Policy recommendation related to inoculant regulation and cross border trade

Milestones 3.5.1 and 3.5.2

Jeroen Huising

with contributions from

Paul Woomer, Judith de Wolf, Barthlomew Chataika, Robert Abaidoo, Cargele Masso, Speciose Kantengwa, Steve Boahen and Jeanmarie Sanginga

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N2Africa

Putting nitrogen fixation to work for smallholder farmers in Africa

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Email: n2africa.office@wur.nl
Internet: www.N2Africa.org

Authors of this report and contact details

Name: Jeroen Huising
Address: CIAT TSBF Nairobi, Kenya
E-mail: j.huising @cgiar.org

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1. Introduction

In this milestone report we review the status of the production of inoculants in the initial eight participating countries in the N2Africa project and the cross border trade between them, as well as the regulations that governs trade in these products. We conclude with policy recommendations for improving availability of quality inoculants to smallholder farmers in the respective countries.

Milestone 3.5.1 is formulated as ”At least 3 policy briefs related to legume and inoculant regulation and cross border trade produced per impact zone”. Regulations related to national variety release (NVR) and procedures that apply, like conducting National Performance Trials (NPT), are generally well established, and apply to legume crops. This is less the case in relation inoculant regulation and this is therefore the subject of this report. For variety selection and forwarding of the breeding materials of the four targeted legume crops to TLII and other breeding programs see Baijukya (N2Africa report no. 56, in preparation). This includes performance trials conducted in support of release of varieties in countries like Rwanda.

Regulations concerning the trade of inoculants evolve around the requirements for product registration (e.g. in order to obtain an import permit) and requirements for the quality of the product. The regulatory frameworks also specify how the quality control is performed and by whom. It is not the specific task of N2Africa to look into regulations regarding the registration and trade of inoculant products, or to facilitate the establishment of regulatory frameworks for these purposes. However, in view of achieving sustainable impact of the project activities, the project has an interest in the availability of quality inoculants to smallholder farmers in its mandate areas, and it recognises the importance of regulations concerning cross border trade and inoculant product quality. The project has not issued any policy briefs as such, but we have issued a number of reports in which we advocate and propose inoculant quality standards and in which procedures for quality control are detailed. The project through its national staff is generally consulted when legislation is being prepared at national level and through our collaboration with COMPROII[1] we aim to influence the establishment of regulatory frameworks and quality standards in the various countries.

The project has demonstrated the effectiveness of inoculants for a number of legume crops, soyabean in particular, and as such it is concerned with the sustainable supply of inoculants to smallholder famers. For its dissemination activities the project has generally imported inoculants on a research permit; we will need to work towards a more sustainable solution for the supply of inoculant the smallholder farmers though. The project has also invested substantially in national laboratory facilities and training for research purposes as well as quality control. These facilities are now being used to produce inoculants. The question, though, is whether this will lead to sustainable supply of inoculants, with concerns about the economic viability of these enterprises. The project is interested in enhancing production capacity within the African continent to the benefit of smallholder farmer in the eight target countries and beyond. In the report we will discuss how this is best done.

The quality of inoculants is of great importance. An inferior product will not give any response and farmers will lose their confidence in such a product. And once this is lost it will be difficult to regain. As such it is as important that quality standards are established and adhered to, which requires a control mechanism. Finally, the distribution of the product is important and mechanisms need to be in place to assure that smallholder farmers can access these inoculant products. We have therefore included the existence of distribution network as a criterion in our review.

N2Africa has generally been responsible for the distribution of the inoculants to farmers and has encountered difficulties with the importation of inoculants in some cases. Much in this report is based on the experience and insight gained during the implementation of project activities in the countries where we operate. We have relied on the country coordinators for the input to this report.

[1] COMPRO is an abbreviation for ‘commercial products’. The project is funded by the BMGF. The second phase of the project (COMPROII) started in April 2012 and aims at the ‘institutionalization of quality assurance mechanism and dissemination of top quality commercial products to increase crop yields and improve food security of smallholder farmers in sub-Saharan Africa,’ and plans is to raise awareness among over two million smallholder farmers on effective and profitable commercial biological products by 2016 through public-private partnership.

Kenya seems to have progressed farthest with the establishment of a regulatory framework with a bio-fertilizer act before parliament for approval. Some countries are in the process of drafting legislation towards this end. We will briefly review the standards and requirements proposed in the Kenya bio-fertilizer act.

Further, we hope through the distribution of this document to contribute to the formulation of policies and establishment of regulatory frameworks that will improve the availability and accessibility of inoculant products to the smallholder farmer.

We recommend that:

1. Measures are taken that facilitate importation of quality inoculants rather than restrict it; action to be taken to harmonize requirements and procedures to register products between countries and improve data and information exchange such that when a product is already registered in one country it can easily get registered in the other.

2. Mechanisms are put in place to ensure the quality of the products, and a regulatory framework put in place that allows for the control of quality at the different stages along the supply chain

3 Investments are made in the microbiology labs first and foremost for the quality control of inoculants and for further research into elites strains; that investments in production facilities are done with a view of promoting private enterprise and for business incubation.

4. Investments are made in the distribution network such that inoculants can be delivered to the farmer at an affordable and reasonable price.

This report is written in collaboration with the COMPRO project, which focuses on inoculants and other commercial biological products and that is more directly involved in advocacy work to get these regulatory frameworks established.

In the subsequent sections we review the status of the production, importation and regulation around inoculant products, comment upon the draft legislation in Kenya on the regulation of bio-fertilizers, comment on procedures for the exchange and access to rhizobial strains between labs across countries and provide recommendations for policy development and reform.

2. Production, importation and regulation of inoculant products in the target countries

Table 1 provides an overview of the N2Africa countries on where they stand with respect to the production and/or importation of inoculants and with respect to policies and regulations put in place regarding quality control and distribution of inoculant products.

