TechniCAL, INC.
Washington D.C. Area Office

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US Department of Agriculture
Food Safety & Inspection Service
Room 102, Cotton Annex
300 12th St., SW
Washington, DC 20250-3700

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William R. Cole

Dear Sir or Madam:

I am writing with comments regarding the above docket number, the proposal of the US Department of Agriculture, Food Safety & Inspection Service to establish performance standards for the production of processed meat and poultry products., as published in the Federal Register on February 27, 2001. My comments will be directed solely towards Section VI: Thermally-Processed, Commercially Sterile Products.

I am currently the Director of HACCP Programs and Regulatory Affairs for TechniCAL, Inc. a New Orleans, LA –based food safety consulting service with national and international coverage. In addition to other services, TechniCAL is a recognized process authority, tasked with establishing scheduled processes for both the low-acid canned food (LACF) and acidified foods(AF) industries, and evaluating the health hazard significance of deviations from scheduled processes. Prior to my joining TechniCAL in 1997, I was an Investigator for the US Food and Drug Administration from 1971 to 1997, specializing in HACCP-oriented inspections of a broad spectrum of the food processing industry, nationally and internationally, with a considerable degree of specialization in thermally-processed low-acid canned foods. From 1982 to 1994, I was one of the Office of Regulatory Affairs' National Experts in Food Processing; from 1994-1997, I was Special Operations Officer in the Division of HACCP Programs/Office of Field Programs, Center for Food Safety & Applied Nutrition. I was originally trained in the use of HACCP as an inspectional tool in 1973; and have been presenting HACCP training courses, nationally and internationally, to industry, academia and government representatives since 1976.

With respect to the proposal to include Thermally-Processed, Commercially Sterile Products (TPCSP) in establishing performance standards for the processed meat and poultry industry, there are two potential questions to be addressed:

(1) *Could* TPCSP be incorporated into the HACCP format, given the fact that both the current USDA/FSIS canning regulations (9 CFR Parts 318 and 381) and the US Food

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and Drug Administration regulations (21 CFR Part 108, 113 and 114) are, admittedly, HACCP-based, although not in the 7-Principles- of- HACCP format?

The answer to this question is "Yes," although not easily and not well, especially considering FSIS does not currently recognize prerequisite programs as capable of controlling any food safety hazards, necessitating the placement of all control measures for all food safety hazards into a HACCP plan. In fact, prerequisite programs are capable of controlling the majority of food safety hazards – predominantly the lower risk, lower severity types – while HACCP controls should be reserved for those food safety hazards *which most directly and most critically affect the safety of the product.*

(2) *Should* the FSIS canning regulations be revoked and TPCSP be folded in with other meat and poultry products into the requirements of 9 CFR Part 417, reducing the current canning regulations to guidelines and the extremely generalized requirements of proposed 9 CFR Part 430.5?

The answer to this question is an unequivocal "No."

There were a number of comments – both prepared and extemporaneous - which were delivered in a public hearing on the subject, held on Thursday, May 10, 2001 at the Washington Plaza Hotel, in Washington, DC. I don't wish to recount all of the valid comments made – notably, all were negative with respect to revoking the current canning regulations in favor of control under Part 417 and proposed 430.5 – but will state that they all pointed to a central theme, namely that TPCSP, among all the products that the USDA/FSIS is charged with regulating are unique in their requirements for safe processing and production.

No other categories of heat- processed foods are required to be commercially sterile. The vast majority of heat-processed meat and poultry products are minimally-heat treated (e.g. pasteurized) , then refrigerated or frozen (some are dehydrated, such as beef jerky). No other category of heat-processed foods have such an experimental data base supporting the establishment of the scheduled process, going back to the first science-based process established by the National Canners Association (now the National Food Processors Association) in 1910 for whole kernel corn in brine. In fact, no other category of heat-processed food even comes close. The reason for this, of course, is due to the principle organism of concern in TPCSP – *Clostridium botulinum.*

Because of this, and because of the history of contamination of commercially-processed LACF and AF with *C. botulinum* and/or its toxin, the USFDA requires (in 21 CFR Part 108.35(c)(1)

and (2)), the registration of all establishments (domestic and foreign) which process LACF and AF; and the submission of data relative to the establishment of the scheduled process for each product, for agency review and acceptance. The agency puts each process so submitted through a rigorous technical editing procedure, prior to deciding whether to accept the process for filing in its tracking and master file systems; followed by a more rigorous evaluation for adequacy at a later date.

These requirements for registration and process filing are placed on no other class of foods, with the exception that all manufacturers of infant formula (powdered and LACF) are required to register with the agency.

The USDA does not require registration and process filing in like manner because each establishment must be registered and receive a USDA establishment number regardless of type of meat and poultry products (fresh, refrigerated, frozen, canned) produced; and each establishment is under continuous inspection by FSIS (for processed products this is interpreted to be at least daily) with *all* information pertinent to the establishment of the scheduled process being required to be made available at any time to a Program employee.

