

## Annexes to FAMI-QS Code of Practice

### Guidance on implementation

Annex 1: Guidance on the implementation of HACCP .....	2
Operational Examples .....	9
a) Risk assessment on Prerequisite Program (PRP).....	10
b) Risk assessment on standard fermentation process .....	15
c) Risk assessment on mining process.....	22
d) Risk assessment on standard processes for the manufacture of premixtures ....	27
e) Risk assessment on chemical processes.....	32
f) Risk assessment on an extraction process.....	37
Annex 2: Guidance on the implementation of a complaint handling system.....	40
Annex 3: Guidance on transport .....	45
Annex 4: Guidance on homogeneity .....	49
Annex 5: Guidance on carry-over .....	53
Annex 6: Guidance on sampling .....	55
Annex 7: Guidance on biological hazards.....	59
Annex 8: Guidance on compliance with the EU legislation on feed additives and premixtures for product realisation.....	60
Annex 9: Guidance on product recall and crisis management.....	66
Annex10: Tables of references of FAMI-QS requirements with the correspondent legal text.....	69

## Annex 1: GUIDANCE ON THE IMPLEMENTATION OF HACCP

### Introduction:

HACCP is a risk assessment tool that helps an operator identify feed safety hazards and evaluate the risk associated with their product(s) and processes with the view of controlling their occurrence. The system enables the operator to document, control and verify the effectiveness of these control measures. This guidance is directed at feed business operators and aims to give guidance on the implementation of procedures based on HACCP principles and on flexibility with regard to the implementation of such procedures.

### Definitions specific to this annex:

**Control (noun):** The state wherein correct procedures are being followed and criteria are being met (*Codex Alimentarius*).

**Control (verb):** To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP Plan (*Codex Alimentarius*).

**Control measure:** Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (*Codex Alimentarius*).

**Corrective action:** Any action to be taken when the results of monitoring at the CCP indicate loss of control (*Codex Alimentarius*).

**Critical Control Point (CCP):** A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level (*Codex Alimentarius*).

**Critical limit:** A criterion which separates acceptability from unacceptability (*Codex Alimentarius*).

**Deviation:** Failure to meet a critical limit (*Codex Alimentarius*).

**Feed Hygiene:** See definition in the Code.

**Feed safety:** See definition in the Code.

**Food safety:** See definition in the Code.

**Flow diagram:** A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular item (*Codex Alimentarius*).

**HACCP:** See definition in the Code.

**Hazard:** See definition in the Code.

**Hazard analysis:** See definition in the Code.

**Monitor:** The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control (*Codex Alimentarius*).

**Point of Attention (POA):** General control measures that are not necessarily linked to a single process step but have a global nature.

**Prerequisite Program (PRP):** Basic conditions and activities which are necessary to maintain a hygienic environment throughout the feed/food chain suitable for the production, handling and provision of safe end products (*ISO 22000:2005*).

**Risk:** See definition in the Code.

**Risk Analysis:** A process consisting of three interconnected components: risk assessment, risk management and risk communication (*Regulation (EC) No 178/2002*).

**Risk Assessment:** A scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization (*Regulation (EC) No 178/2002*).

**Risk Communication:** The interactive exchange of information and options throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions (*Regulation (EC) No 178/2002*).

**Risk Management:** The process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options (*Regulation (EC) No 178/2002*).

**Step:** A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption (*Codex Alimentarius*).

**Validation:** Obtaining evidence that the elements of the HACCP plan are effective (*Codex Alimentarius*).

**Verification:** The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan (*Codex Alimentarius*).

### **General requirements:**

The HACCP concept is a required tool to control hazards for feed additives and premixtures businesses.

It ensures you have an effective PRP in place to manage the daily tasks of good hygienic practice, good manufacturing practice (GMP) or other equivalent prerequisite program. The PRP is the backbone of any quality or safety system and without it no management program is likely to be successful. These procedures will give you a solid operating foundation allowing your HACCP team to focus on the few critical issues that may not be addressed as part of your daily program but still require special care.

Examples of common topics in a PRP are cleaning and sanitation, approved/controlled suppliers, employee training, stock control, preventative maintenance, product identification and traceability etc.