Table 1 Characteristics and status of member countries with respect to production and importation of inoculants and regulations in place

Country	Commercial production	Pilot production (public)	Importation	Standard in place	Regulation in place	Commercial distribution network	Returning policy in place
Kenya	✓			+	+	+	(+)
Zimbabwe	✓ (parastatal)			+	(+)	(+)	(+)
Malawi		✓		–	–	–	–
Mozambique			✓	–	–		–
Rwanda		✓		(+)	–	(+)	–
DRC			✓	–	–	–	–
Ghana			✓	–	–	–	–
Nigeria			✓	–		–	–

'++' Standards, regulation or returning policy are in place and enforced through regulatory body, or fully operational distribution network and inoculants are readily available, '+' standards, regulation or returning policy defined, but might not be operational or enforced yet, or some commercial distribution taking place, but with limited reach, '(+)' production company have set their own standards and conduct their own quality control, not officially regulated; existing distribution network for agricultural inputs that could easily be used for distribution on inoculants, or company has its own distribution network, '–' No standards and no regulation of quality, no commercial distribution of inoculants.

2.1 Malawi

In Malawi, the rhizobiology section of the Department of Agricultural Research Services (DARS) produces inoculants at a very modest level since 1975. The product is known under the name of 'Chitedze Inoculant' and was 'released' by the Technology Release Committee of Malawi in 1975

DARS has struggled to maintain the facilities (basic equipment and supplies, power supply, etc.) and the production has been very irregular over the years. The capacity to expand production, within the existing unit is limited, with basic facilities, like a storage room lacking.

The production has been 10,000 sachets per year at the maximum. In the 2012-2013 season the department produced 15,000 sachets of 50g. The plans are to increase production to 50,000 sachets for the 2013-2014 season, following upgrading of the equipment. It is, however, doubtful that this can be achieved in such short time. Moreover, there are concerns about the quality of the product (quality control is not done on a regular basis, and no data on quality control are available).

The potential demand is estimated to be far above the 50,000 packets. Inoculants products have been imported in previous years, but in 2013 no permits have been granted. Importation for research purposes is not restricted. Allowing for importation of inoculants and engaging agrodealer networks in the distribution of inoculants seems for as yet the quickest way of satisfying that demand.

Figure 1 Freshly inoculated packs in the DARS laboratory ready for curing

Efforts are underway to establish a public-private-partnership for the production of inoculants, under the Rural Livelihood and Economic Development Programme (RLEEP). In the proposed PPP, DARS will be providing the facilities and the expertise, whereas the private company (Agro-Input Suppliers Limited - AISL) will be responsible for operating the facility, marketing and distribution. They target to increase production to 250 kg per year, where the potential demand is estimated to be around 400 kg per year (according to the proposal for the PPP). Future plans are to build a separate production facility.

Needed improvements in packaging materials, sterilization procedures, quality control and long-term storage of stock cultures are noted, which poses quite a challenge.

Questions have been raised on how to source USDA 110 strain to refresh their mother strain collection or to source possible other strains for inoculant production and whether this requires these strain to be 'officially released'. The section below explains, however, that rhizobium strains are not protected and that only a material transfer agreement is needed for their transfer.

The quality standard adopted is $1x10^9$ cells per gram, but that is an internal standard and we have no information whether those standards are achieved.

For the importation of inoculants for commercial purposes registration is required and this can only be done if the product is 'released' by he TRC. There is no regulatory framework in place that controls this process or that controls the quality of the products.

There is no distribution network in place, though the N2Africa project has taken initiative to interest agro-dealers and seed companies in setting up such a distribution network.

There is no policy in place for returning of inoculants that are beyond the expiry date. This is not relevant at this point of time because inoculants are not being stocked by agro-dealers currently. The project does sensitize farmers not to use inoculants from the previous season.

2.2 Zimbabwe

In Zimbabwe, the Soil Productivity Research Laboratory (SPRL) of the Chemistry and Soils Research Institute (CSRI), under the Department of Research and Specialist Services (DR&SS) of the Ministry of Agriculture is the designated facility for the production of inoculants. SPRL is a government institution and not a parastatal in the sense that the production facility does not have its own financial and legal structure.

SPRL produces inoculants for the various crops as indicated below (followed by the rhizobium strain used):

1. Soya bean – (USDA 110) MAR 1491
2. Sugar bean – CIAT899
3. Groundnut, Cowpea, Sunnhemp – MAR1510
4. Lucerne – MAR 1251
5. Peas – MAR 833
6. Calliandra – MAR1520
7. Leucaena – MAR1436

The production process involves the injection of pure culture in pre-packed bagasse carrier medium that has been autoclaved for sterilization. Average production is around 85 000 sachets (100g) per year, with almost 80 000 being rhizobium inoculants for soyabean. The annual production targets are based on the expected acreage or area targets set for that particular crop for that particular year. National production in 2013 was 86 747 ha of groundnut (having declined sharply since 2010/11), 76 933 ha of soyabean (increasing steadily since the decline in 2009/10 season) and 15 184 ha of common bean (declining since 2008/09), all mainly related to commercial production. The uptake of rhizobium bio-fertilizer is around 60% of what is produced for soyabean and less for groundnut, but all of the 3266 of bean inoculants units produced were sold (Freeman et al., 2013)

The factory has separate rooms for carrier preparation, autoclaving, preparing of the broth, for injection, for curing under regulated conditions and cold rooms for storage. Zimbabwe has a long-standing tradition in the production and use of inoculants especially for soyabeans. Inoculant production in Zimbabwe started in 1962. The process is manual and are close to the maximum production capacity that is possible with the current facility. The facility reportedly lacks the funds to maintain or invest in equipment, and the production is regularly interrupted because of this.

