WEBVTT

00:00:10.226 --> 00:00:11.316 All right.

00:00:11.486 --> 00:00:16.737 Welcome everyone to the ready to eat fermented salt cured and

00:00:16.737 --> 00:00:19.616 dried products guideline webinar.

00:00:20.066 --> 00:00:23.470 This webinar is being recorded and the recording will be

00:00:23.470 --> 00:00:26.336 available on the events page after the meeting.

00:00:27.066 --> 00:00:31.004 Now I will turn it over to Paul Kicker, administrator of the US

00:00:31.004 --> 00:00:34.942 Department of Agriculture's Food Safety and Inspection Service,

00:00:34.942 --> 00:00:36.726 to give opening remarks well.

00:00:38.276 --> 00:00:38.986 Thank you.

00:00:39.196 --> 00:00:43.390 I'm Paul kicker, the FSIS administrator, and I wanna thank

00:00:43.390 --> 00:00:47.655 you for joining us for our webinar on the emphasis IS ready

00:00:47.655 --> 00:00:51.066

to eat fermented salt cured and dried products.

00:00:51.076 --> 00:00:56.000 Guideline this guideline issued on May 5th and announce in the

00:00:56.000 --> 00:01:00.142 Federal Register, provides information on the agency

00:01:00.142 --> 00:01:04.518 regulatory requirements associated with safe production

00:01:04.518 --> 00:01:09.363 of ready to eat, shelf stable fermented salt, cured and dried

00:01:09.363 --> 00:01:14.052 products that rely on multiple hurdle approaches to achieve

00:01:14.052 --> 00:01:16.396 lethality and shelf stability.

00:01:17.596 --> 00:01:21.479 We will be accepting comments on the guideline until July 5th of

00:01:21.479 --> 00:01:22.076 this year.

00:01:23.376 --> 00:01:27.254 It's designed to respond to commonly asked questions from

00:01:27.254 --> 00:01:30.663 small and very small establishments concerning the

00:01:30.663 --> 00:01:34.874 food safety hazards associated with these products and the key 00:01:34.874 --> 00:01:38.016 steps in each process needed to ensure safety.

00:01:39.576 --> 00:01:44.081 It was developed in response to an increasing interest in

00:01:44.081 --> 00:01:48.740 producing these artisanal niche products and the challenges

00:01:48.740 --> 00:01:53.477 associated with them and the problem with finding scientific

00:01:53.477 --> 00:01:58.448 support that demonstrates that an establishments unique process

00:01:58.448 --> 00:02:03.185 achieves A5 log reduction in salmonella recommendations made

00:02:03.185 --> 00:02:07.456 by the National Advisory Committee on meat and Poultry

00:02:07.456 --> 00:02:11.106 Inspection also contributed to the guidelines.

00:02:12.316 --> 00:02:17.201 Specifically, the link to the niche meat processors assistance

00:02:17.201 --> 00:02:21.077 network and the Hasof coordinator listing are two

00:02:21.077 --> 00:02:24.566 resources included in the guidance document.

00:02:24.636 --> 00:02:29.120 Based on these recommendations, Ephesians also included guidance

00:02:29.120 --> 00:02:33.258 on products such as those that are solved, cured, where the

00:02:33.258 --> 00:02:37.466 initial validation period may extend beyond 90 calendar days

00:02:37.466 --> 00:02:41.949 due to the nature of the process and the length of time it takes

00:02:41.949 --> 00:02:45.674 to implement the critical operational parameters that

00:02:45.674 --> 00:02:46.846 impact lethality.

00:02:48.486 --> 00:02:51.997 This guideline replaces and expands upon information

00:02:51.997 --> 00:02:55.707 previously found in other guidance documents addressing

00:02:55.707 --> 00:02:59.880 the safe production of ready to eat fermented meat and poultry

00:02:59.880 --> 00:03:00.476 products.

00:03:02.066 --> 00:03:05.359 Ephesians is giving establishments time to review

00:03:05.359 --> 00:03:06.676 the guideline there.

00:03:06.686 --> 00:03:11.125 Hazard analysis and scientific 00:03:11.125 --> 00:03:14.836 adequate, and I want to emphasize that outreach is

00:03:14.836 --> 00:03:19.421 available to our small and very small regulated establishments

00:03:19.421 --> 00:03:23.932 to assist in complying with this guideline by contacting your

00:03:23.932 --> 00:03:25.096 district office.

00:03:26.346 --> 00:03:30.976 This webinar has been organized for you in response to feedback

00:03:30.976 --> 00:03:31.916 and requests.

00:03:31.926 --> 00:03:36.493 For more information, please feel free to ask any questions

00:03:36.493 --> 00:03:40.984 you have as we hope to make this webinar as interactive as

00:03:40.984 --> 00:03:45.779 possible and please keep sending us your feedback if you still

00:03:45.779 --> 00:03:49.889 have questions after participating in this webinar or

00:03:49.889 --> 00:03:53.771 reading the guideline, we recommend you search the

00:03:53.771 --> 00:03:58.110

publicly posted knowledge articles called public Q&A

00:03:58.110 --> 00:03:59.936 in the ASK FIS database.

00:04:00.736 --> 00:04:02.706 You can also ask questions through.

00:04:02.716 --> 00:04:05.666 Ask emphasis by selecting Hassett.

00:04:05.676 --> 00:04:11.137 Deviation and hassop validation as the inquiry type or you can

00:04:11.137 --> 00:04:16.598 ask your questions via telephone 1-800-233-3935 and now Doctor

00:04:16.598 --> 00:04:21.538 Merrill Silverman, the senior food technologist with the

00:04:21.538 --> 00:04:26.305 Office of Policy and Program Development, will walk us

00:04:26.305 --> 00:04:31.766 through the guideline and answer any questions at the close of

00:04:31.766 --> 00:04:34.366 the Webinar, Doctor Silverman.

00:04:37.636 --> 00:04:38.686 Thank you, Paul.

00:04:38.956 --> 00:04:42.894 As Paul indicated today, I'm going to be giving you an

00:04:42.894 --> 00:04:47.475

overview of ready to eat shelf stable fermented salt, cured and

00:04:47.475 --> 00:04:50.696 dried products, and epistasis new guideline.

00:04:53.276 --> 00:04:56.213 So I'm going to be giving some background on outbreaks that

00:04:56.213 --> 00:04:59.199 have been associated with these products and lessons learned

00:04:59.199 --> 00:05:00.226 from those outbreaks.

00:05:01.086 --> 00:05:04.700 I'm going to be covering FSS's new guidance including

00:05:04.700 --> 00:05:09.050 recommended lethality and shelf stability targets, and I'm gonna

00:05:09.050 --> 00:05:12.530 be talking about some unique considerations for the

00:05:12.530 --> 00:05:16.479 validation of the lethality, treatment for fermented cell,

00:05:16.479 --> 00:05:19.356 cured and dried meat and poultry products.

00:05:19.366 --> 00:05:22.615 Products I am going to be focusing on the lethality

00:05:22.615 --> 00:05:26.676 treatment because that is where we see the most questions and is

00:05:26.676 --> 00:05:30.487 a big focus of the recently issued ready to eat shelf stable

00:05:30.487 --> 00:05:33.736 fermented, soft cared and dried product Skype line.

00:05:36.816 --> 00:05:40.641 So as Paul mentioned, there's been an increasing interest for

00:05:40.641 --> 00:05:44.157 many years in producing artisanal or niche shelf stable,

00:05:44.157 --> 00:05:47.981 ready to eat fermented salt, cured and dried meat and poultry

00:05:47.981 --> 00:05:48.536 products.

00:05:49.536 --> 00:05:54.460 These multi hurdle products rely on multiple hurdles other than

00:05:54.460 --> 00:05:58.844 cooking alone, such as salt nitrite, reduced pH, reduced

00:05:58.844 --> 00:06:03.383 water activity and drying time for lethality for red shelf

00:06:03.383 --> 00:06:07.460 stable meat and poultry products, FSS recommends the

00:06:07.460 --> 00:06:12.306 process achieve at least A5 log reduction in salmonella and at

00:06:12.306 --> 00:06:17.306 least A5 log reduction in sugar

toxin producing Escherichia coli

00:06:17.306 --> 00:06:20.306

or stack for products containing beef.

00:06:20.316 --> 00:06:23.586 To support that the product is ready to eat under the axe.

00:06:24.516 --> 00:06:29.037 Uh about how establishments may support an alternative lethality

00:06:29.037 --> 00:06:33.141 or reduction that provides an equivalent probability of no

00:06:33.141 --> 00:06:37.662 salmonella organisms present in the finished product, but it can

00:06:37.662 --> 00:06:41.140 be difficult to find support that demonstrates an

00:06:41.140 --> 00:06:45.035 establishments unique process achieves A5 log reduction

00:06:45.035 --> 00:06:46.426 because the hurdles.

00:06:46.436 --> 00:06:49.266 Again, that salt nitrate reduced pH.

00:06:49.276 --> 00:06:53.757 Reduce water activity and drying time are typically not as

00:06:53.757 --> 00:06:56.566 effective at cooking as cooking has.

00:06:56.576 --> 00:06:59.952 Establishments often also want to modify the critical

00:06:59.952 --> 00:07:04.016 operational parameters from the scientific support for their own

00:07:04.016 --> 00:07:07.516 unique process, which can create additional challenges.

00:07:10.796 --> 00:07:15.104 And really lack of support that the combination of hurdles were

00:07:15.104 --> 00:07:18.268 effective at achieving significant significant

00:07:18.268 --> 00:07:22.172 reductions in salmonella was a contributing factor in two

00:07:22.172 --> 00:07:24.326 salmonellosis outbreaks in 2021.

00:07:24.476 --> 00:07:28.876 That second over 70 people while processing controls, including

00:07:28.876 --> 00:07:32.794 meeting degree hours parameters for Staphylococcus orias

00:07:32.794 --> 00:07:36.574 control, following Amendment number of drying days for

00:07:36.574 --> 00:07:40.836 trichinella elimination, and achieving a final water activity

00:07:40.836 --> 00:07:44.685 level for shelf stability where

00:07:44.685 --> 00:07:45.716 establishments.

00:07:46.146 --> 00:07:49.633 These controls were not validated to achieve at least A5

00:07:49.633 --> 00:07:51.346 log reduction in salmonella.

00:07:52.596 --> 00:07:56.263 Another key finding from the investigations was that small

00:07:56.263 --> 00:08:00.055 diameter products may require longer drying times to achieve

00:08:00.055 --> 00:08:02.416 significant reductions in salmonella.

00:08:03.476 --> 00:08:07.029 So while the establishment may be drawing the product to the

00:08:07.029 --> 00:08:10.756 finished water activity needed for shelf stability, it can take

00:08:10.756 --> 00:08:13.726 more drying days in order to eliminate salmonella.

00:08:14.276 --> 00:08:18.061 Therefore, if an establishment produces different diameter

00:08:18.061 --> 00:08:22.103 products, but only has a study performed with one diameter, it

00:08:22.103 --> 00:08:25.887

must determine the impact of differences from the study to

00:08:25.887 --> 00:08:27.106 the actual process.