For each of these prerequisites, and any not specified here, you should have a written procedure on how to carry it out, how its efficacy is to be verified and how it should be audited. Please be aware that, as far as an auditor is concerned, if it is not documented, it does not exist!

### **HACCP consists of the following 7 principles:**

1. Conduct a hazard analysis;
2. Determine the critical control points (CCPs);
3. Establish critical limits;
4. Establish a system to monitor the control of each CCP;
5. Establish the corrective action to be taken if controls should fail;
6. Establish a procedure to verify that all the aspects of the HACCP system are working effectively;
7. Document all procedures and records to demonstrate the HACCP system is working effectively.

The following paragraphs provide guidance for operators on the implementation of the above guidelines.

### 1. Assemble a HACCP team

Form a small multi-disciplinary team that will have responsibility for establishing, developing, maintaining and reviewing the HACCP system. It is vital this group has the full support of the senior management and ideally a management representative should lead the team. The team should include people who are very familiar with the products, processes and associated risks.

### 2. Formulate the finished product specifications

Full and detailed information regarding each product is required in order to assess hazards presented by the process or delivery to the end user. Be sure to consider:

- composition (*e.g.* raw materials, ingredients, additives *etc.*);
- physico-chemical characteristics;
- processing;
- packaging;
- storage and distribution conditions;
- required shelf life;
- instructions for use;
- any microbiological or chemical criteria applicable.

For practical reasons it is advisable to group similar products where appropriate.

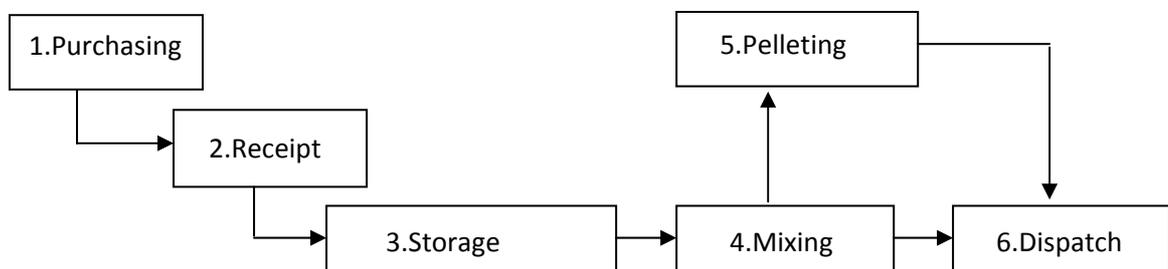
### 3. Identify the intended use of the product

The product specification must detail the target groups for which it is intended. It should also specify the animal species, directions for use, storage and shelf life guaranteed analysis *etc.* The more information you can identify and add to your specification the better.

### 4. Construct a diagram of the process flow

Draw up a process flow diagram for each product group. This diagram should indicate the steps taken to produce the product and should include details of by-products, intermediate products, storage, transport *etc.* One block in the process flow should reflect each step in the process.

Make the diagram as simple as possible, with clear diagrams and unambiguous terms. A very basic example is given here:



Other types of flow charts are seen in the five examples on how to carry through a risk assessment.

## 5. Confirm the accuracy of the process flow diagram *in situ*

If the diagram is drawn up in an office, make sure it is accurate by checking it against the actual operating process in your facility. This will help make sure you do not miss any steps.

## 6. Identify and analyse the hazards

Use the diagram to access potential hazards at each process step from the perspective of:

- i. Chemical - Pesticides, lubricants, dioxins, heavy metals, cleaning agents *etc.*
- ii. Biological - Undesirable microorganisms such as salmonella, *E. coli etc.*
- iii. Physical - Foreign bodies such as glass, wood, jewellery, stones *etc.*

For example, for Step 1, your first consideration should always be, “How good is the material being supplied to me?”

You must consider the chemical, biological and chemical hazards associated with each material you are bringing on site. Potential chemical, biological and physical hazards must be considered for each subsequent step in the process, in each case taking the particular circumstances with regard to the step into account.

When conducting hazard analysis, the following should be considered:

- the likelihood of hazards occurring;
- the severity of their adverse health effects.