Because of incidents of contamination of commercially-processed LACF and AF with *C. botulinum* in the past, the FDA regulates these products under Section 404 - Emergency Permit Control - of the Federal Food, Drug and Cosmetic Act. While Section 404 deals with microbiological contamination of any class of food distributed in interstate commerce, its provisions have only been invoked with respect to LACF and AF. It is instructive to note, that in its passage of its seafood HACCP regulation (21 CFR Part 123) and juice HACCP regulation (21 CFR Part 120), the FDA chose not to bring either of these classes of product (with the exception of canned seafood) under the scope of Section 404.

This industry is also unique in that there have been published guidelines for the industry to adopt relative to equipment set-up and operation (i.e. process delivery) , in the form of National Food Processors Association Bulletins 26-L - *Thermal Processes for Low-Acid Foods in Metal Containers* - and 30-L- *Thermal Processes for Low-Acid Foods in Glass Container* since 1930 and 1948, respectively. I know of no other such guidelines for other segments of the heat-processed foods industry. I will be addressing these in more detail shortly. One additional note: the processing conditions and equipment listed in Bulletins 26-L and 30-L are the same regardless of type of product; however, the scheduled processes provided cover only non-meat and poultry commodities.

Finally, the industry is unique in that there is a regulatory requirement for supervisors of retort operators and container closure examiners, to attend, and satisfactorily complete, an approved

school – known generically as the Better Process Control School (BPCS) – which, among other topics, gives instruction in retort operations, aseptic processing and packaging system operations or other thermal processing systems operation, and container closure inspections. . "Satisfactory completion" means that said supervisory personnel must be tested during the course on subjects pertinent to their area(s) of responsibility *and* must pass the tests in order to be certified by the University presenting the course. The purpose of training supervisors, instead of the retort operators and closure examiners themselves (although many firms send these personnel to the schools also) is that they are in a position of responsibility and, as such, are best positioned to ensure (1) that retorting and container closure operations are carried out correctly and (2) that appropriate corrective action is taken when they are not.

The FDA regulation (21 CFR Part 108.35(g) and 113.10 stipulate that the course of instruction must be approved by the agency. This approval process was, and continues to be, very detailed – involving agency approval of sponsors, course content, instructors and testing materials – and, when initially established, involved numerous discussions with industry personnel, particularly the (then) National Canners Association, and academia.

The USDA/FSIS regulation (e.g. 318.310) states only that such supervisory personnel "shall have successfully completed a school of instruction that is generally recognized as adequate...." Nevertheless the BPCS manual (6th edition, 1995), published by the Food Processors Institute, is prefaced by letters from the US Food and Drug Administration and USDA/FSIS acknowledging the importance and status of the BPCS. In his letter, the USDA/FSIS Deputy Administrator, Regulatory Programs, states: "FSIS has long acknowledged that the Better Process Control Schools sponsored by the Food and Drug Administration provide such an approved course of instruction. Moreover, the Food Processors Institute manual, which has been used many years as the basic text by the Better Process Control Schools, provides excellent coverage of those areas of instruction that FSIS considers *critical to properly train canning plant personnel* (emphasis mine). We, along with canning experts in industry and academia, are confident that individuals who successfully complete a course of instruction that uses this Food Processors Institute text will be better equipped to ensure the safety and stability of heat-processed canned product."

I know of no other category of heat-processed food which has such specific requirements, and requires such a long, detailed approval process for the training of those representatives of plant management most responsible for ensuring the adequacy of process establishment, delivery and container integrity.

Under Section 417.7 (b) it states simply "The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the principles to meat and poultry processing, including a segment on the

development of a HACCP plan for a specific product and on record review." As opposed to the history of development and implementation of the current BPCS, FSIS states in the preamble of the final rule – relative to 417.7 – "The provisions of 417.7 are consistent with FSIS's view that training is central to the success of HACCP, *that there are many avenues for HACCP training needs, and that responsible establishment officials are in the best position to determine the training needs for each establishment* (emphasis mine).

Interestingly, while FSIS proposes to revoke the canning regulations, they still intend to retain the requirement for a specific BPCS (proposed 430.5(d)). The million dollar questions are: what sections of the current BPCS manual will be retained; and who will make that decision? I personally do not feel that responsible establishment officials are in the best position to determine what a revised BPCS should look like. A *lot* of effort went into devising the current BPCS, to ensure that *all* the appropriate areas related to the processing and production of TPCSP were covered; and it requires a substantial commitment of time on the part of establishments sending representatives to the course. If allowed to independently determine what their individual establishment training needs are, there may be those in the industry who determine that the current substantial commitment of time is not really necessary, that a shorter (maybe, much shorter) course would do.

As indicated, the two most critical parts of a TPCSP operation involve the scheduled process and the achievement of a hermetic seal. This proposal attempts to cover those areas in 430.5 (a) and (b) – for the scheduled process; and 430 (c) – for attainment of commercial sterility and a hermetic seal. I am going to limit my comments to discussing 430.5 (a) and (c). Acidified foods is really a separate area of control; in fact, the FDA has a separate regulation governing the processing of acidified foods (21 CFR Part 108.25 and 114). However, while not as detailed in the requirements for process establishment, delivery, documentation of delivery and container integrity, this does not minimize their importance.

