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project

Development of a vaccine for the control of Gumboro in village and small poultry holdings in Indonesia

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2 Executive summary

Infectious Bursal Disease, or Gumboro, is one of the most important poultry diseases in Indonesia. Infectious Bursal Disease Virus (IBDV) infection suppress chicken normal immune responses, meaning that the infected chick is unable to fight other infections that are numerous in commercial poultry. In addition, other more virulent forms of virus, known as vvIBDV, cause also high mortality. For that reason in all countries where vvIBDV are present all poultry are vaccinated from an early age with live attenuated vaccines in order to prevent mortalities and immunosuppression. Even though a number of IBDV vaccines exist for control of less virulent strains, these vaccines are less effective against the vvIBDV strains, particularly in Indonesia.

Village and small-holder chickens are an important source of protein for rural families in Indonesia. They are also a marketable commodity and generate employment and income for local village families. Very often, women and children invest time and money to take care of them which in some way adds to their socio-economic significance. It is estimated that village and small-holder chickens contribute to more than 50% of poultry meat production in Indonesia. The Indonesian government has been supporting programs for the further development and increased sustainability of small-holder and village chicken production, aiming to increase the levels of available protein in rural areas.

We have previously surveyed village and small poultry holdings across Indonesia for incidence of Gumboro and found that it occurs commonly in these flocks and causes significant mortality and loss. The majority of the surveyed farmers however did not vaccinate their chickens against Gumboro. The main reasons were cost, packaging size and insufficient protection. For that reason we aimed to develop an IBDV vaccine from a local strain of IBDV, that would provide better flock protection and available in small dosses.

In the previous ACIAR project AS2000/83 we selected three Indonesian IBDV strains, including two vvIBDV strains isolated from village chickens, and made these viruses less virulent by attenuation. During attenuation genetic, antigenic and pathogenic changes were monitored. By using such approach, three IBDV clones were selected and tested in chickens in laboratory to make certain that they have characteristics of a safe and effective IBDV vaccine. According to laboratory testing three selected clones were either intermediate or mild vaccine strains. Although laboratory testing of developed vaccines is necessary and useful, it is vaccine performance in the field that is the most relevant for measuring vaccine efficacy and safety. In Indonesia, infections caused by the virulent Newcastle Disease Virus are common and chickens are often made more susceptible to Newcastle Disease if they are vaccinated with an IBDV vaccine that is not adequately attenuated.

In this project extension we aimed to compare efficacy of three candidate vaccine clones in field trials, choose the most efficacious vaccine and offer it for commercialisation. Prior to field trials, the stocks of vaccine seeds were made in sufficient quantities to ensure all chickens are vaccinated with the same batch of a vaccine. It was also ascertained that vaccine viruses grow consistently to a high titre and remained genetically stable. In field trials efficacy of three vaccines was compared in both village and smallholder chickens, layers and meat-type chicks, as these production systems differ vastly. For each type of chickens, flocks at three different locations were used, for example broiler flocks on farms located around Medan. Yogyakarta and Bogor, reflecting different maternal antibody status and husbandry conditions. Flock sizes varied between 1000 and 10,000 for broilers and layers, and between 60 and 1000 for village type enterprises. All chicks were vaccinated via drinking water at either 8, 10 or 12 days of age, and village type chicks were revaccinated 28 days of age. Two different commercial live IBD vaccine were used for comparison on two broiler farms and on one village chicken farm. In these instances broilers in one shed were vaccinated with a commercial vaccine and broilers in the other shed with either Ind4BV or Ind18BV. IBDV and NDV antibodies were measured at hatch,

prior to, at between 10 and 15 days after vaccination or at the end of growing period. Bursa to body ratio was also determined at this time. In all field trials, Ind4BV and Ind18BV vaccines were equally efficacious in all type of chickens. All vaccinated flocks had vaccination response that was dependent on age of vaccination, showed no mortality from Gumboro during the entire growing period, showed no signs of immunosuppression as measured by Newcastle Disease Virus antibodies, and growth performance at the end of growing period, was as expected. Comparison of Ind4BV and Ind18BV with two commercial vaccines in broiler and village chickens indicated that both were as safe and as efficacious as the two commercial vaccines. Since in all field trials two of the vaccines performed well, they were consequently offered to local veterinary vaccine manufacturers for commercialisation in Indonesia. From three companies that expressed interest, two commercial partners were selected, Caprifarmindo and Vaksindo. An agreement has been signed between Bbalitvet and Caprifarmindo for access to master seed of developed vaccines and two master seeds have been transferred to Caprifarmindo. The agreement covers non-exclusive use of the master seeds and Caprifarmindo currently intend to use the master seed for production of an inactivated IBD vaccine. An agreement has also been signed between Bbalitvet and Vaksindo for transfer of three master seeds for the production of live IBD vaccines

3 Background

Gumboro disease is one of the most important diseases affecting the poultry around the world. The significance of the disease is due to its highly immunosuppressive nature (Faragher et al 1974; Lasher & Shane 1994). Upon infection, IBDV replicates and completely destroys the chicken's immature B cells. As a result a chick become depleted of mature B cells and is unable to mount an antibody response and defend itself against a wide range of invading pathogens. This immunosuppressive state lasts for between 4 and 72 weeks during which many opportunistic infections develop affecting the chick's health and productivity performance. This sub-clinical immunosuppressive form of disease has been successfully controlled by vaccination (van den Berg 2000). Protective immunity is achieved through the vaccination of breeder hens by initially priming them with mild live attenuated IBDV strains (live IBD vaccines) followed by an administration of an inactivated vaccine. This type of immunisation produces high antibody levels in breeder hens. These antibodies are then transferred to young chicks via the egg yolk, thereby protecting them until approximately 15 days of age.

