OPCW

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NOTE BY THE DIRECTOR-GENERAL

REPORT ON SCHEDULE 2 SAMPLING AND ANALYSIS START-UP PERIOD

Introduction

1. This note summarises the experience and progress made on the implementation of sampling and analysis (S&A) at Schedule 2 plant sites during the one-and-a-half year start-up period. In addition, plans for further use of S&A in Schedule 2 inspections are outlined.

Executive Summary

2. The Technical Secretariat (hereinafter the 'Secretariat') has implemented a one-and-a-half year start-up period for conducting S&A on a limited basis during subsequent Schedule 2 inspections. The start-up period began in September 2006 and ended in March 2008, with a total of 13 Schedule 2 S&A inspections completed in 13 Member States. Support from Member States hosting S&A inspections has been excellent. The Secretariat has been able to demonstrate that it can effectively conduct S&A at Schedule 2 plant sites under a wide variety of conditions. These included the operation of the OPCW analytical equipment in both "open" and "blinded' mode, samples being analysed at laboratories outside the declared plant site, and analysis of chemicals in both aqueous and solvent solutions, etc. The results of the analyses carried out by the OPCW inspection teams have indicated that none of the inspected plant sites were producing, processing or consuming undeclared scheduled chemicals. The incremental costs for conducting a Schedule 2 S&A inspection are about EUR 15,000 per inspection due to the larger size of the Inspection Team (IT) and the additional cost of shipping the OPCW analytical equipment. The Secretariat continues to learn from each S&A inspection and plans to gradually increase the number of Schedule 2 S&A inspections over the next several years. The Secretariat will also implement some modifications to the way in which Schedule 2 plant sites are selected for S&A.

Background

3. Part VII, paragraph 27, of the Verification Annex unequivocally states that "Sampling and analysis **shall be undertaken** to check for the absence of undeclared chemicals" (emphasis added).

4. Part VIII, paragraph 22, of the Verification Annex states in its first sentence that "Sampling and on-site analysis **may be undertaken** to check for the absence of undeclared scheduled chemicals" (emphasis added).

5. Similarly, the text of the first sentence of Part IX, paragraph 19, states that "Sampling and on-site analysis **may be undertaken** to check for the absence of undeclared scheduled chemicals" (emphasis added).

6. In accordance with the provisions of Part VII, paragraph 27, of the Verification Annex, which makes S&A a verification tool compulsory for Schedule 2 inspections, the Director-General announced in his opening statement to the Forty-Third session of the Executive Council his intention that the Secretariat would, in the third quarter of 2006, begin using S&A on a limited basis for inspection of Schedule 2 plant sites. He indicated that this would be done on a trial basis for approximately one-and-a-half years so that the Secretariat could build up experience and evaluate its future use.

7. The Director-General also highlighted in his announcement that the S&A would be used in strict compliance with the Convention, to check for the absence of undeclared scheduled chemicals. At the beginning of 2006, Member States were informed of the logistical requirements for receiving the shipment of analytical equipment at inspected plant sites and for the provision of minimum support required to receive a Schedule 2 inspection with S&A (S/548/2006 dated 10 February 2006).

8. In preparation for hosting an inspection with S&A, the Director-General invited all Member States to approach the Secretariat to discuss S&A individually and a number of such meetings and familiarisation visits have been held during the past two years.

9. The Secretariat, with broad-based participation of the Inspectorate and the Verification Division, completed extensive preparations for implementing S&A. The Secretariat then began using this verification tool as planned during a Schedule 2 inspection in September 2006. This was the beginning of the one-and-a-half year start-up period that included the anticipated use of S&A during 13 subsequent Schedule 2 inspections in 13 Member States.

Summary of the Results of the 13 Schedule 2 Inspections with S&A:

10. Thirteen S&A Schedule 2 inspections have been completed so far (2 in 2006, 9 in 2007, and 2 in 2008). These inspections have taken place in the following countries: Switzerland, China, the United Kingdom of Great Britain and Northern Ireland, India, Italy, the Netherlands, the Republic of Korea, Japan, France, Germany, the United States of America, Australia and Sweden. The cooperation of the inspected State Party (ISP) for each S&A inspection has been excellent.

