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SAMPLING SYSTEMS

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IMPROVE THE SAMPLING PROCESS — THINK SHACP!

ARTICLES BY JACK VAN DER SANDEN

JACK VAN DER SANDEN has over 30 years of experience in the global food industry across the supply chain. He previously worked as the General Manager of Food Safety & Quality Assurance at Fonterra. There he redesigned the company's food safety and quality standards for HACCP and EPM, with an extensive review of the manufacturing process. Today, Jack enjoys spending more time in the garden and shares his knowledge and expertise with selective projects. We are excited to work with Jack and pick his brain about in-process, hygienic sampling.

THE SHACP EXPLAINED

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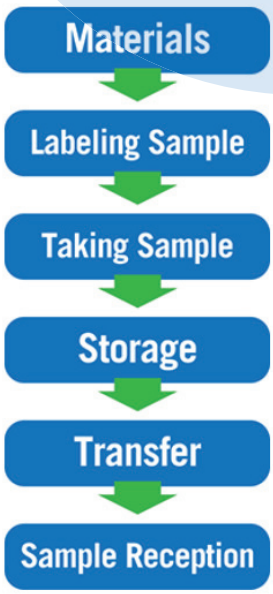
I trust we all know HACCP. HACCP and me go back a long way; as a matter of fact, we were conceived in the same year! When I came across HACCP during my student years, I thought it was really boring; HACCP being methodical, slow and elaborate and me being young and restless. However these days, HACCP has become a big part of my professional life and I have applied the HACCP principles in many different ways. This means I must have changed somewhat, because I don't believe the HACCP principles have changed since their inception.

The basic premise of HACCP is this: if we have a process, we can map this process and ask ourselves at each process step: "how do we control this step and what can go wrong?". Once we have identified those things that can go wrong (the "hazards"), we can start thinking about how these hazards could effect the outcome of our process (determine risk) and what additional controls we can introduce to strengthen the process.

HACCP is a risk-based, preventive tool and the idea of SHACCP is to apply this tool on our diagnostics process. To illustrate, lets map a typical process flow from taking the sample to the sample reception in the laboratory:



As you can see, we already have quite a few process steps, and we haven't even included sub-sampling or the laboratory yet! Putting on our SHACCP hat, we can now start thinking about the hazards that may affect our sample integrity, and ultimately, our test result. Let's throw in some risks I have seen during my career.

Materials

Do we have the right sample container?

Do we have the correct sample tool?

Will the sample be representative?

What are the potential risks of my sample tool?

Have we got the right disinfectant?

Labeling Sample

Do we have an exact labeling protocol?

Do we pre-label or label Just-In-Time?

Do we capture all the information?

Taking Sample

Have we clearly defined our method?

Is it an aseptic technique?

Does the sampler disinfect their hands?

Does the sampler operate the sampling equipment correctly?

Do we have adequate training and clear procedures?

Storage

Are samples stored in a controlled environment?

Are samples stored in a clean environment?

How long are samples stored?

And the list goes on!

As you can see, my preferred way to identify hazards is by asking questions. Ideally, we do this with a team, which should include a sampler and a laboratory technician, to get the most comprehensive list.

Finding a whole list of hazards may feel overwhelming. However, most items on the list will already be controlled in some form and not be a significant risk. For example, we may have a system with pre-labeled sample containers, which are issued each day, and the only hazard that remains is that the operator fills the right box at the right time.

So, how do we turn a hazard into a risk? Let's look at the sample transfer time. If we ship our samples to an off-site laboratory, a danger is that we encounter delays as a result of traffic disruptions. To determine the risk of the transfer delay hazard on our sample, we can use likelihood versus impact.

For sensitive, non-stable food samples, the impact of a significant transfer delay may be microbiological growth or decline in the sample with the micro test result likely to be affected. The likelihood of the delay depends on where you are in the world; however, even in rural New Zealand, we have experienced some significant delays due to weather events. That means if we have a sensitive sample and a likelihood of transfer delays, the transfer delay hazard has turned into an actual risk for our sample integrity.

So, what can we do? How do we strengthen our controls of the diagnostic process transfer step and manage this transfer delay risk? One thought would be to instruct the laboratory monitor the "sample to receipt" time for our sensitive micro samples and not test if it exceeds X hours. This change in expectations is because the sample would no longer reflect the actual process conditions, and the test result may be false.

What happens if we decide to test the sample anyway? After all, it was chilled, right? Well, we may not only pay for an inaccurate test result but also run the risk of getting an unpleasant surprise. Particularly when it comes to food safety tests, you should never take the risk of testing a compromised sample, because you will need to act, even if you can subsequently point to a significant transfer delay!