00:08:27.116 --> 00:08:30.783 And that's mainly going to be to drawing time to make sure the

00:08:30.783 --> 00:08:34.275 process is still effective in achieving the target pipeline

00:08:34.275 --> 00:08:35.846 reduction for all products.

00:08:39.986 --> 00:08:43.871 So in part, in response to these outbreaks, EVE SAS has issued

00:08:43.871 --> 00:08:47.571 guidance to establishments to ensure that they're aware the

00:08:47.571 --> 00:08:51.025 recommended targets for reduction or prevention of each

00:08:51.025 --> 00:08:51.456 hazard.

00:08:51.966 --> 00:08:55.816 The key steps in each process needed to ensure safety.

00:08:56.186 --> 00:08:59.956 The critical operational parameters associated with each

00:08:59.956 --> 00:09:04.123 step and the biological hazards associated with and scientific

00:09:04.123 --> 00:09:07.893

support available to help produce common fermented salt,

00:09:07.893 --> 00:09:09.546 cured and dried products.

00:09:10.346 --> 00:09:10.776 I'm really.

00:09:10.786 --> 00:09:14.132 We learned from the 2021 outbreaks that establishments

00:09:14.132 --> 00:09:17.782 just weren't aware that the controls they had in place were

00:09:17.782 --> 00:09:19.546 not validated for salmonella.

00:09:22.486 --> 00:09:27.480 So, per FSIS, notice 19-23, and as Paul mentioned, FSS is giving

00:09:27.480 --> 00:09:30.936 establishments time to review the guideline.

00:09:31.166 --> 00:09:35.187 Their hazard analysis and scientific support to determine

00:09:35.187 --> 00:09:39.207 if it is adequate inspection program personnel or IPP are

00:09:39.207 --> 00:09:43.575 instructed to find out if the establishment needs more than 90

00:09:43.575 --> 00:09:45.446 days to gather new support.

00:09:45.846 --> 00:09:50.210 For example, if it's conducting a challenge study or reviewing

00:09:50.210 --> 00:09:54.296 the scientific literature, and I appeared to document this

00:09:54.296 --> 00:09:58.521 discussion in a memorandum of interview or Moi after 90 days

00:09:58.521 --> 00:10:00.876 after the issuance of the notice.

00:10:01.206 --> 00:10:05.358 If the establishment has adequate scientific support, IP

00:10:05.358 --> 00:10:09.728 are to schedule a directed hazard analysis, verification or

00:10:09.728 --> 00:10:10.456 have task.

00:10:10.966 --> 00:10:14.694 However, if the establishment has communicated it needs

00:10:14.694 --> 00:10:18.421 additional time to gather scientific support, IP are to

00:10:18.421 --> 00:10:22.614 wait until the support has been gathered before performing the

00:10:22.614 --> 00:10:23.346 have tasks.

00:10:24.136 --> 00:10:27.799 The one exception would be that Fsas will not wait to verify an

00:10:27.799 --> 00:10:31.346

establishment has scientific support for their hassop system.

00:10:31.736 --> 00:10:35.932 If it has a salmonella sugar toxin producing Escherichia coli

00:10:35.932 --> 00:10:39.924 or stack or LM positive, either through its own testing or

00:10:39.924 --> 00:10:43.714 emphasis testing, or are associated with an outbreak of

00:10:43.714 --> 00:10:44.796 these pathogens.

00:10:47.476 --> 00:10:52.369 Fsis, notice 19-23 also has instructions for enforcement

00:10:52.369 --> 00:10:54.686 investigation and analysis.

00:10:54.736 --> 00:10:58.920 Officers or E I/O if any IO performs a public health risk

00:10:58.920 --> 00:11:03.320 evaluation at an establishment producing ready to eat, shelf

00:11:03.320 --> 00:11:07.936 stable fermented salt, cured or dried meat or poultry products.

00:11:08.306 --> 00:11:11.464 They've been instructed to review the memorandum of

00:11:11.464 --> 00:11:14.986 interviews to see if the establishment has communicated a 00:11:14.986 --> 00:11:18.629 plan for gathering additional support to inspection program

00:11:18.629 --> 00:11:19.236 personnel.

00:11:19.246 --> 00:11:21.646 So it's really important to have that communication.

00:11:23.186 --> 00:11:26.887 If the establishment needs time to gather scientific support,

00:11:26.887 --> 00:11:30.409 EIO are to wait until the support has been gathered before

00:11:30.409 --> 00:11:32.736 performing the food safety assessment.

00:11:32.746 --> 00:11:37.128 If it's recommended as part of the Pre, again the exception

00:11:37.128 --> 00:11:41.363 though is the IO will not wait to verify an establishment

00:11:41.363 --> 00:11:45.525 support if they've had a salmonella stack or LM positive

00:11:45.525 --> 00:11:49.176 through their own testing or through FSS testing.

00:11:49.466 --> 00:11:54.710 So FSF SSIS has a salmonella or LM positive through its ready

00:11:54.710 --> 00:11:55.386 testing.

00:11:55.556 --> 00:11:59.455 Yeah, iOS will not wait to perform the public health risk

00:11:59.455 --> 00:12:03.622 evaluation and if needed, any intensified verification or IVT

00:12:03.622 --> 00:12:06.646 testing as part of a food safety assessment.

00:12:11.556 --> 00:12:15.935 As Paul mentioned, FSIS has also prepared outreach materials for

00:12:15.935 --> 00:12:20.313 E iOS to use, and these contain an overview of hazards, critical

00:12:20.313 --> 00:12:24.018 operational parameters and available support in two to

00:12:24.018 --> 00:12:24.826 three pages.

00:12:25.176 --> 00:12:29.027 And they come right from the guideline, which has overviews

00:12:29.027 --> 00:12:32.941 of fermentation, salt, curing and drying in the short 2 to 3

00:12:32.941 --> 00:12:33.326 pages.

00:12:33.976 --> 00:12:37.486 They're intended to be handed out or sent electronically, and

00:12:37.486 --> 00:12:41.165 if they're sent electronically, they contain links to all of the

00:12:41.165 --> 00:12:44.731 journal articles we're aware of and have access to that can be

00:12:44.731 --> 00:12:45.636 used as support.

00:12:45.646 --> 00:12:50.299 So these articles are available through Open Access or PDFs, and

00:12:50.299 --> 00:12:54.521 there are also available Asian web page under resources if

00:12:54.521 --> 00:12:57.026 you'd like to request to outreach.

00:12:57.036 --> 00:13:00.047 As Paul mentioned, that goes through your district office and

00:13:00.047 --> 00:13:02.426 we've included the link here for your reference.

00:13:05.516 --> 00:13:08.876 Before going into more details, we always like to start with an

00:13:08.876 --> 00:13:11.606 overview of the product groups we're talking about.

00:13:11.616 --> 00:13:15.398 So it's what we mean when we're talking about products that are

00:13:15.398 --> 00:13:17.406 fermented, salt, cured and dried.

00:13:18.016 --> 00:13:21.469

Products in each of these categories include those on the

00:13:21.469 --> 00:13:21.826 slide.

00:13:21.876 --> 00:13:26.708 So for men to products include those like Jenna was salami,

00:13:26.708 --> 00:13:29.526 hard salami, pepperoni sojac, etc.

00:13:30.156 --> 00:13:30.986 I'm so pure.

00:13:30.996 --> 00:13:35.788 Products include prosciutto, ham, country cured ham, basturma

00:13:35.788 --> 00:13:38.956 and bresaola, and then for dry products.

00:13:38.966 --> 00:13:43.595 These include products like dried beef, beef jerky drawers

00:13:43.595 --> 00:13:44.536 and biltong.

00:13:44.666 --> 00:13:47.804 Although products like beef jerky are not covered here

00:13:47.804 --> 00:13:51.398 because they're covered within our cooking guideline and jerky

00:13:51.398 --> 00:13:55.048 guideline, and those processes tend to rely on cooking as a way

00:13:55.048 --> 00:13:56.246

to achieve lethality.

00:13:59.356 --> 00:14:03.111 So I mentioned earlier that there were two outbreaks in 2021

00:14:03.111 --> 00:14:05.326 associated with fermented products.

00:14:05.676 --> 00:14:08.806 And this slide has an overview of all of the outbreaks

00:14:08.806 --> 00:14:12.220 associated with these products that have occurred in the US

00:14:12.220 --> 00:14:12.846 since 2010.

00:14:13.256 --> 00:14:17.084 This information can also be found within the guideline and

00:14:17.084 --> 00:14:20.529 as you can see from the far right column, last equate

00:14:20.529 --> 00:14:24.229 scientific support for A5 log reduction, otherwise called

00:14:24.229 --> 00:14:27.674 under processing was a contributing factor in most of

00:14:27.674 --> 00:14:31.118 these outbreaks, including the two recent ones that I

00:14:31.118 --> 00:14:31.756 discussed.

00:14:32.466 --> 00:14:35.378

So again, that's why it's important establishments are

00:14:35.378 --> 00:14:38.607 aware of all the scientific support needed for the lethality

00:14:38.607 --> 00:14:39.136 treatment.

00:14:42.686 --> 00:14:46.762 And this slide shows you the various ways these processes get

00:14:46.762 --> 00:14:48.536 lethality or kill bacteria.

00:14:48.956 --> 00:14:52.712 Again, these products rely on multiple hurdles other than

00:14:52.712 --> 00:14:56.338 cooking alone, such as salt nitrite, reduced pH, reduce

00:14:56.338 --> 00:15:00.547 water activity, and drying time for lethality, and these hurdles

00:15:00.547 --> 00:15:04.368 again are typically not as effective as cooking at killing

00:15:04.368 --> 00:15:08.383 bacteria and the effectiveness of each hurdle also depends on

00:15:08.383 --> 00:15:11.944 the implementation of a number of critical operational

00:15:11.944 --> 00:15:12.656 parameters.

00:15:13.516 --> 00:15:13.706

I'm.

00:15:13.716 --> 00:15:17.089 I'm not going to go each of these processes in detail today,

00:15:17.089 --> 00:15:20.406 but all the information here can be found in the guideline.

00:15:23.836 --> 00:15:27.090 And so the first step to ensuring the lethality treatment

00:15:27.090 --> 00:15:30.456 is effective is to ensure that establishments, as required,

00:15:30.456 --> 00:15:33.766 consider the appropriate hazards in their hazard analysis.

00:15:34.136 --> 00:15:38.025 And identify the appropriate targets to ensure the hazards

00:15:38.025 --> 00:15:41.847 are prevented, reduced or eliminated to acceptable levels

00:15:41.847 --> 00:15:45.933 and targets are the quantifiable pathogen reduction levels or

00:15:45.933 --> 00:15:49.360 growth limits set by establishments to produce safe

00:15:49.360 --> 00:15:53.051 products in the absence of performance standards set by

00:15:53.051 --> 00:15:56.742 FSIS, targets are used by establishments to demonstrate 00:15:56.742 --> 00:16:00.433 that the lethality and stabilization processes achieved

00:16:00.433 --> 00:16:04.123 by the food safety system prevent, eliminate, or reduce

00:16:04.123 --> 00:16:06.166 pathogens to acceptable levels.