## 7. Determine the CCP and control measure(s)

After hazard identification, it is important to evaluate whether or not a hazard will lead to a risk. If a hazard needs a specific control and there is no point further down stream in the process that can reduce or eliminate the risk associated to it, it is a Critical Control Point (CCP). If it is not a CCP then no control will be required and the correct application of your prerequisite program will suffice. Useful questions to ask yourself when you are establishing CCPs are:

- i. If I do not control this risk, is the safety of the end user compromised?
- ii. If I do not apply controls to this hazard at this step, are there other controls further on in the process that will ensure consumer safety?

There are two recognised guidance methods to apply when determining CCPs.

One is using a **decision matrix**, that will help you decide how severe the potential risk is and how likely it is to occur. It is based on the concept that the risk level is the result of the probability that a hazard will occur and the severity if it occurs.

The matrix can be simple or more sophisticated.

This tool is useful and implementation is recommended by FAMI-QS but it is not a mandatory requirement. Three different examples for inspiration are shown below.

Example a)

Severity ↓			
Large	3	4	4
Moderate	2	3	4
Small	1	2	3
→ Risk of occurrence	Small	Moderate	Large

Risk level 1: no need for measures  
 Risk level 2: once-only periodical measures  
 Risk level 3: general control measures, control of points of attention  
 Risk level 4: specific control measures → control at critical control points (CCPs)

Four risk levels can be determined with the risk evaluation model. In the event of risk level 1, no measures are necessary. In the event of risk level 2, periodic measures – often activities to be performed just once - have to be carried out. Risk level 3 requires general control measures, such as hygiene programs, maintenance and calibration, purchasing procedures, etc . In the event of risk level 4, specific control measures are necessary for that particular situation.

Example b)

Risk		Severity/Potential impact				
		Insignificant	Minor	Moderate	Major	Fundamental
Likelihood	Almost certain					
	Likely					
	Moderate					
	Unlikely					
	Rare					

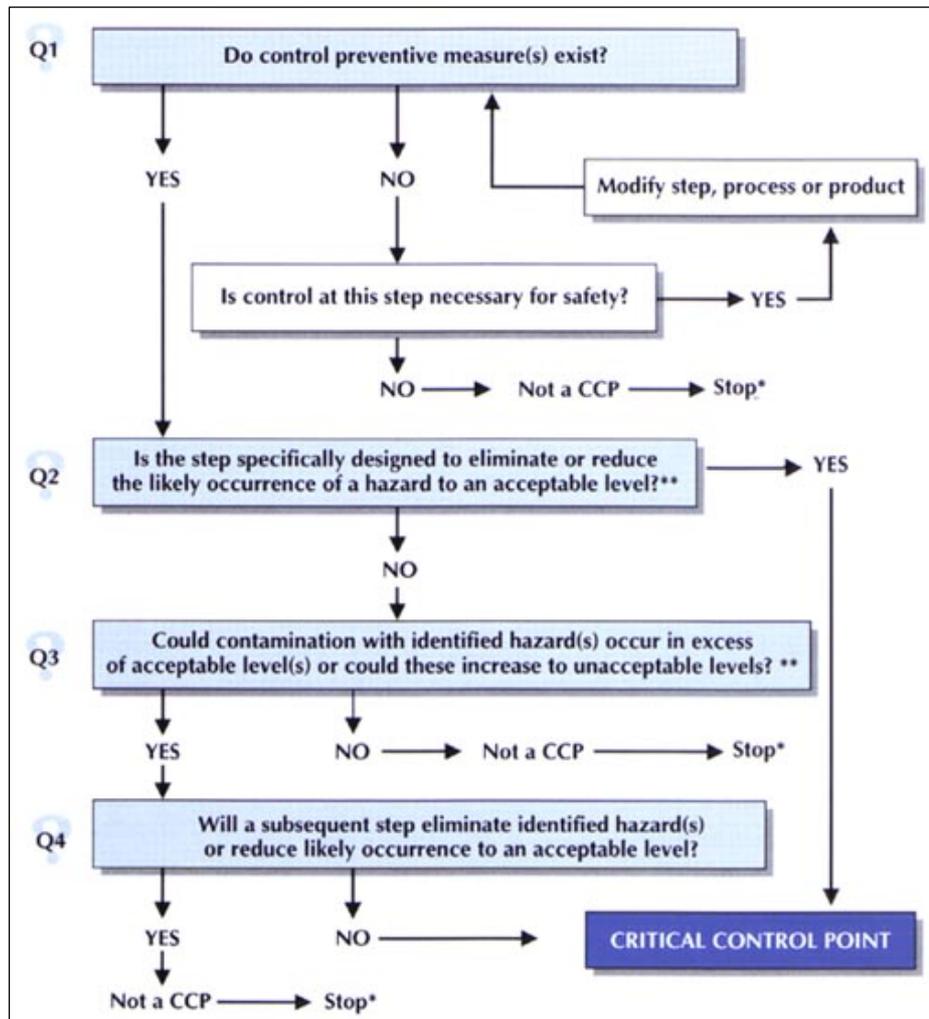
	High risk	CCP
	Significant risk	POA
	Moderate risk	POA
	Low risk	PRP

