STDF PROJECT PREPARATION GRANT (PPG)

APPLICATION FORM

The Standards and Trade Development Facility (STDF) provides Project Preparation Grants (PPGs), up to a maximum of US$50,000, for the following purposes (or a combination thereof):

- application of SPS-related capacity evaluation and prioritization tools;
- preparation of feasibility studies that may precede project development to assess the potential impact and economic viability of proposals in terms of their expected costs and benefits; and/or
- Preparation of projects proposals that promote compliance with international SPS requirements, for funding by the STDF or other donors.

Applications that meet the STDF's eligibility criteria are considered by the STDF Working Group, which makes the final decision on funding requests. Complete details on eligibility criteria and other requirements are available in the *Guidance Note for Applicants* on the STDF website (www.standardsfacility.org). Please read the *Guidance Note* before completing this form. Completed applications should be sent by email (as Word documents) to STDFSecretariat@wto.org.

PPG Title	**Development of information resource on veterinary drug residues to support trade in safe products of animal origin**
Budget requested from STDF	$48,710 PPG, $27,540 stakeholder workshop
Full name and contact details of the requesting organization(s)	CABI, Nosworthy Way, Wallingford, Oxfordshire, OX10 8DE, United Kingdom
Full name and contact details of contact person for follow-up	Mr. Robert Taylor, Head of Veterinary Market Development, CABI, Nosworthy Way, Wallingford, Oxfordshire, OX10 8DE, United Kingdom Tel: +44 (0)1491 829450 Email: r.taylor@cabi.org

I. BACKGROUND AND RATIONALE

1. What is the purpose of this PPG? Explain whether it is requested to: (i) apply an SPS-related capacity evaluation or prioritization tool; (ii) prepare a feasibility study (prior to project development) to assess the potential impact and economic viability of proposals in terms of their expected costs and benefits; and/or (iii) prepare a project proposal for consideration by the STDF or other donors?

The purpose of the PPG is to conduct a feasibility study into the potential of creating a global information resource on veterinary drug residues (a Global Veterinary Drug Database; GVDD) to safeguard human health and to support trade in safe animal products. This feasibility study will provide an informed basis for the development of a business plan and full proposal for a project to create this information resource. It will assess the potential

impact and benefits that could be realised as a result of providing a global information resource that complements existing datasets, such as the Codex Alimentarius and JECFA databases. It will identify target users and their information needs, test the economic viability in terms of costs and economic benefits of the concept, and the business plan will identify wider stakeholder and donor partners who would support long term sustainability.

2. Explain the key SPS problems and/or opportunities to be addressed. Clarify why these issues are important, with attention to market access and poverty reduction. Describe, if relevant, how these issues relate to SPS priorities in the Enhanced Integrated Framework's Diagnostic Trade Integration Studies (DTIS), the findings of SPS-related capacity evaluations, national poverty reduction strategies, sector development strategies or policies, etc. See Qn. 7. (b) – (d) of the Guidance Note.

Background and problem statement

Trade is the 'lifeblood of global economies' (DFID, 2011[1]), driving economic growth and reducing poverty. Increasing a country's trade by 10% can raise national income by 5% (Feyrer, 2009[2]). As a consequence, there is now more emphasis than ever in international development on promoting trade and developing trade capacity.

Global population growth, urbanization and higher incomes in developing countries are fuelling a large increase in demand for food of animal origin. Livestock systems currently occupy 45% of the global surface area and have a value of at least $1.4 trillion, and represent a significant source of livelihoods. The sector employs at least 1.3 billion people globally, and with the growth in animal protein demand, could provide increased income for many national economies and the rural poor.

The level of milk and meat consumption in the developed world is at least five times higher than in the developing world, but demand in developing countries is raising rapidly mainly as a consequence of growth of human population and rising incomes. Livestock pose a risk to human health in both high and low intensity production systems. As well as the risk of zoonotic diseases from livestock, food contaminated with residues of veterinary drugs is also a risk to human health.

Standards for food safety and animal health exist to safeguard human health, but can be seen as a non-tariff barrier to trade in live animals and livestock products. A key concern is the ability of exporters to know about the standards of their target market, and to implement procedures to ensure their products meet them. Advanced technologies and information are not equally available to all producers and small holders, or between countries; those with poor access to the latest information and regulatory standards find themselves unable to compete on an equal basis.

