

more rapidly with the surroundings. Anyhow, in this particular case, the logic structure of the facility greatly facilitated the rapid familiarization with the basic layout of the plant.

11. Types of records needed and/or audited

By using the documents mentioned in part B.11, it is possible, on the basis of accountancy operations, to "trace" a chemical, i.e. to verify when, where and how it has been used/synthesized (traceability). However, for the purposes of this particular inspection, traceability appeared to be less useful, since under this type of inspection mainly qualitative data (related to the structural formula of the produced chemical) were needed.

All documents were in the Dutch language; moreover frequent use is made of abbreviations and code numbers. Fluent knowledge of the language used at the facility seems to be a necessity for at least one of the inspectors.

12. Plant orientation tour

For this type of facility one hour would have been largely sufficient for an orientation tour (only the surroundings).

13. Inspection of areas and facility equipment

In the conduct of the inspection, the inspectors were not subject to any restriction on access to plant areas; however, access to storage areas of dangerous products would be more cumbersome due to additional security measures.

14. Inspection of operating procedures

Provided the inspectors do not copy relevant parts of the operating instructions, they have the possibility to check them on the site. Never should such operating instructions and other relevant documents leave the facility.

15. Sampling

As stated earlier, sampling of batch operations will normally occur after termination of the batch and preferably after drying of the product. Sample taking during batch operation might result in a complex sample that is sometimes difficult to analyse and that does not reflect the normal end product(s) of the batch; moreover in that particular case of sample taking during batch operation the temperature would have to be lowered to room temperature, resulting in loss of time; in some cases, e.g. synthesis under inert atmosphere (nitrogen), opening of the reactor might result in important product loss.