A small majority of communal farmers are aware of inoculants, but more importantly the inoculants are not easily readily accessed. SPRL as a government institution is only distributing the inoculants to AGRITEX (the extension service) and does not advertise its products in the media. Most of the products are sold through the own organisation (CSRI/SPRL) and directly to companies like SeedCo.

Standards are set and maintained by the organisation. The rhizobial cell count should be $>10^9$/g viable cells (wet weight) and contaminants should be $<10^6$ / g viable (wet weight). According to the standards proposed by N2Africa this would be high grade A class product.

Quality control is done at the factory at the different steps in the production process, of the mother culture, the broth and the bagasse based inoculant product. Quality control procedures are well defined. The quality is not assessed once the products have left the factory or even before being sold after storage at the facility. This is because the product is mostly sold from the factory directly to the end-user. The quality control is based on purity and viable cell counts, and is routinely done by testing two randomly picket sachets from every batch of 500. The cell count is done using the drop plate methods, using Congo Red YEMA. Results for the 2011 showed an average cell count of 1.16×10^9 C.F.U. per gram. The counts ranged from 6.04×10^8 to 2.4×10^9 C.F.U. per gram with a Coefficient of Variation (CV) of 39.1%.

Figure 2 Cold-room for storage of inoculants at SPRL

The bulk of the inoculants are either sold to farmers directly from the factory at Grasslands Research station, Marondera, or at CSRI at Harare. Some are distributed to a few AGRITEX district offices in areas where there is potential for soya bean production. Agro-dealers are not incentivised to stock or sell inoculants, because they are not allowed to put a mark-up from the gazetted price of USD 5 per 100g bag. The price that farmers who know about inoculants and are interested in buying, actually pay for the inoculants may vary as there is little control. Finally seed and fertilizer companies purchase inoculants for resale to farmers.

All inoculants that are not sold at the end of the season stay at the factory or are being returned to SPRL and are discarded.

2.3 Rwanda

Rwanda Agriculture Board (RAB) uses their microbiology lab in Rubona as a pilot facility for the production of inoculants. Currently they are producing around 8,000 packages of 80g inoculant for both common bean and soyabean. They do this using upscaled laboratory methods, meaning that carrier is prepared by hand and sterilized using a limited capacity autoclave. Injection is done by hand and also the sealing and packaging is done by hand. The layout of the laboratory facility is such that is difficult to control contamination (no sealed rooms and much movement in and between the rooms). Nevertheless, their target is to product inoculants with more than 10^9 viable cells per gram. Independent quality assessment showed that the inoculants currently fall slightly below the target.

The policy is to expand production considerably at the facility at Rubona to support the government initiative to expand the production of soyabean in the country and to supply the recently established factory that produces vegetable oil from soyabean and sunflower.

Inoculants are in the same category with other agriculture inputs, if it can be proven that they are not locally produced they can be imported. Currently no inoculants are being imported and no inoculants are available on the market.

The Rwandan Bureau of Standards (RBS) controls the quality of many types of products. Standards for inoculants are yet to be developed and these are to be developed by RAB and then submitted to RBS. The production unit at Rubona has requested N2Africa to assist with standards for quality control purposes.

The Ministry of Agriculture has inspectors on the ground that do control on inputs sold by agro-dealers (like fertilizers, seeds, chemicals) that are registered in the districts. To register as an input dealer, a request is sent to the Ministry of Agriculture who will provide a registration number if the company complies with the requirements (for example related to storage facilities). Thus, there is a structure in place that could easily be applied to the registration and control of inoculants products even those that are sold at the end line in the input supply chain. The importation of fertilizers, planting materials and chemicals is regulated through permits.

There is a well-organized distribution network for agriculture inputs in Rwanda. The Ministry of Agriculture imports fertilizers and auctions them to national distributors to provincial level. From there companies may bid for distribution at district level, selling to agro-dealers who represent the end line in the distribution network. The same structure could well be applied for the distribution of inoculants.

There is no returning policy in place for inoculants that have expired.

2.4 Kenya

MEA Ltd produces BIOFIX inoculant for several legumes (bean, soyabean, pea, groundnut, lucerne, others). It produced 4-5 tons of inoculant over the past year (about 70,000 packets of different size – 50g, 100g and 150g, with recently also 10g packs made available). MEA aims to expand production to about 10 tons in 2014 to satisfy increasing demand.

MEA Ltd acquired rights for the production, marketing and distribution of the legume inoculant with a trading name, BIOFIX® from the University of Nairobi. The University of Nairobi conducts research to identify new elite strains and the quality of the production process up to the final product (BIOFIX®) that is sent out to farmers.

Internal industry standards are $>10^9$ CFU rhizobia and $< 10^6$ contaminants per g of product. The pending Biofertilizer Act specifies $>10^7$ target organisms and $<10^5$ contaminants per g or ml for all biofertilizers, including legume inoculants. N2Africa argued for higher standards and separate consideration for rhizobia but this was not included in the Act. The methods recommended by the Microbial Resource Centre (MIRCEN) of the University of Nairobi, *viz.* plate count MPN, were included as appendices of the Act.

MIRCEN has been appointed recently by the Kenya Bureau of Standards to act as the inspection agent for all bio-fertilizers in Kenya. Presently, MIRCEN conducts independent analysis of BIOFIX, evaluating 0.2% of the product (2 packets per 1000 unit batch) using drop plate counts on CR YMA.

MEA is a private business and do not divulge details on its marketing strategy and product distribution. Hundred (100) packets (100 g) are placed into cardboard boxes and wholesaled for $2.00 per packet. There are a few selected MEA stockist and distributors who purchase the product on wholesale basis and retail at recommended prices. Otherwise the Kenya Agrodealer Association (KENADA) purchases inoculant, as does several larger farmer associations (BUSSFFO, KESOFA, MFAGRO) and large commercial farms.