The Gumboro situation drastically changed in 1987 when a pathogenic variant of IBDV emerged in Europe (van en Berg 2000). These new strains known as vvIBDV caused up to 30% of mortality in broilers and up to 70% mortality in layers. VvIBDV are also immunosuppressive and thus high mortality is compounded by very poor performance of the surviving birds (van den Berg 2000). VvIBDV have spread from Europe and are now endemic in many countries including those in the Middle East, Asia and Africa where they have caused substantial economic losses. In Indonesia, the first outbreaks suspected to be due to vvIBDV occurred in 1991 near Medan and subsequently involved poultry flocks across Indonesia. Mortality ranged from 30% in broilers to 60% in layers (Parede 1993; Parede 1994; Parede et al 1998). In some village-chick holdings, mortality rate of 40% occurred, whereas in others, the clinical disease was present without mortalities (Parede 2000). Characterisation of more than twenty isolates at the Indonesian Centre for Research in Veterinary Science (BBalitvet) and CSIRO Australian Animal Health Laboratory (AAHL) confirmed that they were vvIBDV strains (Parede et al 2003). On the molecular level, the majority of isolates were vvIBDV whereas only two were classical-like strains indicating a high prevalence of vvIBDV in the field. The molecular analysis also showed that some isolates from village chicks were identical to vvIBDV that were isolated from commercial ones, whereas in some strains, small differences were detected.

Control of vvIBDV differs from that which is used to control classical form of Gumboro, which is mainly an immunosuppressive disease. VvIBDV is able to break through maternal antibody levels that are usually protective against challenges caused by immunosuppressive strains of IBDV. This ability of vvIBDV to break through maternal antibodies usually takes place early in life, causing mortalities and effecting growth performance. For this reason, vaccination of growing birds with live attenuated viruses has become a necessity. Such live vaccination would booster the chick's antibody levels and prevents field challenges with vvIBDV, thereby significantly minimizing losses from mortalities or immunosuppressive states. Many vaccines are available for the control of vvIBDV. These live IBDV vaccines originate from different classical IBDV strains which virulence for chicks has been reduced by passage through embryonating chicken eggs or tissue culture (Yamaguchi et al 2000). The process is laborious, as different strains require a variable number of passages. For example, live attenuated IBDV vaccines were passaged between 8 and 71 times *in vitro* to achieve attenuation in pathogenicity (Snedeker et al 1967; Winterfield 1969; Lutticken & Cornelissen 1985; Melchior & Melson 1989; Gutter 1998). Currently in Indonesia there are 17 different IBDV vaccines available and these include mild, intermediate and hot strains. The majority of these (90%) are directly imported whereas only a small number of vaccines are manufactured in Indonesia, using overseas IBDV strains under license. These vaccines satisfy only 35% to 40% of the existing demand in Indonesia. Additionally, some of these vaccines are not adequate for the control of Gumboro that is caused by vvIBDV, and have resulted in unsuccessful vaccination programs. This has given rise to some degree of dissatisfaction towards Gumboro vaccination in Indonesia, particularly among small-poultry operators.

It has become apparent that passaging *in vitro* of an IBDV isolate not only reduces strain virulence but also alters its antigenicity. Thus almost every single live attenuated vaccine available today has a different passage history and subsequently shows a different level of virulence and antigenicity (Guittet et al 1992). It is believed that an antigenically superior vaccine can be obtained from vvIBDV strains providing that attenuation of virulence is adequately achieved. Three vaccines have been developed from vvIBDV strains by passaging between 40 and 71 times in tissue culture (Melchior & Melson 1989).

Attenuation of a vvIBDV strain is now a relatively simple process. Markers for attenuation of virulence have been studied and two critical amino acid changes have been identified within the protective VP2 antigen of IBDV (Yamaguchi et al 1996). Thus all *in vitro* attenuated IBDV vaccines have both of these two changes. At a practical level the existence of such markers enables us to: (a) determine if a clone has an attenuated phenotype without the need to passage it blindly through tissue culture; (b) differentiate between a field isolate (strain without markers of attenuation) and a vaccine strain (strain with markers of attenuation) and (c) examine vaccine stability during its field application as some vaccines have propensity to re-gain virulence by serial passage in chicks (Yamaguchi et al 1996).

This project was an extension of an earlier ACIAR project, AS1/2000/83, the aim of which was to develop a live attenuated vaccine from an Indonesian strain of IBDV. The AS1/2000/83 project commenced in 2000 and the majority of objectives were completed as planned however field testings and commercialisation of the vaccine were not achieved. The AS1/2000/83 project was reviewed in November 2003 with recommendation for an extension to complete field testings and commercialisation of the vaccine since factors external to the project hindered the progress of planned work. The Project extension commenced in 2005 and was to finish in December 2006. In September 2006 the project was reviewed and finding was that all technical aims of the project were achieved however commercialisation of the vaccine was not accomplished. An informal extension to the project was recommended to allow commercialisation of the project to be completed. Completion of a signed contract between Bbalitvet and the commercialiser of the vaccine was agreed to be an appropriate end point of the project.

4 Objectives

The objectives of this project extension were:

1. To conduct field trials of the new vaccine.
2. To commercialise the vaccine.
3. To prepare a Laboratory Manual for the release of the seed and to promote the vaccine.