The scheduled process really has three main control areas of concern:

(1) The establishment of the scheduled process (determining all the factors relative to achieving commercial sterility in the product *and* proper validation of the sterilization system to ensure that all containers receive at least the scheduled process).
(2) The delivery of the scheduled process, to include measuring and controlling *all* factors deemed critical to achieving commercial sterility, not just retort time and temperature; and
(3) Documentation of delivery of the scheduled process.

These, along with container integrity issues, will be discussed with respect to difficulties I perceive in attempting to change the current regulations to guidelines; and moving control of *C. botulinum* and other microbial hazards under the auspices of Part 417 and proposed 430.5. Doing so will require an establishment to:

(1) Re-evaluate its HACCP plan for all potential microbial hazards – not just *C. botulinum* – in accordance with the requirements of 417.4(a)(3). This will involve consideration of controls for *Listeria monocytogenes, Salmonella* and *Escherichia coli* O157:H:7, since the proposal deals with these organisms at length. Even determining that the scheduled process obviates concerns over these microorganisms, they will still have to be dealt with on at least a potential post-processing contamination basis.

This will require a new written hazard analysis.

(2) Establishment of the control measures, and the appropriate critical control points (CCPs) for those measures deemed necessary to control those hazards which most critically and directly affect the safety of the product. Obviously, the retorting procedure and sealing operations are in the forefront for consideration; however, there may also be critical factors related to the product, the container and the sterilizing equipment which will also need to be evaluated.

(3) Establishment of critical limits for all defined CCPs.

(4) Establishment of the appropriate monitoring procedures, in terms of *what* is monitored (e.g. initial temperature); *how* it is monitored (e.g. by dial-type metal stem thermometer); the *frequency of monitoring* (e.g. every retort load); and *who* is responsible for monitoring (e.g. the retort operator).

(5) Establishment of appropriate corrective actions.

(6) Establishment of the appropriate verification procedures

(7) Establishment of a record-keeping system supporting, most importantly, :
   (a) The decision-making process for identification of all CCPs and CLs, as well as monitoring procedures and frequencies. This involves, among other things, a *written* hazard analysis.
   (b) Monitoring procedures

(c) Corrective action procedures
(d) Calibration of all critical control point process monitoring instruments
(e) Records created during verification procedures

In the cost analysis to move TPCSP from the regulatory purview of the canning regulation to Part 417 and proposed 430.5, I noted with interest that FSIS believes that the potential first-year total direct costs to manufacturers of TPCSP (Group IV in all the charts) is *zero.* I can only assume this conclusion was arrived at by another assumption on the part of FSIS: that Group IV establishments will have the current canning regulations to use as a model for incorporation into their HACCP plans extant for chemical and physical hazards. I fail to see how they can accomplish this at no cost – or even minimal cost – given the seven (7) areas above that will have to be addressed. Furthermore, in took years for the current canning regulations to be effectively implemented on an industry-wide basis. I am concerned that in making the transition from a control system firmly grounded in the canning regulations, to one rooted in Part 417, the potential for confusion – and therefore, errors – increases on the plant floor. It is one thing for someone to design an effective HACCP-based program. Everything always looks good on paper. Then you have to translate it to the "chaos" of the plant floor. Commitment to HACCP – or any other food safety control system has to be from the top- down. Successful implementation, however, is from the bottom – that individual line employee – up.

The thinking at FSIS may be that its is nothing more than a transfer of the same requirements from one system to another. However, there is a very large question of what type of transfer of which of the current requirements of the canning regulations will occur, since this enforceable mandate will become voluntary guidelines. My greatest concern in how effectively the industry is able to do this, revolve principally around Items (2) through (5) above, for which there is currently a strict regimen for control in the canning regulation. The following are of utmost concern to me:

Establishment of the Scheduled Process

Scheduled processes for all TPCSP, and come-up schedules for the sterilizers to ensure uniform and adequate temperature distribution prior to initiation of the scheduled process are currently established by persons and organizations identified as "process authorities." In the proposal, FSIS is recommending removal of the terms "process authority" and "process schedule" from Part 301.2. While 301.2 specifically states that these definitions *do not apply* to Subpart G of 318, by revoking the canning regulations (318 and 381), FSIS will be *de facto* revoking the current requirement that process schedules for the product, and come-up schedules for sterilizers be established by process authorities. When I raised the question in the public meeting on May 10 of "If processes are not going to be required to be established by process authorities, who

else will FSIS consider to be qualified," the answer seemed to be that the agency wishes to allow the establishments more flexibility in the persons/organizations who establish scheduled processes for them, such as possibly individuals working for them who may possess the necessary expertise.

We need to further clarify this point. There are organizations in the industry – external to the processing establishments – that are recognized (by the industry) as being competent process authorities. These are organizations such as TechniCAL, Inc., the National Food Laboratories of the NFPA; certain container manufacturers; certain equipment manufacturers, and certain individuals in academia. However, there are also qualified individuals working directly for firms who are recognized by their peers in the industry as being competent process authorities. It is not where an individual works – it is that individual's training and experience, as well as the organization backing that individual – that is important in consideration of a process authority's credentials. And let me make this *absolutely clear*: I can think of few changes more dangerous to the public health, than to revoke the requirement that process and come-up schedules be established by process authorities and, thereby, possibly open the door to unqualified individuals to do so.