MEA serves the Kenyan, Tanzanian (under provisional license), Zambian and Ugandan market (product registration underway). In the past BIOFIX was exported to Malawi, but recently the permit was refused. Challenges in product registration included, but are not limited to, long and expensive evaluation product trial period. It is not guaranteed that the product will be registered even, which is a disincentive for private sector investment in inoculant trade.

MEA was slow to formalize its return policy in part because it required assurance that customers handled the product responsibly. N2Africa provided agrodealer training on inoculant marketing and

brokered a return policy. The expiry period is six months and unsold product may be returned for replacement (not repayment).

The COMPRO-II project is working in collaboration with the Kenyan Plan Health Inspectorate Services (KEPHIS) and other stakeholders in Kenya including policy makers, scientists, product proponents, and farmer organizations to develop and implement registration guidelines for microbiological products including rhizobium inoculants. The registration guidelines are expected to be implemented early 2014. Product proponents interested in product manufacturing and/or importation will be informed about the regulatory requirements so that they could develop their business plan accordingly.

Under COMPRO-I, Legumefix, a rhizobium inoculants manufactured by Legume Technologies Ltd in UK, was found profitable for soyabean producers. The company is interested in registering its products in Kenya once the regulatory framework is in place.

2.5 Ghana

Ghana does not produce inoculants commercially; neither do they have pilot facilities set up. So far all the required inoculants have been imported. This has been possible for research purposes only. Over the past 4 years in the N2Africa project imported 592 kg of inoculants for its program (from Legume Technology Ltd. UK).

There are no standards in place for the quality of the imported products. The Ministry of Food and Agriculture, through its Plant Protection & Regulatory Services department (PPRSD), intends to develop a regulatory framework for fertilizer quality control that will cover bio-fertilizers (fertilizers from microbial source) as part of the fertilizer policy. The Ministry of Food and Agriculture (MoFA) is working with the COMPROII project to develop and implement registration guidelines.

Quality control is not regulated at the moment, but procedures for the quality control will be specified in the Fertilizer Policy, which will include samples to be analysed at a designated and government approved laboratory.

For importation of inoculants an import permit is required. To obtain and import permit only a sanitary certificate from the PPRSD is required.

The general policy on expiry goods will apply to inoculants being a perishable good. The issue a of a returning policy will be addressed by the regulatory guidelines for bio-fertilizers expected to be put in place by the COMPRO-II project early 2014.

2.6 Mozambique

Mozambique does not produce inoculants, instead relies on inoculant products to be imported from Brazil ('Total Nitro' from Total Biotecnologia and 'Masterfix' from Stoller do Brasil), Uruguay, South Africa, Kenya and Canada, mainly through Agri-Focus Lda, and Agro Quimicos Lda. For the 2012-2013 season alone 1790 kg of inoculants were imported. The bulk of this was for Technoserve for their project associated with N2Africa. N2Africa itself imported from Argentina (Laboratorios Biagro S.A.) and IITA imported limited quantities from South Africa (Soygro Pty) and Canada (Novozymes). Volume of imported inoculants is determined by the order placed from larger NGOs and commercial farmers or companies. Some is sold directly to individual farmers. The picture below shows the range of products (different formulations) that were used.

Figure 3 Range of imported rhizobium inoculants products used by N2Africa and associated projects.

There is no restriction on the importation of inoculants. There is no regulatory framework in place nor regulations for requiring an import permit; no standards for the quality of the inoculant are applied.

Distribution of the inoculants was done through the farmers' associations that were cooperating with the N2Africa project. There is no independent well-articulated distribution network through which inoculants are being distributed, due to the fact that the agro-dealers are very scarce on the ground in the rural areas.

As such there is no returning policy in place, not officially adopted and not also not adopted by the project.

As soyabean production is rapidly expanding in Mozambique and demand for inoculants will increase there is a need for regulations that govern the importation and production of inoculants.

2.7 Nigeria

Nigeria does not produce inoculants. However, a new company is in the process of implementing a plant in the area of Zaria for inoculant production. The International Institute for Tropical Agriculture (IITA) is constructing an inoculant manufacturing plant as part of a larger business incubation platform (Woomer et al, 2013). Production will start in December and inoculants will be sold under the brand name of Nodumax. The business incubation unit aims to stimulate private investment in inoculant production by demonstrating state of the art inoculant production technology, developing the market and demonstrating the economic viability of the enterprise, providing training and other services to the business community.

So far, there are no inoculants commercially available. Larger companies that require inoculants acquire these by ordering directly from abroad. No regulations are in place to control quality. The National Agency for Food and Drug Administration and Control (NAFDAC) is working in collaboration with the COMPRO-II project to develop and implement registration guidelines for microbiological products including rhizobium inoculants and prescribed standards. The guidelines should be implemented in 2014.

The potential demand for inoculants in Nigeria is high with an estimated 500 000 ha under soyabean cultivation. If all the soyabean were to be inoculated, at an assumed cost of USD 15.00 per ha (600g

of quality inoculant required per ha @ US$ 2.50 per 100g pack) this would represent a total value of USD 7.5 million of inoculants required to give an indication.

2.8 East DR Congo

The Kalambo Agricultural Research centre, recently established in Bukavu, produces inoculants for experimental purpose (for soyabean and common bean). The product was named Rhizofix and is exclusively used for research within the N2Africa project. Inoculants required for the N2Africa project dissemination activities over the past few years have been imported from Kenya (BIOFIX) and distributed through its development partners. Otherwise, and apart from for the N2Africa and other associated projects no inoculants are being used. N2Africa has created a demand for inoculants, through the dissemination of the legumes and BNF technology, but the availability of inoculants to the famers remains a big problem. Importation of inoculants will be relatively costly and there is no distribution network in place to get the inoculants to the farmer. There is no regulatory framework and there aren't any standards applied to the quality of the inoculants.

