# **Terminal Evaluation**

## Middle East

## 1. Outline of the Project

Country: Project title:

Syria Improvement in the Quality Inspection for Veterinary Vaccine

Issue/Sector: Cooperation scheme:

Animal Industry Expert Team Dispatch Program

Division in charge: Total cost:

February 2003

Middle East and Europe Division, Regional Department IV(Africa, Middle East and Europe)

Period of Cooperation 1 March 2000 - 28 Partner Country's Implementing Organization:

Section of Quality Control of Veterinary Drug and Vaccine (QCS), Directorate of Animal Health (DAH), Ministry of Agriculture and Agrarian Reform

**Supporting Organization in Japan:** 

National Veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries of Japan

#### **Related Cooperation:**

Grant Aid; "Project for the Capacity Building of Faculty of Veterinary Medicine, Al Baath" Project-type Technical Cooperation; "Paultry Disease Control Center Project" Dispatch of Expert Team; "Improvement in the Quality Inspection of Veterianary Vaccine"

### 1-1 Background of the Project

In Syria, the increase of food production is one of the major national development programs with its rapid increase in population. Animal products account for about one third of national agricultural products and household expenditure of food. The protection and prevention of diseases among livestock animals and poultry is one of the major national issues. However, the Directorate of Animal Health (DAH), the Ministry of Agriculture and Agrarian Reform which were in charge of the quality inspection for veterinary vaccine did not have necessary resources such as the personnel, equipment, and techniques, so they could not implement sufficient inspections. Because of that, unqualified vaccine was distributed, and problems occurred with the protection and prevention of diseases among livestock animals and poultry. Under these circumstances, the government of Syria requested the government of Japan to implement technical cooperation for the improvement in the Quality Inspection for Veterinary Vaccine. Because the government of Syria highly evaluated the past cooperation activities implemented by Japan such as "Paultry Disease Control Center Project" and "Improvement in the Quality Inspection of Veterianary Vaccine"

### 1-2 Project Overview

The project together with the Section of Quality Control of Veterinary Drug and Vaccine (QCS), DAH, the Ministry of Agriculture and Agrarian Reform as an implementing organization, cooperated to improve the technical capabilities of quality inspection for veterinary vaccines.

(1) Overall Goal

To supply the appropriate veterinary vaccine which is necessary to prevent major livestock diseases.

(2) Project Purpose

To improve the technical level of quality inspection of vaccines at QCS of Veterinary Drugs and Vaccines.

- (3) Outputs
- 1) The Syrian counterparts learn the basic techniques of quality control.
- 2) The Syrian counterparts learn the techniques of quality control for veterinary vaccines.
- 3) To establish the methods for the quality inspection for veterinary vaccines.
- (4) Inputs

Japanese side:

Long-term Experts 2 Equipment 42 million yen

Short-term Experts 4 Local Cost approx.1 million yen/year

Participants received 4

Syrian side:

9 Counterparts

Land and Facilities

**Local Cost** 9 thousand USD (for 3 years)

#### 2. Evaluation Team

**Team** 

Members of Evaluation Team Leader/General/Vaccine Quality Control: Hirotaka MAKIE, Head, Assay Division I, National

Veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries of Japan

Evaluation Planning: Haruko ISHII, Staff, Middle East and Europe Division, Regional Department

IV, JICA

Evaluation Analysis: Michiyuki KENMOTSU, Chuo Kaihatsu Corp.

Period of Evaluation

8 December 2002 - 21

Type of Evaluation:

December 2002

Terminal Evaluation

#### 3. Results of Evaluation

# 3-1 Summary of Evaluation Results

### (1) Relevance

In Syria, animal products account for about one third of national agricultural product and household expenditure of food, and one of the major export products. However its sanitary condition was not good. The improvement of the sanitary conditions is one of the major national concerns. Although protecting the prevalence of preventable veterinary diseases is crucial for promoting the animal health, the lack of equipment, personnel and techniques interfered with the sufficient inspection for veterinary vaccine and an unqualified vaccine was distributed nationwide. Therefore, it was necessary to develop and improve a quality inspection system. In the meantime, there was an occasional difference of opinions in the DAH, between the manufacturing department and the QCS. The DAH was the counterpart organization of the project. The difference of opinion was about the judgment of acceptance/rejection for vaccine, and that the counterparts were demotivated to learn the techniques of vaccine inspection.

