

Preparing a Due Diligence Analysis Plan for a Brewery

A food safety analysis (due diligence) plan provides a risk-based approach to food safety analyses. It ensures that all analyses needed to prove legal compliance / safe products are included and minimises costs by targeting essential analyses. It also ensures regular checks and evidence of compliance to Regulations, industry guidelines and in-house specifications. This gives assurance to stakeholders and provides part of the defence for the company in case things go wrong. We can help you to design a suitable Due Diligence plan.

It is not possible to measure every potential food safety issue in every material or product. It is therefore essential to identify the main risks and where they occur. It is also important to consider the risk of non-compliance with legal limits as well as health risks related to contaminants or other substances which are not subject to legal limits.

Reliable numerical data is essential. However, the correct interpretation of the data is also required in order to correctly target actions. As a general rule, the closer a contaminant is to the final end-product, the greater the risk, since some undesirable materials are eliminated or reduced by processing.

How can you ensure that your plan includes the essential elements and is cost effective?

This paper describes some key steps in preparing a food safety due diligence plan; this is based on our experience of working with breweries of all sizes to create due diligence plans.

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Advantages of a Due Diligence Plan

The key advantages of a Due Diligence plan are:

- It provides a risk-based approach to food safety analyses; this ensures that all analyses needed to prove legal compliance and ensure safe products are included in the plan
- It ensures that all relevant materials, processes and products are considered
- It minimises costs by targeting analyses where they are needed and avoiding unnecessary analyses
- It ensures that analyses are done on a regular, scheduled basis
- Analysis of the data can be used to continuously improve the food safety analysis plan
- The data obtained will provide assurance of compliance to Regulations, industry guidelines and in-house specifications
- Gives assurance to stakeholders
- The plan, together with the analytical data, provides part of the defence for the company in case things go wrong

Preparing a Due Diligence Plan

The key steps in preparing the plan are:

- **Identify the Risks and Limits**

This must be done for all the different product types. Particular attention is needed for novel ingredients and products. Different risks may be associated with these.

It is important to understand the mechanism of formation. Table 1 shows the occurrence of the mycotoxin fumonisin which results from infection of cereals with *Fusarium* in the field. The risk is high for maize and wheat, but is low for barley, rice and hops; hence, it is only necessary to check maize and wheat for fumonisin mycotoxins.

Table 1: Risk assessment and sampling for fumonisin

Raw material	Risk	What to sample	Sampling frequency	Taking samples
Malted barley	Low	Not applicable	Not applicable	Not applicable
Wheat	Moderate	Wheat plus occasional checks on beer	Depends on the size of the brewery, the proportion of material used and the dilution factor in brewing	Sample different parts of the batch (depending on the batch size), mix, take a sample (preferably 1 kg), divide into two and retain half
Maize	High	Maize with occasional checks on beer	Depends on the size of the brewery, the proportion of material used and the dilution factor in brewing	Sample different parts of the batch (depending on the batch size), mix, take a sample (preferably 1 kg), divide into two and retain half
Rice	Low	Not applicable	Not applicable	Not applicable
Hops	Very low	Not applicable	Not applicable	Not applicable

The plan should also include legal, voluntary industry or in-house limits for each risk identified. These need to be valid for the appropriate country where product is sold.

Table 2 shows the regulatory data for fumonisin. There is a limit in the EU for maize but not for malted barley. There is no legal limit for beer, but legally the concentration should not exceed that for maize, taking into account the proportion of maize used in the grist and the dilution factor during the brewing process. Hence maize should be analysed for fumonisins, but it is good practice that beer is also tested when maize is used as an adjunct.