3 Regulation of bio-fertilizers and quality requirements (the example of Kenya)

In Kenya, the bio-fertilizer act is currently before parliament to be voted into law. The draft legislation provides for general and specific quality requirements. No distinction is made, however, between the different types of bio-fertilizers. For the viable cell count a minimum of 10^7 is set per g of product or per ml of liquid product. Further no contamination at the 10^5 dilutions must be observed (meaning less then 10^6 contaminants per g). Further, there are requirements for the pH and for the particle size of the carrier material (all material to pass through 0.150 – 0.212 mm IS sieve). Moisture (by weight percentage) should be between 30-40% for carrier-based materials. To demonstrate the effectiveness of the rhizobium inoculants it is only required that nodulation is shown on all crops for which the inoculant is intended as listed on the packet.

We consider these requirements insufficient to guarantee the quality of rhizobium inoculant products. As illustrated by the examples in the previous section, the various companies or production facilities use internal quality standards that are more stringent than those formulated in the Act. N2Africa advocates that a separate standard is formulated for rhizobium inoculants and proposes the use of 3 grades of inoculants quality (Woomer, 2013b):

- Grade "B" legume inoculant product that contain $>10^8$ viable rhizobial cells and $<10^7$ contaminants per g of product with a two-months shelf life
- Grade "A' legume inoculant product, containing $>10^9$ rhizobial cells and $<10^6$ contaminants per g of product with a 6-months shelf life
- Grade "AA" legume inoculant product, containing $>10^9$ rhizobial cells and no contaminants at 10^5 dilution level with a 12-months shelf life

The Kenyan bio-fertilizer act specifies general requirements for the packaging and the labelling (to list the strain contained, the carrier composition and the expiry date, for example). In addition, N2Africa proposes the information on the legume inoculant package to include at least (Woomer, 2013b):

1. Name of the crops for which the inoculant is intended
2. Guarantees of number of live rhizobia and contaminants per gram
3. Expiration date beyond which the product cannot be used
4. Lot number for quality control feedback
5. Instructions for use (translated into local languages)
6. Net weight of inoculant
7. Trade name, manufacturer and address
8. Necessary storage conditions

The Kenyan bio-fertilizer act describes quality control procedures for bio-fertilizers in an appendix. These are normative and not prescriptive. For rhizobium inoculants, for example, quality checks on the mother culture, the broth and the peat-based inoculant are provided.

The mother culture is checked on the growth, purity and the gram stain characteristics. Purity is checked on gram-positive agar, which will reveal contaminants by growth and colour changes of cultures after incubation of 24 hours. Staining is done to confirm the rhizobium cells, which are gram-negative.

Broth test includes test on pH and staining (both to confirm presence of rhizobium cells and absence of contamination) after which it can be examined under the microscope. Also, test on optical density of the broth are proposed, which provides information density or concentration of the bacterial cells, and test on total count of cells and viable cell count.

For the peat inoculants the pH is checked, the moisture content is measured, the viable number determined and a plant infection method is described to assess plant infection on nodulation.

For quality assurance protocols to determine viable cell counts, test for contaminants and enumeration of rhizobia see Bala *et al.* (2011). Further standard protocols and laboratory methods in rhizobiology see Woomer *et al.* (2011) The quality control requirements considered by the COMPRO-II project will include effectiveness testing under field conditions. This will be included in the registration guidelines based on the requirements established by the regulatory bodies.

4 Procedures for exchange of rhizobial strains

Exchange of rhizobial strains between labs is needed to maintain healthy population of sources materials and for the development of new improved inoculant products. N2Africa has identified elite strains that show promise for new and improved formulation of rhizobium inoculants and may identify further candidate elite strains in future research (Woomer, 2013c). These strain need to be availed for further testing at different locations. These strains are not protected by intellectual property rights and cannot be patented and there should be no restriction on the exchange of rhizobial strains.

The exchange of rhizobium strains is regulated internationally and request for cultures can be met with Material Transfer Agreements (MTAs) that is an agreement between two parties, one that provides the strain and the one requesting. Strains cannot be forwarded to a third party (Bala, 2011; Project report no. 20). An example of a MTA is given in Project Report no. 20. For shipping these materials, a Material Safety Data sheet is required, an example of which is provided in Annex A. National legislation, where needed, should adhere to these conventions and facilitate such exchange.

5 Observations and conclusions

5.1 Demand for inoculant product generated by smallholder farmers

The project has sensitised farmers on the use of rhizobium inoculants and demonstrated its useful application (Huising, 2013). Farmers have appreciated the legume and BNF technologies, however adoption of inoculant and fertilizer technologies is severely constraint by their limited availability. In Kenya where inoculants and P-fertilizers are available the adoption of the full technology reached 61% (Franke, 2013). There is generally a ready market for grain legumes and farmer households stand to benefit from increased production of legume crops. In particular, there is a large and increasing demand for soyabean that is generally satisfied through imports. Smallholder farmers stand to benefit if they can access those markets, thereby contributing savings in foreign currency through import substitution.

The gains the project has made so far and opportunities generated for smallholder farmers to improve their livelihood through cultivating legume crops are threatened by the limited availability and accessibility of quality inoculants. Currently, in the N2frica countries, apart from in Kenya and Zimbabwe, inoculants are not readily available and accessible to (smallholder) farmers. Also in Kenya and Zimbabwe there are challenges. In Kenya inoculants are distributed to the western region and are difficult to obtain in other regions of the country. And, even though the percentage of agro-dealer that stock inoculants has increased considerably the access to inoculants is still limited to most of the farmers in western Kenya. Likewise, in Zimbabwe there are good opportunities to improve the distribution and access to inoculants to smallholder farmers.