Contamination of food of animal origin is a major concern for all parts of animal agriculture and food production. The misuse of drugs can damage reputations of producers as well as lead to an increase in drug resistant bacteria, threatening human health. Residues in the animal protein chain are a food safety issue, can raise production costs, damage reputations, close off international trade and threaten human health. In addition to the adverse food safety implications of tissue residues in meat, milk and eggs, such residues

[1] DFID; The engine of development: The private sector and prosperity for poor people.

[2] Feyrer, J. Trade and Income – Exploiting time series in Geography. NBER Working Paper Series, Working Paper 14910, 2009

have negative economic consequences for producers because they violate regulatory limits in destination countries resulting trade barriers for their products. For example, in 2011 a Namibian feedlot that exports to Germany was banned from exporting to the Europe after EU inspectors found phenylbutazone in their pharmacy. The drug is licensed for use in South Africa and Namibia, but banned in food animals in the EU. The discovery led to the halting of a shipment of 6000 carcasses, for which another market had to be found. This expensive problem could have been avoided if the exporting company had access to information on drugs that are banned in their export market, and how they could avoid breaking the rules.

In a study by J. S. Wilson, et. al. (2003[3]), analysis found that if international standards set by the Codex were followed in antibiotics, global trade in beef would rise by more than $3.2 billion. Information on withdrawal times that would be provided by a veterinary drug resource such as the proposed GVDD would enable the producing countries to meet international standards and still use veterinary drugs to maintain health of their livestock.

An international consultation in 2010

In 2010 CABI and FARAD organized an international consultation (funded by the US Food and Drug Administration) into the need for a GVDD. The consultation involved OIE, EU regulatory bodies, pharmaceutical companies, and academic researchers. The aims and outcomes of the consultation are listed in section 4.

The 2010 consultation established that the GVDD should aim to bring together existing datasets [such as Codex and JECFA databases] combining them with FARAD and CABI data rather than building completely new datasets, so as to avoid a duplication of purpose and effort. A primary aim would be unification of existing data sets in a way that they complement each other.

Project feasibility study

There is currently a robust databank of information on drug residues, and withdrawal times for veterinary drugs (including extra-label drugs) used in the USA and this is accessible both on the web (www.farad.org) and as an "app" on mobile platforms. What is lacking is a similar resource covering the residues, regulations and withdrawal times for drugs used in food animals from other developed and developing countries. FARAD has previously defined the data elements required for such a database.

The proposed Global Veterinary Drug Database (GVDD) will provide information on veterinary drug residues, including withdrawal times, needed by producers to prevent the persistence of drug residues entering the food chain and being present in their end products creating a health risk for consumers.

Work carried out with support from this PPG will result in a feasibility study and report that will outline the business plan for the development of a full project proposal for the creation of a database/information resource that will support both developed and developing countries in improving market access for safe products of animal origin. The feasibility study will include the development of a prototype, a user-needs survey, and a stakeholder workshop to evaluate and review the concept, prototype and business plan. The objectives of the full project would be:

[3] Balancing food safety risk: do drug residue limits affect international trade in beef? American Agricultural Economics Association Annual Meeting, Montreal, Canada, July 27-30,

- increasing awareness of regulatory requirements and standards for the use of veterinary drugs and avoidance of residues in animal products

- providing guidance on withdrawal times for drugs used in food animals before their products can be considered safe for human consumption

- promoting compliance for residue levels with the food safety standards in importing countries, to facilitate trade

- Improving the safety of food of animal origin for domestic consumption and international trade

Under the period of the PPG we will produce a prototype covering a specific area of production, a set number of drugs, and a limited number of countries. The prototype GVDD will focus on dairy systems and will define the specifications of the key components, its delivery, and sustainability. Dairy systems have been chosen as an example because they are relevant in most parts of the world, and drug residues in milk are a recognized problem. It will also identify users, stakeholders and other beneficiaries. The development of the business plan for the full proposal will be done in close consultation with key food safety and public health stakeholders (FAO, OIE and WHO – referred to as the 'key stakeholders' in this proposal) to ensure the GVDD complements existing resources. The business plan will be evaluated and reviewed at an international workshop involving stakeholders and experts in the field including the key stakeholders and representatives of EFSA, AU-IBAR, food industry, and drug regulators, leading to a robust proposal and agreed business plan for the full project to create the GVDD.

