Validation in relation to threat assessment critical control points (TACCP)

by Richard Leathers, Quality Management Systems Specialist, Campden BRI, Station Road, Chipping Campden, Glos GL55 6LD, UK.

Validation is a key element in many disciplines of food safety and quality management systems, and applying it to the principles of threat and TACCP is no exception. Firstly though, what is TACCP?

It is a method, partly similar in tools and techniques to those used with HACCP (Hazard Analysis and Critical Control Points), that assesses hazards and risks to the business, process or product from attack for malicious purposes, fraud, or gain for individuals or groups at the expense of the targeted organisation. The threat or attack may come from either internal or external sources.

These threats can then be evaluated, documented, reduced and mitigated.

Guiding documents

One of the major guiding documents for TACCP is the PAS 96:2010 Defending food and drink: guidance for the deterrence, detection and defeat of ideologically motivated and other forms of malicious attack on food and drink and their supply arrangements. This involves elements such as personnel, premises, process, services, logistics and cybercrime. PAS 96 aims to provide broad guidelines to industry operators which should help them assess (via Clauses 6 and 7) and reduce (Clauses 8 to 13) the risk to their businesses and to mitigate (Clause 14) the consequences of an attack.

TACCP and the PAS 96 provide some approaches to the developing problem of malicious attack and compromise of integrity for the food and drink industry. Its implementation and application should be both practical and proportionate, and should help businesses deter potential attackers. TACCP team members should consider characterising the types of threat identified in PAS96:

- Malicious contamination with materials causing ill-health or even death.
- Sabotage of the supply chain leading to food issues.

Validated analytical methods are a key part of TACCP.

- Misuse of food and drink materials for terrorist or criminal purposes.
- Food fraud would also be factored into the characterisation process at this stage, particularly regarding ‘commodity items’, for example olive oil and basmati rice.

There are some similarities with HACCP: team selection, process flow diagram, listing potential hazards, hazard analysis, assessing control measures, selecting appropriate corrective actions, verification and documentation/records are common to both, although the approaches to implementation may subtly differ.

Different to HACCP

Some of the aspects of TACCP that are different to HACCP form an integral part in the additional validation work that will be necessary to prove that the systems and protocols put in place are capable of defending the organisation.

- The team may need to cover slightly different or additional disciplines from the one used for conducting a HACCP study, such as security and material sourcing/purchasing, information technology and human resources. The skills and experience of this team would then need to document, review and validate the TACCP in these extra areas to ensure that it was fit for purpose to defend the organisation against threats of cybercrime, also for supply chain robustness and transparency, site security measures and protection from deliberate attacks from internal employees.

- Because the TACCP Process Flow Diagram (PFD) will be written to capture the entire process, not just that which takes place at the manufacturer’s site, it will almost certainly therefore be more detailed and involved than a conventional HACCP PFD. This in itself presents additional issues regarding validation, in that the complexity of the supply chain may mean that parts of this extended process are not witnessed and authenticated by the organisation itself. Walking the line and observing each process step to weigh up its capability may not be possible, so testing, analytical data and precise documentation could bridge this gap.

- The potential hazards may detail not only chemical, physical and biological hazards as with a conventional HACCP study, but also might cover the elements of radiological hazards and of adulteration and/or sabotage. Sabotage particularly is difficult to assess and evaluate, therefore making it harder to control and validate. Lone acts by

Continued on page 14
groups or a single disgruntled employee are, by definition, difficult to predict. What can be validated, however, are the control mechanisms in place, and the fact that all potential points of attack are dealt with in the study.

Measures to control this may include: pre-employment checks; lone worker policies; equipment and process access; internal/external site security systems; training; employee awareness/vigilance; pack integrity and traceability.

**Real life challenges**

With each of the TACCP control measures, it is essential that they are challenged and tested in real life scenarios. For example, a potential threat to a business from a cybercrime attack must be validated involving actual IT system users, and where relocation is a business continuity strategy then users must test availability of services from these alternative locations.

Similarly, when validating systems that are designed to reduce, detect and eliminate food fraud and adulteration threats, key considerations would need to be:
- What are the specific adulterants or contaminants that need to be tested for?
- Do methods of analysis exist for these adulterants or contaminants?
- Are legal limits or codes of practice in place for the products in question or the adulterants themselves?
- Are the methods of analysis able to detect to the legal or Code of Practice limits?
- Is the sampling regime and mechanism used sufficient to give statistical confidence in the results and authenticity or compliance of the product?
- Is the testing laboratory competent and capable of performing and reporting the analysis on a repeatable basis?
- At what point could the adulteration or food fraud take place?
- What other control measures are in place?
- How does testing and analysis fit in with other control measures?
- What is the risk rating of the product, process, material and/or supplier?
- Has the worst case scenario been considered?
- Have all of the process and material variables been considered?
- What would be the overall impact of the issue to the business?
- Part of the validation process may involve an assessment of systems implemented by an independent third party.
- In addition, guidance and advice can be sought on best practice and the tools, techniques, considerations and mechanisms needed to effectively conduct a TACCP study. Campden BRI can assist organisations in each of these areas.

---

*A TACCP plan requires input from people with a variety of expert knowledge.*