Production of inoculants in the countries is too limited, imports (if at all) are not sufficient and distribution networks non-existent or defunct, in consideration of potential demand and in support of string increase in uptake of inoculant technology. There is an important role to play by government in providing the proper infrastructure, regulatory framework and incentive mechanisms for a proper functioning input supply system for inoculants. However, government policies and rules and regulations, when in place, are often counter productive and no stimulus is provided to promote the development of such input supply system.

5.2 Challenges for production of inoculants in Africa

The commercial production of inoculant in Africa faces several challenges. Production and market volumes are relatively small, because legume production is a nascent but developing industry (in most countries), and because of the small amounts of inoculant that is required to inoculate seed.

Because the product consists of live material with a relatively short shelf life, the production process and environment need to satisfy strict criteria to produce a quality product. Also transport and storage facilities are required to maintain the quality of the product. The costs for the ingredients are limited which helps keeping the price for inoculants low. However, considerable investments are required for the production facility and equipment.

Distribution is a challenge, especially if the smallholder farmer community is to be served, taking small trading volumes required storage facilities into account.

All the above means that the business prospects are limited and that starting up an inoculation business is not without risk. A study be Freeman et al (2013) on the economics of rhizobium bio-fertilizer utilization among small scale farming systems in Zimbabwe and the role for policy, indicates that a break-even point (where total revenue equals total cost) is reached at the production of around 40,000 – 50,000 units (100g). This applies to the Soil Productivity and Research Laboratory (SPRL) facility at Marondera, Zimbabwe. A sales level of 50,000 units was only achieved in the 2012/13 season over the past five years. Production far outstrips the sales level leading to a large number of discarded units every year. The low adoption rate (or sales levels) are explained by lack of awareness and a distribution system that is not well articulated.

Our own calculations indicate that inoculant production can certainly be profitable, and that it is possible to recover initial investments in 3 -5 years time, but only if large sale volumes are considered (Woomer, 2013a) that apply to a market like the one for Nigeria. Further, production beyond the 50,000 units per year requires investment in industrial production techniques that require considerable investments. Production of up to the 50,000 – 80,000 units can still be achieved with the up-scaled laboratory methods, which is used so far in all facilities in the 8 N2Africa countries.

Stimulus measures like providing some kind of financial security and putting infrastructure in place, would help in developing such inoculant production industry. Protective measures, like restriction on imports, might be counter productive in that it would limit the availability of the inoculants to farmers, which would also restrict the development of the market.

5.3 Challenges in exporting and importing of inoculant products

The inoculant production companies that N2Africa engages with have reported difficulty in gaining access to markets in various countries. For example, LegumeTechnology Ltd. has not been able to put an effective distribution into place in any African country, as gaining right to import is difficult (personal communication). As Bruce Knight of Legume Technology states: “They would target Kenya and Nigeria as the most attractive market, and would want to enter the Tanzanian market as well. The biggest barrier to pursuing commercial sales is the confidence that we will be able to export to markets in these countries. To do this we would need to find a distribution partner who can negotiate the bureaucracy surrounding import permissions and represent us effectively.”

Registration of the product is often cumbersome and time demanding. Importation for commercial purposes is often restricted. Each country has its procedures and requirements for registration, which are generally not that different. It would ease the process and reduce costs if registration obtained in one country could be considered for registration of the same product in another. This would benefit the inoculant production companies that are often small and do not have the financial resources to sustain repeated and prolonged registration procedures. Registration in some countries requires that the effectiveness of the product needs to be demonstrated under field conditions in three consecutive seasons. In case of rhizobium inoculants, when the product (defined by the bacterial strain used and the formulation) has been tested under various conditions, subsequent testing for three consecutive seasons in a particular country is not going to add much relevant information. Most inoculants use the industrial standard (strain) that has been used for many years and the effectiveness has been demonstrated. It is the formulation of the products that will determine the effectiveness. COMPOII has been evaluating various rhizobium inoculant products with various formulations.

To address this issue the COMPRO-II project has initiated discussion with the regulatory bodies to allow accelerated trials for product registration (i.e. in single growing season with increase number of sites; the spatial variability will address the issue of seasonal/temporal variability particularly when trials are conducted in various agro-ecological zones.

In most countries there are no quality standards applied and no regulatory framework is put in place. Companies would benefit from these quality standards however. Standards provide for a level playing field and help to build trust of the consumer. In this way a company that does provide a quality product does not have to suffer from the negative effects on the market that a poor quality competing product may assert. Quality requirements should not be set that high that those standards are difficult to achieve that ban starting enterprises from entering the market. On the other hand minimum requirements need to be put in place for the measure to be effective. The project recommends adopting a graded system in which different quality standards are applied.

To facilitate cross-border trade, the COMPRO-II project intends to bring various regulatory bodies in the project countries including Ghana, Kenya, and Nigeria, together to discuss the harmonization of the quality control requirements and minimize the duplication of efforts when a product is to be imported in those countries. We would like to see this effort extended to other countries in the N2Africa project and beyond.

5.4 Conclusion

Companies need access to foreign markets to achieve economies of scale and build profitable enterprises, if they are from countries with relative small national market for inoculant products. This is evidenced by companies like LegumeTechnology Ltd and MEA Ltd that actively seek export markets to sustain their business. The prospects are different for a country like Nigeria with a potential large demand for inoculant products. Governments should consider carefully whether or not and how to develop an inoculant industry that is still at its infancy, with a view on the viability of the industry for the longer term. There are different modalities to be considered, ranging from having the complete process under own management, to importing sterilized carrier material and injection to be done at their own facilities, to importing the complete inoculant product. Which is most economic depends on the scale of production. At the same time the Project advocates governments to lift import restrictions, liberalize the market and focus on regulatory aspects and quality control, in order to assure the availability of quality inoculants in the immediate term. Measures like import restriction to protect a nascent inoculant industry will likely affect availability of inoculants on the shorter term, while not providing a guarantee for the availability on for the longer term.

