SUMMARY

Food companies collect data on non-conformances within their operations but this valuable data is often lost in paper piles and poorly designed systems. In this whitepaper we will take a closer look at what exactly is a non-conformance, why we need to record them in the first place and how to design the systems that facilitate effective analysis and improvement in your business.

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1 Introduction

Every day, food companies collect data on non-conformances within their operations but this valuable information can often be lost in paper piles and poorly designed systems that have been devised for analysing the data. In this whitepaper we will take a closer look at what exactly is a non-conformance, why we need to record them in the first place and how to design the systems that will facilitate effective analysis and improvement in your business. Finally, we will provide tips on how to set up your non-conformance categories in Safefood 360º.

2 What is a non-conformance?

The variation in how companies manage non-conformances in their food safety system is vast, and the design of these systems can either support or hinder the effectiveness of the continuous improvement policy. Good design and management of non-conformance data and specifically non-conformance categories is crucial to making improvement a real part of the company’s activities and not just a documented policy.

Non-conformance relates to a failure to comply with requirements. A requirement is a need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties.

There are many types of requirements. Some of these include food safety requirements, quality requirements, process requirements, product requirements, customer requirements, management systems requirements, and legal requirements.

Whenever your organization fails to meet one of these requirements, a non-conformity occurs. For example, the ISO 22000 standard defines food safety management system requirements. When your organization deviates from these requirements, a non-conformance or nonconformity occurs. Requirements by type include food safety, quality, process, product, material, supplier, systems and legal.

3 How are non-conformances identified?

Within a typical food safety management system non-conformances are identified through a number of channels. These include customer complaints, internal audits, product recalls / withdrawals, external audits, regulatory notifications, incoming as well as in-process and final product inspection, testing and casual observation. A food business with a food safety management system certified to a specific standard will have in place a system for recording these non-conformances. These standards will include the ISO 22000, GFSI and other industry standards.
4 Why record non-conformances?

There are two reasons why a food business will record non-conformances.

- Compliance Requirements – to meet the specific requirements of a customer, standard or regulatory obligation.
- Process Improvement – recording non-conformance data can facilitate analysis leading to incremental and continuous improvement in business and operational processes.

5 Corrective and preventive action

Like most entities in a food safety management system, a non-conformance does not exist in an insulated bubble. It maintains a close relationship with corrective and preventive actions which often occur together with the identification of non-conformances. For example, the ISO 22000 requires a business to have a non-conformance procedure in place with data capture as a prerequisite to taking specific actions.

It is this relationship between Non-conformances and Corrective and Preventive Actions which will define the character of the management system and some key processes.

Figure 1 (below) illustrates the relationship between a non-conformance and actions.

As we have already covered, a non-conformance is a failure to meet a requirement. When this occurs, the company should take action. There are two main types of action. Preventive action is an action taken to eliminate a potential non-conformance. Corrective action is an action taken to eliminate the cause of a non-conformance. We can see we have two main elements at play: non-conformance and actions. To fully understand these elements and their relationship we need to introduce the concepts of Cause and Effect.

6 Cause and Effect Analysis

In recent years, food safety standards have introduced the requirement of Root Cause Analysis (RCA). In times past, companies only needed to record
the non-conformance and then implement corrective action. The requirement to explain the basis for the action was not specifically asked for and as a result actions were taken on an ad hoc basis with little concern for their effectiveness. The powers that be recognised that a more robust approach was needed.

When a non-conformance is identified, in addition to recording the details, the company must examine all possible reasons that may have caused it. Only then can the company consider taking the appropriate actions. This approach has many benefits including finding timely and permanent solutions. We can now develop our model a little further:

Figure 2 (above) illustrates the relationship between non-conformance and actions with root cause analysis.

Cause and Effect Analysis is typically used to identify the root cause of the non-conformance. The technique employs a structured brainstorming and the use of diagrams to drive you towards the possible causes of the issue. Pioneered by Professor Kaoru Ishikawa the approach is now widely used in manufacturing as a quality management tool and is gaining increasing acceptability within the food sector. The tool is better known as the Fishbone Diagram.

