Operators perspective for residue analyses and sampling

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BioKap and BioTrust

O.Q.A.

Assurance Tool

Legal

Residue Monitoring

Efficiency
BioKap and BioTrust
Aims and objectives

- Risk based priority setting for verification of raw material risks
- Risk based process control based on open source
- Practical tool that can be used in existing QA systems
- Risks comparable and discussable among active members
- Demonstrable
- Meets the requirements of the organic law
- Cooperation and exchange between companies possible
Approach to Food Fraud Prevention

Food Safety

HACCP
Hazards
Prevention of unintentional / accidental adulteration
- Science based
- Food borne illness

Food Defence

TACCP
Threats
Prevention of intentional adulteration
- Behaviourally or ideologically motivated

Food Fraud

VACCP
Vulnerabilities
Prevention of intentional adulteration
- Economically motivated
PDCA cycle

Plan
- Define & Analyse a Problem and Identify the Root Cause

Act
- Standardise Solution
- Review and Define Next Issues

Check
- Confirm Outcomes Against Plan
- Identify Deviations and Issues

Do
- Devise a Solution
- Develop Detailed Action Plan & Implement It Systematically

Commitment and Mandate
- Policy Statement
- Risk Management Plan
- Assurance plan
- Standards
- Procedures/Guidelines

Communicate and Train
- Communications and reporting plan
- Training strategy
- RM Network

Measure and review
- Control assurance
- RM Plan progress
- Governance reporting
- Benchmarking
- Performance criteria

Organise and Allocate
- Board RM Committee
- Exec RM Committee
- Manager, RM
- RM Champions
- Risk, Control, Risk owners
- Assurance providers

Common Approach Used in ISO Management System Standards
BioTrust process: 6 steps

**STEP 1: Define Risk Matrix**

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Impact</th>
</tr>
</thead>
</table>

**STEP 2: Define General Product – Process Hazard**

f.e. Contamination with conventional

**STEP 3: Modify Risk**

<table>
<thead>
<tr>
<th>Country Risk</th>
<th>Relationship Risk</th>
</tr>
</thead>
</table>

**STEP 4: Validate the Risk**

| Low | Medium | High |

**STEP 5: Reduce the risks**

Design an action plan

**STEP 6: Implement and evaluate acc. PDCA cycle**
## Step 1: define the risk matrix

<table>
<thead>
<tr>
<th>Description</th>
<th>Extra clarification</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>A non-conformity with long term consequences and violation of the organic principles. Or a systematic non-conformity with implication on multiple products</td>
<td>Impact on more products or lots over a longer period, likely to cause media attention, e.g.: high residue levels, large scale mixture with regular, systematically violation of the legislation</td>
<td>3 Low Medium High High</td>
</tr>
<tr>
<td>A non-conformity with (in)direct implication on the product</td>
<td>Impact on one product or lot, likely no media attention, e.g.: low residue levels around limits, GGO below 0,9</td>
<td>2 Low Low Medium High</td>
</tr>
<tr>
<td>A non-conformity with no (direct) implication on the product</td>
<td>No impact on the product, e.g.: administration</td>
<td>1 Low Low Low Medium</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>1 Very small</th>
<th>2 Small</th>
<th>3 Medium</th>
<th>4 High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>Very small</td>
<td>Small</td>
<td>Medium</td>
<td>High</td>
</tr>
<tr>
<td>% of non-conformities</td>
<td>&lt;1</td>
<td>&lt;5</td>
<td>&lt;10</td>
<td>&gt;10</td>
</tr>
</tbody>
</table>
Step 2: define the general hazards

<table>
<thead>
<tr>
<th>Process</th>
<th>Process section</th>
<th>Process section</th>
<th>Hazards</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>inconversion product sold as organic</td>
<td>3</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>use or misuse of not permitted basic materials (seeds)</td>
<td>3</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>use or misuse of not permitted fertilizers</td>
<td>2</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>incorrect application of crop rotation</td>
<td>2</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>use of not permitted ground covers</td>
<td>2</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>use of not permitted pesticides</td>
<td>2</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>use of not permitted crop enhancers</td>
<td>2</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>use of not permitted products for cleaning and sanitization/decontamination of installations or buildings</td>
<td>2</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>not permitted crops cultivated on substratum</td>
<td>2</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>use of sanitization/decontamination products during substratum cultivation</td>
<td>2</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>use of not permitted &quot;dekaarde&quot;</td>
<td>2</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>use of not permitted raw materials in substratum</td>
<td>2</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>presence of GGO in raw materials used in substratum</td>
<td>2</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>insufficient separation between organic and regular plots</td>
<td>3</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>cultivation of the same crop as organic and regular on the same farm</td>
<td>3</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>exceeding the duration of use regular livestock on a plot</td>
<td>2</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>cultivation</td>
<td>exceeding the nitrogen/hectare using livestock</td>
<td>2</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>administration crop and feed</td>
<td>insufficient or no cultivation plan for past en present year</td>
<td>1</td>
</tr>
<tr>
<td>primary sector</td>
<td>crop and feedcrop</td>
<td>administration crop and feed</td>
<td>insufficient or no fertilize administration</td>
<td>1</td>
</tr>
</tbody>
</table>
What do we know of the country?

01. Corruption index
02. Organic legislation
03. Residue track record

Country risk
What do we know of our relation?
Final Risk

01. Likelihood

02. Impact

03. Country Risk

04. Relationship risk

Final Risk
## Risk Analysis

<table>
<thead>
<tr>
<th>Raw material</th>
<th>Hazard</th>
<th>Impact</th>
<th>Likelihood</th>
<th>Likelihood motivation</th>
<th>Country Risk Factor</th>
<th>Relationship Risk factor</th>
<th>(Country + 2*Relationship)/3</th>
<th>Likelihood with Country and Relationship</th>
<th>Total Raw material Risk</th>
<th>Which verification measurements are necessary?</th>
</tr>
</thead>
<tbody>
<tr>
<td>apricot</td>
<td>contamination conventional</td>
<td>3</td>
<td>2</td>
<td>difficult crop</td>
<td>1,2</td>
<td>1,4</td>
<td>1,3</td>
<td>2,7</td>
<td>MEDIUM</td>
<td>audit supplier</td>
</tr>
<tr>
<td>apricot</td>
<td>contamination conventional</td>
<td>3</td>
<td>2</td>
<td>difficult crop</td>
<td>0,5</td>
<td>1</td>
<td>0,8</td>
<td>1,7</td>
<td>LOW</td>
<td></td>
</tr>
</tbody>
</table>
I. Apply risk-based matrix with the following parameters:
- Relationship & knowledge about the supplier: + 5 years = low risk
- Risks related to the specific product / ingredient
- Risk of the country of origin
- Risk in the chain of transport, storage and transparancy till source
- History of the supplier
- Minimal control frequency per supplier / ingredient-product

II. Follow new developments with substances based on labs and market-info

III. Aim to reduce the pressure on increasing number of analyses
In general only systematic approach towards ingredients (and not the end product).

Experiences that residues can pop-up after processing steps (very disturbing and confusing when the ingredient was free from substances).

Operators in general still working with concentration factors.

In general the way of sampling is very much depending on the type of product.

In most cases operators choose for representative samples: take different samples from the whole batch and put the together as one representative sample.

Operators keep a second sample in case a quality issue appears (brought forward by a buyer abroad).

There are no real sampling requirements from CB’s towards operators.

Challenges ingredients for processed food are much higher than for fresh products.