Example c)

Another and simpler matrix is shown below.

RISK		Severity		
		Small	Medium	High
Probability	High	POA	CCP	CCP
	Moderate	Periodic measures	POA	CCP
	Small	No measures	Periodic measures	POA

The other is to use a **decision tree** to determine if a risk could be a CCP (see figure below, which indicates, by means of four questions, a logic approach). The figure below is an example of a decision tree; other logical approaches may be used.



\*) Proceed to the next identified hazard in the described process

\*\*\*) Acceptable and unacceptable levels need to be determined within the overall objectives in identifying the CCPs of the HACCP plan

The number of CCPs you have will depend on your system but try and keep the total number as low as possible. You can monitor a few key CCPs much more effectively than a vast array.

Once you have identified a hazard that needs a specific control you must identify the process step where the control measure should be associated. Keep in mind that controls must be possible and measurable, the control must eliminate or reduce the risk to an acceptable level, and if a CCP fails, immediate corrective action must be possible.

## 8. Determine the target values and critical limits for the CCP

Establish a target value you expect as an average and a critical limit that will separate the acceptable from the unacceptable. These limits must comply with all legislative obligations but if there are no legal limits one's own research; analytical and bibliographic, and experience (either your own or a consultant's) should be used to strike the right balance between safety and operability.

## 9. Construct monitoring procedures for the CCP

Monitoring of a CCP is planned measurement of the process parameters to establish if a CCP is under control. It must have a schedule, limits as defined above, a written procedure, associated responsible employees with appropriate training and a written record of the measurements/observations/results.

## 10. Determine corrective actions

These are the decisions that must be taken once a critical limit has been breached. For example, a faulty raw material or finished good may be placed on hold, reworked, destroyed *etc.* A written procedure must be in place that details how this process should be undertaken and someone must have responsibility for this process.

Example:

Step	Hazard	Category	CCP	Monitoring				Critical limit	Corrective action	Record and verification
				What	How	When	Who			
4.Mixing	Any form of physical contamination	Physical	3 (3 <sup>rd</sup> in process)	Sieve	Inspected to ensure it is operating and in good condition	Daily	Maintenance Dept.	All holes < 2 mm  Sieve is rotating at 50 revs/minute	Replace or repair sieve if any holes >2mm or reset its speed if it is out of spec.  Re-sieve all product made since the sieves' last positive inspection.	Results of monitoring and corrective action

## 11. Verify the system

The system must be verified periodically to ensure it is effective and up to date. This review should cover all aspects of the HACCP system and processes including the prerequisites, deviations and customer complaints. All records of this review should be documented and ideally be part of the company's internal audit schedule.

## 12. Draw up the necessary documentation

There are a number of documents that will be necessary as part of your HACCP system. A minimal list is prescribed here:

- HACCP team (members and expertise);
- end product specifications;
- process diagrams;
- prerequisites;
- risk analysis tables;
- operating procedures for CCP's;
- corrective actions and associated documents;
- verification procedures and results for all of the above.

## 13. References

Formal guidance on the implementation of HACCP principles is available from the Codex Alimentarius ([www.codexalimentarius.net](http://www.codexalimentarius.net)). General principles of Food Hygiene (CAC/RCP 1 – 1969, Rev 4 – 2003. Annex on Hazard Analysis Critical Control Point (HACCP) System and Guidelines for its Application.)