When using the tool, the first step is to clearly identify the problem or non-conformance e.g. the poor shelf life of a product. Supporting information should also be recorded as much as possible, including which products were affected, times and dates, quantities, trends and so on. Taking the fishbone diagram, the non-conformance is written into a box on the left-hand side. A line is drawn horizontally across the page from the box, as is illustrated by the figure below.
The important point here is to define the issue or non-conformance clearly. Einstein once said that if he only had one hour to come up with a solution, he would spend 50 minutes thinking about the problem and 10 minutes about the solution itself. This is simply a reflection of the fact that if you do not know what it is you are trying to solve it is very unlikely you will solve it.

The next step is to identify the various factors that may contribute to the problem. In the case of a food manufacturing business these can include systems, equipment, materials, objective factors, human resources and so on. You should draw out these factors from the main spine of the diagram and label each as indicated in the above illustration.

Once these are developed, the team should brainstorm around these areas to determine the possible causes. These can be drawn as shorter lines coming off the ‘bones’ in the diagram. The approach can be broken down in as much detail as is required. For example, if the problem is a short product shelf life we might identify ‘heat treatment’ under the Factor that’s called ‘Process’.

For each of the factors, the brainstorming should continue for the possible causes. For example, ‘heat treatment inadequate’. This may lead to the question why? The team may suggest:

‘No calibration of the ‘temperature probe’

‘Auto divert is not working’

‘Set temperature was too low’
Now we are beginning to unravel the true *Cause* and not just the *Effect* (which is the non-conformance).

Once the diagram has been fully developed the team should analyse it to identify the most likely causes. Further investigation may be required but only now can the team implement effective actions based on an understanding of the root cause.

Actions may include ‘inclusion of the probe in a calibration program’, ‘increasing the set temperature point’, ‘implementing a flow divert check at the beginning and end of each shift’.

7 The True Nature of Non-conformances

Based on the cause and effect analysis we can now see that most non-conformance management systems are designed to record the *Effect* and not the *Cause*. This is understandable since the cause is seldom immediately obvious. On the other hand, the effect is clear and can be factually recorded for analysis later on.

To ensure this system is effective, it is critical that the recording of the effect (non-conformance) is well organised and managed. This requires the following to be in place:

1. A well designed system of categorising and recording of non-conformances
2. A well designed management process covering root cause analysis, corrective and preventive actions

A typical issue is that we don’t record the non-conformances in a clear and organised fashion and we are losing this very valuable information which could be used for further analysis.
8 Developing a Robust Non-conformance Structure

As with any structured system, a little forethought goes a long way. You are seeking to obtain a balance between too much data and too little. Clear criteria can be helpful in doing this. For example, if we were to record every non-conformance identified based purely on its separate existence, we would quickly build up a database of worthless information and the only thing you might infer from the data is an overall trend in the number of non-conformances. Instead it is better to create clear groups, categories and sub-categories. This way we can develop more meaningful reports and cause analysis.

At the highest level the best way is to organise non-conformances under their main source of identification such as:

- Product
- Process (Equipment)
- System
- Materials / Service
- Suppliers
- People

These are the main factors found in the fishbone diagram. Once these have been defined we can then categorise non-conformances sub-categories if required. The bulk detail of non-conformances can be recorded using an open form so nothing is lost in the event more analysis is required; however, the principle of recording non-conformance categories needs to be maintained. The following section explains how this can all be achieved in the Safefood 360° software, but the same lessons can be applied in any food safety management system.

9 Organising Folders and Categories in Safefood 360°

Once the main folders have been identified, you will then build your non-conformance categories using these top level categories. A different logic is usually required for each Non-conformance type and guidance is provided in the table below.

Tables on the following pages explain how to categorize non-conformances into logical folders in the Safefood 360° software.

9.1 Management of Non-conformances and Actions

It is crucial to have in place a clear and well written procedure for the management of corrective actions. In a follow up whitepaper we will address the management of corrective actions arising from non-conformances in detail.
### High Level Category

<table>
<thead>
<tr>
<th>Product Non-conformances</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>These non-conformances relate to specific final product issues and defects including food safety issues. They are the ‘Effect’ issues as covered above. They will typically be identified from:</td>
</tr>
<tr>
<td></td>
<td>• Customer complaints</td>
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<tr>
<td></td>
<td>• Product non-conformances arising from operations, production, processing and handling</td>
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<tr>
<td></td>
<td>• Other third party sources</td>
</tr>
</tbody>
</table>

**Category Management:**

The key here is to identify the general categories relating to product issues and then identify the necessary sub categories. For example, you may have many potential foreign body contamination issues. These should be categorised under the general heading Foreign Body. Then each specific foreign body can be classified as a sub category:

- Foreign Body: Glass
- Foreign Body: Plastic
- Foreign Body: Wood
- Foreign Body: Metal

**Similarly for labelling issues:**

- Label: No label
- Label: Wrong label
- Label: Label damaged
- Label: No date code

The above approach allows you to get the ‘big picture’ while retaining the detail that may be required later for analysis.