00:16:07.326 --> 00:16:11.263 Unlike Appendix A, which has tables for achieving a 6 1/2 or

00:16:11.263 --> 00:16:15.200 7 log reduction in salmonella and meat and poultry products,

00:16:15.200 --> 00:16:19.137 it's not always clear looking at an establishment scientific

00:16:19.137 --> 00:16:22.815 support scientific support, the targeted reduction being

00:16:22.815 --> 00:16:23.396 achieved.

00:16:23.866 --> 00:16:27.212 So it's important establishments clearly identify as part of

00:16:27.212 --> 00:16:29.406 their hassle, plan or other supporting.

00:16:30.306 --> 00:16:31.256 And what?

00:16:31.266 --> 00:16:34.887 Their lethality target is again that five log reduction or 00:16:34.887 --> 00:16:37.096 whatever the targeted reduction is.

00:16:37.526 --> 00:16:40.226 And if they do not, noncompliance may exist.

00:16:41.626 --> 00:16:45.556 So as we said, for ready to eat shelf stable meat and poultry

00:16:45.556 --> 00:16:49.485 products, FSIS recommends the process achieve at least A5 log

00:16:49.485 --> 00:16:53.478 reduction of salmonella and at least A5 log reduction of stack

00:16:53.478 --> 00:16:55.316 for products containing beef.

00:16:55.326 --> 00:16:57.906 In order to support the products are ready to eat.

00:17:00.316 --> 00:17:04.241 In addition to salmonella, the valley treatment of ready to eat

00:17:04.241 --> 00:17:08.043 shelf stable meat and poultry products should also achieve at

00:17:08.043 --> 00:17:11.416 least a three log reduction in Listeria monocytogenes.

00:17:11.476 --> 00:17:14.960 Although A5 log reduction or greater is desirable for

00:17:14.960 --> 00:17:18.895 providing an even greater safety

00:17:18.895 --> 00:17:22.056 cannot grow to detectable levels during storage.

00:17:23.746 --> 00:17:27.439 However, establishments are not required to validate their

00:17:27.439 --> 00:17:31.319 process achieves the three log reduction in at lab or even A5

00:17:31.319 --> 00:17:34.636 log reduction of stack for products containing beef.

00:17:34.806 --> 00:17:38.839 If they have scientific support, the process achieves significant

00:17:38.839 --> 00:17:40.366 reductions in salmonella.

00:17:41.776 --> 00:17:45.271 Also, just be aware there's lots of combinations or ways

00:17:45.271 --> 00:17:47.846 establishments may support their process.

00:17:48.296 --> 00:17:52.561 For an example, establishment may have scientific support in

00:17:52.561 --> 00:17:57.104 which the process of this study only included E coli O 15787 and

00:17:57.104 --> 00:18:00.879 that could be used as support that there's sufficient

00:18:00.879 --> 00:18:03.116 reductions of salmonella and LM.

00:18:03.986 --> 00:18:07.737 These acceptable combinations of support are all outlined in the

00:18:07.737 --> 00:18:10.622 guidance document, and we're having those systems

00:18:10.622 --> 00:18:13.796 stablishment's in ask aphasias if there are questions.

00:18:13.806 --> 00:18:14.216 Questions.

00:18:15.326 --> 00:18:19.158 I also want to add for ready to eat shelf stable meat products

00:18:19.158 --> 00:18:20.556 produced from raw pork.

00:18:20.746 --> 00:18:24.495 The Hassop system must also address to cut trick analysis

00:18:24.495 --> 00:18:27.857 paralysis, but we do want everyone to be aware that

00:18:27.857 --> 00:18:30.959 scientific support for reductions in salmonella

00:18:30.959 --> 00:18:34.967 salmonella lethality cannot be used to support any particular

00:18:34.967 --> 00:18:37.746 reductions in trichina have been achieved.

00:18:38.266 --> 00:18:41.870 And the same thing for scientific support for Dracaena

00:18:41.870 --> 00:18:42.656 elimination.

00:18:42.666 --> 00:18:46.102 That cannot be used to support any particular reductions in

00:18:46.102 --> 00:18:49.710 salmonella have been achieved and that's because we just don't

00:18:49.710 --> 00:18:53.203 have any information suggesting that there's any correlation

00:18:53.203 --> 00:18:54.806 between those two pathogens.

00:18:59.076 --> 00:19:03.346 Although I recommended target is a 5 log reduction in salmonella.

00:19:03.396 --> 00:19:06.586 It can be difficult to find scientific support that

00:19:06.586 --> 00:19:10.267 demonstrates at least A5 log reduction again, because those

00:19:10.267 --> 00:19:13.456 hurdles are just not as effective as cooking alone.

00:19:14.396 --> 00:19:18.110 Establishments may support an alternative lethality or

00:19:18.110 --> 00:19:21.891 reduction that provides an equivalent probability of no 00:19:21.891 --> 00:19:26.077 salmonella organisms present in the finished product, and one

00:19:26.077 --> 00:19:30.061 common way establishments do this is by following the Blue

00:19:30.061 --> 00:19:34.382 Ribbon task force option #5 in which it's recommended that each

00:19:34.382 --> 00:19:38.501 and every lot of raw batter is tested in combination with A2

00:19:38.501 --> 00:19:39.446 log reduction.

00:19:40.146 --> 00:19:44.992 The initial raw better testing option was to test each and

00:19:44.992 --> 00:19:49.839 every lot of raw batter for E coli, O157H7 and combination

00:19:49.839 --> 00:19:53.206 with A2 log reduction in E coli O 15787.

00:19:53.676 --> 00:19:57.115 But this process can also be applied in which Arab first

00:19:57.115 --> 00:20:00.373 tested for salmonella in combination with the two log

00:20:00.373 --> 00:20:00.976 reduction.

00:20:01.326 --> 00:20:04.145 Again, there's many ways this can be applied, and these are $00:20:04.145 \rightarrow 00:20:05.836$ all addressed within the guideline.

00:20:06.966 --> 00:20:10.389 This type of testing though, does provide less assurance of

00:20:10.389 --> 00:20:13.526 Product Safety, so it's important that testing that is

00:20:13.526 --> 00:20:17.120 performed provides a high degree of confidence that there's no

00:20:17.120 --> 00:20:18.146 pathogens present.

00:20:19.106 --> 00:20:22.988 Umm, I also want to mention that we've adapted this concept for

00:20:22.988 --> 00:20:26.869 whole muscle type products like biltong where the raw materials

00:20:26.869 --> 00:20:30.205 would be strips instead of raw batter and so this this

00:20:30.205 --> 00:20:33.116 information can also be found in the guideline.

00:20:34.356 --> 00:20:38.276 Finally, I just want to mention that FSS does not consider

00:20:38.276 --> 00:20:42.262 testing hold also sometimes described as option #3 from the

00:20:42.262 --> 00:20:45.916

Blue Ribbon Task Force document as acceptable support.

00:20:46.656 --> 00:20:51.836 This option was developed before Hassop was finished.

00:20:51.846 --> 00:20:55.610 Product testing alone is really inconsistent with the hassop

00:20:55.610 --> 00:20:59.312 requirements because it does not support any particular log

00:20:59.312 --> 00:21:02.952 reduction in levels of target pathogens is achieved, so it

00:21:02.952 --> 00:21:06.407 does not support that the establishment system provides

00:21:06.407 --> 00:21:08.196 any control over the process.

00:21:13.576 --> 00:21:17.433 So that's an overview of Aphasias guidance related to

00:21:17.433 --> 00:21:20.646 lethality targets in terms of stabilization.

00:21:20.656 --> 00:21:24.366 This is a little different than what we're used to for cooked

00:21:24.366 --> 00:21:27.836 products because the products are typically stabilized by

00:21:27.836 --> 00:21:31.246 reduced pH and reduce water activity and not by cooling.

00:21:31.636 --> 00:21:35.310 Remember, stabilization is the process of preventing or

00:21:35.310 --> 00:21:39.049 limiting the growth of spore forming bacteria capable of

00:21:39.049 --> 00:21:43.378 producing toxins in the product, like Clostridium botulinum or in

00:21:43.378 --> 00:21:45.936 the human intestine after consumption.

00:21:46.146 --> 00:21:50.571 I clustered your preference, Ken for quick products were used to

00:21:50.571 --> 00:21:54.316 rapid cooling being the primary control for Clostridia

00:21:54.316 --> 00:21:54.996 outgrowth.

00:21:55.286 --> 00:21:59.661 But for for fermented software and dry products, these controls

00:21:59.661 --> 00:22:03.557 can be more complicated for fermented products, controls

00:22:03.557 --> 00:22:07.180 include salt concentration, presence of lactic acid,

00:22:07.180 --> 00:22:11.076 bacteria use of dextrose and use of nitrate and nitrite.

00:22:12.856 --> 00:22:16.964 Personal care products the resting or equalization phase is

00:22:16.964 --> 00:22:21.413 a critical step for inhibiting C botulinum and products like dry

00:22:21.413 --> 00:22:22.166 cured hams.

00:22:22.916 --> 00:22:26.702 If you've not considered these hazards in the past, we have

00:22:26.702 --> 00:22:30.550 included the main articles that we're aware of that support,

00:22:30.550 --> 00:22:32.506 yes, are these common controls.

00:22:33.036 --> 00:22:36.921 So we think you'll find the will be really helpful for supporting

00:22:36.921 --> 00:22:39.216 decisions within your House up system.

00:22:41.306 --> 00:22:44.853 Fsis also recommends that establishments ensure the

00:22:44.853 --> 00:22:49.286 process allows no more than two lux growth of staff orius during

00:22:49.286 --> 00:22:53.651 processing again, in order that the product is ready to eat for

00:22:53.651 --> 00:22:57.606 fermented products, the amount of time and hours above 60

00:22:57.606 --> 00:23:01.698

degrees it takes a specific temperature to reduce the pH to

00:23:01.698 --> 00:23:05.654 5.3 or below, known as degree hours, is typically used to

00:23:05.654 --> 00:23:08.586 ensure that staff oreas growth is limited.

00:23:09.766 --> 00:23:14.051 Although the original scientific support that was used all of the

00:23:14.051 --> 00:23:18.011 degree hours does not include the amount of outgrowth that a

00:23:18.011 --> 00:23:22.231 meeting, the degree hours limits FSS has verified that achieving

00:23:22.231 --> 00:23:26.126 degree hours would limit staff orius growth to safe levels.

00:23:26.136 --> 00:23:30.616 And it's an acceptable control and support used for staff oreas

00:23:30.616 --> 00:23:32.506 growth during fermentation.

00:23:36.556 --> 00:23:40.389 So the last type of pathogen, pathogen, target we would expect

00:23:40.389 --> 00:23:44.039 is related to shelf stability and fermentation, salt curing

00:23:44.039 --> 00:23:47.749 and drying typically render the product shelf stable at room 00:23:47.749 --> 00:23:51.460 temperature and shelf stability as shown on the slide is the

00:23:51.460 --> 00:23:55.293 condition achieved for meat and poultry products can be stored

00:23:55.293 --> 00:23:58.760 under ambient temperature and humidity conditions if the

00:23:58.760 --> 00:24:02.471 package integrity is maintained during storage, shipping and

00:24:02.471 --> 00:24:06.181 display at retail on the home and the product will not spoil

00:24:06.181 --> 00:24:09.892 or become unsafe throughout the manufacturer specified shelf

00:24:09.892 --> 00:24:10.196 life.