5 Methodology

Objective 1. To conduct field trials with the developed IBD vaccines

Laboratory trials in SPF chickens with three candidates IBDV vaccines, Ind4BV, Ind11BV and Ind18BV, have indicated that all three vaccines are safe and efficacious. However, Ind4BV, Ind11BV and Ind18BV differ in regard to their pathogenicity for bursa of chicks, being either intermediate, mild or intermediate plus, respectively. For control of vvIBDV in Indonesia, intermediate vaccines are considered to be the most appropriate and hence, according to the laboratory trials, the prime candidate for an ACIAR vaccine, is the seed Ind4BV. However, in field conditions and in particular in areas where vvIBDV challenge is heavy, or husbandry conditions are not at the optimum, it might be necessary to use intermediate plus vaccines such as Ind18BV. Since only field trials in commercial chicks are able to demonstrate the efficacy of each vaccine seed, all three vaccines were tested and compared in village and smallholder broiler or layer chicks.

Initially three candidate IBDV vaccines were produced in quantities equivalent to large-scale commercial vaccine, and sufficient for all field trials. Costs of producing 100,000 doses, in cell culture and embryonated SPF eggs, were estimated from the cost of material used. Vaccine preparations were tested for sterility and their stability as a wet vaccine by determining virus titres in storage over the period of one year. Three vaccines produced in batches of 100,000 doses were sequenced to confirm that the molecular characteristic of the vaccines generated under simulated commercial conditions (obtained by two rounds of replication of master seed) remain the same as that of seeds. Also three vaccines were passaged in chicks six times to ascertain that they did not re-gain virulence.

Safety and efficacy of vaccines was tested under different field conditions. There were two types of field trials. In the first type of trials, all broiler chicks at two farms in Bogor area were vaccinated at 10 days of age with either Ind4BV, Ind11BV or Ind18BV vaccines via drinking water. Vaccinated chicks remained on farms until approximately 5 weeks of age and were monitored for antibody response, bursal, thymus and spleen weight as well as histological lesions, body weight, and antibody response. They were then transferred to the laboratory and challenged with an Indonesian vvIBDV strain. This type of experiment aimed to demonstrate that all three vaccines were effective in antibody positive, commercial chicks and that these chicks are protected against controlled vvIBDV exposure. Controlled vvIBDV challenge of vaccinated village and small-holder chicks was necessary since there is no guarantee that at the time of vaccination farms will experience natural vvIBDV challenge.

In the second type of vaccination trials, chicks were vaccinated on farms via drinking water and where they remained until slaughter to face natural exposure. In each case entire flock on a farm was vaccinated; flock size varied from 1000 to 10,000 chicks per flock or farm. These type of vaccination trials involved village, broiler and layer chicks at four different locations, all with highest concentration of poultry in Indonesia and where it was known that vvIBDV outbreaks occur. These vaccination trials aimed to compare vaccines performance under different farm conditions, such as for example antibody

levels at vaccination, challenge exposure and husbandry conditions, that usually vary among farms. The vaccination protocol, shown to be effective in laboratory trials in SPF chicks (vaccination at 10 days of age via drinking water), was used to confirm that it is also effective under field conditions. It was adjusted following the vaccination in field trials and recommended protocol consisted of vaccination of broiler chicks at 8 to 12 days of age whereas vaccination of native chicks was optimum between 12 and 28 days of age, via drinking water. Mortality, clinical signs, bursa/body ratio and antibody response were measured to ascertain vaccine take and protection against IBDV exposure. Antibody response to NDV vaccination was also measured to determine if either of three vaccine candidates interferes with NDV vaccination. In three field trials performance of two candidate vaccines were compared with performance of two different commercial IBD vaccines that are already available in Indonesia.

Results from a number of vaccine evaluation trials conducted either at Bbalitvet or in field, are given in more details in the Laboratory Manual on Development of Vaccine for Control of Infectious Bursal Disease in Chickens in Indonesia.

Objective 2. Testing of master seed by BPMSOH, registration of vaccine and patenting of master seed.

Three experimental vaccines, each produced in batches of 100,000 doses, were to be submitted for testing to Veterinary Drug Assay Laboratory of Indonesia (BPMSOH). The result of BPMSOH testing was to confirm our results obtained in Laboratory on virus content, vaccine sterility, safety, efficacy and pathogenic type. The BPMSOH results are required for vaccine registration and were to be used as supporting data in negotiations with vaccine manufacturers and vaccine promotion.

The commercialisation strategy was to approach three veterinary vaccine manufacturers in Indonesia that had showed variable degree of interest in the ACIAR IBDV vaccine during its development. Several visits were made to each company, and limited data on vaccine performance presented. The manufacturing and support capacity of three companies were also considered. An Australian advisor was engaged by ACIAR in early 2007 to develop a document that could assist Bbalitvet in commercialisation of the vaccine. This document was translated into Bahasa Indonesia and considered various options for commercialisation. It was agreed that following agreement with the chosen vaccine manufacturer the master seed of one vaccine will be transferred to the selected vaccine company for commercial vaccine production. This step constituted the end of commercialisation process. The manual for vaccine production, data on vaccine stability, safety, efficacy and pathogenicity, as well as the recommended method of vaccine administration were also to be transferred to the commercial partner following signing of an agreement.

Objective 3. Prepare Laboratory Manual for the release of the seed & promote the vaccine

A Laboratory Manual for the new IBD vaccine was produced in English and is attached as a separate document entitled “Laboratory Manual on Development of Vaccine for Control of Infectious Bursal Disease in Chickens in Indonesia” This manual differs from the originally proposed manual, which was to describe developed vaccine, and the conditions required for its manufacture. In particular the originally proposed manual was intended to assist commercial partners without prior experience in the manufacture of poultry vaccines by providing them with all requirements related to manufacture, quality control and vaccine evaluation. Since both commercial partners have comprehensive experience in production of avian vaccines, the content of the originally proposed manual has been modified and now contains only the results on vaccine development and assessment.