EN ISO 22000:2005 on Food safety management systems - Requirements for any organization in the food chain may also be a source of inspiration.

### **Operational Examples**

In the following pages, six risk assessments are shown:

- one on a prerequisite program (PRP), and
- five on different specific manufacturing processes
  - Fermentation
  - Mining
  - Premixtures
  - Chemical
  - Extraction

In order to illustrate the flexibility likely in documentation of a risk analysis, different types of flow charts are used.

## a) Risk assessment on Prerequisite Program (PRP)

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
Incoming materials: • Raw materials	Purchase and sourcing of raw materials	Presence of foreign objects like glass, metal parts, ropes, scoops, synthetic materials, (small) stones, tools, internal liners of equipment, insulation materials, wood, jewellery from operators	P	<ul style="list-style-type: none"> <li>Raw material specification and receiving inspection</li> <li>Suitable process design and downstream filtration steps</li> </ul>	
		Presence of undesirable substances, <i>e.g.</i> heavy metals, pesticides, as described in Directive 2002/32/EC and its amendments	C	<ul style="list-style-type: none"> <li>Raw material specification and receiving inspection.</li> <li>Supplier information, <i>e.g.</i> certificates, conformance statements, or contractual agreements</li> <li>Measures to remove or reduce these contaminants in the downstream processes like filtration, crystallization</li> </ul>	
		Presence of micro-organisms or (including viruses)	B	<ul style="list-style-type: none"> <li>Raw material specification and receiving inspection.</li> <li>Supplier information, <i>e.g.</i> certificates, conformance statements, or contractual agreements</li> <li>Measures to remove or reduce these contaminants in the downstream process like filtration, crystallization, heating</li> </ul>	

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
	Purchase and sourcing of raw materials used in the downstream purification steps	<b>Raw materials used in the downstream purification steps, certain contaminants are considered when establishing the raw material specification, e.g. pathogenic micro-organisms</b>	<b>B</b>	<ul style="list-style-type: none"> <li>• Raw material specification and receiving inspection</li> <li>• Contractual agreements</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Indirect materials</b></li> </ul>	Purchase of materials not in direct contact, e.g. lubricants, cleaning agents	<b>Presence of toxic substances may result in contaminated products</b>	<b>C</b>	<ul style="list-style-type: none"> <li>• Ensure suitable supplier documentation</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Water</b></li> </ul>	Water may be supplied from communities or from wells, and used as process ingredient and cleaning	<b>Water pipes and reservoirs may contribute to</b> <ul style="list-style-type: none"> <li>▪ growth of microbes, and</li> <li>▪ dissolution of substances.</li> </ul> <b>In certain cases, purification systems may be established due to product quality.</b>	<b>BC</b>	<ul style="list-style-type: none"> <li>• When an ingredient, use potable water or a quality suitable for animal feeding</li> <li>• Prevent storage at temperatures which support growth of microbes</li> <li>• Monitor official control of potable water or the alternative water source</li> <li>• Separate non-potable water systems from potable water systems</li> </ul>	

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
<ul style="list-style-type: none"> <li>Packaging material</li> </ul>	Purchase, sourcing, use and possible re-use of packaging	<p><b>Contamination via packaging containers or materials or parts of it.</b></p> <p><b>Specific considerations:</b></p> <ul style="list-style-type: none"> <li>Special units like drying bags may present a contamination risk</li> </ul>	CBP	<ul style="list-style-type: none"> <li>Measures to avoid contamination of empty containers, bags, lids, etc.</li> <li>Packaging design and materials shall provide adequate protection for products to minimize product contamination during use</li> <li>Minimize damage during handling</li> <li>Accommodate proper labelling</li> <li>Re-saleable packaging (also internal usage) shall be suitable, durable, easy to clean and, where necessary, disinfect</li> <li>Measures to prevent Silica gel drying bags or closing straps contaminating the product</li> </ul>	
Maintenance	Maintenance work may conflict with on-going processes	Possible contamination of equipment after maintenance	CP	<ul style="list-style-type: none"> <li>Documented cleaning after maintenance</li> <li>Ensure that excess of lubricants are prevented from entering the process equipment</li> </ul>	
Cleaning	Cleaning of product contact surfaces and the production environment	<p>Possible contamination if equipment is not cleaned to an acceptable level.</p> <p>Possible residues of cleaning agents. The environment may cause cross contamination.</p> <p>Wet cleaning of equipment used for dry products may support growth of microbes.</p>	<p>C</p> <p>B</p>	<ul style="list-style-type: none"> <li>Ensure adequate cleaning programs of equipment</li> <li>Ensure cleaning is documented</li> <li>Control carry-over</li> <li>Ensure an adequate level of environmental hygiene (rooms, floors, the outside of equipment)</li> <li>Prevent condensate from entering process equipment</li> </ul>	