11. All thirteen S&A Schedule 2 inspections have been completed within the normal inspection time period (no more than 96 hours for Schedule 2 inspections)[1].

12. For 3 out of the 13 inspections, the space provided for the OPCW laboratory equipment was outside the plant site (within 2 hours' drive); these arrangements were

[1] Several inspection teams returned one day early. In one case, an inspection lasted to the end of the allowed inspection time.

necessary because the plant sites were very small and laboratory space at the sites was not available. These 'outside' locations required the OPCW analytical sub-team to work in the laboratory space provided at a separate location from the inspected plant site. This was a workable arrangement for the Secretariat and it is expected that this type of arrangement will continue to be used in the future, when necessary.

13. The analysis during one inspection revealed that the OPCW Central Analytical Database (OCAD) did not contain analytical data on 3 out of the 4 declared Schedule 2 chemicals. The gaps noted in OCAD for the missing commercially-produced Schedule 2 compounds need to be filled so that database covers the broadest possible list of scheduled chemicals – in particular, scheduled chemicals that are handled commercially. The Secretariat is pursuing this.

14. During a number of inspections, the GC/MS analysis conducted by the OPCW identified low-level process impurities that matched with the OCAD. The presence of these compounds was expected based on the knowledge of the process chemistry and production activity at the plant site. In accordance with the current OPCW analytical procedures, the IT only performs qualitative analysis and does not undertake quantitative analysis.

15. No major logistical problems were encountered with delivery of the S&A cargo in the 13 Schedule 2 S&A inspections conducted. A number of areas have been identified for future improvement and are included in the Annex, in the summary of lessons learned.

16. In 12 out of the 13 inspections, the S&A cargo was shipped directly to the site and the point of entry (POE) procedures were carried out at the site. This practice worked very well and saved an extra step of unpacking and then repacking the S&A cargo at the declared POE.

17. Analyses during 11 inspections were conducted with the gas chromatograph/mass spectrometer (GC/MS) operating in "open" mode, with 2 inspections in "blinded" mode. This indicates that the majority of the inspected States Parties have been reassured that the operation of the analytical equipment in "open" mode does not compromise the site's confidential business information. In addition, these inspected States Parties have accepted the Secretariat's argument that the operation of the equipment in "open" mode provides access to additional analytical tools available to the Secretariat (such as the US National Institute of Standards and Technology commercial library of chemicals) capable of clarifying those cases where ambiguities about the identity of chemicals analysed using OCAD only occur.

Commentary on the Results of Sampling and Analysis

18. The overall progress in implementing sampling and analysis has been very positive. The start-up period has provided an excellent test for the Secretariat under a wide range of conditions to demonstrate that its equipment and procedures are adequate for the task and that its personnel are well trained. The Secretariat has adopted a policy of continuous improvement of its practices and procedures for the implementation of Schedule 2 S&A and, as previously mentioned, utilises lessons learned after each inspection with S&A to optimise the procedures and improve overall inspection execution.

19. Advance planning and preparation by the Secretariat and the Member States in question were very important factors in the successful launch of Schedule 2 S&A inspections. A total of 11 State Party familiarisation visits to the OPCW Laboratory (lasting a full day) helped prepare the concerned National Authorities for S&A inspections. These meetings included S&A presentations by the Verification Division and the OPCW Laboratory, as well as a full demonstration of the GC/MS instrumentation. In addition, a two-hour meeting was held with one other State Party and a one-hour teleconference was held with another State Party. A special one-day meeting was also held for "Conseil européen des fédérations de l'industrie chimiques" (CEFIC) representatives.