00:24:11.406 --> 00:24:15.541 Shelf stable product should have characteristics that ensure no

00:24:15.541 --> 00:24:19.224 growth of staff orients may occur during storage of room

00:24:19.224 --> 00:24:23.489 temperature and appendix five of the fermented salt cured and dry

00:24:23.489 --> 00:24:27.430 product skyline includes the valuable scientific support for

00:24:27.430 --> 00:24:31.113 shelf stability for various

combinations of pH and water

00:24:31.113 --> 00:24:33.826 activity, either alone or in combination.

00:24:35.206 --> 00:24:37.616 So I think you'll find that information very helpful.

00:24:38.716 --> 00:24:41.566 Our measures should also be taken to address mold growth.

00:24:44.256 --> 00:24:47.751 And we do get a lot of questions about mold related to these

00:24:47.751 --> 00:24:48.266 products.

00:24:48.596 --> 00:24:52.890 Molds may grow unfermented soy cured and dried products because

00:24:52.890 --> 00:24:56.379 the high salt and low temperature conditions do not

00:24:56.379 --> 00:25:00.002 inhibit these organisms, and here it's the sanitation

00:25:00.002 --> 00:25:00.606 standard.

00:25:00.616 --> 00:25:05.501 Operating procedures or SSO's is critical to prevent undesirable

00:25:05.501 --> 00:25:09.935 mold growth, along with short inventory dates, low pH, low

00:25:09.935 --> 00:25:14.068

water activity, antimycotic coatings packaging such as

00:25:14.068 --> 00:25:18.276 vacuum packaging, or any combination of these measures.

00:25:19.286 --> 00:25:22.860 If mold is present, depending on the type, establishments may

00:25:22.860 --> 00:25:26.261 package the product with the mold on or may scrub the mold

00:25:26.261 --> 00:25:29.719 off with a stiff vegetable brush or may trim it to maintain

00:25:29.719 --> 00:25:30.526 wholesomeness.

00:25:31.856 --> 00:25:35.835 Have basis does not recommend washing the mold off with hoses,

00:25:35.835 --> 00:25:39.813 including those that are high pressure because that can result

00:25:39.813 --> 00:25:43.791 in cross contamination from the environment to the product and

00:25:43.791 --> 00:25:47.075 is generally not recommended as to prevent LM cross

00:25:47.075 --> 00:25:48.906 contamination post lethality.

00:25:50.756 --> 00:25:54.040 We also get questions about whether the presence of mold
00:25:54.040 --> 00:25:57.726 requires specific labeling and that does not other our labeling

00:25:57.726 --> 00:26:00.894 staff recommends that the establishments label include

00:26:00.894 --> 00:26:04.120 instructions to consumers regarding removal of the mold

00:26:04.120 --> 00:26:06.136 before consumption if appropriate.

00:26:09.846 --> 00:26:13.759 Dry white mold, often seen on fermented and dried sausages, is

00:26:13.759 --> 00:26:17.609 generally considered to be a good mold because it can prevent

00:26:17.609 --> 00:26:19.596 so called bad mold from growing.

00:26:19.886 --> 00:26:23.552 But we do want to be clear that color is not necessarily an

00:26:23.552 --> 00:26:24.896 indicator of bad mold.

00:26:24.946 --> 00:26:28.118 So we can't assume just based off of the color of the mold

00:26:28.118 --> 00:26:29.246 that it's a bad mold.

00:26:30.276 --> 00:26:34.071 Sometimes a commercial mold culture will be applied prior to 00:26:34.071 --> 00:26:37.431 fermentation, so either the product will be dipped or

00:26:37.431 --> 00:26:41.475 sprayed with a active live mold culture to prevent the growth of

00:26:41.475 --> 00:26:44.336 undesirable molds and for flavor development.

00:26:45.946 --> 00:26:48.996 If a multi culture is not applied and mold growth is

00:26:48.996 --> 00:26:52.505 desirable for quality reasons, establishments should provide

00:26:52.505 --> 00:26:56.072 support for their process and describe the controls they have

00:26:56.072 --> 00:26:59.409 in place over the critical operational parameters such as

00:26:59.409 --> 00:27:02.458 relative humidity, air temperature and air flow that

00:27:02.458 --> 00:27:05.795 result in mold production that provides desirable quality

00:27:05.795 --> 00:27:07.406 attributes to their product.

00:27:11.166 --> 00:27:14.242 So those are the recommended targets for lethality

00:27:14.242 --> 00:27:15.086 stabilization.

00:27:15.626 --> 00:27:18.670 Out shelf stability establishments then must have

00:27:18.670 --> 00:27:22.201 scientific for Technical Support that those lethality and

00:27:22.201 --> 00:27:25.306 stabilization and shelf stability targets are met.

00:27:26.146 --> 00:27:30.274 Examples of scientific support that may be used for fermented

00:27:30.274 --> 00:27:34.203 salt cured and dried products include published processing

00:27:34.203 --> 00:27:38.131 guidelines, peer reviewed, scientific or technical data or

00:27:38.131 --> 00:27:41.860 information, expert advice from processing authorities,

00:27:41.860 --> 00:27:45.788 challenge or inoculated pack studies, validate a pathogen,

00:27:45.788 --> 00:27:49.584 modeling programs and data gathered by the establishment

00:27:49.584 --> 00:27:50.116 implant.

00:27:50.586 --> 00:27:53.558 I'm going to talk about each of these types of support in

00:27:53.558 --> 00:27:53.916 detail.

00:27:54.346 --> 00:27:57.446 There are other types of scientific support that I'll not

00:27:57.446 --> 00:28:00.545 talk about, such as regulatory have performance standards

00:28:00.545 --> 00:28:04.019 because we don't have those for these types of products and also

00:28:04.019 --> 00:28:07.119 best practice guidelines we're not aware of best practice

00:28:07.119 --> 00:28:09.256 guidelines for these types of products.

00:28:12.796 --> 00:28:16.163 So in terms of published processing guidelines, FSS does

00:28:16.163 --> 00:28:19.531 not have any guidance that includes critical operational

00:28:19.531 --> 00:28:22.898 parameters like we do for cooking meth time, temperature

00:28:22.898 --> 00:28:24.906 and relative humidity parameters.

00:28:25.356 --> 00:28:29.056 But we do have the new Ready team, fermented salt cured and

00:28:29.056 --> 00:28:32.509 dry products guideline that includes summaries of other 00:28:32.509 --> 00:28:36.208 types of support such as peer reviewed articles that may be

00:28:36.208 --> 00:28:37.626 used by establishments.

00:28:38.156 --> 00:28:41.879 Establishments need the complete scientific support document on

00:28:41.879 --> 00:28:44.496 file, so they need that old journal article.

00:28:44.866 --> 00:28:49.218 I'm not just the guideline the good manufacturing practices for

00:28:49.218 --> 00:28:52.890 fermented dry and semi dry sausage is another type of

00:28:52.890 --> 00:28:55.746 published processing guideline available.

00:28:56.156 --> 00:28:59.685 This supports the use of that degree hours concept I was

00:28:59.685 --> 00:29:02.966 describing for controlling staff orius growth during

00:29:02.966 --> 00:29:06.805 fermentation, but we do want you to be aware that it does not

00:29:06.805 --> 00:29:10.395 support degree hours achieves any particular lethality in

00:29:10.395 --> 00:29:11.076 salmonella.

00:29:12.876 --> 00:29:17.051 As I mentioned earlier, the FSI is guideline for prevention and

00:29:17.051 --> 00:29:21.226 control of TRICHINELLA includes critical operational parameters

00:29:21.226 --> 00:29:24.226 validated to destroy China in these products.

00:29:24.496 --> 00:29:27.741 But it does not support any particularly faulty of

00:29:27.741 --> 00:29:31.812 salmonella when those parameters are followed and then aphasias

00:29:31.812 --> 00:29:35.502 is guideline for meat and poultry jerky includes critical

00:29:35.502 --> 00:29:38.746 operational parameters validated to prevent staph.

00:29:38.756 --> 00:29:40.866 Aureus outgrowth during storage.

00:29:40.876 --> 00:29:44.692 So to support the shelf stability of dried products, but

00:29:44.692 --> 00:29:48.173 it does not support any lethality of salmonella for

00:29:48.173 --> 00:29:51.586 uncooked fermented salt, cured and dried products.

00:29:54.706 --> 00:29:57.968 So one common question we've gotten and this comes right from

00:29:57.968 --> 00:30:01.124 the guideline is what if I meet the degree hours and dry my

00:30:01.124 --> 00:30:04.385 product following one of the methods in the guideline for the

00:30:04.385 --> 00:30:06.436 prevention and control of trichinella.

00:30:06.806 --> 00:30:10.219 And I tried to a reduced water activities such as water

00:30:10.219 --> 00:30:13.996 activity below .85 which can be found in the jerky guideline.

00:30:14.346 --> 00:30:18.498 Isn't that enough to show biological hazards are addressed

00:30:18.498 --> 00:30:19.976 and the answer is no.

00:30:20.276 --> 00:30:24.344 I this combination of controls has not been validated to

00:30:24.344 --> 00:30:28.055 achieve any particular reductions in salmonella and

00:30:28.055 --> 00:30:32.051 products have to often be fermented to pH is lower than

00:30:32.051 --> 00:30:36.119 5.3 that critical limit or critical parameter for degree 00:30:36.119 --> 00:30:39.973 hours and drive longer than is needed to achieve self

00:30:39.973 --> 00:30:40.686 stability.

00:30:40.696 --> 00:30:44.904 That .85 water activity to get significant reductions in

00:30:44.904 --> 00:30:45.716 salmonella.

00:30:50.986 --> 00:30:54.705 So really the most common type of scientific support we see our

00:30:54.705 --> 00:30:58.134 peer reviewed scientific or technical data or information,

00:30:58.134 --> 00:31:01.446 particularly for fermented salt, cured and dry products.

00:31:02.546 --> 00:31:05.596 These articles can be used alone and are available.

00:31:05.606 --> 00:31:08.782 I mentioned we have links to many articles within the

00:31:08.782 --> 00:31:12.310 guideline, but what's most important is that establishments

00:31:12.310 --> 00:31:16.014 do a careful comparison of the critical operational parameters

00:31:16.014 --> 00:31:19.718 and we note sometimes they're missing and those all need to be 00:31:19.718 --> 00:31:23.188 available in order to compare and make sure the scientific

00:31:23.188 --> 00:31:26.186 support matches the establishments actual process.

00:31:27.326 --> 00:31:31.336 Umm, so we do have links to all of the number of articles that

00:31:31.336 --> 00:31:34.964 are available through Open Access or where we've include

00:31:34.964 --> 00:31:38.974 the PDF versions of the articles and so establishments can use

00:31:38.974 --> 00:31:42.793 the guideline to really help identify what journal articles

00:31:42.793 --> 00:31:46.739 may match their process and then they need to have that whole

00:31:46.739 --> 00:31:50.494 article on file and do this careful comparison and we have

00:31:50.494 --> 00:31:53.931 an example here of where an establishment is using an

00:31:53.931 --> 00:31:58.004 optional post fermentation low temperature heat step to achieve

00:31:58.004 --> 00:31:59.786 lethality for their process.

