

TechniCAL has a software program that is currently used throughout the Low Acid Canned Foods industry. This program is called "CALSoft" and is used to collect time/temperature data during a heat penetration or temperature distribution test, evaluate that data, and calculate a thermal process schedule or come-up time/vent schedule.

FDA has new regulations addressing Electronic Records and Electronic Signatures (21 CFR Part 11) that went into affect in 1997. TechniCAL has reviewed these regulations in detail and it is our opinion that Part 11 **DOES NOT** apply to CALSoft.

To better understand our position, you should first understand

- (1) our CALSoft software and how it is used in the industry, and
- (2) our interpretation of Part 11.

1. CALSoft:

TechniCAL developed this software back in 1980 as an internal tool for use in conducting heat penetration testing for our customers. At that time, the only method of conducting heat penetration testing of canned foods was to manually record time and temperatures onto a paper record after visually taking the reading from a potentiometer. TechniCAL changed this by using a personal computer and our CALSoft software, along with a datalogger and thermocouples. The idea was to have the software scan the datalogger and record time/temperature readings during the heat penetration test. The final result would be computer file of time/temperature readings that could later be evaluated (plotted) and calculated (using the Ball Formula method or General Method calculations).

The CALSoft program in use today is a sophisticated 32 bit Windows based system consisting of 3 modules... CALSoft Collect, CALSoft Analyze, and CALSoft Calculate.

CALSoft COLLECT: This module of the software allows the user to easily create a data file (by running heat penetration or temperature distribution test, importing existing data files, or manually entering time/temperature data readings). The user can easily set up the test information, including process critical factors, and graphically watch the data collection. After data collection, the software automatically assigns a file name to the time/temperature file and stores it on the designated computer disk drive.

CALSoft ANALYZE: This module of the software allows for CALSoft data files to be automatically plotted, evaluated, and printed in a number of different formats. Raw data printouts and "min-max" comparisons can be printed to evaluate each test. Each thermocouple is plotted on-screen and can be manually adjusted or "re-plotted", while process heating factors are updated in real time. This module is simply used as a tool for the user to analyze the time/temperature data and decide what the heating factors are for a particular test condition.

CALSoft CALCULATE: After the data is evaluated, a thermal process can be generated using either the ball Formula Method or the General Method. The final result is a detailed "Scheduled Process" which is printed. This Scheduled Process including process critical factors, process calculation factors, and process time/temperatures for a range of product initial temperatures and retort temperatures.

Once the printed final result (the Process Schedule) has been completed, CALSoft's job is done. This printed Scheduled Process is usually included as an attachment in a "Process Letter" written separately by the Process Authority. If this process will be used for regular production, an FDA Filing Form 2541a is also created by the processor (using the Scheduled Process information) and submitted to

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FDA. This process letter, Scheduled Process, and Filing Form are required by FDA regulations to be kept on file at the processor's location as backup documentation to the process being used during daily production.

2. OUR OPINION ON PART 11:

In summary, it is our opinion that 21 CFR Part 11 applies to electronic recordkeeping systems where the PRIMARY method of recordkeeping is electronic, or "paper-less". CALSoft is simply a tool used to create a final result -- a printed Schedule Process. It is also important to note that nothing printed by CALSoft is sent to FDA. The permanent file (the paper copy of the time/temperature data and the Scheduled Process) is kept on site-by the processors as required in the regulations. The data files created by CALSoft are saved after the printed result is issued simply for data backup reasons. In fact, sometimes these data files are simply deleted after the result has been issued.

During our research into Part 11, we discovered that the issue regarding electronic records and signatures actually first started in 1991 when representatives of the pharmaceutical industry met with FDA to determine how they could develop and maintain paperless record-keeping systems that would comply with the GMP's for drugs (21 CFR Parts 210 & 211). Because of the tremendous volume of paper that had to be submitted and maintained by the drug companies - in support of Investigational New Drug applications and, especially New Drug Applications - and given the fact that storage capacity on computer systems was advancing rapidly, the drug industry was extremely interested in seeing if they could go with an all electronic data base filing system. Therefore, the original driving force behind Part 11 was really the pharmaceutical industry pursuing a standard for paper-less systems.

Looking at the specific regulation itself, 21 CFR Part 11.1(b) states in part:

"This part (i.e. Part 11 in its entirety) applies to records in electronic form that are *created, modified, maintained, archived* (keep this in mind, especially for what follows), *retrieved or transmitted, under records requirement* of the Federal Food, Drug, and Cosmetic Act, and the

Public Health Service Act However, this part does not apply to paper records that are, or have been, transmitted by electronic means."

Looking further into the preamble for Part 11.1 (b) we discovered the following (from Page 13437 of the Preamble)::

"The key to determining part 11 applicability, under 11.1(b), is *the nature of the system* used to create, modify, and maintain records, as well as the nature of the records themselves.

Part 11 is not intended to apply to computer systems that are merely incidental to the creation of paper records that are subsequently *maintained in traditional paper-based systems* . In such cases, the computer systems would function essentially like manual typewriters or pens and any signatures would be traditional hand-written signatures. *Record storage and retrieval would be of the "file cabinet" variety*. More importantly, overall reliability, trustworthiness, and FDA's ability to access the records would derive *primarily from well-established and generally accepted procedures and controls for paper records* .

When records intended to meet regulatory requirements are in electronic form, part 11 would apply to those records (*including their creation, signing, modification, storage, access and retrieval*. *Thus the software and hardware used to create records that are retained in electronic form for purposes of meeting the regulations* would be subject to part 11."

Furthermore, in the most recent Industry Guidance Document issued by FDA on February 20, 2003, the scope of the regulation is more narrowly defined as follows:

"...when persons use computers to generate paper printouts of electronic records, and those paper records meet all the requirements of the applicable predicate rule (such as 21 CFR 113), and persons rely on the paper records to perform their regulated activities, the merely incidental use of computers in those instances WOULD NOT trigger Part 11...."



For these reasons, CALSoft, in our opinion, would be exempt from Part 11 because CALSoft records are maintained in traditional paper-based systems and are NOT maintained solely in electronic formats. As explained above, the printed Process Schedules & Process Letters are kept in a paper-based recordkeeping system at the processor's site.

If CALSoft ever gets to the point that it replaces the paper-based filing system and data is collected, transmitted, reduced, evaluated, and a process generated - all electronically – within the software, then the CALSoft data logging system and all its accouterments will, in our opinion, be subject to Part 11 at that time. But until that time, it is our opinion that Part 11 does NOT apply to CALSoft. ■

For more information on CALSoft or Part 11, please contact TechniCAL

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