

**AD HOC GROUP OF THE STATES PARTIES
TO THE CONVENTION ON THE PROHIBITION
OF THE DEVELOPMENT, PRODUCTION AND
STOCKPILING OF BACTERIOLOGICAL
(BIOLOGICAL) AND TOXIN WEAPONS
AND ON THEIR DESTRUCTION**

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**REPORT ON A TRIAL INSPECTION BASED ON A RANDOM VISIT
TO A VACCINE PRODUCTION FACILITY**

I. Introduction

1. On 27, 28 and 29 April this year, the Swiss Government organized a trial inspection involving a “random visit” to a Swiss enterprise producing vaccines. The purpose of this exercise was, *inter alia*, to assess the role and impact of transparency measures such as “random visits”, to train the representatives of the national authority and to promote awareness on the part of an enterprise potentially affected by this type of measure by means of a practical trial.
2. This working paper is designed to share the results of the trial with the Ad Hoc Group.

II. Preparations

3. The exercise was based on the rolling text (BWC/AD HOC GROUP/45) in the form used in the March 1999 negotiations. Given the number of brackets and the proposals made at that stage of the negotiations, it was agreed to follow the most demanding and restrictive version of the elements of the text, where applicable. For that reason, all the basic documents such as the declaration, the notification and the mandate were drawn up on the basis of the rolling text.
4. Four members from the competent departments which will form part of the future national authority took part actively and discharged the role and activities of representatives of the State party, while four military experts acted as the visiting team. A representative of the Ministry of Defence of Austria took part as an observer by invitation, together with a second observer from Switzerland.
5. Briefing and preparatory sessions were organized for the information of the

participants and officials from the enterprise involved. This afforded an opportunity to explain the rules of the exercise and allocate roles and tasks. The declaration was provided to the head of the facility, returned to the organizers of the exercise and sent to the inspection team two weeks before the visit. A fictitious notification on the notepaper of the future organization was sent to the national authority, together with the mandate, one week before the visit. The mandate comprised the following elements:

- Study of the conformity of the facility declaration with the activities on the site;
- Discussion and examination of the firm's declaration;
- Settlement of issues relating to the difference in interpretation of the requirements of the declaration and the data declared;
- Assessment of the relationship between the activities relating to the data declared and the activities on the site.

6. The visiting team and the two observers arrived at their hotel during the morning of Tuesday 27 April in order to make preparations.

III. Progress of the trial inspection

7. In keeping with the rolling text, the visit did not exceed 48 hours.

8. For practical reasons, the exercise began directly on Wednesday 28 April at 9 a.m. with a briefing and a tour of the facility and ended on Thursday 29 April at 4.30 p.m. with the presentation of the internal assessments and the delivery of the visiting team's report. The initial phase, which normally includes the point of entry, customs formalities and equipment checks, was not carried out in practice but simulated over time.

A. Briefing (28/04/99, 10.30-11.45 a.m)

9. It was preceded by a welcome ceremony and the introduction of the participants and leaders of the exercise.

10. The briefing, which was presented by a management official and the heads of research and production, was very thorough and comprehensive. It covered, inter alia, the enterprise itself, with detailed information on economic, financial and personnel matters, its historical development, its activities, its output and its products. Maps and photographs of the

installations were made available. It also covered safety and health aspects, with precise information on containment levels, methods of waste treatment and disposal and rules relating to the animal holding area.

11. On this occasion, the officials of the facility, with the consent of the organizers of the exercise, briefed the participants on the maintenance of confidentiality and informed them of the restrictions placed on the exercise in order to prevent any adverse impact or possible contamination of the products. It was agreed in particular, once the laboratories dealing with bacteriology had been inspected, that the virology laboratories would not be visited. These stipulations inevitably had an impact on the drafting of the visit plan.

12. Several questions seeking clarification were put to the facility officials by the visiting team, in the presence of the representatives of the national authority.

13. The briefing lasted longer than planned as a result of the large volume of information supplied by the facility officials. The visiting team asked the facility officials to confine themselves to essentials. The length of the briefing nevertheless impinged on the time allocated for the drafting of the visit plan and its presentation.

B. Drafting and presentation of the visit plan
(28/04/99, 11.45 a.m.-1.15 p.m.)

14. The visit plan was drawn up in the main on the basis of the declaration, the briefing and the restrictions, as well as the totality of the information collected by the visiting team during the briefing. Also involved in the drafting of this plan was the need to take account of the managed access and to make the best use of the time allowed. In order to derive maximum benefit from the visit, the visiting team decided to split into two groups to visit the facility separately.

15. The presentation was limited to half an hour. Although the representatives of the national authority had only a limited time to assess all the implications of the visit plan, it was accepted with a few modifications stemming from the restrictions related to the sequence of the activities and the managed access to the various installations.

C. Facility visit

16. The two groups that were formed contained at all times members of the visiting team, representatives of the national authority and a facility official, in the presence of the

organizers of the exercise and the two outside observers participating in the exercise as a whole.

Day 1 (28/04/99, 2.15-5.30 p.m.)