20. Limiting the conduct of S&A to subsequent Schedule 2 inspections has allowed for more detailed technical planning, which has helped the Secretariat to prepare more thoroughly, as information was available from previous inspection reports on the process chemistry, possible sample points, etc. In a number of cases where a Facility Agreement was drafted or in place, it already contained an agreed provision for the conduct of S&A that facilitated technical preparation.

21. The S&A inspections in the start-up phase have demonstrated that OPCW inspectors are well trained for conducting S&A inspections within the industry verification regime. The group of inspectors used in the start-up phase for S&A inspections is being expanded to include additional inspectors, so as to provide for greater flexibility in personnel planning within the Inspectorate.

22. With the exception of one inspection, the GC/MS equipment worked well on site. Some on-site repair work was needed during this particular inspection to operate the Laptop computer for the GC/MS (dead battery replaced) and also the MS (filament replaced). This highlighted the need for bringing more spare parts for the analytical equipment; this matter has been addressed for future inspections.

23. The five-day inspection notification is helpful for both the ISP and the Secretariat to work through and resolve any logistical issues. The information in the notification was expanded to indicate whether major equipment items (such as fume hood, gas cylinders) would be included with the S&A cargo. This helped confirm prior to the inspection what was expected to be available on site based on previous knowledge and agreements, as well as the logistical support the ISP needs to provide.

24. More resources are required for the conduct of Schedule 2 inspections with S&A when compared to the same inspection without S&A. In the case of inspections with S&A, two analytical chemists (ACs) are added to the Inspection Team so that the sample analysis can proceed in parallel with other inspection activities. This typically increases the total team size from three to five inspectors. In addition, the extra cost (compared to a typical Schedule 2 inspection without S&A) is about EUR 15,000, which covers the extra cost for shipping the S&A cargo and the travel and DSA costs for the additional two inspectors.

25. Lessons learned after each inspection have been documented and shared within the group responsible for the planning of S&A inspections. This has allowed the Secretariat to continuously improve the preparation and conduct of S&A inspections. A list of lessons learned is presented in the Annex.

26. The use of S&A complements other verification activities (records check, physical observations and compiling a material balance).

27. The true value of S&A cannot be assessed solely in terms of the cost vs. benefits. This is, however, not specific to S&A – it is true for most verification activities. It should be noted, however, that S&A offers the only verification tool for screening a chemical sample to identify possible undeclared scheduled chemicals. Consequently, analysing a sample from a chemical process, or associated other auxiliary vessels, offers a unique way to establish if there are any undeclared scheduled chemicals present (including Schedule 1 chemicals) at the point in time the sample is taken. An OPCW inspector cannot look at a process vessel and tell what chemicals are present inside, nor can this be done with absolute assurance by only checking production or inventory records. Along these lines, the use of S&A, when coupled with other verification activities, provides a higher level of assurance that no scheduled chemicals that should have been declared are present at the plant site, and therefore more certainty that the activities of the site are in compliance with the Convention.

Subsequent Steps for the Future Use of Schedule 2 Sampling and Analysis

28. Future Schedule 2 plant site inspection frequency: The Secretariat is obligated to use risk assessment as a basis for determining the frequency and intensity of Schedule 2 inspections in accordance with the Convention (Part VII, paragraph 20, of the Verification Annex). Using the risk-assessment criteria in the Convention, the Secretariat developed a simplified risk algorithm in 2007 along with updated guidelines on the frequency of inspection for plant sites with different categories of risk. The application of these guidelines for inspection frequency over a period of 10 years (i.e. two inspections for low risk, two-and-a-half inspections for medium risk, and three-and-a-half inspections for high risk), combined with the requirement to undertake initial inspections at newly-declared Schedule 2 sites, will be used as a basis for selecting sites to be inspected each year (42 Schedule 2 inspections budgeted for 2008).