Initially it was planned that following completion of field trials and vaccine assessment by BPMSOH, data obtained were to be presented in an easy to understand format, in a leaflet form. These leaflets were to be used for vaccine promotion, extension and

application. Two project Leaders were to actively promote the vaccine utilising a number of means such as:

- through vaccine manufacturers sales & distribution network
- professional poultry organisations activities such as fares, expositions, workshops, seminars and publications
- governmental institutions activities such as seminars and workshops
- involvement of DGLS through four regional DICs and Regional Veterinary Services participation through IBDV network.

Promotion of the vaccine remains to be done. We anticipate that following its release both project leaders will be engaged in promoting the vaccine via workshops, seminars and publications.

Currently the Indonesian project leader is providing support to Caprifarmindo in establishing laboratory expertise needed for production and testing of poultry vaccines, including IBD vaccine.

6 Achievements against activities and outputs/milestones

Objective 1: To conduct field trials

no.	activity	outputs/ milestones	completion date	comments
1.1	Produce three candidate vaccines in quantities equivalent to large scale commercial vaccine	Vaccines available in sufficient quantities (≥100,000 doses) for field trials & for testing by BPMSOH. Vaccine produced in expected titres	Jan 2005	Ind4BV & Ind18BV vaccine seeds: each produced approx 600,000 doses Ind11BV vaccine seed: produced approx 100,000 doses (See Laboratory Manual for details)
1.2	Vaccine quality established eg. titres, dose, storage stability & cost of vaccine/dose	Wet vaccine titres to remain stable during long-term storage	April 2006	High titres were consistently produced. For all three vaccines (See Laboratory Manual for details). Titres reduced during lyophilization (1log10) & dependent on type of stabiliser used Loss of titre occurred in storage of 0.5 log10. Vaccinating dose of between 2.5 to 3.5 log10. Cost per dose of 8 Rp.
1.3	Genetic stability of vaccine confirmed	Genetic (molecular) identity of three vaccine clones, Ind4BV, Ind11BV and Ind18BV does not change upon application in field & after six passages in SPF chickens.	Oct 2006	Ind4BV, Ind11BV, and Ind18BV master seeds: each has unique amino acid sequence in the protective VP2 antigen. This sequence remained stable following propagation for vaccine stock and 5 passages in chicks (See Laboratory Manual for details).

1.4	Safety & efficacy of vaccines tested under different field conditions	Data on vaccine safety & efficacy confirmed in all targeted breeds of chicks & under different husbandry conditions. One vaccine suitable for most conditions & chosen for commercial production	Feb 2006	Broiler trials conducted on six farms around Bogor, Tasikmalaya, Medan and Yogyakarta. Trials in native chicks conducted on three locations in Garut, Bogor and Medan Field trials in both broilers and native chicks showed that the vaccine Ind4 and Ind18 are safe & efficacious for administration to both broilers and native chickens (See Laboratory Manual for details).
1.5	Vaccination protocol tested in different farm conditions & effective	The proposed vaccination protocol effective in all targeted breeds of chicks & under different husbandry conditions	Feb 2006	Vaccination protocols: Broilers: vaccination at 8 - 12 day of age via drinking water Native chicks: vaccination at 12 and 28 days of age, drinking water (See Laboratory Manual for details).

Objective 2: To commercialise the vaccine

no.	activity	outputs/ milestones	completion date	comments
2.1	Testing of master seed by BPMSOH; registration of vaccine; patenting of the selected master seed	BPMSOH data for all three vaccines candidates agree withBbalitvet results & comply with BPMSOH safety requirements. One vaccine registered in Indonesia; One master seed patented in Indonesia	May 2006	BPMSOH testing was to independently assess ACIAR vaccine safety and efficacy and using test procedure that have been used to assess all IBDV vaccines registered in Indonesia. Results were to be used in negotiations to secure its commercialisation. BPMSOH testing was to be conducted in June 06 after being delayed on two occasions due to AI having the priority in the country and BPMSO. In June 06 the decision has been made at BBalitvet that such testing was no longer required. Patenting of master seeds and registration was to take place following testing by BPMSOH. Decision made in June 2006 that BBalitvet no longer wishes to patent the vaccine, nor register the vaccine.

2.2	Enter into agreement with one commercial vaccine manufacturer	Ascertain if three local vaccine manufacturers are interested in ACIAR IBD vaccine. Decision made as to if PusVetMa will be one of the commercial partners. A partner for vaccine production chosen	March 2006 Changed in 2006 Review to 31 December 2007	Initial contacts were made in 2002 with Sanbe, the parent company of Caprifarmindo, In 2007 Balitvet agreed to release an IBDV master seed, for production of inactivated vaccine. The agreement on non-exclusive access to and use of ACIAR IBD vaccines seeds signed between Bbalitvet and Caprifarmindo. Two master seeds transferred to Caprifarmindo, including the methodology for vaccine propagation. Caprifarmindo intends to manufacture initially an inactivated IBD vaccine only. Data on the efficacy of an inactivated vaccine from Ind4 have been obtained at Bbaitvet during the conduct of this project and data are to be released to Caprifarmindo by Bbaitvet. Development and, in particular, assessment of an inactivated IBD vaccine was not planed in the project and this work was additional to development of live IBD vaccine. Contacts made in 2004 & 2005 with another two vaccine companies: Vaksindo and Pusvetma. In 2005 Bbalitvet requested approval from MoA for commercialisation in Pusvetma. However decision was made to abandon this pathway (production of vaccine by Government Sector) and use a commercial company instead. Provisional agreement made with Vaksindo in 2006. Bbalitvet presented data on vaccine efficacy during 2006 & 2007. In 2007/08 however Vaksindo was subject of an takeover, which was completed early in 2008. The new owners of Vaksindo have resumed in September 2008 negotiation with Bbalitvet on acquiring ACIAR IBD vaccine. Agreement has been signed on transfer of master seeds to Vaksindo, including the data on the claimed vaccine properties.
2.3	To provide tested seed vaccine to vaccine producers for them to commercialise the IBD vaccine	Agreement under negotiation. The master seed and Manual for vaccine production provided to the vaccine manufacturer	March 2006 Changed in 2006 Review to after 31 December 2007	Agreements signed. Master seeds transferred, including part of the data. Further Data to be provided to Caprifarmindo and Vaksindo.
2.4	Live IBDV available as a commercial vaccine	Live vaccine produced by the manufacturer according to the agreed specifications & available commercially	Dec 2006 Amended in 2006 Review	Not achieved. There were significant delays in realising commercial offers made by vaccine manufacturers