Starting businesses will use up-scaled laboratory methods for the production of inoculants, because advanced technology is not available in Africa and would require too high an investment. With up-scaled laboratory methods a ceiling in production is reached with probably around 40000 – 50000 packets per year (depending on the size). To increase production larger investments are needed, in 'industrial' (larger volume) autoclaves or other techniques for sterilizing the carrier material, and in equipment for packaging and other. Investments are also needed in (semi-)automated techniques to reduce the risk of contamination, to reduce the number of times product is 'handled' during the whole production process. Companies will require access to capital to make such investments possible.

In order to reach the smallholder farmer an extensive distribution network is required. Setting up such a distribution network is expensive if the companies cannot make use of an existing distribution network already in place. Most companies retain their margins by serving the commercial, larger farmer, for which only a few outlets are required. In exceptional cases where companies sell fertilizers in smaller denominations to serve the smallholder farmer they can make use of their own distribution network. Collaboration is therefor required with distributors and this often will need facilitation, to include the training of the local stockists and agrodealers, for example.

6 Recommendations

Based on the above we make the following recommendations:

1. The requirements for the registration of inoculant products should be streamlined and harmonized (between countries) and be less stringent in order to speed up the registration process and make it less costly. A company that has registered a product in one country should find it easier to register the same product in another country. Governments should not impose import restrictions or put other measures in place to protect national or nascent inoculant production industry.
2. Governments should focus on the quality control of inoculants that are being brought onto the market, putting a regulatory framework and control mechanisms in place. For the purpose of quality control existing laboratory facilities can be used, but often these need to be facilitated, and upgraded and procedures need to be put in place for routine quality control. Quality control should be carried out at the different stages in the input supply chain.
3. Production of inoculants and the quality control should be physically separated and carried out independently from the production organisations.
4. Governments should stimulate commercial production of inoculants by private companies or through public-private partnerships (PPP), through technical assistance and providing financial stimulus.
5. Governments should invest in, or stimulate development of, distribution networks through which inoculants can be made available at affordable prices to the smallholder farmer.

References

Baijukya, F.P. 2013. Identified soybean, common bean, cowpea and groundnut varieties with high biological nitrogen fixation potential in N2Africa impact zones. N2Africa Report no. 56 (in prep.).

Bala, A., 2011. Collection and maintenance of elite rhizobia strains. Milestone report 3.2.1, N2Africa Report No. 20 (www.n2africa.org)

Bala, A. 2011. Quality assurance protocols based on African capacities and international standards. Milestone Report 3.3.1. N2Africa Report No. 19 (www.n2africa.org).

Bala, A. 2011. Update on Inoculant production by cooperating laboratories. Milestone Report 3.4.3. N2Africa Report No. 27 (www.n2africa.org).

Bala, A., Karanja, N., Murwira, M., Lwimbi, L., Abaidoo, R. and Giller, K. 2011. Production and use of Rhizobial inoculants in Africa. Milestone Report 3.4.1. N2Africa Report No. 13.

Franke, L., Wolf, J. de, Huising, E.J. 2013. Evaluation of the progress towards achieving the Vision of Success in N2Africa. N2Africa Report No. 61.

Freeman, G., Kamba, S., Chikwari, E., Tumbure, A. and Zvomuya, M. 2013. The Economics of Rhizobium Biofertilizer Utilization Among Small-Scale Farming Systems in Zimbabwe and the Role for Policy. Chemistry and Soil Research Institute (CSRI) research study report.

Huising, J. (2013). N2Africa Project Progress Report Month 42. N2Africa Report No. 54. www.n2africa.org.

Woomer, P.L., Karanja, N., Kisamuli, S.M., Murwira, M. and Bala, A. 2011. A revised manual for rhizobium methods and standard protocols. Milestone Report 5.5.2. N2Africa Report No. 26. www.n2africa.org.

Woomer, P.L., Mahamadi, D., Wafullah, T., Balume, I., Uwizerwa, M., Boahen S. and Mhango, J. 2013a. Improving legume inoculants and developing strategic alliances for their advancement. Milestone Reports 3.3.2. and 3.4.5. N2Africa Report No. 59. www.n2africa.org.

Woomer, P.L. 2013b. A N2Africa universal logo representing inoculant quality assurance. Milestone Report 3.3.3. N2Africa Report No. 57. www.n2africa.org.

Woomer, P.L., Mahamadi, D., Karanja, N.K., Uwizerwa, M., Ndusa, B., Abaidoo, R. and Mhango, J. 2013c. Rhizobium collection, testing and identification of candidate elite strains (four Milestone Reports N2Africa Report No. 60. www.n2africa.org.

Appendix A: Example of Material Safety Data Sheet for *Bradyrhizobium japonicum* Inoculant

Material Safety Data Sheet — *Bradyrhizobium japonicum* Inoculant

Emergency First Aid Procedures:
Eyes: Flush with flowing water and consult a physician.
Skin: Wash affected area with soap and water. If irritation develops, consult a physician.
Inhalation: If difficulty breathing occurs, move to fresh air and consult a physician.
Ingestion: Consult a physician.

Other Health Information: Rhizobia are naturally occurring, soil-living bacteria that are not known to be pathogenic to plants, animals or humans.

Carcinogenicity?	NTP?	IARC Monographs?	OSHA Regulated?
None	None	None	No

Section VII Precautions for Safe Handling and Use

Steps to be Taken in Case Material is Released or Spilled: May be cleaned with a water flush of the area.

Waste Disposal Method: Dispose of in accordance with local, state and federal regulations. This material is Non-Hazardous.

Precautions to be Taken in Handling and Storage: Product should be stored off the floor on shelving or pallets without contact to walls or ceiling. Storage areas should be well ventilated and free of strong or objectionable odors. Store in original packaging in a cool, dark environment. Avoid elevated temperatures or repeated freeze/thaw cycles.