### Process Non-conformance

Process non-conformances usually relate to issues arising from operations, processing, equipment and handling. They differ from most other non-conformance types in that they may not relate directly to the Effect displayed, e.g. ‘temperature below limit’. While the temperature limit failure is considered a non-conformance, its full effect may be ‘short shelf life’ in the product.

This is appropriate and can be very useful when it comes to cause effect analysis. Relating an increase in Product Non-conformances of a particular category to an increase in a Process non-conformance category can provide valuable insight into the root cause.

Process non-conformances may also relate to downtime, machine problems, hygiene programme failures and so on.
<table>
<thead>
<tr>
<th>High Level Category</th>
<th>Notes</th>
</tr>
</thead>
</table>
| **Process Non-conformances (continued)** | **Category Management:**  
For this type it is best to conduct a survey of the various processes in your operation critical for quality and food safety. For example, you could focus on a heat treatment step and develop a clear list of non-conformances:  

- Heat Treatment: Low temperature  
- Heat Treatment: Over temperature  
- Heat Treatment: Divert alarm fail  
- Heat Treatment: Integrity check fail  

These categories could also be organised under subfolders per machine, process, or production line etc. Often these non-conformances relate to CCP’s or oPRP’s and therefore taking sufficient time to design this area is worthwhile. |

<table>
<thead>
<tr>
<th><strong>System Non-conformance</strong></th>
<th>These non-conformances relate usually to those detects arising from internal audits of processes and systems. The internal audit system will identify failings which in turn will generate corrective actions. At this point the non-conformance will be categorized for more effective analysis, trending and reporting.</th>
</tr>
</thead>
</table>
| **Category Management:**  
The best way to approach this section is to ask yourself the following question: “We conduct all these audits during the year; how do I want to see the non-conformances summary report to identify emerging or trending issues and ensure we are always compliant with the standards.”  
Often the best way to do this is to refer back to the audited standards and relate the non-conformance to a specific requirement or clause. For example, under the ISO 22000 you will audit the HACCP system. The audited requirement will say ‘process flows shall be verified by the HACCP team’. You could consider having a system non-conformance category called ‘HACCP flow not verified’. Developing this out you may have the following:  

- HACCP: Team member not trained  
- HACCP: Corrective action not defined for CCP  
- HACCP: Flow diagram not correct  
- HACCP: Flow diagram not verified  

Simply go through the standard and compile a concise list against the requirements. One more tip: Don't be too forensic in this, just ensure the high to medium level stuff is covered. You can always drill down further into the detail if issues arise. |
Managing Non-conformance Categories

<table>
<thead>
<tr>
<th>High Level Category</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material Non-conformances</td>
<td>This category relates to non-conformances of materials and ingredients, as well as non-conformances regarding the quality of service from specific suppliers such as pest control contractors. Specifically they are non-conformances against the defined specification of the material or service. For example, a delivered ingredient which is over the specified temperature or damaged could cause a material non-conformance. Similarly if issues such as foreign matter contamination are detected in the material during utilization, these could be a cause for logging a material non-conformance.</td>
</tr>
</tbody>
</table>

Category Management:

These can be organized by material type, risk, supplier etc.

| Supplier Non-conformances | Supplier non-conformances relate specifically to Supplier issues outside the specific materials or service they supply. This could be in regard to other aspects of the service, price, documentation and general performance. |

People Non-conformances | These are specific non-conformances relating to human resource inputs into the process and operation. Non-conformance may arise from training events, supervision, poor personal hygiene, record keeping etc. |

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Have you thought about updating your food safety management system?

Safefood 360° contains all elements of a robust food safety management system in one, intuitive solution

- HACCP-planning
- Management tools
- PRP control
- Supply chain management
- Monitoring programs
- Document control
- Reporting

Our software offers you full alignment with the following standards and regulations among others

- SQF
- BRC Series
- IFS Series
- ISO / FSSC 22 000
- FSMA & USDA Regulations
- EU Legislations

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