The PPG will work on a specific dataset using a number of key drugs used in dairy production, and regulatory data from a sample of countries, to test out the concept of the GVDD and inform the design of the database that will aim to cover all drug residues in meat, milk and eggs.

The initial drugs would include:

Antibiotics	ceftiofur, enrofloxacin, penicillin G, sulfamethazine and tetracycline
Non-Steroidal Antiinflammatory Drugs	flunixin, ketoprofen and meloxicam, phenylbutazone
Antiparasitics	albendazole, ivermectin, and permethrin
Hormones	dinoprost, oxytocin and melengestrol acetate (MGA)

The prototype will include data from sample countries (initially it is suggested that we include 2-5 sample countries) which will identify the range of information that will be included in the GVDD. Countries would be selected from dairy producing regions including developed and developing countries, and could include developing countries with seasonal fluctuations in production looking to take advantage of the export trade opportunities. Countries would be selected to provide a good comparison of capacity and the potential positive impact of the database to be gauged for each. Initial discussions between CABI and FARAD suggest that they could include USA, European Union countries, South Africa, and representation from East Africa (Ethiopia, Uganda and Rwanda). Data from participating countries will include rejection rates, incidents, cost of loss, potential impact on human health and trade.

The prototype development phase will firstly define what information is currently available and, secondly, how it could be efficiently collected, updated and presented. The prototype will provide essential information on the workflows required to collect pharmacokinetic data, and regulatory information, and inform the decision on the ideal frequency for updating it.

The database content

The content that would be included in the Prototype includes the following information, which would be accessible via the online user interface, and retrievable via searches or dropdown menus. The final specifications of the GVDD will be approved of by the stakeholder workshop. They will include components such as:

- Drugs that are approved for use in food-producing animals (by country)
- Withdrawal times (by dose, formulation, indication, destination country)
- Special precautions (e.g., repeated injections for flunixin; aminoglycosides; the effect of disease)

- Restrictions on the use of drugs in food-producing animals
- National or regional regulations restricting particular drugs
- Drugs that are illegal for use in food-producing animals
- Restrictions on extra-label use

- Rapid tests for residues in milk (by drug)
- Suitability of these tests for products in different countries and regions
- Accurate drug recognition and identification of counterfeit drugs (e.g. Photographs of formulation packaging, Bar codes, QR codes)

Information for the prototype database should be drawn from a range of reliable sources; FARAD, CABI and access to datasets from other organizations will be sought and agreed (Codex Alimentarius, JECFA databases and others). The relationship between the GVDD and existing databases will be included in the business plan, and considered for approval at the Stakeholders Workshop. Identifying the exact sources of information and the criteria for collecting the information will be determined during the PPG period with the advice of the key stakeholders, and presented to the Stakeholder Workshop for evaluation.

Database Users

As the first step in building the business plan we will identify who the main users are and determine their needs from the GVDD. This will be done using a combination of on-line surveys and telephone interviews: CABI's contacts in AU-IBAR, as well as in veterinary and regulatory services and food industry in a number of countries, including CABI Member countries.

Based on experience with the FARAD Database we envisage that the main user groups will be:

- Producers (Farmers, dairy companies/cooperatives, meat companies)
- Food Product Manufacturers
- Food companies, food exporters, food importers
- Researchers
- Veterinarians

- Animal Health Technicians, meat inspectors
- Regulators, sanitary (public health) inspectors, quarantine officers

The user-needs assessment survey will also investigate the most appropriate delivery channel for the different database users, taking into account factors such as geography, language and connectivity, to determine how best they can access the information in the GVDD .

Delivery method

Based on an initial consideration of user requirements, the GVDD should be available for users via the internet and accessible by mobile devices. The experience of FARAD indicates that producers and technicians/veterinarians find the mobile version of FARAD's database in the US more appropriate, whereas regulators, being office-based, prefer the full online version. The information database could be organized to provide different layers of information accessible to different users. The user interface will be designed with the end user in mind, which will take into consideration factors such as literacy, cultural and language barriers.