Objective 3: To produce Laboratory Manual and promote vaccine

no.	activity	outputs/ milestones	completion date	comments
3.1	3.1 A Laboratory Manual in English and Indonesian languages for the preparation of IBD vaccine & quality testing	Available for transfer to a vaccine manufacturer at time the seed is handed over	March 2006	Manual was intended for vaccine manufacturers not previously engaged in production of poultry vaccines. Laboratory Manual in English and Indonesian prepared. This Manual has been now amended to include selected data on vaccine evaluation. This Manual is attached to this Report as a separate document. Bbalitvet has been assisting Caprifarmindo with adoption of technique for production of inactivated IBD vaccine.
3.2	Extension of benefits of the new vaccine to public and private sectors & poultry industry (Indo & Aust); IBDV Seminar atBbalitvet (Indo & Aust)	Completed data available; Sufficient and demonstrable interest generated among small poultry holders & other non-governmental poultry industry.	Oct 06	Not done as nether inactivated nor live vaccine have been manufactured to date. To occur in consultation with commercial partners & following release of two vaccines

7 Key results and discussion

Research was implemented in the time frame planned however commercialisation process was significantly delayed. Key results were:

- Three selected vaccine candidates were produced in sufficient quantities for field trials.
- Vaccine quality established (e.g. titres, dose, storage stability & cost of vaccine/dose) in accord with commercial requirements.
- Each of three master seeds had the unique amino acid sequence in the protective VP2 antigen enabling testing of vaccine identity and stability.
- Vaccines were genetically stable following propagation of master seed and application in chicks without reversion to virulence or change in genetic sequence.

Field trials in broilers and native chicks showed that two vaccines are safe & effective: See “Laboratory Manual on Development of Vaccine for Control of Infectious Bursal Disease in Chickens in Indonesia”

- Contacts made, agreements signed, and master seeds transferred to two vaccine manufacturers for production of live and inactivated vaccines.
- An amended Laboratory Manual for developed vaccine generated and provided to ACIAR as a separate document.

8 Impacts

8.1 Scientific impacts – now and in 5 years

The Poultry Sector is one the heaviest users of veterinary vaccines. Currently in Indonesia a great proportion of poultry vaccines are imported (estimated at >90%), either directly or

under licensed. In many instances imported vaccine strains differ from local circulating strains. It is recognized that for many pathogens homologous vaccines provide better protection then vaccines based on heterologous strains. In Indonesia development of vaccines from local strains has attracted little interest or investment. Although some local vaccine manufacturers are willing to engage in local vaccine development and exploitation there are only a few commercially available vaccines that were developed in Indonesia.

The Gumboro vaccine developed in this project could potentially provide an example that development and adoption of local vaccines is possible and that Indonesian veterinary research capacity and its standing could be significantly enhanced by a greater effort towards development of veterinary vaccines. This would be a gradual process that needs to be assisted by Government policies to foster and invest into development of local expertise in this area. A good example of magnitude of deficiency in this area is the current situation with vaccines for control of highly pathogenic avian influenza, where the profitability and survival of the poultry industry is almost entirely dependent on vaccines and strains that are all imported.

8.2 Capacity impacts – now and in 5 years

The project has had considerable capacity building impacts at Bbalivet in terms of transfer of both scientific and technical skills. This has been achieved by staff training in new techniques in virus attenuation and characterisation in Australia and applying these atBbalitvet. Bbalitvet is now recognized as a Centre of Excellence for IBDV research in Indonesia, and also in South East Asia. This has been evident by numerous requests that Dr Parede group received over the last three years from various sectors of Indonesian poultry industry for assistance in dealing with IBDV-associated problems. A high level of co-operation has been established between Australian and the Indonesian project team and Bbalitvet management. This level of cooperation has lead to development of an ACIAR project on “Control and characterisation of highly pathogenic avian influenza in Indonesia” which is based at Bbalitvet.

While Bbalitvet has been involved in development of several vaccines for use in livestock they were largely experimental vaccines. The commercialisation of developed IBDV vaccine is the first occasion that Bbalitvet has engaged in a full scale commercialisation. Consequently there were many unknowns and challenges to overcome, all time consuming. Product development and commercialisation has become of greater importance in Bbalitvet which has now dedicated staff responsible for commercialisation issues. Experiences gained during commercialisation phase of this project were sufficiently illustrative in many aspects.

8.3 Community impacts – now and in 5 years

Village and small-holder chickens are an important source of protein for rural families in Indonesia. They are also a marketable commodity and generate employment and income for local village families. Often, women and children invest time and money to take care of them which in some way adds to their socio-economic significance. It is estimated that village and small-holder chickens contribute to more than 50% of poultry meat production in Indonesia. The Indonesian government has been supporting programs for the further development and increased sustainability of small-holder and village chicken production, aiming to increase the levels of available protein in rural areas.