29. Subsequent and initial Schedule 2 inspections: The Secretariat plans to continue conducting S&A primarily for subsequent Schedule 2 inspections for the next two to three years. The risk assessment for these facilities has been done during the initial inspection in accordance with the Convention (Part VII, paragraphs 18, 19 and 20, of the Verification Annex) and the detailed plant site and process descriptions from the initial inspection allow for a comprehensive technical preparation by the inspection team (IT). However, the Convention does not limit the conduct of S&A to subsequent Schedule 2 inspections and therefore the Secretariat cannot rule out the possibility of using S&A during an initial inspection. It will be more challenging to use S&A during an initial Schedule 2 inspection where little is known about key factors such as chemical processes used by the plant site, its technical characteristics, and the nature of activities carried out there. When the Secretariat has more S&A experience with broader knowledge of Schedule 2 chemistries, the utilisation of S&A will be expanded to include initial Schedule 2 inspections.

30. Selecting Schedule 2 plant sites for S&A: The risk assessment criteria for Schedule 2 plant sites include “the characteristics of the plant site” (Part VII, paragraph 18, of the Verification Annex). The process-equipment configuration (batch process vs.

continuous process and multipurpose vs. dedicated equipment) is an important element included in the "characteristics of the plant site" risk criteria and has a direct bearing on the sites technical capability to produce undeclared scheduled chemicals. For the conduct of S&A during the one-and-a-half year start-up period, the Secretariat selected only plant sites that had batch and/or multipurpose equipment configurations. This type of equipment arrangement, due to its higher flexibility, is more likely to have the capability to produce undeclared scheduled chemicals and thus is considered of higher relevance for the conduct of S&A. When selecting plant sites for S&A in the future, more weight will be given to facilities that have more flexible equipment configurations. However, no Schedule 2 plant site will be excluded from consideration in the selection process for the use of S&A.

31. Geographical distribution for Schedule 2 S&A inspections in the Long Term: A key consideration is whether geographical distribution should be a factor in the selection process. However, adopting a specific geographic selection criterion would be contrary to the risk-based approach (using the technical characteristics, which include equipment configuration) that was discussed in the previous paragraphs. Therefore, the Secretariat does not plan to apply a "geographic proportionality factor" in the site-selection process since this type of criterion is not related to the risk elements specified in the Convention (please refer to Part VII, paragraph 18 of the Verification Annex).

32. There are 22 countries with inspectable Schedule 2 plant sites, which leaves nine countries that have not been subjected to an S&A inspection during the start-up period. For 2008 and 2009, consideration will be given to conducting S&A in the nine countries that have not yet had an S&A inspection, so that the experience gained by the Secretariat will be as broad as possible. Selecting Schedule 2 sites for S&A in these States Parties will take place while still maintaining normal inspection frequency, and taking into account the technical characteristics of the plant sites.

33. Sample collection points: As a guideline to the IT, the primary sample locations will remain in the declared Schedule 2 plant(s) and related support facilities (such as warehouse storage), as these areas are the focus of the inspection (Part VII, paragraph 25, of the Verification Annex). During the one-and-a-half year start-up period, the Secretariat made a point of not taking samples outside the declared plant and communicated this to Member States as a pre-condition before S&A inspections started. However, the Secretariat does not rule out collecting a sample beyond the declared plant, within the declared plant site. The Convention does not limit the sample taking to the declared plant and consequently the Secretariat cannot impose more restrictive criteria on itself. There could be good reason to take a sample within the declared plant site at a location that is outside of the declared plant, based on the observations and findings of the IT.

34. Number of samples per inspection: For practical reasons, the number of samples taken during each inspection will, in general, remain low (one to three). This does not preclude taking more samples if needed (for example, if there are multiple declared Schedule 2 plants within the plant site or the analytical results raise additional questions). At the same time, the work by the OPCW Laboratory to develop less time-consuming sample preparation procedures is expected to continue in order to shorten the overall time required for on-site analysis. In the long term, to increase the

credibility of the S&A verification tool, the number of samples taken and analysed must be increased.