Table 2: Limits and Actions for Fumonisin

Material	EU legal limit	Potential range	Limit of Detection	Example of Action Limit	Corrective actions
Maize	<p>Particle size >500 microns: 1400 µg/kg</p> <p>Particle size <500 microns: 2000 µg/kg</p>	Depends on geographical source	5 µg/kg	500 µg/kg	<p>Contact the person responsible for compliance in-house</p> <p>Repeat the analysis using the retained sample. If the reading is still high:</p> <p>Discuss with supplier of the raw material</p> <p>Arrange a meeting of the recall team</p>
Malted barley	No limit	Not applicable		Not applicable	Not applicable
Beer	No limit set, but legally concentration should not exceed that for maize, taking into account the proportion used and dilution factors	Not applicable	1 µg/litre	10 µg/litre	<p>Contact the person responsible for compliance in-house</p> <p>Repeat the analysis using the retained sample. If the reading is still high:</p> <p>Discuss with supplier of the raw material</p> <p>Arrange a meeting of the recall team</p>

The actual levels normally present in maize will depend on the source of the maize.

Based on the legal limits, warning and action levels can also be included to trigger actions before legal limits are approached. These can be based on previous experience of levels normally occurring in a brewery's products.

Limits of detection should be included in the plan, so that it is clear, when interpreting results, whether results reported indicate that a substance has actually been detected or whether the limit of detection is quoted. For example, in the methods that we use, the LOD for fumonisin B1 and B2 in maize is 5 µg/ kg, whilst that for beer is lower at 1µg/kg.

Finally, the actions to be taken by staff if the warning or action limits are exceeded can be defined in the plan. For example, if the limits are exceeded in maize or beer then the analyses should firstly be repeated using the retained sample; if the results are confirmed then the supplier should be contacted and a decision made on quarantining existing stocks and whether a recall of products is necessary.

- **Sampling and Analysis**

Samples should be taken using the appropriate methods to ensure a statistically accurate result. It is useful to take two samples so that one can be retained and used for any re-testing needed. Information on the sampling technique, the volume of sample needed and the most suitable container to use can be supplied by the contract laboratory used. These factors could be included in the due diligence plan.

Analyses can be done in-house or by a contract laboratory. The latter has the advantage of providing results from an independent laboratory. To assure the quality of the data, the laboratory should meet the requirements of an external standard such as ISO17025 or ISO9001.

- **Understanding the Analysis Results**

Correct interpretation of results is important. A breach of any of the legal or action limits should be flagged up immediately to the relevant staff to enable appropriate actions to be taken. If analyses are done by a contract laboratory then prompt notification of out-of-specification results can be part of the contract and will make use of the expertise and experience of the staff of the contract laboratory.

Even when the results are within the legal or action limits set, a lot of useful information can be gleaned by monitoring trends. Trends can be used to:

- Identify risks that are increasing over time and hence enable appropriate actions to be taken
- Identify risks that are trending down and hence identify best practice that can be used in other breweries in the group
- Review the frequency needed for tests and hence reduce the costs of the programme

Trending can be done in-house. However, there are advantages in having a contract with an external laboratory to review the data, flag up any anomalies or trends and make recommendations based on the data – especially when the contract laboratory has expertise and experience with Due Diligence analyses for breweries.

The data can also be used to update the due diligence plan. It can highlight analyses where the frequency of checks should be increased or decreased depending on the risks and the data obtained. The plan could be updated at the completion of each set of analyses.

- **Review the Plan**

The plan should be reviewed whenever raw materials and additives (or their sources) or product formulation are changed. The review should include both an evaluation of additional risks as well as whether some risks can be removed from the plan for those products. It should also be reviewed if there are changes in legislation, to ensure that the analysis schedule meets the new regulations. Hence, it is useful to have an Information source such as our Brewing and Malting Regulatory Update.

Food safety issues do arise from time to time, so the plan will be need to be checked whenever these arise. It is therefore important to have systems in place to flag up changes in legislation and to identify emerging issues. This can be an in-house team or a subscription to a service that provides this information.

Even if there are no obvious changes it should be reviewed on a scheduled basis to ensure that it is still valid and up to date.

How can we help? If you would like to discuss our helping you with planning your Due Diligence analyses or analysing your samples then please contact:

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