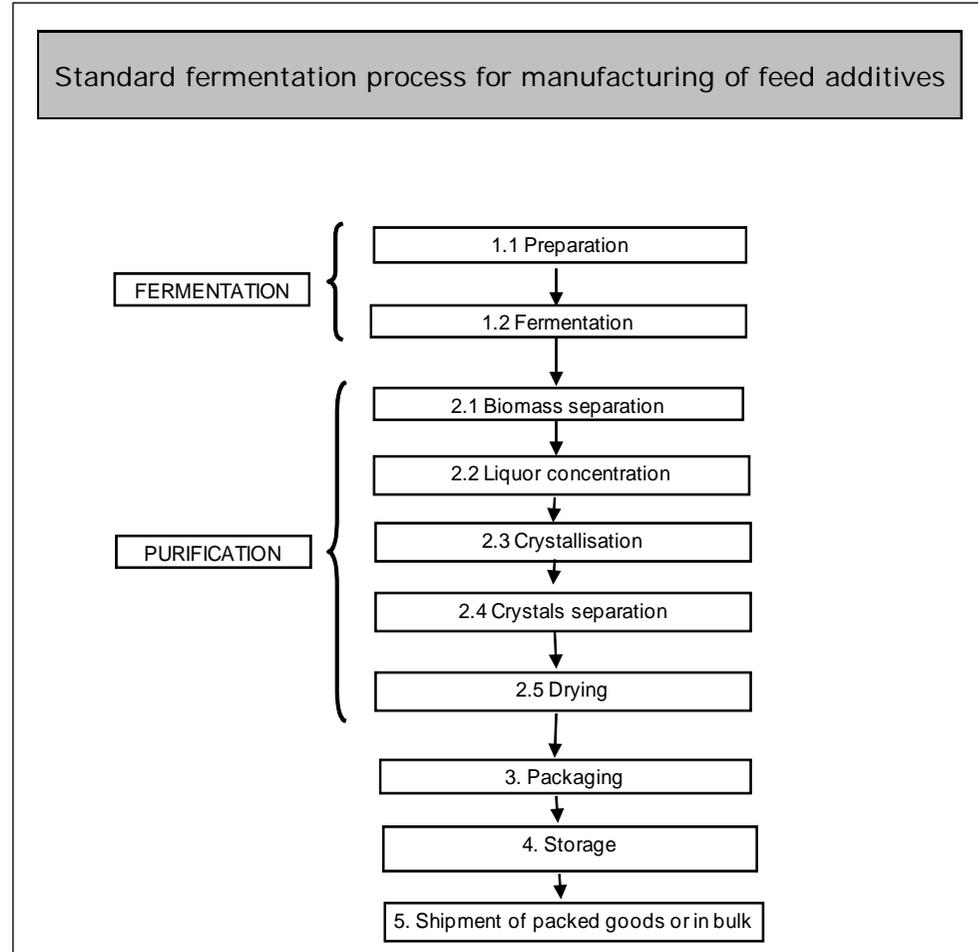
Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
Sampling operations		Dirty sampling tool → Foreign body Glass sampling tool → Chip of glass	P	<ul style="list-style-type: none"> <li>• Cleaning of sampling tool</li> <li>• Storage of sampling tool</li> <li>• Hands washing</li> <li>• Have a glass control policy</li> </ul>	
Open air steps		Use of dirty tool → Foreign body	P	<ul style="list-style-type: none"> <li>• Cleaning of tool</li> <li>• Hands washing</li> <li>• Storage of tool</li> </ul>	
		Use of tool made up of wood → Chip of wood	P	<ul style="list-style-type: none"> <li>• Have a wood control policy</li> </ul>	
		Loss of object → Foreign body	P	<ul style="list-style-type: none"> <li>• Rules about jewellery and wearing of other objects (<i>e.g.</i> pencil)</li> </ul>	
		Insects / Rodents → Foreign body or bacteriological contamination	P/B	<ul style="list-style-type: none"> <li>• Closing of accesses from outside</li> <li>• Pest control</li> </ul>	
		Flakes of ceiling paintwork / Flakes of rust → Foreign body	P	<ul style="list-style-type: none"> <li>• Infrastructure maintenance</li> </ul>	
Transport (see also Annex 3) • Incoming	Bulk transport of incoming ingredients	Possible contamination from previous bulk loads or different loads carried on the same vehicle	CBP	<ul style="list-style-type: none"> <li>▪ Contractual agreements with suppliers</li> <li>▪ Dedicated tank transport</li> <li>▪ Ask for cleaning certificates and previous loads before unloading</li> <li>▪ Use only transporters that use the requirements of the Code</li> </ul>	