00:32:00.056 --> 00:32:03.385 In this case, they're following 00:32:03.385 --> 00:32:06.535 validated the effectiveness of achieving an internal

00:32:06.535 --> 00:32:09.626 temperature of 128 degrees Fahrenheit for one hour.

00:32:10.126 --> 00:32:13.928 In this example, though, the establishment wants to use a

00:32:13.928 --> 00:32:17.927 higher cooking temperature, and in this case they're able to

00:32:17.927 --> 00:32:21.663 support that by referencing FSS cooking guideline, which

00:32:21.663 --> 00:32:25.792 supports that using a same or higher temperature with the same

00:32:25.792 --> 00:32:29.594 or longer dwell time is going to be the same or even more

00:32:29.594 --> 00:32:31.626 effective at reducing bacteria.

00:32:34.136 --> 00:32:37.547 After modeling programs are another type of support that can

00:32:37.547 --> 00:32:39.056 be used for fermented salt.

00:32:39.066 --> 00:32:40.566 Cured and dry products.

00:32:41.256 --> 00:32:45.278 But the is that these models should not be used alone unless

00:32:45.278 --> 00:32:49.168 they've been validated and there are a number of available

00:32:49.168 --> 00:32:52.266 validated models for these types of processes.

00:32:52.536 --> 00:32:57.132 So the Danish Technological Institute, or D MRI, has a

00:32:57.132 --> 00:33:00.056 confirm model available down here.

00:33:00.276 --> 00:33:04.634 This model has been validated for estimating the reductions of

00:33:04.634 --> 00:33:08.785 salmonella stack and LM and fermented products up to A3 log

00:33:08.785 --> 00:33:09.476 reduction.

00:33:09.846 --> 00:33:13.892 So we noticed earlier that FSS recommends at least a pie blog

00:33:13.892 --> 00:33:16.176 reduction in salmonella and stack.

00:33:16.226 --> 00:33:20.043 So this type of model would be limited to supporting a process

00:33:20.043 --> 00:33:23.618 like that raw batter testing I mentioned in which each and 00:33:23.618 --> 00:33:27.132 every lot of raw batter is tested in combination with the

00:33:27.132 --> 00:33:30.706 process validated to achieve at least a two log reduction.

00:33:32.426 --> 00:33:36.274 The University of Wisconsin has a shelf stability predictor

00:33:36.274 --> 00:33:40.251 available on their website, and this model has been validated

00:33:40.251 --> 00:33:44.483 for estimating the likelihood of staff orius and LM growth during

00:33:44.483 --> 00:33:44.996 storage.

00:33:45.086 --> 00:33:48.748 This is a great tool for supporting shelf stability and

00:33:48.748 --> 00:33:52.540 then the DRI or Danish Meat Research Institute also has a

00:33:52.540 --> 00:33:56.528 staff talks predictor model that's been validated to predict

00:33:56.528 --> 00:34:00.647 the growth of staff orius and potential toxin formation during

00:34:00.647 --> 00:34:04.047 mild heat treatment and during constant temperature

00:34:04.047 --> 00:34:05.616 fermentation of sausage.

00:34:05.846 --> 00:34:09.041 So this model can be used to assist with fermentation

00:34:09.041 --> 00:34:11.526 deviations and evaluating Product Safety.

00:34:14.256 --> 00:34:17.759 There are other models that are also available, but you should

00:34:17.759 --> 00:34:21.094 be aware that they've not been validated and so the results

00:34:21.094 --> 00:34:22.706 cannot be relied upon a loan.

00:34:23.236 --> 00:34:27.618 One example is the agricultural Research Services pathogen

00:34:27.618 --> 00:34:30.366 modeling program for E coli O 15787.

00:34:30.376 --> 00:34:32.946 Survival for fermented sausage.

00:34:33.316 --> 00:34:36.803 This model has not been validated and also it only

00:34:36.803 --> 00:34:39.606 includes the input for one parameter pH.

00:34:39.616 --> 00:34:43.997 So it really simplifies all the various critical operational

00:34:43.997 --> 00:34:47.946 parameters that can impact effectiveness of lethality.

00:34:48.306 --> 00:34:51.869 But it's a great tool to give an initial estimate for the

00:34:51.869 --> 00:34:55.492 effectiveness of a process, which then must be followed up

00:34:55.492 --> 00:34:58.870 by other support, like a challenge, study the meat and

00:34:58.870 --> 00:35:02.371 livestock model, E coli inactivation model and fermented

00:35:02.371 --> 00:35:05.995 meat is another example of a model that's great for giving

00:35:05.995 --> 00:35:07.346 that initial estimate.

00:35:07.616 --> 00:35:10.482 But since it hasn't been validated, we need to be

00:35:10.482 --> 00:35:14.150 followed up by a challenge study and could not be relied upon a

00:35:14.150 --> 00:35:14.436 loan.

00:35:19.376 --> 00:35:22.929 Establishments also often use challenge studies to support

00:35:22.929 --> 00:35:26.603 their process because all the unique combination of critical

00:35:26.603 --> 00:35:29.735 operational parameters which

00:35:29.735 --> 00:35:33.348 literature or other types of support, and the well designed

00:35:33.348 --> 00:35:37.202 challenge study, should include details about all the following

00:35:37.202 --> 00:35:40.093 on the slide the product studied, including the

00:35:40.093 --> 00:35:43.706 formulation, types and number of strains of microorganisms.

00:35:43.996 --> 00:35:47.797 And we do include within the guideline various non pathogenic

00:35:47.797 --> 00:35:50.985 surrogates that can be introduced in plant, because

00:35:50.985 --> 00:35:54.786 otherwise we would not want a challenge study to be performed

00:35:54.786 --> 00:35:57.176 in a plant environment with pathogens.

00:35:57.186 --> 00:35:59.912 We would not want to introduce pathogens into the plant

00:35:59.912 --> 00:36:00.496 environment.

00:36:01.236 --> 00:36:04.078 Umm, there's other factors here that should be included and 00:36:04.078 --> 00:36:06.636 they're all described in detail within the guideline.

00:36:11.166 --> 00:36:14.641 Finally, data gathered implant has particular value for

00:36:14.641 --> 00:36:17.246 fermented salt, cured and dried products.

00:36:17.656 --> 00:36:21.602 Establishments are required to gather implant validation data,

00:36:21.602 --> 00:36:24.796 demonstrating the hassop system works as intended.

00:36:25.276 --> 00:36:28.193 The data must demonstrate the effectiveness of the

00:36:28.193 --> 00:36:31.681 implementation of the critical operational parameters and we

00:36:31.681 --> 00:36:34.712 recommend for at least one product for each House of

00:36:34.712 --> 00:36:35.226 category.

00:36:35.756 --> 00:36:39.559 As you heard from Paul, the guideline includes information

00:36:39.559 --> 00:36:43.749 about validation data, including for products such as those that

00:36:43.749 --> 00:36:47.358 are salt cured, where the initial validation period may

00:36:47.358 --> 00:36:49.356 extend beyond 90 calendar days.

00:36:49.746 --> 00:36:54.006 Due to the nature of the process and the length of time it takes

00:36:54.006 --> 00:36:57.544 to implement the critical operational parameters that

00:36:57.544 --> 00:37:00.886 impact lethality when establishment has scientific

00:37:00.886 --> 00:37:05.146 support, such as a peer reviewed journal article and it wants to

00:37:05.146 --> 00:37:08.684 use different critical operational parameters and may

00:37:08.684 --> 00:37:12.878 consider also gathering implant microbiological data to support

00:37:12.878 --> 00:37:16.941 the new combination of steps achieves sufficiently lethality,

00:37:16.941 --> 00:37:20.479 particularly if data or scientific principles are not

00:37:20.479 --> 00:37:22.576 available to support the change.

00:37:23.766 --> 00:37:24.696 Turn example.

00:37:24.706 --> 00:37:28.756 If an establishment is producing a dried meat and it identifies a 00:37:28.756 --> 00:37:32.807 journal article that matches its process, but it intends to use a

00:37:32.807 --> 00:37:35.997 slightly lower drying temperature, say two or three

00:37:35.997 --> 00:37:40.048 degrees lower than what was used in the support, it may choose to

00:37:40.048 --> 00:37:44.036 collect implant microbiological data to support that difference.

00:37:44.046 --> 00:37:48.126 Is doesn't have a significant impact in this case.

00:37:48.136 --> 00:37:52.480 The establishment would take a statistically significant number

00:37:52.480 --> 00:37:56.756 of samples it produces during those first 90 calendar days and

00:37:56.756 --> 00:38:01.099 do finished product testing for pathogens like salmonella stack

00:38:01.099 --> 00:38:01.506 or LM.

00:38:02.866 --> 00:38:06.373 If the establishment produces the product less than 13 days

00:38:06.373 --> 00:38:10.113 within a 90 calendar day period, it should continue to test the

00:38:10.113 --> 00:38:13.560

product until 13 different lots have been tested and found

00:38:13.560 --> 00:38:14.086 negative.

00:38:14.976 --> 00:38:18.549 It would not be appropriate, though, to use this type of

00:38:18.549 --> 00:38:21.746 testing when there are big differences between the

00:38:21.746 --> 00:38:25.005 establishments, scientific support and their actual

00:38:25.005 --> 00:38:25.506 process.

00:38:25.776 --> 00:38:29.089 And again, that's because the test and whole concept is really

00:38:29.089 --> 00:38:30.456 inconsistent with passive.

00:38:31.206 --> 00:38:35.023 Umm, what's considered a large difference is going to depend on

00:38:35.023 --> 00:38:38.422 the parameter and the process, but it would again not be

00:38:38.422 --> 00:38:42.178 appropriate to rely on implant microbiological data if there's

00:38:42.178 --> 00:38:45.816 very large differences between an establishments process and

00:38:45.816 --> 00:38:47.306

their scientific support.

00:38:47.606 --> 00:38:51.005 In that case, a challenge study or other type of support may be

00:38:51.005 --> 00:38:51.376 needed.

00:38:54.766 --> 00:38:58.407 So I've been establishment is using the scientific support as

00:38:58.407 --> 00:39:02.225 support for the development of a critical control point and it's

00:39:02.225 --> 00:39:05.690 critical limits to prevent, reduce or eliminate the hazard

00:39:05.690 --> 00:39:08.156 identified as reasonably likely to occur.

00:39:08.566 --> 00:39:11.920 The establishment should incorporate all of the critical

00:39:11.920 --> 00:39:15.803 operational parameters, from its support into the critical limits

00:39:15.803 --> 00:39:18.686 of its CCP, and the establishment may determine.

00:39:18.696 --> 00:39:21.957 However, based on its decision making that some other

00:39:21.957 --> 00:39:25.641 parameters can be monitored on an ongoing basis as part of a

00:39:25.641 --> 00:39:29.143 prerequisite program, an establishment may also determine

00:39:29.143 --> 00:39:32.887 that it only needs to ensure some of the critical operational

00:39:32.887 --> 00:39:36.269 parameters are implementing consistent with the support

00:39:36.269 --> 00:39:39.046 during the initial implant validation period.

00:39:39.056 --> 00:39:43.331 This could be something like the formulation, but again, if for

00:39:43.331 --> 00:39:47.404 critical operational parameter is implemented differently in

00:39:47.404 --> 00:39:51.812 the actual process than what was used in this scientific support,

00:39:51.812 --> 00:39:55.619 the establishment must provide justification for why the

00:39:55.619 --> 00:39:59.826 difference would still result in an equally effective process.