Who – or what - is a process authority? While the FDA does not specifically define "process authority," the term is used in several places in 21 CFR Parts 108 and 113. A process authority's duties, however, are clearly defined in 21 CFR Part 113.83 as follows:

> "Scheduled processes for low-acid foods shall be established by qualified *persons* having *expert knowledge* of *thermal processing requirements* for low-acid foods in hermetically-sealed containers and having *adequate facilities* for making such *determinations*. The *type, range and combination of variations* encountered in commercial practice shall be adequately provided for in establishing the scheduled process. Critical factors, e.g. minimum headspace, consistency, maximum fill-in or drained weight, aw, etc. *that may affect the scheduled process*, shall be specified in the scheduled process. Acceptable scientific methods of establishing heat sterilization processes shall include, when necessary, *but shall not be limited to,* microbial death time data, process calculations based on product heat penetration data, and inoculated packs. Calculation shall be performed *according to procedures recognized by competent processing authorities* ....(emphasis mine).

Of immediate note is the use of the term "persons" instead of "person." The reason for this (which is different from the FDA's acidified food regulation and the definition in 318 and 381, which allow a single person to be designated a process authority) is that in the category of LACF, the FDA determined early on that it is difficult, if not impossible, for a single person to

be uniquely knowledgeable in all aspects of process establishment and, therefore, to effectively function entirely on his or her own. Even though a process source document is signed by a single individual, that individual has other individuals at his/her disposal with whom to collaborate and, more importantly, should have the support and oversight of an organization. This is where the term "adequate facilities" really begins to show its importance.

The importance of the word "determinations" is often overlooked in a reading of 113.83. It has a clear scientific/mathematical connotation, and is tied directly to the phrases "expert knowledge," and "type, range and combination of variations." Anyone can be taught to follow a written procedure for process establishment in short order, assuming they have the proper equipment and the proper record-keeping system. That is not what qualifies a process authority. What truly differentiates an "authority" from a "technician" is:

(1) Knowing what type of data to accumulate
(2) Knowing when enough data have been taken with which to make a evaluation, and
(3) Being capable of conducting a proper evaluation of the data so accumulated, which means ultimate issuance of a source document which not only states a retort process, but also *clearly defines* all "critical factors... that may affect the scheduled process..." and clearly instructs the establishment to control these factors and to document this control.

In short, process authorities are directly involved in identification of TPCSP/CCPs related to the scheduled process; and in the determination of the CLs at these points, as well as assisting factory personnel in determining how best to monitor the CLs. Furthermore, a process authority's job revolves around process establishment and deviation evaluation. While they may work for an organization which provides other food processing-related services, they themselves can not – and should not – be responsible for development, implementation , verification and modification of the entire HACCP program, container integrity or other plant operational issues.

The ability to do this adequately can only come from years of experience, coupled with the stark realization of what is really on the line – the public health. Accordingly, there are many technicians operating in the realm of process establishment; the numbers of true process authorities are somewhat smaller.

In proposed 430.5(a) it is stated that LACF which are heat-treated or receive some other type of sporicidal lethality processing (i.e. are not controlled by a combination of heat - to destroy vegetative forms of microorganisms of concern - *and* certain other factors, such as water-activity control) must be "validated" to achieve a probability of 10 -9 that there are spores of *C. botulinum* in a container that are capable of growing; *as well as* the condition known as

"commercial sterility." It does not specify that this must be done by a process authority. Currently, the definition for commercial sterility accepted by most recognized process authorities, where heat is the sole barrier applied, is the one contained in 21 CFR Part 113.3 (e), namely: the condition achieved by application of heat which renders the food free of –

(1) Microorganisms capable of reproducing in the food under normal non-refrigerated conditions of storage and distribution; and
(2) Viable microorganisms (including spores) of public health significance

As may be seen, the necessity of destroying *C. botulinum* – call it a "12D cook" or the probability of a non-sterile unit being 10 –9 – is already contained within the definition of commercial sterility achieved by thermal processing alone. Recognized process authorities not only have had this as a performance standard for years, but in addition, have *already quantitated* both the destruction of *C. botulinum* and commercial sterility in terms of the sterilization value – expressed as either an "Fo" or "Integrated Sterilization Value (ISV)" – necessary *for each,* dependent on the product being processed. The problem with having a single Fo or ISV performance standard for all products is that you have to ensure that it covers a "worst-case" situation relative to the theoretical initial load of microorganisms at the time the thermal process begins. There have been attempts to do this in the past with the Fo value; however, with some quality-sensitive products it is not necessary from the public health standpoint; and would result in significant quality degradation. Accordingly, process authorities have preferred to assign specific values to specific products.

Another issue: neither proposed 430.5(a) (or (b)), nor the preamble, discusses at all what is meant by the term "validation." This was also not clarified at the public hearing. Some of the industry comments delivered at the public hearing on May 10 indicate an interpretation that use of this term will require microbiological confirmation, through mechanisms such as thermal death time studies, of all processes currently being used. Most of the TDT work on meat and poultry products, as with other LACF, was performed years ago. If this work has already been done relative to all current products being processed, will it be necessary to do it again for all products, just certain products, or only on new products not previously processed by anyone? On even a single product, we are talking about a <u>lot</u> of work.