17. The first group began by visiting the virology department, which was located in premises with a BL3 containment level. Visual observations were made in the virus and vaccine storage containers, while auditing extended to lists and registers. Checks on modes of access for personnel within the containment zone were set up. This group continued its visit in the bacteriology department, where further visual observations occurred in the laboratories equipped with fermenters which engaged *inter alia* in toxin production, filtration and inactivation. The visiting team made continuous use of interviews with the department heads and facility staff.

18. At the same time, the second group began by concentrating on the declaration supplied by the firm. An analysis carried out jointly by the visiting team, the representatives of the national authority and the facility officials enabled several points to be clarified. A small number of questions and possible uncertainties arising from the declaration and the activities on the site were dealt with on this occasion. They were originally caused by sometimes misleading elements and questions in the declaration in its present version. Thereafter, this group visited the refrigerated warehouses containing separately raw materials, quarantined stocks and products ready for distribution. Records and protocols were verified on the occasion of a surprise check of the internal ordering of a product, its warehouse exit voucher and the confirmation of its dispatch to a foreign country. Interviews were also held throughout the visit.

Day 2 (29/04/99, 9.15-10.45 a.m.)

19. The two groups concentrated on the virology department. They examined laboratories which made use of fertilized eggs for vaccine production, as well as the storage of incubating eggs. Interviews were also held on this occasion. In addition, interviews were arranged with a research official, in order to obtain clarification concerning the development of a nasal aerosol. No research on larger-scale application was observed. Lastly, a visit to the animal holding area provided the visiting team with additional evidence of the nature and scope of the products and experimentation with them.

D. Intermediate assessments and presentation of the preliminary report

20. The schedule for the exercise contained provision for intervals (28/04/99, 6-6.30 p.m.; 29/04/99, 9-9.30 a.m.) for taking stock and offering the participants an opportunity to clarify any intermediate issue among themselves, as well as to allow the organizers of the exercise to supply information on matters of substance or administrative issues. The organizers of the exercise did not have to suspend the progress of the exercise in order to reorient it.

21. The plan also allowed time (29/04/99, 12.15-1 p.m.; 2-3.30 p.m.) for the preparation of the internal assessments and the presentation of the preliminary report. This report was composed of the following elements:

- General information relating to the facility: descriptions and geographical location of the sites, economic and financial status of the company;
- Information relating to the business, the installations, the staff, the products and micro-organisms, the production sectors;
- Information relating to managed access;
- Information relating to cooperation on the part of the company;
- Assessment relating to whether the declaration was in conformity with the activities on the site (with reference to the mandate);
- Risk assessment.

22. Attached to this preliminary report were: the mandate, the plans of the facility, the documents on the firm's briefing, the firm's progress report, the safety regulations within and around the installation, organization and responsibilities within the bacteriology department, the corrected version of the declaration with an explanation of the changes made, all the

organizational charts of the firm's departments and lastly the sequence of events.

IV. Lessons drawn

23. Firstly, this exercise gave rise to a number of lessons of a practical nature in relation to the various activities and events during the visit.

Briefing

24. A clear and comprehensive briefing on the part of the firm will have positive consequences for the remainder of the visit, i.e. for the drafting of the visit plan, the visit itself and the conclusions of the visiting team. The briefing makes it possible to spell out restrictions and additional information clearly and thus to eliminate various uncertainties connected with the declaration. It is important for the national authority to ensure that the briefing is limited to essential points of interest to the visiting team, not exceeding an hour in length, so as to allow the visiting team enough time to prepare with care its plan to be presented to and discussed with the representatives of the facility and the national authority.

Presentation and discussion of the visit plan

25. These exchanges promote a cooperative attitude on the part of the visiting team and the others involved and thus increase trust and transparency. In particular, they enable misunderstandings to be avoided by making the ground rules clear. They offer the additional advantage of strengthening the special link between the firm and the national authority.

26. Bearing in mind the time allocated, the visit plan should specify priorities and focus on particular installations and activities. It is neither necessary nor practicable to verify all the elements of the declaration.

Facility visit

27. It should comply closely with the visit plan. The representatives of the national authority should ensure that they are fully prepared and stand ready to take action, where necessary, in respect of all the activities of the visiting team.

28. Both the mandate and the rules relating to intellectual and industrial property are sound means of safeguarding the firm's interests. The information policy can of course be voluntarily extended beyond the mandate, provided that confidentiality is respected.

29. This is why the heads of the firm should not go beyond their role of replying to

questions and providing the information required. Excessive zeal in providing information could prove counter-productive and awaken suspicions on the part of the visiting team.

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30. This exercise also highlighted the following specific points:

- The 48 hours assigned cannot be sufficient to allow the visiting team to discharge its mandate, unless it sets priorities and focused objectives.
- A small visiting team is adequate for this purpose. The four-member team is balanced and allows two sub_groups to be formed.
- The representatives of the national authority should prepare the firm to be visited in advance. They can be more effective by seeking the help, inter alia, of specialists in microbiology.

31. Finally, it should be emphasized that this trial inspection demonstrated that visits offer major benefits in obtaining a clear idea of the profile and activities in a plant that cannot be provided by a declaration alone.