00:40:00.896 --> 00:40:04.648 So that's why it's important to do that careful comparison of

00:40:04.648 --> 00:40:07.977 the critical operational parameters and the support to

00:40:07.977 --> 00:40:09.126 the actual process.

00:40:09.476 --> 00:40:12.744 And in order to do that, you need to know what those critical

00:40:12.744 --> 00:40:14.166 operational parameters are.

00:40:14.436 --> 00:40:17.542 And so we have outlined within the guideline the critical

00:40:17.542 --> 00:40:20.486 operational parameters for each of the critical steps.

00:40:20.856 --> 00:40:24.417 So here we have them for fermentation low temperature,

00:40:24.417 --> 00:40:25.776 heat step and drying.

00:40:26.896 --> 00:40:30.658 For fermentation, these parameters include those like

00:40:30.658 --> 00:40:34.559 fermentation temperature, target, pH, time to reach pH,

00:40:34.559 --> 00:40:35.186 etcetera.

00:40:35.596 --> 00:40:38.969 We also include the critical operational parameters for a low

00:40:38.969 --> 00:40:40.166 temperature heat step.

00:40:40.356 --> 00:40:43.740 Establishments can also absolutely cook fermented 00:40:43.740 --> 00:40:47.326 products using something like FSS cooking guideline.

00:40:47.636 --> 00:40:51.785 That's not covered here because cooking is well explained within

00:40:51.785 --> 00:40:54.976 epiphysis cooking guideline and revised appendix.

00:40:55.056 --> 00:40:55.386 A.

00:40:55.696 --> 00:40:57.676 That's certainly an option here.

00:40:57.686 --> 00:41:01.284 We're focusing on the low temperature heat step because

00:41:01.284 --> 00:41:04.947 that hasn't been covered and other aphasias guidance for

00:41:04.947 --> 00:41:05.396 drying.

00:41:05.406 --> 00:41:08.875 There's critical operational parameters like the drying room,

00:41:08.875 --> 00:41:12.232 temperature, drying time, target water activity and product

00:41:12.232 --> 00:41:15.477 characteristics, and we also note here there are critical

00:41:15.477 --> 00:41:18.666 operational parameters that do not need to be addressed.

00:41:18.916 --> 00:41:19.586 So you heard.

00:41:19.596 --> 00:41:23.136 Paul talked about that National Advisory committee for meat and

00:41:23.136 --> 00:41:24.186 poultry inspection.

00:41:24.476 --> 00:41:28.067 One thing they also recommended Aphasias do was convene a group

00:41:28.067 --> 00:41:31.715 of researchers to give feedback on these products, and they were

00:41:31.715 --> 00:41:35.194 able to give us really helpful feedback, including that there

00:41:35.194 --> 00:41:38.672 are some critical operations, grandmothers that are not gonna

00:41:38.672 --> 00:41:42.151 impact the effectiveness of the lethality treatment for these

00:41:42.151 --> 00:41:42.656 products.

00:41:42.966 --> 00:41:46.781 So for fermentation, this includes relative humidity and

00:41:46.781 --> 00:41:50.329 casing type for the low temperature heat staff, this

00:41:50.329 --> 00:41:54.545 would be relative humidity and for drying these include casing 00:41:54.545 --> 00:41:58.226 type presence of mold, relative humidity and air flow.

00:41:58.436 --> 00:42:02.255 So what this means is that establishments can support that

00:42:02.255 --> 00:42:06.138 differences in these parameters are not going to impact the

00:42:06.138 --> 00:42:09.826 effectiveness of the process by using aphasias guidance.

00:42:11.916 --> 00:42:15.844 There's also a number of critical operational parameters

00:42:15.844 --> 00:42:19.427 for dry curing and salt equalization, including the

00:42:19.427 --> 00:42:22.666 curing and equalization temperature curing and

00:42:22.666 --> 00:42:25.766 equalization time, salt coverage, et cetera.

00:42:25.776 --> 00:42:29.756 And these are all shown here and the same critical operational

00:42:29.756 --> 00:42:33.735 parameters occur for drying the drying room, temp drying time,

00:42:33.735 --> 00:42:36.956 target water activity and product characteristics.

00:42:37.306 --> 00:42:40.785

And again, there are other critical operational parameters

00:42:40.785 --> 00:42:44.322 that we've identified do not need to be addressed and these

00:42:44.322 --> 00:42:47.800 include relative humidity and air flow for drying and salt

00:42:47.800 --> 00:42:48.566 equalization.

00:42:48.576 --> 00:42:51.976 And again, the casing type, presence of mold, relative

00:42:51.976 --> 00:42:53.336 humidity and air flow.

00:42:53.406 --> 00:42:56.930 Again, this is because these parameters are not going to

00:42:56.930 --> 00:43:00.824 impact the effectiveness of the salt curing, dry curing or dry

00:43:00.824 --> 00:43:01.256 curing.

00:43:01.266 --> 00:43:03.526 Salt equalization or drying steps.

00:43:05.806 --> 00:43:09.695 And then last, we have dry products like BILTONG and drewer

00:43:09.695 --> 00:43:10.926 shown on the slide.

00:43:11.016 --> 00:43:14.397 And for these products, there's typically the critical steps

00:43:14.397 --> 00:43:16.946 include a marination or seasoning and drying.

00:43:17.296 --> 00:43:21.123 And for marination or seasoning, the product formulation and

00:43:21.123 --> 00:43:25.076 antimicrobial application, like the concentration, pH coverage

00:43:25.076 --> 00:43:29.091 and contact time are all going to be critical again for drawing

00:43:29.091 --> 00:43:32.667 the drawing room, temperature, drying time, target water

00:43:32.667 --> 00:43:35.930 activity and product characteristics can all impact

00:43:35.930 --> 00:43:38.376 the effectiveness of that drying step.

00:43:38.806 --> 00:43:42.645 But the casing type, presence of mold, relative humidity and air

00:43:42.645 --> 00:43:46.247 flow are critical operational parameters that do not need to

00:43:46.247 --> 00:43:49.376 be addressed, and that's supported by the guideline.

00:43:52.636 --> 00:43:56.310 So finally, to summarize, a contributing factor in several 00:43:56.310 --> 00:43:59.859 outbreaks associated with fermented salt cured and dried

00:43:59.859 --> 00:44:03.595 products has been a lack of support that the combination of

00:44:03.595 --> 00:44:06.646 hurdles used were effectively faulty treatments.

00:44:07.236 --> 00:44:11.243 FSS has issued a guideline to assist establishments and

00:44:11.243 --> 00:44:15.464 complying with the House of Requirement did salt cured and

00:44:15.464 --> 00:44:19.899 dried meat and poultry products enforcement investigation and

00:44:19.899 --> 00:44:24.192 analysis officers or EIO, have access to outreach materials

00:44:24.192 --> 00:44:28.412 related to fermented cell cured and dried meat and poultry

00:44:28.412 --> 00:44:29.056 products?

00:44:29.246 --> 00:44:32.619 And establishments can request outreach assistance through

00:44:32.619 --> 00:44:33.876 their district office.

00:44:34.226 --> 00:44:38.071 The IO have also attended a webinar as establishments are 00:44:38.071 --> 00:44:42.048 being given time to gather scientific support if needed and

00:44:42.048 --> 00:44:45.893 I have been instructed to wait until the support has been

00:44:45.893 --> 00:44:49.937 gathered for four performing a food safety assessment during

00:44:49.937 --> 00:44:51.726 the food safety assessment.

00:44:51.736 --> 00:44:55.334 EIO will verify the establishment has considered the

00:44:55.334 --> 00:44:58.932 appropriate hazards and its hazard analysis, and has

00:44:58.932 --> 00:45:02.801 identified the appropriate targets to ensure the hazards

00:45:02.801 --> 00:45:06.806 are prevented, reduced or eliminated to acceptable levels.

00:45:07.456 --> 00:45:10.509 They'll also verify the establishment has scientific

00:45:10.509 --> 00:45:14.081 support that is processed, can meet the targets it identified

00:45:14.081 --> 00:45:17.595 and implemented the critical operational parameters in their

00:45:17.595 --> 00:45:20.936

actual process, consistent with their scientific support.

00:45:24.186 --> 00:45:26.146 With that, we have time for questions.

00:45:26.156 --> 00:45:29.432 I want to thank you for your time and attention, and I do

00:45:29.432 --> 00:45:32.707 also want to mention, as you heard from Paul, that if you

00:45:32.707 --> 00:45:36.039 have any questions after this webinar, please submit those

00:45:36.039 --> 00:45:39.653 through, ask if it's IIS using the hasset validation and hassab

00:45:39.653 --> 00:45:40.556 deviation queue.

00:45:41.066 --> 00:45:44.450 You also heard that there are links in the guideline to the

00:45:44.450 --> 00:45:47.722 niche assistance meat processors network and the House of

00:45:47.722 --> 00:45:50.936 Coordinators who may also be able to provide assistance.

00:45:51.406 --> 00:45:54.548 But with that, I'm going to turn it over to Kimberly to share the

00:45:54.548 --> 00:45:55.166 instructions.

00:45:55.586 --> 00:45:57.126 Uh for asking a question.

00:45:59.376 --> 00:46:01.286 Alright, thank you, Doctor Silverman.

00:46:01.856 --> 00:46:06.406 OK, there are a few ways to ask a question or make a comment.

00:46:06.456 --> 00:46:10.279 So for those using the teams app, you can press the raise

00:46:10.279 --> 00:46:14.366 your hand feature and we can call on you and unmute your mic.

00:46:14.816 --> 00:46:16.806 You can also enter your guestionnaire.

00:46:16.816 --> 00:46:20.990 Comment in the chat box and for those using your phone, you can

00:46:20.990 --> 00:46:24.968 press star 5 to raise your hand and that will put you in the

00:46:24.968 --> 00:46:28.947 queue and we'll call you by announcing the last four numbers

00:46:28.947 --> 00:46:30.316 of your phone number.

00:46:31.866 --> 00:46:32.516 Alright.

00:46:32.586 --> 00:46:36.197 And I see that someone has their hand raised, so let me go ahead 00:46:36.197 --> 00:46:37.086 and unmute them.

00:46:48.786 --> 00:46:50.576 Alright, Karen, you're unmuted.

00:46:50.946 --> 00:46:51.286 Go ahead.

00:46:51.736 --> 00:46:53.286 Hi, thank you so much.

00:46:53.296 --> 00:46:59.000 Doctor Silverman, you mentioned earlier in the presentation that

00:46:59.000 --> 00:47:04.440 as long as you are showing umm the appropriate log reductions

00:47:04.440 --> 00:47:09.617 in salmonella that there is not a requirement to also show

00:47:09.617 --> 00:47:12.776 reductions in listeria or in S TEC.

00:47:12.866 --> 00:47:14.696 Can you tell me a little bit more about that?

00:47:14.706 --> 00:47:20.096 I wasn't familiar with that not needing to be shown.

00:47:21.706 --> 00:47:22.096 Yeah.