There is no immediate impact from the vaccine developed in this project as its production and adoption has not commenced as yet. Application of such a vaccine in the future however would lead to reduction in mortality from Gumboro in village and small-holder chickens, with a number of immediate impacts:

1. increase in economic return and contribution towards long-term viability of village and small-holder chicken operations
2. increase in availability of meat and eggs in rural communities
3. reducing wastage and negative environmental impacts arising from improper disposal of dead birds.

8.3.1 Economic impacts

Chicken meat is the preferred source of protein diet in Indonesia, with poultry meat representing some 61% of the country's total meat output in 2002 (Soejoedono 2004). Prior to the onset of the economic crisis in 1997, the poultry sector consisted of small rural holdings and integrated growers which constituted 70% and 30% of the broiler based sector, respectively (Shane 2000). Additionally the kampung (village) chick sector, which consists of traditionally (backyard) and semi-intensive (smallholder) raised chicks contributed another 200 million. The economic crisis during 1997/98 forced closure of many of the small holding farms (kampung, meat and egg producing chicks) resulting in the sharp decline of available poultry meat/eggs and per capita consumption. This drastic change, mostly in rural areas, has contributed to the reduction in meat consumption, loss of income and increased unemployment. Analysis of the Indonesian poultry industry suggested that during 97/98 there was a profound change in the industry in favour of the integrated growers.

The Indonesian Government is attempting to re-establish the smallholder units in rural areas through the program known as "Self Sufficiency Action on Animal Protein 2001". The Program is heavily leaning towards poultry, with 53% of the total projected budget in 98/99 assigned for the development of the poultry sector alone (Hatmono 1999). This fact testifies to the socio - economic significance of this sector as a food source and for the future prosperity of the Indonesian society outside of the large cities. To facilitate the success of this program the Indonesian government is also developing aligned programs of which one is the education and training of workers and farmers regarding disease control. In this Program the government has recognized Newcastle disease, Gumboro, fowl pox and pullorum as the major threats for the Programs success, profitability and sustainability (Hatmono 1999). The traditional backyard farming of village chicks is expected to continue with more households adopting some degree of semi-intensification in response to the high demand for village chick meat, a trend which has been growing steadily over the last ten years.

Village chickens are raised in Indonesia by almost every village household either by traditional or semi-intensive means and are an important source of meat and eggs for those families. They are also a marketable commodity, being in high demand and therefore generate an income. Analysis of Indonesian poultry industry suggests that village chicken population has risen from some 252 millions in 1998 to 280 millions in 2002 (total poultry population of 1100 millions) and is likely to increase (Soejoedono 2004). Small scale poultry raisers also represent an important source of meat and eggs for rural Indonesia. Although small-scale poultry raisers favour production of village chickens, those raising layer and commercial broilers are also common as only a small amount of money is required to set up such units. A typical example would be a village-based farmer housing up to 500 meat and up to 200 layer chickens. Additionally, they represent an important source of employment and income to local village families.

Gumboro is the second viral disease after Newcastle disease (ND) that is of economic significance for the poultry industry. It is a severe disease that causes marked immunosuppression thereby impacting on control of all other diseases, particularly virulent ND. An IBDV vaccine dose costs more in Indonesia then in developed countries making the ratio of vaccine cost to chicken sale value exceptionally high. Furthermore the packaging size of 1,000 doses/vial is not suitable for small holders which have between 200 – 500 chickens and therefore waste 50%-75% of the vaccine purchased. For those

reasons village chicken and small scale poultry raisers do not tend to use imported IBDV vaccines and either accept a high mortality rate or use home made vaccines crudely prepared from ground up bursal glands which can in some cases cause mortalities just as severe as a vvIBDV outbreak.

Availability of the low cost Gumboro vaccine, in small doses, produced from the local strain of virus will have multiple saving effects for village chicken and small poultry farmers; it should reduce the amount of money spent per vaccine dose and save costs associated with purchase of excessive numbers of vaccine doses. Increased vaccine use will reduce losses from IBDV mortality and thus increase return on the investment.

8.3.2 Social impacts

In developing countries, many rural households keep poultry in their farmyard (Hatmono 1999; Shane 2000). It is mostly women and children who look after poultry. In a West Java study, children were found to prefer to manage small animals and poultry rather than join their parents in cultivating crop. Development of village chickens system stands to markedly improve the nutritional status of the population by adding more protein to their diet and helping to alleviate protein deficiency. There is renewed interest in traditional systems of poultry production and there has been significant consumer demand for village chicken meat. Government development organisations consider projects to improve these systems to be vehicles for rural development that can create employment and improve nutritional status of the people. IBD is an important cause of direct and indirect loss of chickens and a constraint to village chicken productivity in Indonesia (Hatmono 1999). It is expected that availability of cheaper effective vaccines and particularly in the small doses (100 doses/vial), which are now not available, will be effective in reducing losses from disease in village and small poultry holdings and thus increasing their income.

8.3.3 Environmental impacts

Chickens can help control weeds and insect pests, reducing the need for chemical weedicide and pesticides. Reducing mortality will alleviate need in some small poultry operations for elimination of infected carcases and hence reducing environmental pollution and usage of chemicals needed to disinfect houses following major outbreaks of mortalities. In comparison to large commercial poultry enterprises that produced a large amounts of waste which is becoming difficult and costly to dispose of in environmentally friendly manner, small scale operators produce an amount of waste that is usually used on premises, or nearby, as organic fertilisers. No substantial negative environment impact is apparent.