According this survey, a strenuous negotiation was carried out on the side of the manufacturing department in response, and the survey team confirmed that there were some cases that the rejection judgment among the QCS became the final judgment. This could be one of the reasons why the national standard for vaccine in Syria was not settled. There might have been the fear for the steep decline of vaccine supply in the country. The country is thought to be at a transition phase in terms of the policy about the national standard. However, the Syrian government aimed to establish the standard according to the world standard and to improve animal product quality for the future. These showed the relevance of the project. Meanwhile, JICA advocated that stable and continuous agricultural development as one of the major aid items in JICA Country Program, and the Project Purpose and Overall Goal of the project are consistent with the policies of both countries. Therefore, the relevance of this project is highly evaluated.

#### (2) Effectiveness

Two or more counterparts for each element of basic techniques and one or more counterpart for each element of techniques on vaccine quality have been reached to the level that they can implement the inspection by themselves. Many documents on the standard operation procedures (SOPs) on the variety of elements for quality control have been generated at the terminal evaluation and collection of methods based on the SOP will be issued by implementation organization by the termination of the project. These effects will help accomplish the project purpose, and therefore the effectiveness of the project is assured.

## (3) Efficiency

The arrival of the equipment was far behind schedule and caused some damage to the smooth completion of the project. One of the counterparts trained in Japan left the project soon after returning home. The shortage of equipment, consumables and experimental animals negatively affected the project. In spite of those problems, as a whole, the efficiency of the project was assured because the minor inputs accomplished the outputs as planned.

## (4) Impact

It is impossible to prove the correlation between the overall goal, "accidents will not occur by injection of the vaccine which is passed the quality inspection" and the purpose of the project. This may be due to the increase/decrease of the number of accidents that did not show the causal relation between the overall goal of the project and the effects of the project. However, the fact that the number of the accidents was fifty in 2000 and two in 2002 indicated the possibility that the project contributed to the accomplishment of the overall goal. Meanwhile, the Syrian government started to study the establishment of the National Standard of veterinary vaccines quality control referring to the successful transfer of inspection techniques by Japanese experts and the Japanese National Standards of veterinary vaccines quality control. It is considered that this change was a result of the positive effects over the framework of the project. Other positive impacts could be observed such as the expansion of communication and cooperation between QCS and its related organizations (Vaccine Manufacturing Department, Veterinary Diagnosis Department, Bath University). However, it may be too early to judge the persistence of such impacts. No negative impact was observed at the time of evaluation.

#### (5) Sustainability

With the achievement of the planned outputs of the project, two of the three items of the outputs planned were achieved. Those are "learning the basic techniques of quality control" and "learning the techniques of quality control for veterinary vaccines". The project purpose, "improvement of the technical level of quality inspection of vaccines", has also been achieved. The potential for the sustainability is high if the accomplished effects of technical transfer are maintained and the following steps are secured.

Step 1: Authorization of SOP draft. This assures the current techniques of the counterpart personnel not to cease at a personal level, but to be obtained as organizational techniques, and that the techniques can be utilized in the training for future participants.

Step 2: Supply of consumables and experimental animals. These supplies will make it possible to apply the techniques to the inspection in Syria. Previously, they were applied only to the inspection conducted in the training in Japan.

Step 3: Developing and authorizing National Standards of veterinary vaccines quality control. There was a proposal for an activity in the original plan--advice for the development of National Standards. The judgment has so far been made in the inspection by referring to the Medicines Act in Britain and the OIE Standard (veterinary vaccine manufacturing and inspection standard organized by Office International des Epizooties). The quality control fully utilizing transferred techniques will be guaranteed as a national system if the National Standard of quality control is organized and authorized with the balance of above mentioned international standards and the status of Syria's own vaccine supply and demand.

Among the three steps mentioned above, the supply of consumables and experimental animals, which was the chief concern in the implementation of the project, will be realized with high possibility due to (1) the agreement to raise the budget for animal facility and now waiting for the bid in January 2003 and (2) plans made by the head of DAH to allocate US\$20,000 per year for the purchase of consumables and experimental animals in FY 2003. From the organizational point of view, the implementing organization was also acted for the Dispatch of Expert Team "Improvement in the Quality Inspection of Veterianary Vaccin" which concluded with success. This project is still currently in progress, and the quality inspection for drugs and medicines utilizing the program's effects is conducted. Considering these facts, it is assumed that the budget planning after the termination of the project described above will be highly realizable.