Another question arising is: will microbiological confirmation, once accepted as having been initially completed, have to be done at least annually to meet the requirements of 417.4 (a)(3) – *Re-assessment of the HACCP plan*? Of particular concern to me here is the statement that such annual re-assessment of the HACCP plan shall be performed by someone who has been trained in accordance with 417.7 – that is, someone who has been trained in the seven principles of HACCP, the adequacy of which is established by "responsible establishment officials (who) are

in the best position to determine the training needs for each establishment." Again, this would seem to open the door to removing the process authority from making such determinations.

Currently, process authorities issue process source documents for products – usually a signed, dated letter or intra-establishment memorandum or other document - which state that the process described is designed to deliver a commercially sterile product, or words to that effect. Under proposed 430.5(a) and (c) could process authorities simply modify this phrase to read: "designed to deliver a probability of 10-9 that there are spores of *C. botulinum* in any container, as well as commercial sterility;" or will some type of microbiological validation be required? And, more importantly, if microbiological confirmation is required, who will be considered qualified to do it?

Finally, in specifying a specific quantitative microbiological performance standard, we run the risk, particularly when this is translated for foreign establishments shipping to the US – of the firms believing they can collect a sample of 12-24 flat cans per lot after processing, incubate them, and if there is no growth, they have met the requirements for a 10 –9 reduction for *C. botulinum.* At TechniCAL, we are still finding foreign firms who employ a food safety control system that designates incubation and analysis of such a limited number of cans as their final check to ensure commercial sterility.

Such a check ensures nothing. In fact, negative results are more dangerous to the assurance of proper processing than positive results, because negative results on such a statistically-insignificant sample gives the factory a false sense of security. Where the scheduled process is concerned, only the proper establishment, delivery and documentation of delivery of the scheduled process can achieve a microbiologically-safe and sound product.

Delivery of the Scheduled Process

When things have gone wrong in a cannery, with respect to the scheduled process, it has usually been in this critical area. Delivery of the scheduled process is currently more than adequately controlled by adherence to the requirements of Parts 318 or 381. The set-up and proper operation of equipment (to include appropriate calibration of equipment/instruments) has been provided for in detail. The FSIS canning regulations are based in no small measure on the FDA canning regulation, and both are harmonious with the Codex Alimentarius' "Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low Acid Canned Foods." A number of comments were made at the public hearing relative to how revoking the FSIS canning regulations would be inconsistent with the FDA regulation and Codex; and a number of firms produce both USDA and FDA-regulated products, as well as products for export. Since that viewpoint is already well known, it needs no further elaboration.

What I do wish to point out is that revoking the regulations and transforming them into guidelines – which can then be used as a model for incorporation into a HACCP plan under Principle No. 4 – Monitoring – risks allowing processors to "pick-and-choose" which monitoring equipment and procedures they wish to use. For example, is it really necessary to equip retorts with *both* an indicating thermometer *and* a continuous recording thermometer? Of course it is. Will processors be allowed to choose only one to put into their HACCP plan as a requirement if the regulations are revoked? What about the current calibration requirements for the indicating thermometer? Currently they are required to be calibrated upon installation and *at least annually.* There is no mandatory minimum time frame for calibration under Part 417. Part 417.4(a)(2) simply states: "*Ongoing verification activities.* Ongoing verification activities include but are not limited to: (1) the calibration of process monitoring activities." What is meant by "ongoing?"

I mentioned above how the equipment and procedures mentioned in both the FSIS and FDA regulations did not originate from those agencies. They have been very specific *recommendations, i.e. guidelines*, to the industry since at least 1930, contained in industry documents such as NFPA Bulletins 26-L and 30-L. In his comments presented at the public hearing on May 10, the NFPA representative stated that following a food poisoning incident in 1971 involving failure to properly apply a heat process to commercially canned product, the (then) National Canners Association petitioned the FDA to publish new regulations to address the problem. In 1981, following several incidents and one death from commercially canned meat and poultry products in the 1970's, the (now) NFPA similarly petitioned FSIS to establish specific good manufacturing practice regulations for these canneries.

Several verbal comments delivered during the hearing on May 10 focused on the fact that while the recommendations in documents such as Bulletins 26-L and 30-L were commendable, *regulations,* not guidelines, were needed because guidelines were enforceable by no one and, in order to level the playing field for *all* processors of LACF, and thereby benefit the entire industry, regulations were needed. A key section in the NFPA's comments delivered on May 10 is as follows:

"We note that the Agency (i.e. FSIS) very recently released its proposed version of guidelines for industry. Though we haven't had the opportunity to carefully compare these to the existing regulations, it appears that the sole change is the conversion of all required "shalls" to recommended "shoulds." Just as we objected when the initial FSIS proposed rule converted many of the FDA's recommendations to requirements, we find this proposal to make all the provisions advisory to be unfulfilling. *Indeed as guidelines they would not be suitable for regulatory enforcement or compliance purposes* (emphasis mine). Processors, especially new

ones or very small ones would have no basis for knowing which of the requirements are of essential importance and which are merely examples of acceptable practice. *Such a situation would seem to us to invite problems* (emphasis mine)"

The penultimate sentence above is especially telling, since, under Part 417, processors will be allowed to determine "which of the requirements are of essential importance and which are merely examples of acceptable practice." Do we really – I mean, *really* – want this? There were a lot of comments made at the hearing on May 10, relative to the success of the FSIS regulations, once the industry geared up to comply with that enforceable mandate. It didn't happen overnight because for years the industry had been allowed, as an industry, to determine which of the guidelines (e.g. Bulletins 26-L and 30-L) were of essential importance and which were merely examples of acceptable practice. Some did a very good job; others, as the oral testimony indicated, did not.

