**Case studies for Quality and Safety Module:**

1. **Temperature control for quality and safety: Ready-to-Eat (RTE) pasta salad.**

**Background:**

* A RTE grilled vegetable pasta salad is produced for distribution to retail outlets, where it is sold to the consumer. This product is stored refrigerated, with a 7-day shelf life. The salad is labeled with a “consume by” date.
* During production, the pasta is cooked and quickly cooled to 50°F to prevent the germination of potential *Bacillus cereus* spores that may be present on the pasta. A certain weight (lbs.) of pasta is cooked and then cooled by running cold water through the pasta with an established time/temperature control, based on an in-house study. The pasta is cooled to 50°F within one hour of finishing the cooking process. The pasta is mixed with other ingredients to make the salad and is refrigerated and cooled to 40°F within 3 hours of finishing the cooking process.
* The facility’s water source is a well, which they have tested per EPA requirements. The average temperature of the cold water is 50°F.
* Refrigerated storage and good manufacturing practices to prevent contamination are important practices for ensuring the safety of the RTE salad, while maintaining its quality.

**Challenge:**

* One day a new production employee cooked a larger volume of pasta. The time/temperature controls for cooling the pasta were inadequate to cool the larger volume of pasta.
* Bacillus cereus spores may survive the cooking process and growth and toxin production could occur during slow cooling. Time and temperature for cooling the pasta is important to the safety of the product. It is also important to the quality of the product since the pasta may still be cooking while it is warm.

**Solution:**

* The pasta was cooled for a longer time. Since the standard operating procedure for cooling was faster than required for food safety parameters, the pasta was still safe to use. The production line employee monitored the temperature of the pasta. It is important that the pasta be adequately cooled for both safety and quality purposes.
* The extended cool did not impact the quality of the pasta. Production continued as scheduled.

**Case Study Relevance:** This story demonstrates that an unanticipated deviation does not always results in product disposal. Understanding the food safety risk and implementing a corrective action can help to maintain production supply and food safety. It is also important that employees understand their role in producing a safe food product.

1. **Water activity control for quality: textured soy protein**

**Background:**

* A manufacturing company had purchased textured soy protein (TSP) from the same supplier for many years. The manufacturing company hydrated the TSP for use in a vegetarian nugget.
* The product specifications state that the hydration ratio of the TSP was 2 parts water to 1-part TSP.
* These nuggets were fully cooked prior to frozen storage, following validated cook time/temperature parameters.
* The consumer instructions tell them to cook the nuggets to 165°F prior to eating.

**Challenge:**

* One day, the production crew noticed the finished product appeared different resulting in a tougher texture and excess water in the production mixing bowl. Production was stopped to investigate.
* First the oven was checked to make sure it was operating properly. It was.
* Then the production process was looked at, starting at the beginning with the hydration of the TSP. There appeared to be a residual amount of water not absorbing into the TSP, therefore further research was conducted. The Quality Control team tested the hydration of the TSP in the QC laboratory and determined that hydration ratio was 1:1 rather than 2:1, suggesting that the physical properties of the TSP had changed.
* The manufacturing company called their supplier to discuss the issue. The supplier indicated that the lot of TSP came from a new production facility. This impacted the physical and chemical properties of the TSP.

**Solution:**

* The manufacturing company was able to show their supplier that the issue with their production was caused by the TSP, which did not meet product specifications.
* The texture and quality of the nuggets were impacted by the different hydration ratio of the TSP.
* It is unknown how the changes in the TSP impacted the cooking parameters established for food safety; it is unknown if this impacted the safety of the product.
* The manufacturing company made modifications to their product specification to say that the supplier had to notify the manufacturer of any changes to their production. The supplier was ultimately responsible for the implicated product and accountability related to the implicated product was mediated.

**Case Study Relevance:** This story demonstrates the importance of having a supplier approval program and having defined parameters of quality attributes to help reduce product risk.

1. **pH control for safety: shelf-stable salsa**

**Background:**

* A manufacturing company produces a shelf-stable salsa for retail distribution. Production follows the scheduled process approved by a process authority (conditions are pH of 3.9 or below, processing temperature of 185°F which is held for 5 minutes and maintained during the hot fill process).
* Lemon juice is added to the recipe to lower the pH. The equilibrium pH of the salsa must be 3.9 or less.
* The salsa is prepared and heated to 200°F and the jars (8 oz.) are filled with hot salsa.
* The filled jars are adjusted for ¼ inch headspace and the lids are placed on the jars. The jars are then inverted and held for 5 minutes. This inversion and hold ensure the pasteurization of the container headspace and the seal integrity. After 5 minutes, the jars are turned right side up to cool, prior to being labeled.
* For each batch of salsa processed, the equilibrium pH is tested 24 hours after production.

**Challenge**

* During the routine pH testing of a batch, the reported value of the salsa pH was 4.0, which was higher than the scheduled process allowed.
* Production was stopped while the team investigated the problem.
* The investigation found that a different supplier was used for lemon juice due to better pricing. However, this lemon juice had a different acidity than the product traditionally used. This particular lot of lemon juice was pH 3 rather than 2. Lemon juice has a standard of identity for acidity, which must be ≥4.5%, calculated as anhydrous citric acid.

**Solution**

* The manufacturing company developed product specification parameters for lemon juice. They implemented a supplier approval policy to test every new supplier before approving. They also implemented a protocol to test the pH and titratable acidity of the incoming lemon juice on a quarterly basis, to ensure that the product meets the specifications outlined in the customer agreement.
* Note: the natural pH of lemon juice between 2-3. To establish a lower variability in product pH, another option the manufacturing company could have taken would be to use citric acid rather than lemon juice.

**Case Study Relevance:** This study demonstrates the importance of following the scheduled process for product safety and the importance of verifying the equilibrium pH of the finished product. It also highlights the importance of having defined ingredient attributes to the safety of the product.