Only if we submit accurate samples will we get value for money, gain confidence in the results, and become more accepting of the outcomes, even when they are unexpected.

THE SAMPLE – OUR WEAKEST LINK!?

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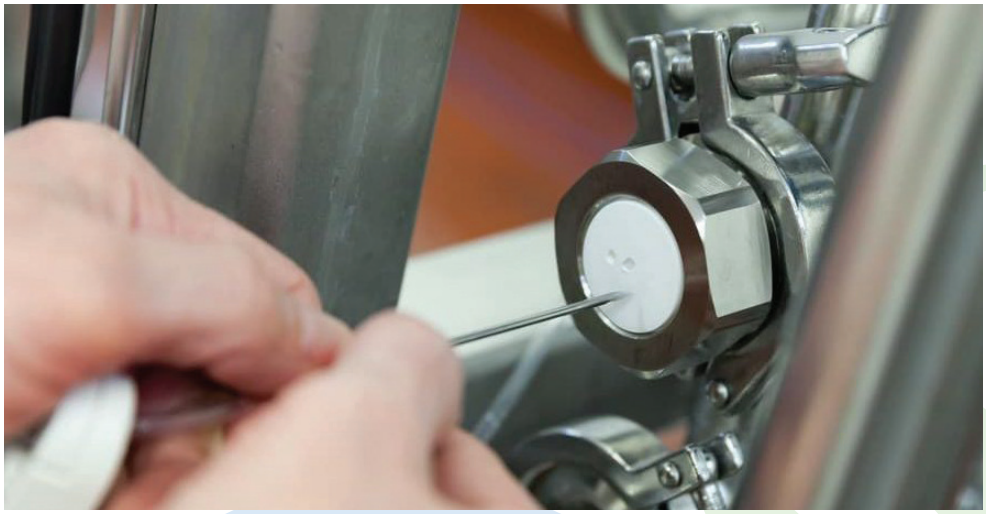

If we trust the sampling and testing process, we are more confident in the result and can make informed decisions. To illustrate, let's look at a non-dairy industry example.

Recently, my doctor ordered a blood sample. Keen to divert my attention from the needle, I looked out of the window and reflected on the seamless chain of events from sample to result when it comes to blood testing. Personally, I have never questioned the result of my blood test, let alone asked for a retest (much to do with that needle, of course).

And then I stumbled across this summary statement in a medical journal:

"For the clinical laboratory, errors that occur in the preanalytical phase of testing may account for up to 75% of total laboratory errors..." [1]

Hold on! Does this mean my blood test result may be wrong? Unfortunately, yes. It's well known in medical circles that mistakes do happen, which can lead to some poor decision making and sometimes dramatic outcomes.

Now, I don't want to scare you, and I still have a lot of confidence in the medical profession; however, that statement did start me thinking about sampling and testing in our dairy industry. If the medical profession has issues with samples, could this mean that samples are also the weakest link in dairy testing?

Using my blood testing analogy, let's explore some of the challenges for sampling that I have experienced in my 30 odd years in the dairy industry. Let's start with the sampling plan and the importance of training.

Medically, my blood tests are initiated by my doctor. She decides on the tests and sets the sampling plan. She also tells me the purpose of the tests and instructs me on what I might need to do in preparation before sampling. The blood sample is drawn by a phlebotomist, a trained, qualified professional. Personally, I'm very pleased that the person with the needles is trained.

This is somewhat different from my dairy industry experience. During the last ten years, I have visited many dairy factories around the world and reviewed their food safety controls. When it comes to sampling, I ask questions like, "Why do you take this sample?" and "Who is responsible for the sampling plan?" Some answers are unlikely to surprise you: "Because it's part of the job" and "I don't know, we have always taken this sample." I recognize these answers, because I've been there.

Jacks unique perspective

I started my New Zealand dairy career as an operator in a butter factory. During cream processing, we took in-process samples for analyses. I had never been formally trained in taking samples; my training was "hands-on" by following another operator around. They showed me where to take it and how to take it, but I was told very little about the reasons for taking it. Sampling was just another task, amongst many other responsibilities. Unsurprisingly, mistakes happened. We occasionally missed a sample, mislabeled a sample, or forgot to put the samples in the fridge.

Formal training in sampling techniques and explaining the "why," is a wise investment. Only samplers can vouch for the integrity of the sample, because only they know how a sample was taken, where it was taken, when it was taken and the process conditions at the time of sampling.

What about the handling of a sample? In the case of our medical example, after filling several tubes, my blood samples were stored in a dedicated fridge, collected by a dedicated courier, and then checked by a dedicated laboratory prior to testing.

This is not always the case in our dairy factories. As mentioned, samples can be mislabeled, stored at the wrong temperature, or sometimes "take the scenic route" between the factory and the laboratory. Laboratory staff don't know a sample's history and will accept a sample for testing after some basic checks, like temperature and "condition".