I understand the concern of the representatives of the industry who provided comments in this regard on May 10, and I share them. I am reminded of a quote from the American philosopher George Santayana:

> "Those who cannot learn from the past are condemned to repeat it."

The industry, at least, appears to have learned from the past.

It is also in the arena of process delivery that we must address another critical issue that involves process authorities, namely: the evaluation of process deviations.

In process deviations, the firm has a choice: to either fully reprocess the product to commercial sterility or; alternatively, set the lot aside for evaluation by a process authority; or for destruction Any process deviation from any factor deemed critical to the adequacy of the scheduled process has public health implications, no matter how slight the deviation. Depending at what point in the process the deviation occurs, the firm may elect to set the lot aside for evaluation, particularly if the deviation occurs late in the thermal processing cycle on a quality-sensitive product.

Next to proper establishment of the scheduled process, the proper handling of process deviations has historically been *the single greatest concern* of the regulatory authorities, and *is* the area which has contributed to the most significant problems for a processor. The evaluation of a process deviation has four possible results:

(1) The product still received a commercially sterile process

(2) The product received a process which is above the process necessary to render it free of microorganisms of public health significance (referred to as a "minimum health" process)
(3) The product received a minimum health process
(4) The product received a process below minimum health.

For both FDA and USDA-regulated products, the evaluation of a process deviation must demonstrate that the product received at least a minimum health process in order to be released. It is in the area of evaluation that results in a declaration of at least a minimum health process, that gives the most concern to the regulatory agencies, as well as process authorities. It is here that the process authorities must be *absolutely* certain that their collected and evaluated process establishment data have given them an accurate definition of the minimum health Fo or ISV. There may be cases where, even though a process did not meet the minimum Fo generally accepted by process authorities as necessary for minimum health, the process authority is able to recommend release of the product. This could be because of data he/she collected at the firm during process establishment, involving use of other control factors (e.g. such as a pH that was reduced below normal, but still above 4.6) that will allow this. The importance of the necessary relationship between processor and process authority cannot become any clearer than it would in a situation such as this. While there are usually numerous safety factors built in during process establishment to ensure minimum health and commercial sterility, there is truly little margin for error when a process authority determines a product can be released on a minimum health basis, especially if the Fo justifying the release is less than that generally established and accepted as necessary by recognized process authorities.

Who will make such determinations if the FSIS canning regulations are revoked, since use of a process authority will no longer be mandated (e.g. Part 318.308(d)(1)(iii))? The current FSIS canning regulations have a very strict procedure involving the handling of process deviations. By contrast, Part 417.3 states in paragraph (a) that "the written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and *assign responsibility* (emphasis mine) for taking corrective action, to ensure: ....(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce."

In 417.3(b) it states: "If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall: ...(2) perform a review to determine the acceptability of the affected product for distribution."

My question is: who is going to "assign responsibility" for taking the appropriate corrective action, if such is listed in the HACCP plan; or "perform the review" if it is not? And who will be

responsible for ensuring that, if product is set aside for evaluation of the health hazard significance, that an appropriate evaluation, *and* that appropriate records of the evaluation, were created?

The implication, from a reading of Part 417 is that this person will be the one who is trained in accordance with Part 417.7 - i.e. who has completed a course of instruction in the seven principles of HACCP determined to be adequate by factory management, as "responsible establishment officials are in the best position to determine the training needs for each establishment." Will this person also be allowed to make evaluations of the public health significance of process deviations? We have already discussed in detail, the qualifications necessary for a recognized process authority to adequately perform his/her duties and the fact that they should *not* be tasked with "other duties as assigned (e.g. the development of a HACCP plan)."

Documentation of Delivery of the Scheduled Process.

The types of records required by current Subpart G, Part 318 and Subpart X, Part 381 are quite specific in their requirements that there be at least two (2) different records of thermal processing which must be correlated in time and temperature – the temperature recording device and the written (hand or by computer, if approved by the Administrator) record. They must not only be correlatable in process time or temperature, but must also agree with respect to the time-of-day, in order to facilitate adequate record review and the assurance of recording chart time accuracy. In addition, there are very specific requirements regarding the temperature scale of temperature recording charts, again to facilitate record review, both by the retort operator, in-process, as well as the record reviewer, after-process.

Under 417, the establishment will have the option of determining what records need to be maintained, relative to not only how often the factors critical to the adequacy of the scheduled process will be monitored, but also what factors will be deemed critical and need to be monitored in the first place, since the proposal will apparently do away with the requirement for process establishments to use process authorities.