35. Quantification capability of low-level process impurities: As mentioned in paragraph 14, the on-site GC/MS analyses conducted during a number of inspections identified low-level process impurities that matched with the OCAD. The presence of these compounds was expected and therefore clarified with the knowledge of the process chemistry and production activity at the plant site. In future cases of this nature, it would be beneficial for the Secretariat to have additional analytical procedures to allow for an approximate quantification of a chemical identified during analysis to assist with the confirmation that it is, for example, a process impurity (or by-product) present at low concentration. The OPCW Laboratory is pursuing this by developing the necessary procedures.

36. The Number of Future Schedule 2 Inspections with S&A: It is not an option to discontinue Article VI sampling and analysis for the Schedule 2 verification regime, since the Convention obligates the Secretariat to use this tool (Part VII, paragraph 27, of the Verification Annex). In addition, there is, in the view of the Secretariat, an added verification value to the use of sampling and analysis as outlined in paragraphs 26-27 of this note. For these reasons, the Secretariat will continue to routinely use S&A in Schedule 2 inspections and gradually expand its use over a number of years as more experience and efficiency are gained, and as OPCW resources and funding allow.

37. For 2008, there are 42 Schedule 2 inspections included in the Programme and Budget and of these; 8-10 Schedule 2 inspections will include S&A. The gradual increase in the number of Schedule 2 inspections with S&A will also allow more time for the Secretariat to resolve outstanding technical and logistical issues encountered during the start-up period. Additional status reports will be prepared for Member States at the end of 2008 and 2009 to indicate progress, as well as future use, and potential further expansion of S&A. By the end of 2008, some Member States will have experienced a second S&A Schedule 2 inspection, which will give these countries some first-hand experience in the progress made since the first S&A inspection.

38. For 2009, the Secretariat will strive to increase the number of S&A inspections slightly (up to 12) and foresees a gradual increase in the number of Schedule 2 inspections utilising S&A over the coming years. Such growth will be carefully balanced against the resources required in terms of personnel and equipment, the added value of undertaking S&A and the budgetary provisions. It is important to keep in mind that, as more experience is gained, the S&A procedures and practices are expected to become more efficient and streamlined in terms of resources and time required for the analysis to be carried out. This is expected to provide for a more efficient and effective implementation of S&A and allow for a gradual expansion of S&A while limiting the resource implications. The Secretariat will monitor progress made on S&A and will track the overall improvements.

Annex

Summary of Lessons Learned – Schedule 2 S&A Start-up Period

1. A method has been developed to seal the GC/MS which is normally set up in a laboratory space that is shared with others performing non-OPCW activities when it is not in use or is unattended.
2. The OPCW equipment list was reviewed and continues to be optimised based on the experience gained in S&A inspections. As an example, a smaller sample preparation kit is now being used.
3. The hard disc for the GC/MS computer has now been set up without the two commercial libraries pre-installed. This provides an additional measure of protection for confidential business information when operating in blinded or open mode, since the commercial libraries are separated from the computer. However, when in open mode, it still gives the Inspection Team the flexibility to install and use the commercial libraries if required and accepted by the ISP. Having the commercial libraries preinstalled on the hard disc was a concern raised by some Member States that has now been addressed.
4. Logistics, in particular the shipment and clearance of S&A cargo through customs, can result in delays and the Secretariat will therefore need to allow more time to clear the POE with S&A cargo.
5. Good communication is essential to avoid misunderstandings between ISP and Secretariat.
6. Equipment reliability and the need to bring spares is an important consideration to assure that the analysis can be completed in a timely manner.
7. There are benefits to having more analytical options when using “open” mode to identify chemicals that match with OCAD more quickly.
8. The capability to use an auto sample injector for GC/MS as a means to make better use of the GC/MS is recognised and is being pursued by the Secretariat.
9. Establishing a Schedule 2 chemistry knowledge database for preparation of future S&A inspections will be helpful and is being pursued by the Secretariat.
10. There is a need to further simplify the analytical and documentation procedures during S&A in order to reduce time and increase efficiency allowing, for more samples to be analysed.

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