The Database Content

Note: Food producing animals includes aquaculture species.

An important aspect of the feasibility study will be to address the issue of collection of the data, with a special emphasis on developing countries. Aspects to be addressed during the PPG period will be the accessibility of in-country data, work-flows to include such data in the GVDD, and the existence and availability of other collections of residue data (e.g. data collected and held by multi-national food companies).

Sustainability and business model

The PPG period will be used to create a business plan to address the funding of the development of the GVDD and to ensure its sustainability. The 2010 International Consultation recommended that the GVDD should be free at the point of use and that we should look for funding from a public-private consortium. A model for the funding and sustainability will be included in the business case and will be considered and decided upon at the Stakeholder Workshop.

Deliverables and Outcomes

The main outcome from the PPG will be a robust project proposal and business plan with the support of key stakeholders including FAO, WHO, OIE, EFSA, food industry and drug regulators. This would be delivered to STDF and other donors via consultations following the Stakeholder Workshop.

The full project proposal will be supported by

- A prototype of the GVDD completed during the PPG period based on data from a sample of veterinary drugs of relevance to the dairy sector, and dairy producing countries
- Component specifications of a fully functional database with multiple modes of access
- Delivery media recommendations

- Business plan for developing and sustaining the GVDD, possibly via public private partnership.

3. Which government agencies, private sector, academic or other organizations support this PPG request? Letters of support from each of these organizations would be advantageous (Appendix 1). See Qn. 7. (e) of the Guidance Note.

Preliminary consultations have been held with a wide range of interested parties, and there has been much interest and support for the concept proposed. We attach and anticipate letters of support from the following organizations to support this PPG grant applications:

- CABI and FARAD
- OIE (World Organization for Animal Health)
- FAO (Food and Agriculture Organization)
- WHO (World Health Organization)
- AU-IBAR (African Union – InterAfrican Bureau of Animal Resources)
- AVMA (American Veterinary Medical Association)
- USDA (United States Department of Agriculture), National Institute for Food and Agriculture

4. How does this PPG complement and/or build on past, ongoing and/or planned national programmes and/or donor-supported projects? See Qn. 7. (f) of the Guidance Note.

In 2010 CABI and FARAD organized an international consultation into the needs for a GVDD [http://www.cabi.org/Uploads/CABI/ExpertConsultGVDD.06.2010.pdf]. The consultation examined the feasibility of doing the following:

- Create a single global source of drugs approved for animal health indications accessible from a single resource
- Provide a central list of food safety tissue tolerances for major regulatory jurisdictions keyed to drugs, species and tissues
- Provide a list of drug screening tests and official assays
- Provide a resource for companies and relevant regulatory agencies
- Provide access to current 'evidence' in scientific research publications

The consultation established that:

- There is currently no resource that allows easy identification of veterinary drugs licensed in different countries worldwide. Such a resource would have value, including identifying veterinary medicines for minor indications for those countries that do not have an authorized medicine available; promoting transparency of use of veterinary drugs globally; and the support of international trade both in veterinary medicines and in the produce/meat of treated animals.
- The GVDD could assist risk assessment and management relating to international trade in animal products.
- The GVDD should aim to bring together existing datasets [such as Codex and JECFA databases] rather than building completely new ones, so as to avoid being a duplication of effort, which might lack international support.
- The resource should be designed as a portal to incorporate interpretation and standardization of information to enable interoperability, and to ensure valid comparisons across amongst different data sources.

- A primary aim would be unification of existing data

One of the main recommendations from the workshop was the development a prototype using data from existing CABI and FARAD knowledge banks to demonstrate the value and potential of the global authoritative resource on veterinary drugs and to provide a proof of concept to assess user needs more extensively.

The GVDD will aim to complement the information provided by the Codex Alimentarius and the JECFA databases (as well FARAD and CABI data and other datasets identified during the PPG period), and provide much more information on how producers can avoid breaching Codex recommendations on MRLs (maximum residue levels), such as by providing withdrawal times.

5. Have you discussed this PPG request – or funding for the project proposal which would result from it – with any potential donors (bilateral, multilateral, Enhanced Integrated Framework, etc.)? If so, provide details below and indicate potential sources of funding for the resulting project. See Qn. 7. (g) of the Guidance Note.