00:47:22.106 --> 00:47:26.204 So this is something that's been in our validation guidance for a

00:47:26.204 --> 00:47:30.116 number of years, but also we get 00:47:30.116 --> 00:47:33.717 fermented sock here and drag guidance just because of the

00:47:33.717 --> 00:47:36.076 combinations of support we have seen.

00:47:36.486 --> 00:47:41.318 We do know that E coli and 15787 and LM can be more tolerant to

00:47:41.318 --> 00:47:45.698 acid and drying, but ultimately establishments could have

00:47:45.698 --> 00:47:50.001 scientific support available that just showed salmonella

00:47:50.001 --> 00:47:50.756 reduction.

00:47:50.766 --> 00:47:55.060 So what that means is that if only salmonella was included in

00:47:55.060 --> 00:47:58.661 the study, it could be a challenge study or journal

00:47:58.661 --> 00:48:03.232 article and stack such as E coli on 5787 and LM were not included

00:48:03.232 --> 00:48:07.456 that study because stand alone as a scientific support if it

00:48:07.456 --> 00:48:11.473 provided that five library duction again the same is true

00:48:11.473 --> 00:48:13.896 if the scientific support just in.

00:48:14.816 --> 00:48:19.299 E coli O157H7 in that blue ribbon task force document from

00:48:19.299 --> 00:48:20.286 the late 90s.

00:48:20.296 --> 00:48:24.557 At the time, there were outbreaks associated with E coli

00:48:24.557 --> 00:48:28.968 owned 5787, so those processes were just validated to show

00:48:28.968 --> 00:48:30.986 reductions in E coli 15787.

00:48:31.236 --> 00:48:33.686 That would be acceptable, even though it did not.

00:48:33.696 --> 00:48:37.206 Also include salmonella or LM.

00:48:37.416 --> 00:48:40.206 Of course, of an establishment is doing a challenge study.

00:48:40.496 --> 00:48:44.388 We recommend all of those pathogens, salmonella, stack and

00:48:44.388 --> 00:48:48.544 LM are included, but again, if just one is included, there are

00:48:48.544 --> 00:48:51.446 various combinations of acceptable support.

00:48:52.196 --> 00:48:53.776 Hopefully that answers the question.

00:48:54.296 --> 00:48:55.626 Yeah, absolutely.

00:48:56.176 --> 00:48:59.513 Can you point me in the direction of a particular FSS

00:48:59.513 --> 00:49:02.416 guidance that discusses that or lays that out?

00:49:03.506 --> 00:49:03.896 Yeah.

00:49:03.906 --> 00:49:08.026 So that is all laid out within this new fermented salt cured

00:49:08.026 --> 00:49:09.376 and dried guideline.

00:49:09.676 --> 00:49:10.096 Awesome.

00:49:09.826 --> 00:49:14.916 And so there's extensive discussion about the targets.

00:49:14.966 --> 00:49:18.195 It's in a section about the reduction targets and then it

00:49:18.195 --> 00:49:20.866 goes through all those combinations of support.

00:49:21.066 --> 00:49:24.838 Generally, there's information in the valid passive systems

00:49:24.838 --> 00:49:28.987

validation guidance, but there's just much more detail because it

00:49:28.987 --> 00:49:32.256 gets more complicated with these types of products.

00:49:32.266 --> 00:49:34.426 So that's covered all within this guideline.

00:49:35.956 --> 00:49:36.696 Thank you so much.

00:49:40.796 --> 00:49:41.516 All right.

00:49:44.156 --> 00:49:49.036 It looks like we have another hand, so let me unmute them.

00:49:51.526 --> 00:49:55.325 Alright Nathan, you are unmuted and you may have to unmute

00:49:55.325 --> 00:49:59.187 yourself and then you can go ahead and ask your question or

00:49:59.187 --> 00:50:00.346 make your comment.

00:50:09.866 --> 00:50:12.756 Nathan, you might be muted on your end.

00:50:12.816 --> 00:50:16.686 We can't hear you, but you have access to unmute yourself.

00:50:27.176 --> 00:50:27.926 Oh, I'm sorry.

00:50:29.166 --> 00:50:30.416 Yes, we can hear you.
00:50:30.476 --> 00:50:30.986 Thank you.

00:50:31.036 --> 00:50:31.286 Go ahead.

00:50:31.036 --> 00:50:34.155 Just following on from the previous question, my

00:50:34.155 --> 00:50:37.974 recollection, I haven't from these guidelines is that while

00:50:37.974 --> 00:50:41.984 they can address someone know alone, without stecker listeria,

00:50:41.984 --> 00:50:45.803 if they were to get a positive for Stecker listeria through

00:50:45.803 --> 00:50:49.813 their testing or testing, then they would have to have support

00:50:49.813 --> 00:50:51.086 for those pathogens.

00:50:51.096 --> 00:50:51.686 Is that correct?

00:50:52.626 --> 00:50:53.016 Yeah.

00:50:53.076 --> 00:50:54.746 That's a good clarification.

00:50:54.756 --> 00:50:55.396 Thank you.

00:50:55.406 --> 00:51:00.931 So, yes, FSS tests ready to eat products for both salmonella and

00:51:00.931 --> 00:51:01.186 LM.

00:51:01.326 --> 00:51:05.207 And so if there was a case where the establishment scientific

00:51:05.207 --> 00:51:09.213 support only included salmonella reductions and there was an LM

00:51:09.213 --> 00:51:13.156 positive, you know, unless the establishment could show it was

00:51:13.156 --> 00:51:16.536 the contamination was the result of postley validity.

00:51:17.216 --> 00:51:19.136 Umm cross contamination?

00:51:19.146 --> 00:51:22.558 Then we would verify the establishment could then support

00:51:22.558 --> 00:51:26.029 sufficient reductions of LM or achieved, and same with the

00:51:26.029 --> 00:51:29.206 establishment, had a positive from their own testing.

00:51:29.216 --> 00:51:32.795 If they did that for E coli colon 5787, or if there was a

00:51:32.795 --> 00:51:36.373 stack outbreak associated with the product, then we would

00:51:36.373 --> 00:51:40.259

verify the establishment support was effective for those other

00:51:40.259 --> 00:51:40.876 pathogens.

00:51:41.196 --> 00:51:45.092 But otherwise, on a routine basis, the establishment can

00:51:45.092 --> 00:51:49.534 support their hassop system with support that just addressed one

00:51:49.534 --> 00:51:50.696 of the pathogens.

00:51:50.926 --> 00:51:52.296 Thank you for that clarification.

00:51:53.396 --> 00:51:53.816 Thank you.

00:51:59.946 --> 00:52:04.349 All right, before I kick it over to Scott to address some of the

00:52:04.349 --> 00:52:08.684 questions in the chat box, just as a reminder, if you'd like to

00:52:08.684 --> 00:52:12.951 make a verbal comment or ask a question, you can use the raise

00:52:12.951 --> 00:52:17.286 your hand feature or if you're on the phone, you can press star

00:52:17.286 --> 00:52:18.776 5 to get in the queue.

00:52:21.886 --> 00:52:22.336 All right. 00:52:22.346 --> 00:52:26.664 And with that, I'll kick it over to Scott for the comment in the

00:52:26.664 --> 00:52:26.996 chat.

00:52:28.656 --> 00:52:29.156 Hi Meryl.

 $00:52:29.166 \rightarrow 00:52:31.236$ We have a couple of questions in the chat.

00:52:31.336 --> 00:52:34.866 The first is, can you please define bad mold?

00:52:37.486 --> 00:52:37.836 Yeah.

00:52:37.846 --> 00:52:41.831 So typically when we're thinking of bad mold or undesirable mold,

00:52:41.831 --> 00:52:42.616 I'll call it.

00:52:42.626 --> 00:52:46.915 It could be molds that produce mycotoxins or other types of

00:52:46.915 --> 00:52:51.204 toxins, but again, we're we don't want to assume by looking

00:52:51.204 --> 00:52:52.276 at the product.

00:52:52.906 --> 00:52:56.110 Strictly, there may have been some thought that if the mold 00:52:56.110 --> 00:52:59.154 was brown or green, it's automatically a bad mold and we

00:52:59.154 --> 00:53:01.076 don't consider that to be the case.

00:53:01.286 --> 00:53:05.420 And really, the key is that establishments that want to have

00:53:05.420 --> 00:53:09.216 mold growth occur in their process other than when it's

00:53:09.216 --> 00:53:13.553 summer filled with a commercial culture would be to ensure they

00:53:13.553 --> 00:53:17.552 have control over making sure they have the desirable mold

00:53:17.552 --> 00:53:18.026 growth.

00:53:18.036 --> 00:53:21.839 And that would be just making sure that they have control over

00:53:21.839 --> 00:53:24.676 the factors that impact mold growth occurring.

00:53:27.306 --> 00:53:30.935 And the next question is in terms of shelf stability, what

00:53:30.935 --> 00:53:33.826 temperature is considered ambient temperature?

00:53:35.636 --> 00:53:39.535 So we're typically looking at room temperature storage, so 00:53:39.535 --> 00:53:43.434 making sure the product can be safe under room temperature

00:53:43.434 --> 00:53:45.416 storage, whatever that may be.

00:53:47.806 --> 00:53:49.666 So non refrigerated storage.

00:53:52.896 --> 00:53:56.318 The next question is, does the guideline provide guidance when

00:53:56.318 --> 00:53:59.414 these products need to be treated as ready to eat during

00:53:59.414 --> 00:54:00.446 the drying process?

00:54:00.806 --> 00:54:02.516 For example, with the salami product.

00:54:03.986 --> 00:54:06.906 Yes, I think there's two aspects to this question.

00:54:06.916 --> 00:54:10.596 The first is whether a product needs to be ready to eat or not.

00:54:10.606 --> 00:54:14.131 I'm not sure if that's part of the question, but we do talk

00:54:14.131 --> 00:54:17.597 about the intended use of these products and how there are

00:54:17.597 --> 00:54:20.945 certain products like built on where the intended use is 00:54:20.945 --> 00:54:22.296 typically ready to eat.

00:54:22.306 --> 00:54:25.655 We know from marketing and other materials that these products

00:54:25.655 --> 00:54:27.196 are marketed as ready to eat.

00:54:27.546 --> 00:54:31.103 And so if an establishment is trying to support a different

00:54:31.103 --> 00:54:34.304 intended use, then we're going to really look at that

00:54:34.304 --> 00:54:38.038 scientific support and evidence how the establishment is going

00:54:38.038 --> 00:54:41.476 to ensure the product is safely prepared by the consumer.

00:54:41.486 --> 00:54:44.508 Again, when we know there's marketing and the other

00:54:44.508 --> 00:54:47.878 information indicating it's commonly consumed as ready to

00:54:47.878 --> 00:54:51.249 eat, I think another part of this question maybe when the

00:54:51.249 --> 00:54:54.852 product is considered postley, faulty, exposed and so that is

00:54:54.852 --> 00:54:56.246 something we do address.

00:54:56.256 --> 00:55:00.128 There's a whole section on Posey power exposure within the

00:55:00.128 --> 00:55:04.196 guideline and how establishments really need to consider when

00:55:04.196 --> 00:55:05.836 that five loggly quality.