8.4 Communication and dissemination activities

Results on characteristics and efficacy of developed Gumboro vaccine were presented, on confidential basis, during contacts and follow up visits to three veterinary vaccine manufacturers during negotiation to secure commercialisation. No other dissemination activities were undertaken since this project extension was largely about commercialisation of the vaccine. The Laboratory Manual on Development of Vaccine for Control of Infectious Bursal Disease in Chickens in Indonesia produced. It should not be made public until two commercial partners agree on the content and method of vaccine promotion and at the discretion of BBalitvet. Some data from the Manual will be used for publication of a scientific paper.

It was planned that following completion of field trials and vaccines assessment by BPMSOH, data obtained on vaccine efficacy in both laboratory (previous project ACIAR/2000/83) and field trials (this project extension) were to be present in an easy to understand format, in a leaflet form. These leaflets were to be used for vaccine promotion, extension and application. Two project Leaders were to actively promote the vaccine utilising a number of means such as: (a) through vaccine manufacturers sales &

distribution network, (b) professional poultry organisations activities such as fares, expositions, workshops, seminars and publications, (c) governmental institutions activities such as seminars and workshops, (d) involvement of DGLS through four regional DICs and Regional Veterinary Services participation through IBDV network.

Two project leaders, now both working on ACIAR highly pathogenic avian influenza project, still intend to assist with vaccine promotion and adoption through both commercial partners, Bbalitvet and National Technical Seminars and Publications, once the two vaccines are manufactured and ready for distribution.

9 Conclusions and recommendations

9.1 Conclusions

Significant scientific collaboration has ensued from this ACIAR project. In the technical area the project has been highly successful. It has achieved all its scientific objectives and all planned work depended on the staff involved, was accomplished. The success is documented by the following outputs:

- Generation of two candidate Gamboro vaccine clones that can be used as both inactivated and live vaccines
- Four scientific publication in international refereed journal
- Increased scientific capacity of Bbalitvet staff
- Benefits for Australia in acquisition of knowledge on type and possible treat of an exotic disease for Australia
- Creating links and opportunities for future collaborations for two Australian commissioned organisations CSIRO Australian Animal Health Laboratory and the University of Melbourne.

Research component of the project was achieved on time, however, the project was less successful in commercialisation of developed vaccines. The reasons for this are multiple. There appear to be few examples in Indonesia of commercialisation of products such as vaccines from research organisations such as Bbalitvet. While two project leaders have canvassed interests in the vaccine early in the project and were confident that vaccine adoption will follow, the process of commercialisation was not straightforward. There was uncertainty as to policies, processes and delegation of responsibilities. Thus long delays and changes in what needs to be done next, ensued. ACIAR attempted to facilitate the process however the lack of experience in the process was evident in all stages. Bbalitvet has however gained valuable experience and should be in the position to deal with the commercialisation issues with ease in the future.

9.2 Recommendations

While the commercialization process of the vaccines developed in this project was difficult, it has been nevertheless a valuable undertaking that has a potential to benefit Bbalitvet and Indonesia. Indonesia is currently engaged in control of highly pathogenic avian influenza and the country is facing shortages of adequate vaccines. A great range of vaccines will likely continue to be imported however the country has a capacity to manufacture vaccines, and this capacity has been increased with involvement and support of international agencies. This effort should be supported to a much greater degree. Bbalitvet should also be encouraged to provide more active support to local vaccine manufacturers in strengthening their vaccine manufacturing capacity by provision of expertise, advice and candidate vaccine strains. This is clearly lacking.

The process of commercialisation

Two project leaders have from the start of the project been actively seeking a commercial partner with the view to insure, early in the project, commercialisation and to accommodate needs of potential commercial partner. These included developing vaccine that can be propagated either in chicken eggs or in tissue culture, developing manual for vaccine production, and providing complete set of data needed for vaccine registration.

It was however apparent form about the middle of the project (2003) that the choice of commercial partner will be largely determined not by commercial limitation of the product, nor lack of commercial interest, but by internal institutional factors including distant decision making process; that is neither the project leaders nor the Director of Bbalitvet were able to make decisions on the choice of commercial partners. Throughout, except for the year 2007, there has been uncertainty as to who is responsible for what and this has contributed to the significant delays in commercialisation of developed vaccines

Choice of the commercial partner(s)

At the start of this project, two project leaders have chosen and engaged in negotiations with SANBE, a large pharmaceutical company from Bandung. At the time SANBE (which veterinary arm is now Caprifarmindo) did not have a vaccine production facilities in Bandung. Our Gumboro vaccine could have been manufactured of shore, at least for the time being. However, the manufacturer could not guarantee that vaccine will be sold only in Indonesia. Bbbalitvet however rejected Caprifarmindo as a possible commercial partner with Pusvetma as a preferred commercial partner, instead. At the beginning of this project extension in 2005, two project leaders visited PusVetma and presented the vaccine efficacy and safety (Laboratory data) and inspected the facility with the view of helping and supporting PusVetma to develop manufacturing capacity for Gumboro vaccine. PusVetma production facilities needed upgrading in a number of areas. Following the visits to PusVetma of two project leaders, a letter of recommendation was sent to then the Minister of Agriculture by Indonesian project Leader outlining the need to upgrade facilities at PusVetma to make it suitable for modern and large scale vaccine production. In June 2006 however Bbalitvet instigated a number of changes in the project, including decision to abandon PusVetma as a commercial partner.