This feasibility study is a first step towards developing the full project proposal. The model needs to be developed and tested in order to attract wider support and funding to ensure its full development and sustainability. Co-finance to support the PPG period will be provided in the form of in-kind contribution of staff and resources from each project partner (CABI and FARAD). Where possible, value will be added and costs economised by combining stakeholder meetings with other arranged business trips. Possibilities for full project funding will be explored and built into the business plan, during the PPG period.

II. IMPLEMENTATION & BUDGET

6. Who will take the lead in implementing this PPG? If particular national experts and/or international consultants are proposed, attach a copy of their Curriculum Vitae and record of achievements (Appendix 2). If no names are provided, the STDF will provide a shortlist of consultants if the PPG request is approved.

CABI will take the lead in implementing this PPG, with support from FARAD.

This collaboration is an ideal vehicle for achieving the GVDD for the following reasons:

- FARAD's pharmacological and food safety expertise
- CABI's remit as an international, intergovernmental science based organization
- CABI's excellent networks throughout its member countries
- CABI's experience of building international consortia involving both public and private organizations
- CABI and FARAD have a strong track record in information projects and database development and sustainability
- Both organizations have a long standing collaboration, having worked together effectively on various projects for over ten years, including the development of the Animal Health and Production Compendium, as well as the International Consultation described above.

CABI improves people's lives worldwide by providing information and applying scientific expertise to solve problems in agriculture and the environment. CABI scientists conduct cutting-edge research in fields such as improving agricultural production methods worldwide, plant protection, microbiology, sanitary and phytosanitary protection, trade in agricultural commodities, and human and animal health and nutrition. Knowledge management is one

of CABI's key focus areas. We are experts in managing knowledge through systematically creating, searching, capturing, repurposing, organising, storing and communicating information in fields such as agriculture, including feed technology, animal nutrition and animal physiology, as well as food, health and the environment. As an organization, we have developed these skills over a century of providing access to the world's agricultural research (including our own) and understanding how to communicate it.

FARAD is a congressionally-mandated risk-management program that is supported by the United States Department of Agriculture (USDA). The program is maintained by a consortium of universities, including University of California-Davis, University of Florida, Kansas State University and North Carolina State University. FARAD's primary mission is to prevent or mitigate illegal or harmful residues of drugs, pesticides, biotoxins and other chemical agents that may contaminate foods of animal origin. Through the assimilation of a comprehensive drug database and the use of state-of-the-art pharmacokinetic modelling, FARAD scientists determine appropriate withdrawal periods for a wide array of chemical entities and provide this information to veterinarians, extension specialists and livestock producers. In addition, FARAD provides rapid response assistance regarding extra-label use of drugs in animal agriculture, and during food contamination emergencies which might arise from accidental exposure to environmental toxins, particularly pesticides, or intentional efforts to contaminate the food supply. Finally, FARAD provides assistance in trade matters related to foreign drug approvals and trains future veterinarians in the principles of residue avoidance.

FARAD is databank of information that is used as the primary source for scientifically-based recommendations regarding safe withdrawal intervals of drugs and chemicals in food-producing animals. It is managed by a national university-based consortium in the USA; by faculty and staff at four colleges or schools of Veterinary Medicine (the University of California-Davis, the University of Florida, Kansas State University and North Carolina State University).

Estimated PPG phase activities schedule and budget

1. User-needs assessment survey: online survey of potential users to gather information on user needs, and opinions on the database content using CABI marketing team. June 2014.

2. Stakeholder planning meeting. Meeting with OIE to present and consult on work plans, and plan stakeholder stage review, and Stakeholder Workshop where the proposal and business plan are presented and discussed. Consider options of venue of the November Stakeholder Workshop (OIE, Paris; RCVS London). Engage with other stakeholders including AU-IBAR, EFSA, and other representatives from developing countries. May 2014.

3. Analyse and collate information gathered from the user-needs assessment, potentially with follow-up more detailed interviews.

4. Partner meeting between CABI and FARAD. Objectives: to plan the project activities, define database elements for the prototype, review technology issues, and delivery options and consider sustainability options of the GVDD. Monitor work packages with completion times. One CABI staff meeting members of FARAD in the USA in July 2014.