So, looking back on my experience, I think sampling and handling may well be the weakest link in dairy testing.

Ironically, we only pay for the test if we submit a sample. Hence, improving sample integrity by training samplers, having a sound sampling plan, and controlled sample logistics are likely to have a quick pay-back. Not only will we pay for samples that are worth testing, it will also increase our confidence in the test results, because accurate test results start with accurate samples.

[1] Green, S.F. (2013, September). The cost of poor blood specimen quality errors in the preanalytical processes. Journal of Clinical Biochemistry, 46, 13-14.

THE DIAGNOSTICS PROCESS

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If we trust the sampling and testing process, we are more confident in the result and can make informed decisions.

During the latter part of my career, I ended up in food safety and quality roles. I occasionally faced the dreaded phone call from the laboratory with the message, "We found X!" X was, of course, a food safety test parameter that had never given us any bother before. During this kind of phone call, you start realizing the importance of the diagnostics process.

When you are informed that X is in your product, two things happen:

- An immediate financial hit because you cannot retest for food safety, and the product has to be dumped.
- All-round excitement, because finding X is rare, and from where could it have come?

One of the first questions routinely asked when trying to find X is whether the test result is valid. Alas, it's a human bias to accept results when they are as expected and to challenge results only when they are out of range. Suddenly the diagnostics process is in the spotlight. The laboratory might face the heat since it found and reported X, but the diagnostics process starts well before the actual test result.

The diagnostics process, as I see it, is the process from sampling through to the result, which involves:

- Taking the sample
- Handling the sample
- Testing the sample
- Processing and reporting the result

Generally, the process involves multiple parties and interfaces with an important decision at the end.

When it comes to the dairy industry's diagnostics process, I have argued that the taking and handling of the samples may well be the weakest link.

Taking the Sample

In my previous article *The Sample – Our Weakest Link!?,* I mentioned some challenges around the person taking the sample. Often, the sampling plan has not been reviewed for some time, and the samplers have had minimal training; however, there are some other, perhaps less apparent areas we should explore.

Is the sample genuinely representative of the production run? I have noted that composite in-line samplers are getting very common these days, and they can be a step up from traditional grab samples. However, when composite sample bags are not changed in a timely manner, they fill up and will have very little sample of the last part of the run. What about those milk silos?

One flawed assumption is that dairy fluids will mix in a silo, and silo contents are considered homogenous. Well, it turns out that agitation and mixing are often not very useful, resulting in layering and separation in the silo. Both cases do not result in a representative sample.

There's also a sample point design.

I'm fascinated with the latest diagnostic tools in the laboratory. Particularly, microbiological testing is going through a revolution. Unfortunately, bacteria are also the first to contaminate your sample. Dirty sample points like worn septum rubbers, poorly cleaned sample taps, or unhygienic utensils can easily lead to a contaminated sample and a "false" result (which is the actual result on an invalid sample). So perhaps, when you consider purchasing the latest micro-test equipment, you may wish to consider your process sampling technology as well.

When it comes to sampling practices, I have rarely come across a full review of the sampling protocols, tools, and techniques to identify sampling gaps. That is the case until X comes knocking, and the sampling practices get our full attention.

Handling the Sample

Samples sometimes enter "no-man's land"; this is the zone where samplers have done their job, and the laboratory has not yet formally accepted the sample for testing.

I became acutely aware of the importance of sample handling when our laboratory was seeking ISO17025 accreditation. Our stance towards incoming samples was this: if it is labelled right, looks right, and is at the right temperature, we test it – no questions asked. The accreditation process forced us to take a good look at all the sample handling steps, including the management of the sample fridge in the factory control room.

It is essential to manage the interfaces in the diagnostics process. If those interfaces are poorly defined, your "no-man's land," like a poorly managed sample fridge, may well affect your sample integrity.

Another critical step in sample handling is sub-sampling. This is when those big composite bags are split up for the different tests. I trust most of us are well aware of the risk of sample contamination during a sub-sampling step. Yet, from what I've seen, sub-sampling rooms can be the "poor cousin" in the diagnostics process, and all that stands between X and your product is the skills of a diligent technician.

To me, understanding and improving the sampling and handling steps of the diagnostics process are some of the most beneficial actions we can take. How about drawing a "sample flow," identifying all potential contamination hazards in our diagnostics process, something like a *Sample Hazard Analysis Critical Control Point (SHACCP)*?

Remember, our food business will only pay for the test if the sample is submitted! Only if we submit accurate samples will we get value for our money, gain confidence in the results, and become more accepting of the outcomes, even when they are unexpected.