Under the current canning regulations, there is no provision made for the individual who creates a critical factor monitoring record to also be allowed to review his/her own work to attest to its adequacy. In addition, the review is to be made by a qualified representative of management within one (1) working day of the process. Under Part 417.5 (c), it states:

> "*Prior to shipping product,* the establishment shall review the records associated with the production of the product...to ensure completeness, including the determination that all

> critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. *Where practical,* this review shall be conducted, dated , and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with 417.7 of this part, *or the responsible establishment official* (words of emphasis mine)."

"Prior to shipping product" could mean days or weeks before the records receive a review, depending on warehouse stocks and/or demand for the product. Allowing an establishment to wait that long increases the chances that product will be shipped *without* a review. Record review is, without a doubt, a tedious exercise, at least if it is done correctly. But it is absolutely essential and, the sooner it is conducted, the sooner a reviewer will catch mistakes that were made and correct them. Requiring an expedited review (e.g. within one (1) working day of the process) gives a higher degree of assurance that process deviations will be caught and appropriately handled.

The person conducting the review of the records, *should never, ever* be the same individual who created the record. Allowing this (i.e. "where practical") is an open invitation to disaster in this industry. What happens if a person who normally does a record review gets tied up so that the review is not done – or goes on vacation – and someone decides that it is "practical" to let the retort operator review his/her own records for just this brief period of time?

Undoubtedly, this phrase was put in for the benefit of very small firms, to allow them a little flexibility. Unfortunately, allowing someone to review his/her own work means just a slight downward adjustment in objectivity. This is one of the reasons why the training requirement in the FDA and USDA regulations specify it be directed at supervisory personnel of retort operators and closure examiners. While there is no specific requirement that these supervisors must be the designated record reviewer, it is generally recognized that either they, or other personnel (other than the retort operators/closure examiners) working for them will, in fact, be doing the record review. And the record reviewer is, practically speaking, the last line of defense against products involved in process deviations being shipped. This is why someone who is familiar with the process and the processing requirements must review the work of someone who actually conducts the process, to ensure the completeness of all the records and that the product received at least the scheduled process.

Finally, the requirements for documentation of the handling of process deviations need to also be reviewed. Of consequence here – Parts 318 and 381 *vis a vis* Part 417.3 – are the requirements for documentation when a deviation is evaluated by a process authority. Among other things, the process authority must provide to the establishment (provide to the Program) "a copy of the evaluation report." In the FDA regulation (Part 113.89) there is a somewhat more specific

requirement that the record include the evaluation procedures used which is especially crucial if the evaluation results indicate a "minimum health" process.

What type of process deviation evaluation documentation will be maintained if the canning regulations are reduced to guidelines? And who will make that decision? Will the decision be made that there is really too much "paperwork" involved in the evaluation of a process deviation (e.g. 318.308) and a phone call can be made to give the process authority (assuming one is, in fact, accessed) the particulars? And that the process authority (or other "qualified" individual) can then issue a brief e-mail summarizing the evaluation?

Because of the significance of the potential health hazard involved whenever there is a deviation from any factor critical to the adequacy of the scheduled process there is a need for ***abundant*** documentation attesting to the handling of the deviation. The proper evaluation of a process deviation has no short cuts. Because it can be costly – in terms of time and money – however, factories are always looking to see if they cannot reduce the costs involved. There were instances during my career as an FDA Investigator where a firm would have a deviation evaluated, involving, for example, a 4°F temperature drop for 10 minutes during the retort process. The evaluation came back as "above minimum health." The next time there was a deviation, it was for 2°F for 5 minutes. The firm did not have an evaluation performed on the second deviation because if a 4°F/10 minute temperature drop was evaluated as above minimum health, then a 2°F/5 minute drop had to "automatically be OK," so why go through the time and expense of having it evaluated? Particularly if there are immediate orders for the product. Never mind that the initial temperatures, other critical factor measurements, the type and style of product, and the time at which the temperature drop occurred were all different in the two incidents.

Also, during my tenure as an FDA Investigator, I was told of a LACF manufacturer that the FDA placed under the Emergency Permit system after several inspections had revealed continuing process deviations involving slight retort temperature drops (1-2°F) below the minimum scheduled process. There weren't really any other significant deviations from the regulations. These continuing process deviations were found by the Investigators to have not been properly handled by either reprocessing or evaluation by a process authority. Each time the firm subsequently had the deviations evaluated – *after* having them pointed out by the Investigators - the evaluations came back as either above minimum health or commercially sterile. Because of this, the firm apparently thought it was not a big deal. Because of this attitude, the firm was placed under the Emergency Permit system.

Again, this is the area that has given regulatory authorities the most concern and has contributed to the most significant problems for the industry. It is, in short, a *very* big deal.

Container Integrity

Container integrity – the ability to achieve an hermetic seal and to maintain the integrity of that seal during post-process handling – presents a different set of issues than does establishment, delivery and documentation of delivery of the scheduled process.