In early 2006, as the process of commercialisation was stationary, it was agreed with the ACIAR that an invitation for expression of interest into developed Gumboro vaccine would be sent to several local poultry vaccine manufacturers, including Caprifarmindo, Vaksindo & Medion (Attachment 1). In August 2006 Vaksindo expressed interest in working with Bbalitvet on vaccine commercialisation and a memorandum of understanding has been exchanged. In September 2006, as no significant progress has been made, ACIAR commissioned an Australian vaccine expert to review the project and provide recommendations for pathways of commercialisation. Complete data on vaccine performance was presented to Vaksindo in January 2008 after which Vaksindo requested the vaccine seed for their in house evaluation. In February 2008 the confidential agreement has been modified by Bbalitvet in order to accommodate a transfer of Gumboro vaccine seeds to Vaksindo for evaluation. In the same time inactivated Gumboro vaccine was released to Caprifarmindo. Bbalitvet now has a Section delegated to work on external contacts and they have been involved to significant degree in commercialisation of Gumboro vaccines.

Testing of master seed by BPMSOH, registration of vaccine and patenting of master seed

It was planned in the Project Extension that BPMSOH, which is a vaccine testing and registration authority, assess ACIAR vaccine safety and efficacy using test procedure that have been used to assess all IBDV vaccines registered in Indonesia. Results were to be used in negotiations to secure vaccine commercialisation. BPMSOH testing was finally scheduled for June 06 after being delayed on two occasions in 2005 and also early in

2006, due to AI having the priority at all levels, including BPMSO. In June 06, however Bbalitvet did not approve the testing and also no longer wished to patent nor register the vaccine.

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11 Attachments

11.1 Attachment 1

Call for expression of interest for exclusive manufacture and sale of an live vaccine for control of Gumboro in poultry

Balai Penelitian Veteriner (Balitvet) Bogor, in collaboration with CSIRO Australian Animal Health Laboratory and ACIAR, has developed a live attenuated IBDV vaccine, IndBVac for control of all forms of Gumboro. The vaccine has been developed from a local, Indonesian strain of IBDV. The developed vaccine has undergone comprehensive testing in Indonesia in laboratory trials using SPF chicks and in field trials using broilers, layer pullets, roosters and scavenging chickens.

Testing to assess all vaccine properties, including safety, efficacy, lack of reversion to virulence and lack of capacity to induce immunosuppression, were conducted according to the methods and standard prescribed by the World Animal Health Organization (OIE). According to those standards, the IndBVac is an intermediate type IBD vaccine designed for use in maternal antibody positive chicks. Vaccine safety and efficacy were tested in field trials using broiler, layer, roosters and scavenging flocks. In all field trials the vaccine was safe and there was no increase in flock mortality following vaccination. Vaccinated flocks were protected from virulent Gumboro challenge until termination dates and no mortalities occurred in vaccinated chicks challenged at Balitvet with very virulent IBDV. Also, no immunosupression was detected in IndBVac flocks where NDV antibody levels were similar to levels in flocks not vaccinated with IndBVac. Performance of IndBVac was compared with three commercially available intermediate IBD vaccines in side-by-side experiments in broiler and scavenging flocks. In all trials IndBVac performance was comparable and equal to those vaccines.

The particular properties of IndBVac, as distinguished features, are

- IndBVac is developed from a local strain of Gumboro and as such is more antigenically related to local Gumboro strains.
- IndBVac is a strain that can be distinguished from all other vaccines currently available on the market, either in Indonesia or in other countries by genetic means, that is unapproved appropriation of vaccine can be detected.
- IndBVac is for exclusive use.
- The vaccine will be patented by Balitvet and licensed to the successful party.

Some specifications of IndBVac vaccine are briefly outlined in the attached document. Full description of the method for vaccine characteristic, including propagation, stability, titres, performance in field, and molecular characteristic are held at Balitvet and will be available to be scrutinized in details by interested party (is) under confidentiality arrangements. A laboratory manual with detailed description of methods used for IndBVac production and quality will be provided at the time of transfer of the master seed. Balitvet will provide expertise and advice in the initial stages of vaccine production, quality testing, and formulation and in initial adoption in field.

Balitvet is now seeking your expression of interest in adopting this vaccine and developing the vaccine into a product for use in commercial and small scale poultry in doses of 2,000, 1000 & 500.

The following vaccine manufacturing capability would be required for IndBVac production:

- Facilities for production of poultry vaccines by either tissue culture or embryonated chicken eggs.

- Capability to implement SOP and quality control as applicable for poultry vaccines production.
- Capability to market vaccine at commercial level (Indonesia only or other SE countries, global?).
- Willingness to consider Balitvet remuneration for exclusive use of the vaccine. This is too weak. I would suggest “Detail of the proposed licensing arrangements for exclusive use of the vaccine including fees”.

Expression of interest should be submitted by 1 May 2004 to:

Dr Abdlu Adjid
The Director
Balai Peneiltia Veteriner (Balitvet)
J.E. Maratdinata 30
Bogor

Expression of interest will be assessed by a panel consisting of Dr Abdlu Adjid, Director, Balitvet, Dr Peter Rolfie (ACIAR), Dr Lies Parede Balitvet and Dr Jagoda Ignjatovic, Melb Uni and using the following criteria: Intention and interest, Capacity and capability and Marketing expertise.

12 Product Specification

Product: IndBDVac: Live attenuated vaccine for control of infectious bursal disease (Gumboro).

Composition: Each dose contains at least 10 2.5 EID50 or TCID50. Available in 2,000, 1,000, and 500 doses.

Administration and dosage: to be administered in drinking water (diluted) using the same procedure as practised for poultry vaccination.

Vaccination age: The optimal age for vaccination depends on the level maternal IBDV antibody levels and recommended to be at 8 – 12 days of age. Birds with no maternal antibodies should be primed with milder vIBDV vaccine strains.

Storage: Store at 2 – 80C (fridge). If stored under these conditions virus will be viable for up to 6 months from the date of production.

Description: IndBDVac is a live vaccine virus grown in chicken embryo fibroblasts (or embryonated SPF eggs). Viral suspension has been lyophilised in vials and sealed under vacuum to preserve stability.