#### 3-2 Factors that promoted realization of effects

#### (1) Factors Concerning the Planning

The target of the inspection by the Dispatch of Expert Team "Improvement in the Quality Inspection of Veterianary Vaccine" which were implemented before was chemical drugs. They were more basic than the vaccine which was the inspection target of the project. Having transferred the inspection method for veterinary general medicine which was comparatively easy to handle, transferring the upper grade techniques at the same implementing organization was correct.

(2) Factors concerning to the Implementation Process

As for the accident that occurred in southern Syria in October 2002 which was questioned to be a vaccine accident, the team consisted of the Japanese experts and the counterparts introduced a detailed survey and submitted the report that the accident was not a vaccine accident. This obtained the reliance from the Vaccine Manufacturing Department and the Veterinary Diagnosis Department, and as a result, the exchange of information and cooperation with related departments became easy.

## 3-3 Factors that impeded realization of effects

- (1) Factors Concerning the Planning
- 1) The outputs and the project purpose were conceptualistic and related persons did not share the common recognition of the level to which they were to aim their accomplishment.
- 2) The general supporting procedure for protection of veterinary diseases is as follows: "Establishing diagnosis techniques on livestock and gathering epidemic information on major diseases", then "manufacturing vaccine for major diseases", and finally "establishing assay techniques for vaccine and developing manufacturing standards". The project was limited due to the human and budgetary resources on the Japanese side, so the project was started with the process that should have been implemented at a later stage. This resulted in the following problems: (1) Insufficient transfer of diagnosis techniques on livestock diseases, which made it difficult to measure the effects of improved vaccine quality quantitatively and correctly based on scientific reasons, and (2) the method of analysis could not be determined without the proper understanding of the manufacturing process since it is the reverse of manufacturing process. It was inevitable that only the Veterinary Diagnosis Department learned the system of inspection and upgraded the inspection standard and did not lead to the increase of vaccine supply with good quality. As a result, because the project contributed to the increase of quality vaccine supply, it was necessary not only to improve quality inspection techniques but also to deal with the issues outside the project such as the promotion of changes in the consciousness of manufacturing technique improvements at the Vaccine Production Department.
- (2) Factors concerning to the Implementation Process

Process management activities were not regularly practiced, and there was no common recognition about the accomplishment stage of the project, the problems and their countermeasures among related persons.

#### 3-4 Conclusion

There was no negative point in terms of the Five Evaluation criteria, and the project was highly evaluated. The framework on quality inspection for veterinary vaccine (learning inspection techniques, and the judgment measure of inspection and the judgment based on this) necessary for Syria has been developed, and the project was evaluated to be successful. By implementing daily works, the framework of technique accumulation and the improvement of capability as well as transferring techniques to the new participants should be established. It is desirable that the Syrian side makes efforts such as assuring funds according to the expansion of their works and to maintain and enhance the project.

#### 3-5 Recommendations

- (1) It is desirable if the unaccomplished outputs are in the present stage accomplished by the termination of the project in order for the project purpose to be fully accomplished.
- (2) Many of the essential elements to accomplish the project purpose in the future are to maintain and develop the frameworks of quality inspection for veterinary vaccines such as the Syrian side establishing the framework independently while enforcing the system. It is also essential to assure organization and funds for vaccine inspection and to enhance the cooperation with related organizations referring to the recommendation of this evaluation research. These should be accomplished by the Syrian side with a proactive attitude.

#### 3-6 Lessons Learned

(1) It was necessary, for the smooth implementation of the project, to consider not only the importance of experts, but also assuring allocation of the system coordinator who provides support to the experts or assures the allocation of experts with adjustment capability.

- (2) No regular monitoring was implemented with the project and related organizations and personnel did not share the common recognition about the level of achievement of the project. Setting the clear target and having the common understanding about progress towards the target among related personnel are necessary for the project to be carried out efficiently.
- (3) At an early stage of the project, related organizations such as the Vaccine Production Department and the Diagnosis Department of DAH did not have a mutual understanding of the project and therefore had difficulties. However, at the later stage the situation was improved and project activities became much smoother. Communication including publication activities with related organizations is highly significant.
- (4) The delay of equipment arrival largely affects project activities in the technical transfer utilizing equipment. It should be recommended to carefully study and prepare the necessary papers for import/expert and customs procedures at both the Japanese and beneficiary country as soon as the necessary equipment is organized.

## 3-7 Follow-up Situation

N/A.