To begin with, there really aren't any "hermetic seal authorities," as such, who establish minimum/maximum values for the seal that can be as readily adopted as critical limits, as there are for critical factors in the scheduled process. There are general operating specifications which are established by the container manufacturers and others with experience in container integrity issues, *and they vary according to container size, type and geometry.* The generally-accepted recommendation to the industry is that if you have a measurement outside the operating specifications you pull another container from that sealing station and re-measure or re-observe. If still outside, then you shut the closing machine down for an adjustment. But even then, unless there is a gross variation from the operating specifications for one of the seam components – as evidenced by the measurements/observations - the potential for a health hazard to exist at this point is generally negligible. Therefore, establishing such guideline specifications as "critical limits" is questionable because by definition, a deviation from critical limits – no matter how slight – represents an immediate potential hazard to health. The ultimate conclusion that a potential health hazard exists – and this has been the case for years in the FDA – is whether the container is either leaking or there is evidence that it has leaked (e.g.. a false seam with a swollen lid). And most cases of container leakage result in non health-hazard type spoilage, although there have been instances of post-processing contamination in meat items (canned corn beef and canned pork products) with *Staphylococcus aureus* and *Salmonella*; and in canned tuna and salmon with Type E *C. botulinum* (Stersky, A., E. Todd, and H. Pivnik. 1980. Food Poisoning Associated with Post-Process Leakage (PPL) in Canned Foods. *Journal of Food Protection.* Vol 43. 465-477). And the sections of the current canning regulations devoted to container integrity issues *are more than adequate to control such problems if followed.*

Just as control over process establishment, delivery and documentation of delivery has been based for years on industry guidelines such as those in Bulletins 26-L and 30-L, the requirements in, for example Part 318. 301, are based upon years of industry experience. This includes the recommended time frames for examination for gross closure defects (at least every 30 minutes during production); and tear-down examinations (at least every 4 hours), as well as which of the seal components are the most important to control. For round metal cans, an expert committee made up of representatives of the NFPA and the Can Manufacturers Institute, in draft guidelines published in 1984, determined these to be "tightness" and "overlap;" and established what are

referred to as minimum "Hold-for-Investigation" guidelines for these seam components. Going below these specifications – which are *less than* the operating specifications for these components – should trigger a hold of the lot(s) involved and further examinations. While some might seize on these as critical limits, the guidelines are clear that going below the HFI specifications does *not mean* the food is necessarily contaminated, only that further examination should be done. Furthermore, this is the only type of container – round, metal – that I know of where such HFI guidelines exist. They were developed as a response to a breach of container integrity in the canned salmon industry in 1982, which resulted in two cases of botulism in Europe, one fatal.

What will be the control measures be for container integrity – which not only consist of measurements and observations of finished seals, but also control over the quality of container cooling waters, and post-processing contamination – if the industry is allowed to "pick-and-choose" its control methods under Part 417? We all would like to think that the control measures will simply be transferred over from the requirements of the canning regulation to a firm's HACCP plan. Will that happen? I don't frankly know.

Do we want to find out?

In summary, I believe the FSIS should *not* revoke the current canning regulations, replacing them with guidelines which will, hopefully, be incorporated as is into HACCP plans, the requirements of which, as stated in 417, are not as specific as the regulations, even supplemented by proposed Part 430.5. The TPCSF industry is unique in its necessary control factors, due to the nature of the principle organism of concern. This uniqueness is reflected in its requirements for process establishment by recognized experts in the thermal processing of low-acid foods packed in hermetically-sealed containers; in the requirement for registration and process filing by establishments regulated by the FDA; in processing equipment set up and operation; in the evaluation of process deviations; in the documentary requirements; and in the requirement for supervisory personnel to have attended a school approved by the FDA and endorsed by the USDA/FSIS.

Transferring the current enforceable requirements of the canning regulations as guidelines to the purview of Part 417 and proposed 430.5, risks having certain segments of the industry "pick-and-choose which of the guidelines they want to follow – as was the case before promulgation of the regulations - thereby potentially reducing control effectiveness. Of utmost public health concern here is who will be allowed to establish scheduled processes and evaluate the health hazard significance of process deviations? What type of documentary system will be required in process establishment and deviation evaluation?

Transferring the control of TPCSP to Part 417 also will not, under any circumstances, be a "no-cost" situation. And transfer, while it may look adequate on paper, risks increasing the chances for error – depending on what is transferred – on the plant floor. It took several years for the entire industry to effectively implement the canning regulations once they became effective, due to the sheer complexity involved in the processing of these products. If the industry does not write the regulations into their HACCP plans virtually as is, they can follow whatever they do write to the letter, but who will determine whether what they have written is adequate and why. History tells us that the canning regulations have been very effective, *as long as they are followed.* Another point of consideration: if the industry dutifully transfers all the canning regulation into a HACCP plan, would failure to follow some aspect effect an FSIS determination of inadequacy under Part 417.6? What would be FSIS's response on a single determination of inadequacy vs. continued (for how long?) determinations of inadequacy?

While the current canning regulations can certainly be modified and improved upon, a wholesale revocation is not called for, and, in giving the industry a virtual "blank check" to determine which provisions are necessary to follow, risks undermining the public health, not improving it.

Sincerely yours,

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