applicators, and civil society in general. Activities proposed by SENASA include dissemination of a Manual on Good Practices in the Use of Agrochemicals; informational workshops and sensitization campaigns; and support for efforts to implement a single national registry of aerial and terrestrial applicators.

11. Public Consultation. Regarding the public consultation process on the proposed standards that revised the criteria for toxicological classification of phytosanitary products – now SENASA Resolution 302/2012 – the Requester insisted on the need to receive information on the analysis and outcome of the inputs provided by civil society. SENASA explained that, to date, the institutional practice has been to return results by: (a) the review –or not– of the standard and its publication; and (b) copy of the process file, by requesting to view it. Motivated by the Request, and as an outcome of this dialogue process, SENASA is preparing a formal and systematic procedure for informing civil society of the outcomes of public consultations related to its proposed standards. SENASA hopes that this procedure will be in force for new consultations. This notwithstanding, for this case, SENASA is considering how to more broadly disseminate Resolution 302/2012, given that the Official Bulletin is not a source normally consulted by the general public.

5. MONITORING OF THE COMMITMENTS

12. The Bank's Project Leader will monitor the commitments of this agreement, keeping the parties and the Mechanism informed.

13. This agreement is signed by the Requester and the Executing Agency, as parties to this case, and by the IDB, as observer.

Buenos Aires, 18 July 2012

Requester: (Signature) (Stamp: Graciela Cristina Gómez, Attorney)

Executing Agency: (Signatures)

IDB Project Team: (Signatures)

ICIM: (Signature) (Isabel Lavadenz - Ombudsperson)