Other Precautions: Avoid open flames and spark sources. Keep out of the reach of children.

Section VIII Control Measures

Respiratory Protection: Not normally required but a face shield or mask may be used to prevent exposure from splashing.

Ventilation: Not normally required but local ventilation may be supplied for user's comfort.

Clothing: Gloves, boots, coveralls or apron may be used to prevent skin contact as needed.

Eye: Safety glasses or face shield are recommended. Wearing contact lenses without goggles is not recommended.

Work/Hygienic Practices: Use standard hygiene practices.

Other: Open wounds should be covered with a chemical resistant patch to minimize absorption risks.

Section IX Shipping and Labeling Information

D.O.T Shipping Data: Not regulated.
D.O.T Hazard Classification: NA
D.O.T Labels Required: NA
D.O.T Identification: NA

HMIS Rating:

Health	Flammability	Reactivity	Physical Hazard
1	1 (packaging only)	0	0

Section X Disclaimer

The information contained herein is based upon data considered to be accurate, however, no warranty is expressed or implied regarding these data. We accept no responsibility for results obtained by the application of this information or the safety and suitability of these products. Users are advised to conduct their own tests to determine the safety and suitability of each product for their specific use and application.

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List of project reports

1. N2Africa Steering Committee Terms of Reference
2. Policy on advanced training grants
3. Rhizobia Strain Isolation and Characterisation Protocol
4. Detailed country-by-country access plan for P and other agro-minerals
5. Workshop Report: Training of Master Trainers on Legume and Inoculant Technologies (Kisumu Hotel, Kisumu, Kenya-24-28 May 2010)
6. Plans for interaction with the Tropical Legumes II project (TLII) and for seed increase on a country-by-country basis
7. Implementation Plan for collaboration between N2Africa and the Soil Health and Market Access Programs of the Alliance for a Green Revolution in Africa (AGRA) plan
8. General approaches and country specific dissemination plans
9. Selected soyabeans, common beans, cowpeas and groundnuts varieties with proven high BNF potential and sufficient seed availability in target impact zones of N2Africa Project
10. Project launch and workshop report
11. Advancing technical skills in rhizobiology: training report
12. Characterisation of the impact zones and mandate areas in the N2Africa project
13. Production and use of rhizobial inoculants in Africa
18. Adaptive research in N2Africa impact zones: Principles, guidelines and implemented research campaigns
19. Quality assurance (QA) protocols based on African capacities and international existing standards developed
20. Collection and maintenance of elite rhizobial strains
21. MSc and PhD status report
22. Production of seed for local distribution by farming communities engaged in the project
23. A report documenting the involvement of women in at least 50% of all farmer-related activities
24. Participatory development of indicators for monitoring and evaluating progress with project activities and their impact
25. Suitable multi-purpose forage and tree legumes for intensive smallholder meat and dairy industries in East and Central Africa N2Africa mandate areas
26. A revised manual for rhizobium methods and standard protocols available on the project website
27. Update on Inoculant production by cooperating laboratories
28. Legume Seed Acquired for Dissemination in the Project Impact Zones
29. Advanced technical skills in rhizobiology: East and Central African, West African and South African Hub
30. Memoranda of Understanding are formalized with key partners along the legume value chains in the impact zones
31. Existing rhizobiology laboratories upgraded
32. N2Africa Baseline report
33. N2Africa Annual country reports 2011
34. Facilitating large-scale dissemination of Biological Nitrogen Fixation

35. Dissemination tools produced
36. Linking legume farmers to markets
37. The role of AGRA and other partners in the project defined and co-funding/financing options for scale-up of inoculum (banks, AGRA, industry) identified
38. Progress Towards Achieving the Vision of Success of N2Africa
39. Quantifying the impact of the N2Africa project on Biological Nitrogen Fixation
40. Training agro-dealers in accessing, managing and distributing information on inoculant use
41. Opportunities for N2Africa in Ethiopia
42. N2Africa Project Progress Report Month 30
43. Review & Planning meeting Zimbabwe
44. Howard G. Buffett Foundation – N2Africa June 2012 Interim Report
45. Number of Extension Events Organized per Season per Country
46. N2Africa narrative reports Month 30
47. Background information on agronomy, farming systems and ongoing projects on grain legumes in Uganda
48. Opportunities for N2Africa in Tanzania
49. Background information on agronomy, farming systems and ongoing projects on grain legumes in Ethiopia
50. Special Events on the Role of Legumes in Household Nutrition and Value-Added Processing
51. Value chain analyses of grain legumes in N2Africa: Kenya, Rwanda, eastern DRC, Ghana, Nigeria, Mozambique, Malawi and Zimbabwe
52. Background information on agronomy, farming systems and ongoing projects on grain legumes in Tanzania
53. Nutritional benefits of legume consumption at household level in rural sub-Saharan Africa: Literature study
54. N2Africa Project Progress Report Month 42
55. Market Analysis of Inoculant Production and Use
56. Identified soyabean, common bean, cowpea and groundnut varieties with high Biological Nitrogen Fixation potential identified in N2Africa impact zones
57. A N2Africa universal logo representing inoculant quality assurance
58. M&E Workstream report
59. Improving legume inoculants and developing strategic alliances for their advancement
60. Rhizobium collection, testing and the identification of candidate elite strains
61. Evaluation of the progress made towards achieving the Vision of Success in N2Africa
62. Policy recommendation related to inoculant regulation and cross border trade

Partners involved in the N2Africa project

Bayero University Kano (BUK)

Caritas Rwanda

Diobass

Eglise Presbyterienne Rwanda

Resource Projects-Kenya

Sasakawa Global; 2000

Université Catholique de Bukavu

MIRCEN
University of Nairobi
MIRCEN

University of Zimbabwe