5. Stakeholder stage review: review with guidance and 'sense-checking' by the key stakeholders (OIE, WHO, FAO). The meeting will present progress on the work programme for 2014, and plan the Stakeholder Workshop (to be organized in November). Examine the relationship with existing databases (Codex and JECFA databases) and how the data can be amalgamated with FARAD and CABI data to enhance the GVDD. August 2014.

6. Prototype development meetings (remote), by phone and video conferencing, between CABI and FARAD to monitor progress. June-October.

7. Obtaining data from sample countries. Gaining access to data to be used in the prototype may require consolidation with in-country information owners and international sources such as AU-IBAR. August – September 2014.

8. Business plan development meetings. To coincide with GFSI and other relevant events where stakeholders are present – engage with private sector in order to develop plans for sustainability with models of public/private partnerships. June-October 2014.

9. Business plan development. CABI staff to produce the plan in consultation with FARAD. August/September/October 2014.

10. Stakeholder workshop (separate Budget). A stakeholder workshop will be held over 2 days at an agreed venue (e.g. OIE, RCVS). Meeting will evaluate and review the prototype and the business plan, covering funding and sustainability. The insight provided by the meeting will be incorporated into the full proposal for the GVDD. October 2014.

11. The workshop report will be produced and circulated to all those attending the workshop within 2-3 weeks of the meeting. The input from the meeting will be used in developing the full proposal for a GVDD. December 2014.

The following are estimates of costs that would be incurred during the Project Preparation Grant/feasibility study phase. The budget for the full project would be fully itemised and include co-finance and in kind contributions. The below budget is separated into the PPG development activities and workshop preparation (such as prototype development meetings, business case development), and the Stakeholder Workshop, to be held in month 6.

Activity	Staff costs	Travel	Total
1. User needs assessment survey development and dissemination	**2080** (CABI staff 3 days $500, 1 day $580)		**2080**
2. Stakeholder planning meeting (Europe; at OIE general assembly)	**2320** 4 days, CABI staff ($580)	**1520** (1 flight at $320, DSA $400x3)	**3840**
3. User needs assessment survey analysis	**2660** (CABI staff 3 days $500, 2 day $580)		**2660**
4. Partner meeting, prototype content/sustainability (US)	**2320** 4 days, CABI staff ($580)	**2560** (1 flight at $960, DSA $400x4)	**4880**
5. Stakeholder stage review meeting at OIE	**1740** 3 days, CABI staff ($580)	**5120** CABI (1 flight at $320, DSA $400x3) FARAD (1 flight at $2400, DSA $400x3)	**6860**
6. Prototype development meetings (remote)	**1740** 3 days, CABI staff ($580)		**1740**
7. Obtaining data from sample countries	**4700** (CABI staff 5 days $580, 3 days $600)		**4700**
8. Business plan development meetings	**3480** 6 days, CABI staff ($580)	**3040** (2 flights at $320, DSA $400x6)	**6520**
9. Business plan development	**7230** 13 days, CABI staff. 6 ($580), 4 ($600), 3 ($450)		**7230**
10. Workshop report/proposal development	**8200** CABI staff: 3 days ($500), 5 days ($580), 3 days ($450), 7 days ($350)		**8200**
Totals	**36470**	**12240**	**48710**

Stakeholder workshop budget

Partner/associate	Staff	Travel	Workshop costs	Total
CABI	**6840** (3 days each at $500, 580, 600, $600)	**4480** (Flight $320x4, DSA $400x8)	**2800** (Materials and supplies $640, Refreshments $2160)	**14120**
FAO		**1120** (Flight $320x1, DSA $400x2)		**1120**
FARAD		**4960** (Flight $1280x2, DSA $400x6)		**4960**
WHO		**1120** (Flight $320x1, DSA $400x2)		**1120**
WTO		**1120** (Flight $320x1, DSA $400x2)		**1120**
AU-IBAR		**2400** (Flight $1200x1, DSA $400x3)		**2400**
Asia representative		**2700** (Flight $1500x1, DSA $400x3)		**2700**
Totals	**6840**	**17900**	**2800**	**27540**

Invitees could also include representatives from EFSA, STDF Working Group, IFAH, SSafe and others