

# Quality assurance aspects in biochemical and chemical information technology

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## Abstract

Tools of information technology became inevitable parts of modern process and system documentation. The exact documentation is a principal problem of quality assurance systems (QAS), from the very beginning of the design to the final implementation and continuous operation of the system. Much of the data produced and recorded in a biochemical and especially in an agricultural QAS is disperse — if they are not directly fuzzy. One important feature in such a database is traceability of the history of the final product. A unique identifier by which for example the climate parameters, the plant protection data or another information can be retrieved from the records achieves this traceability. We have created several test applications running on different database systems (DBS). Through our investigation we have tried to use the simple tools of Microsoft Office, a referential DBS (Ms SQL Server) and GroupWare (Lotus Notes). We show results and examples from these multilevel problems of information technology focused on the special requirements of QA. © 2000 Elsevier Science Ltd. All rights reserved.

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## 1. Introduction

Commerce or processing of fresh and perishable bio-products has to be a flexible fast procedure — the time factor does not allow long quality checking or complicated laboratorial measuring or testing. To ensure on every level the safety of these perishable raw materials for food industry or marketing networks, all subcontractors need quality assurance systems. The quality assurance systems (QAS) requires strict documentation including records provide evidence, but farmers are the least excited about keeping strict records of their actions — that's why the application of computer aided, user friendly but safely working QAS became inevitable part of modern process and system documentation (Kollár & Viczián, 1997). Much of the data produced and recorded in a biochemical and especially in an agricultural QAS is disperse — if they are not directly fuzzy. Recorded data include information about orders and sales, contracts and stock inventory, evaluation of

subcontractors, records provide evidence as plant protection and climate parameters, documents stating requirements as work orders or job descriptions etc.

The principal requirements of QA specific software are the following,

- capability to uniform developing of quality manual, procedures and work orders;
- support of the working system in keeping and evaluating records.

Both requirements include a certain level of word processing, they have to handle DB systems and to support a relative high level of simultaneous working, i.e. GroupWare. A similarly important requirement is the security.

Creating special applications we have found that the software solutions based on Ms Office becomes extremely complicated, as the size of the real database increases, also there is a problem concerning security. The difficulty in referential databases (Tóth, Viczián, Viczián & Dióspatonyi, 1999) is the dispersness of the recordable data. Lotus Notes proved to be far the best solution — it is capable of holding and relating data that are very disperse at the same time.

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First we discuss our general results that are not depending on the special field of application; thereafter we show special examples from food industry, agriculture and horticulture. At last we show a statistical technique including measuring method and instrumentation that serves as a part of quality control in special industrial biotechnology.

## 2. Theoretical results

The exact description of an entire production procedure uses several common theoretical steps in different fields of QAS (Evans & Lindsay, 1993).

An adequately implemented and operational integrated management system (IMS) ensures the continuous and specified quality throughout the food supplier chain 'from farm to fork'. The most important elements of the IMS in the food industry or agri/horticulture, in the biochemical and chemical industries are the following.

- QAS, quality assurance system.
- HACCP, hazard analysis critical control point.
- EMS, environmental management system.
- OHSMS, occupational health and safety management system.
- HAZOP, hazard operability study.

The Fig. 1 shows the contacts of the first three above-mentioned elements focused on necessity of using information technology.

Although each system has a specific focus — e.g. HACCP focuses on food safety, QAS focuses on the continuous quality in the management system, etc. — the common idea in all of these systems is the pre-active approach instead of post-active approach.

Throughout audits within the sectors, it has been proved that the pre-active concept can be achieved and maintained the most effectively by a GroupWare (Lotus Notes, Novell GroupWise). Due to the daily operations the above mentioned systems are ac-

cumulating a large amount of data, which are the objective evidences for the systematic control of the system.

The IMS, supported by a GroupWare database system allows a better control and measurement at all levels, internal audits, second party (customer) audits, and third party (certification) audits.

For the relevant subcontractors specify their internal audits, here we give a short review of the electronic second and third party audits only.

### 2.1. Second party (customer) audits

- Results are compared automatically against specification and highlighted for example using an easy-to-use color coding system, with on-screen graphs to indicate trends. It will provide an ongoing product analysis test method with visual results for both — customer and the grower/producer parties.
- The requirements with respect to safety/quality of food/agri and biochemical products are increasing. Detailed information about products needs to be passed through the food/agricultural supply chain often on a global scale, where the GroupWare system as a tool of managing the IMS seems to be the most effective. When a product is being marketed and continuously assessed by the customer or its representative, the associated product specifications ideally should be given in the form of interactive data sheets. These data sheets are integrated in the IMS and are continuously updated by the software. This fact leads to comply with the different standards and customer specifications from all aspects (quality, safety, etc.) Such computer-based product descriptions (models) allow automated checking for the required function and safety/quality on beforehand.

### 2.2. Third party (certification) audits

- There are ongoing developments of a new software application, which streamline the auditor's reporting process. (Similar developments have been documented for the internal audits — industrial self-assessment — while testing the referential database system. This internal audit tool is the most effective at companies, where there are many sites needed to be assessed.)

A Certification Body (Det Norske Veritas) has developed a new tool as following.

The new tool is called auditor reporting tool (ART) which is fully compatible with the IMS system documentation, where it is supported by the referential database.

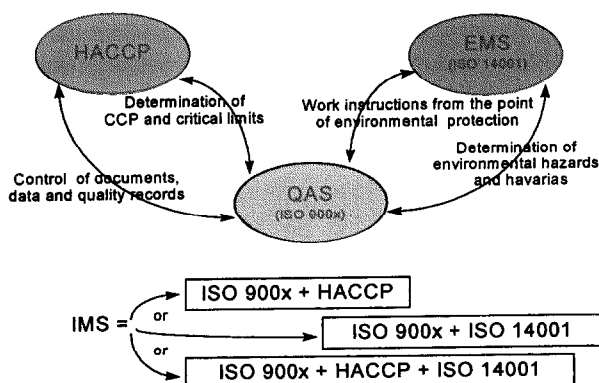


Fig. 1. Contacts in QAS, HACCP, EMS and IMS.

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