00:55:06.196 --> 00:55:10.609 So this is over again because it's those multiple hurdles or

00:55:10.609 --> 00:55:14.660 steps, the five log lethality may not occur until after

00:55:14.660 --> 00:55:18.566 fermentation and a certain number of days of drawing.

00:55:19.566 --> 00:55:23.280 And so it's important that establishment knows when that

00:55:23.280 --> 00:55:27.189 five log occurs, when that lethality is over, because after

00:55:27.189 --> 00:55:31.358 that, then we're entering into the post, leave ALDI environment

00:55:31.358 --> 00:55:35.071 that can also be important for identifying post equality

00:55:35.071 --> 00:55:39.045 treatments because there may be cases where an establishment

00:55:39.045 --> 00:55:43.150

uses fermentation and drying to achieve its five log reduction

00:55:43.150 --> 00:55:47.319 and then adds on top of that a number and the additional number

00:55:47.319 --> 00:55:48.296 of drying days.

00:55:48.306 --> 00:55:51.306 Maybe storage under vacuum for an additional 30 days?

00:55:51.536 --> 00:55:55.524 As a post lethality treatment, so it's just so important that

00:55:55.524 --> 00:55:59.577 the hassab system and all the supporting documentation clearly

00:55:59.577 --> 00:56:03.501 identifies when that lethality ends, so that it's clear when

00:56:03.501 --> 00:56:07.618 that closely quality environment begins and it's important it's

00:56:07.618 --> 00:56:11.670 clear for the establishment for identifying their food contact

00:56:11.670 --> 00:56:15.530 surfaces for their sampling program, and then also for FSIS

00:56:15.530 --> 00:56:19.646 when we do any type of testing in the postlethwait environment.

00:56:19.656 --> 00:56:22.146 So yes, that's definitely covered within the guideline. $00:56:29.816 \rightarrow 00:56:32.096$ I don't see any more questions at this time.

00:56:36.976 --> 00:56:37.566 All right.

00:56:37.296 --> 00:56:37.576 OK.

00:56:37.576 --> 00:56:39.666 We'll do one last call.

00:56:39.676 --> 00:56:41.226 Ohh, looks like there's a hand up.

00:56:41.236 --> 00:56:42.436 Let me unmute them.

00:56:46.356 --> 00:56:46.796 To work.

00:56:47.386 --> 00:56:48.466 All right, Dan, you're unmuted.

00:56:49.696 --> 00:56:50.176 Yeah.

00:56:50.396 --> 00:56:51.266 You, doctor Silverman?

00:56:51.276 --> 00:56:52.346 I had one question.

00:56:52.596 --> 00:56:53.376 We. Yeah.

00:56:53.516 --> 00:56:54.056 Can you hear me?

00:56:54.386 --> 00:56:54.746 Yeah. 00:56:54.676 --> 00:56:54.816 Yes.

00:56:55.406 --> 00:56:56.006 OK.

00:56:56.386 --> 00:57:00.220 I had one question a we we here at this facility, we run a

00:57:00.220 --> 00:57:03.533 pretty standard salami manufacturing process which

00:57:03.533 --> 00:57:07.562 includes lactic acid bacteria, salt and nitrate, nitrites and

00:57:07.562 --> 00:57:08.146 nitrates.

00:57:09.236 --> 00:57:13.043 We're having a difficult time finding support for

00:57:13.043 --> 00:57:17.536 stabilization of Clostridium perfringens umm from the time

00:57:17.536 --> 00:57:22.180 that we stuffed the product to, I guess, uh when we have the

00:57:22.180 --> 00:57:26.901 acceptable pH drop the I think we do have support for when it

00:57:26.901 --> 00:57:29.946 drops to a certain pH for no outgrowth.

00:57:30.476 --> 00:57:34.213 Is there anything that the agency had that could validate 00:57:34.213 --> 00:57:35.566 that time in between?

00:57:36.626 --> 00:57:38.766 It seems like that's our only gap at the moment.

00:57:38.776 --> 00:57:39.526 The whole big thing.

00:57:39.846 --> 00:57:43.555 Yeah, I would recommend looking at the section within the

00:57:43.555 --> 00:57:46.496 guidance about C perfringens and C botulinum.

00:57:46.506 --> 00:57:50.075 So we definitely reference some research which shows those

00:57:50.075 --> 00:57:53.886 standard controls you mentioned lactic acid bacteria, presence

00:57:53.886 --> 00:57:55.156 of dextrose, nitrite.

00:57:55.386 --> 00:57:59.236 Those are going to control posterity, outgrowth.

00:57:59.626 --> 00:58:01.526 How long was Saul throughout the process?

00:58:01.536 --> 00:58:04.158 So please take a look at that section and then if you still

00:58:01.996 --> 00:58:03.016 Then run into the. 00:58:04.158 --> 00:58:06.736 have questions, that'd be a great question to put through.

00:58:05.046 --> 00:58:07.656 Yeah, I want another job like it.

00:58:06.746 --> 00:58:11.483 Ask if asias and we can help see where there might be gaps or or

00:58:11.483 --> 00:58:12.576 more questions.

00:58:13.276 --> 00:58:13.586 OK.

00:58:13.596 --> 00:58:13.906 Thank you.

00:58:13.936 --> 00:58:14.576 Both so much.

00:58:14.936 --> 00:58:15.396 Thank you.

00:58:19.976 --> 00:58:21.826 Merrill, a few more questions came in.

00:58:21.916 --> 00:58:25.809 Did the chat one is the notice states that establishments can

00:58:25.809 --> 00:58:27.566 request more time if needed.

00:58:27.816 --> 00:58:30.572 Is there any direction on how much more time establishments

00:58:30.572 --> 00:58:31.306 will be allowed?

00:58:33.086 --> 00:58:33.656 Ah, no.

00:58:33.666 --> 00:58:37.463 So that's, we've really laughed it up to the establishment to

00:58:37.463 --> 00:58:40.954 discuss that with their inspection program personnel and

00:58:40.954 --> 00:58:44.751 their supervisory chain, because we just know each process is

00:58:44.751 --> 00:58:48.609 gonna be different, sometimes doing a challenge study if we're

00:58:48.609 --> 00:58:52.467 process takes several months to complete is going to take, you

00:58:52.467 --> 00:58:54.916 know, several months plus the planning.

00:58:54.926 --> 00:58:58.402 And so we want to be able to allow for those individual

00:58:58.402 --> 00:58:59.146 differences.

00:59:00.706 --> 00:59:03.714 That may occur in each process, so we didn't want to give a

00:59:03.714 --> 00:59:04.716 specific time frame.

00:59:04.946 --> 00:59:08.316 So really, as the notice states that something to discuss with 00:59:08.316 --> 00:59:11.740 the inspection program personnel and that can be then discussed

 $00:59:11.740 \rightarrow 00:59:13.826$ further through the supervisory chain.

00:59:16.816 --> 00:59:19.758 Then another question is in the new guidance, there were

00:59:19.758 --> 00:59:23.009 labeling considerations for not ready to eat products like dry

00:59:23.009 --> 00:59:23.576 cured hams.

00:59:24.236 --> 00:59:27.829 It mentions including wording like soak in water to validated

00:59:27.829 --> 00:59:29.046 cooking instructions.

00:59:29.316 --> 00:59:32.426 Is this wording edition a requirement or recommendation?

00:59:34.366 --> 00:59:34.686 Yeah.

00:59:34.696 --> 00:59:37.204 So it's not a requirement, but it's something for

00:59:37.204 --> 00:59:37.956 establishments.

00:59:37.966 --> 00:59:41.556 Consider if there's a product like dry cured ham. 00:59:41.706 --> 00:59:45.602 The product is not ready to eat and the establishment is relying

00:59:45.602 --> 00:59:48.899 on consumer cooking as part of their support for their

00:59:48.899 --> 00:59:50.936 decisions in the hazard analysis.

00:59:51.226 --> 00:59:55.037 And they're including a cooking temperature, for example on the

00:59:55.037 --> 00:59:58.788 label, and they're taking that from something like FSS cooking

00:59:58.788 --> 01:00:02.361 guideline, which was really developed for products that are

01:00:02.361 --> 01:00:04.266 moist cooked that are not dried.

01:00:04.636 --> 01:00:08.138 Umm, that would be something to consider, including to make sure

01:00:08.138 --> 01:00:10.616 that that cooking step is effective and drag.

01:00:10.626 --> 01:00:14.463 Your chances are great example where that cooking will be

01:00:14.463 --> 01:00:18.630 effective because those products are typically rehydrated upon

01:00:18.630 --> 01:00:22.798 cooking and so we do often see

instructions like soak in water

01:00:22.798 --> 01:00:27.031 that would ensure that product is rehydrated and the cooking is

01:00:27.031 --> 01:00:28.486 going to be effective.

01:00:28.816 --> 01:00:30.246 But no, it's not required.

01:00:30.256 --> 01:00:33.965 It's going to depend on each establishments decision making

01:00:33.965 --> 01:00:37.180 and their support for their decisions in the hazard

01:00:37.180 --> 01:00:37.736 analysis.

01:00:37.806 --> 01:00:38.096 Yes.

01:00:45.416 --> 01:00:47.196 That's all that's in the chat at this moment.

01:00:48.576 --> 01:00:49.616 So one more just came in.

01:00:49.666 --> 01:00:52.972 Does this guidance apply to dried products such as beef

01:00:52.972 --> 01:00:53.326 jerky?

01:00:54.936 --> 01:00:55.346 No.

01:00:55.356 --> 01:00:59.051

So Aksis has a separate guideline for jerky,

01:00:59.051 --> 01:01:03.566 particularly, and that's gonna cover the use of cause.

01:01:03.576 --> 01:01:07.234 Typically, jerky is cooked along with dry that this guidance that

01:01:07.234 --> 01:01:10.616 we're talking about today is really focused on products that

01:01:10.616 --> 01:01:12.666 are not cooked to achieve lethality.

01:01:12.676 --> 01:01:16.394 They may have a low temperature heat step, but they're not using

01:01:16.394 --> 01:01:19.196 a cooking process like an FIS guidance appendix.

01:01:19.206 --> 01:01:23.575 A S officials has separate jerky guideline that covers all the

01:01:23.575 --> 01:01:27.596 unique considerations with jerky, including how to apply.

01:01:27.786 --> 01:01:30.856 FYI, this cooking guideline to jerky products.

01:01:40.376 --> 01:01:41.346 All right.

01:01:41.406 --> 01:01:46.429 So one last call them, you can use the raise your hand feature $01:01:46.429 \rightarrow 01:01:50.336$ and for those on the phone you can press star 5.

01:01:58.906 --> 01:01:59.356 All right.

01:01:59.366 --> 01:02:01.196 Doctor Silverman, I don't see anything else.

01:02:01.206 --> 01:02:02.836 So I will turn it over to you for closing.

01:02:04.626 --> 01:02:04.926 Great.

01:02:04.936 --> 01:02:07.533 Well, with that, we want to thank you for your time and

01:02:07.533 --> 01:02:09.156 attention and excellent questions.

01:02:09.166 --> 01:02:13.176 Again, if you have questions after the webinar, please follow

01:02:13.176 --> 01:02:16.992 up and ask if asias using the hassle validation and hassop

01:02:16.992 --> 01:02:18.026 deviation queue.

01:02:18.286 --> 01:02:20.756 And with that, this concludes today's webinar.