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
<p>Transport (see also Annex 3)</p> <ul style="list-style-type: none"> <li>▪ Outgoing</li> </ul>	<p>Bulk transport of outgoing products as well as packed products</p>	<p><b>Possible contamination from previous bulk loads or different loads carried on the same vehicle</b></p>	<p><b>CBP</b></p>	<p><b>Packaged products:</b></p> <ul style="list-style-type: none"> <li>▪ Contractual agreements with transporters</li> <li>▪ Inspection of truck before loading</li> <li>▪ Specification for packaging in place, adequate for the protection of the product</li> </ul> <p><b>Bulk:</b></p> <ul style="list-style-type: none"> <li>▪ Contractual agreements with transporters</li> <li>▪ System for inspection before loading or dedicated transport</li> <li>▪ Cleaning certificates</li> <li>▪ Use only transporters that meet the requirements of the Code</li> <li>▪ Audit of transporters by operator to verify performance</li> <li>▪ List of prohibited previous load</li> </ul>	

**b) Risk assessment on standard fermentation process****Production characteristics**

The typical production process here consists of production of molecules/products by microorganisms. The microorganisms are fed a source of carbon, nitrogen raw materials and micronutrients. After a growth step, the microorganisms produce the expected product. Then the target molecule/product is separated from the biomass and is purified.

Flow chart of process →



## HACCP Analysis

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
<b>1.Fermentation</b>					
<b>1.1 Preparation</b>	Growth of production strain population	Failure in asepsis conditions → Growth of contaminating micro organisms	B	• Process rules to avoid any contamination	
		Growth of contaminating micro organisms → Degradation of the intended product including into undesirable substances	C/B	• Process rules to avoid any contamination	
<b>1.2 Fermentation</b>	Production of the intended product	Failure in asepsis conditions → Growth of contaminating micro organisms	B	• Process rules to avoid any contamination	
		Growth of contaminating micro organisms → Degradation of the intended product into undesirable substances	C	• Process rules to avoid any contamination	
		Failure in equipment maintenance → Loss of screw, bolt or part of equipment	P	• Preventive maintenance program	

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
<b>2. Purification</b>					
<b>2.1 Biomass separation</b>	Separation of intended product from the rest of the broth	<b>Favourable pH and T°C conditions → Growth of contaminating micro organisms (e.g. attached growth)</b>	B	<ul style="list-style-type: none"> <li>Pasteurization / sterilization of equipment / Cleaning In Place</li> <li>pH / T°C conditions monitoring</li> </ul>	
		<b>Loss of strain cells through the separation system → Bacteriological contamination</b>	B	<ul style="list-style-type: none"> <li>Preventive maintenance program</li> <li>Turbidity monitoring</li> </ul>	
		<b>Loss of strain cells through the separation system → Cells carbonization in downstream (black spots)</b>	P	<ul style="list-style-type: none"> <li>Preventive maintenance program</li> <li>Turbidity monitoring</li> </ul>	
		<b>Lubricant leak in agitator → Undesirable substances</b>	C	<ul style="list-style-type: none"> <li>Preventive maintenance program</li> <li>Double lubricant tightness</li> <li>Food grade lubricant/grease</li> </ul>	
		<b>Clogging of equipment by cells cream → Growth of contaminating micro organisms</b>	B	<ul style="list-style-type: none"> <li>Cleaning program</li> </ul>	
		<b>Breakage of agitator system → Foreign body contamination</b>	P	<ul style="list-style-type: none"> <li>Preventive maintenance program</li> </ul>	
		<b>Leak of lubricant during the greasing operation of bearings → Undesirable substances</b>	C	<ul style="list-style-type: none"> <li>Instructions</li> <li>Food grade lubricant/grease</li> </ul>	



Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
		Clogging up of spin drier → Growth of undesirable micro organisms	B	<ul style="list-style-type: none"> <li>Cleaning program</li> </ul>	
		Clogging up of belt filter → Growth of undesirable micro organisms	B	<ul style="list-style-type: none"> <li>Cleaning program</li> </ul>	
		Breakage of bucket lifts → Foreign body	P	<ul style="list-style-type: none"> <li>Preventive maintenance program</li> <li>Machine design</li> </ul>	
2.5 Drying	Getting the final product in compliance with the dry matter requirements	Deterioration of outside air system filtration → Contamination with dust and/or filtering media	P	<ul style="list-style-type: none"> <li>Filtration system design</li> <li>Preventive maintenance program</li> </ul>	
	<i>Dryer</i>	Fire extinguisher system set off → Contamination by extinguisher product	C	<ul style="list-style-type: none"> <li>Food grade extinguishment product</li> </ul>	
		Loss of screw or part of equipment → Foreign body contamination	P	<ul style="list-style-type: none"> <li>Machine design</li> <li>Preventive maintenance program</li> </ul>	
		Crack in heating/cooling system → Steam/ non-potable and/or adequately uncontrolled water contamination	C	<ul style="list-style-type: none"> <li>Preventive maintenance program</li> </ul>	
		Lubricant leak in conveyor helix → Undesirable substances	C	<ul style="list-style-type: none"> <li>Machine design</li> <li>Food grade lubricant/grease</li> </ul>	
		Boring of sieve → Chip of sieve	P	<ul style="list-style-type: none"> <li>Preventive maintenance program</li> </ul>	
	<i>Conveyor</i> <i>Sieve</i>	Lubricant leak in crusher → Undesirable substances	C	<ul style="list-style-type: none"> <li>Machine design</li> <li>Food grade lubricant/grease</li> </ul>	

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
3. Packaging	Packaging of the products in bags, boxes, drums, bigbags, IBC's etc.	<b>Contamination via the packaging process</b>	CBP	<ul style="list-style-type: none"> <li>• Packaging via dedicated production lines and packaging machines</li> <li>• Cleaning and inspection procedures</li> <li>• Usage of new and/or clean packaging materials</li> </ul>	
	Identify the products with the right label identification according to the applicable legislation and to be able to track and trace the products in cases where it is necessary to do so	<b>Wrong labelling and identification of the product could lead to wrong usage or unable to do a complete recall in case it would be required</b>	CBP	<ul style="list-style-type: none"> <li>• Labelling procedures</li> <li>• Check on batch identification system</li> </ul>	
4. Storage	Storage and keeping of feed additives	<p><b>Exposure to rain and/or damp conditions</b></p> <p><b>Spoilage due to condensation and mould growth</b></p> <p><b>Cross contamination with other feed</b></p> <p><b>Contamination with other non-feed materials such as chemicals, fertilizers</b></p> <p><b>Deterioration of the product due to poor stock rotation</b></p> <p><b>Products for different species and medicated and un-medicated feeds not adequately segregated</b></p>	CBP	<ul style="list-style-type: none"> <li>• Training and education of employees</li> <li>• Weatherproof storage facilities</li> <li>• Effective segregation of different materials particularly when stored on floors</li> <li>• Cleanout procedures between different types of products</li> <li>• Separate storage areas for feed and non-feed materials</li> <li>• Proper stock rotation</li> <li>• Effective consolidation and sheeting of clamped forages</li> </ul>	

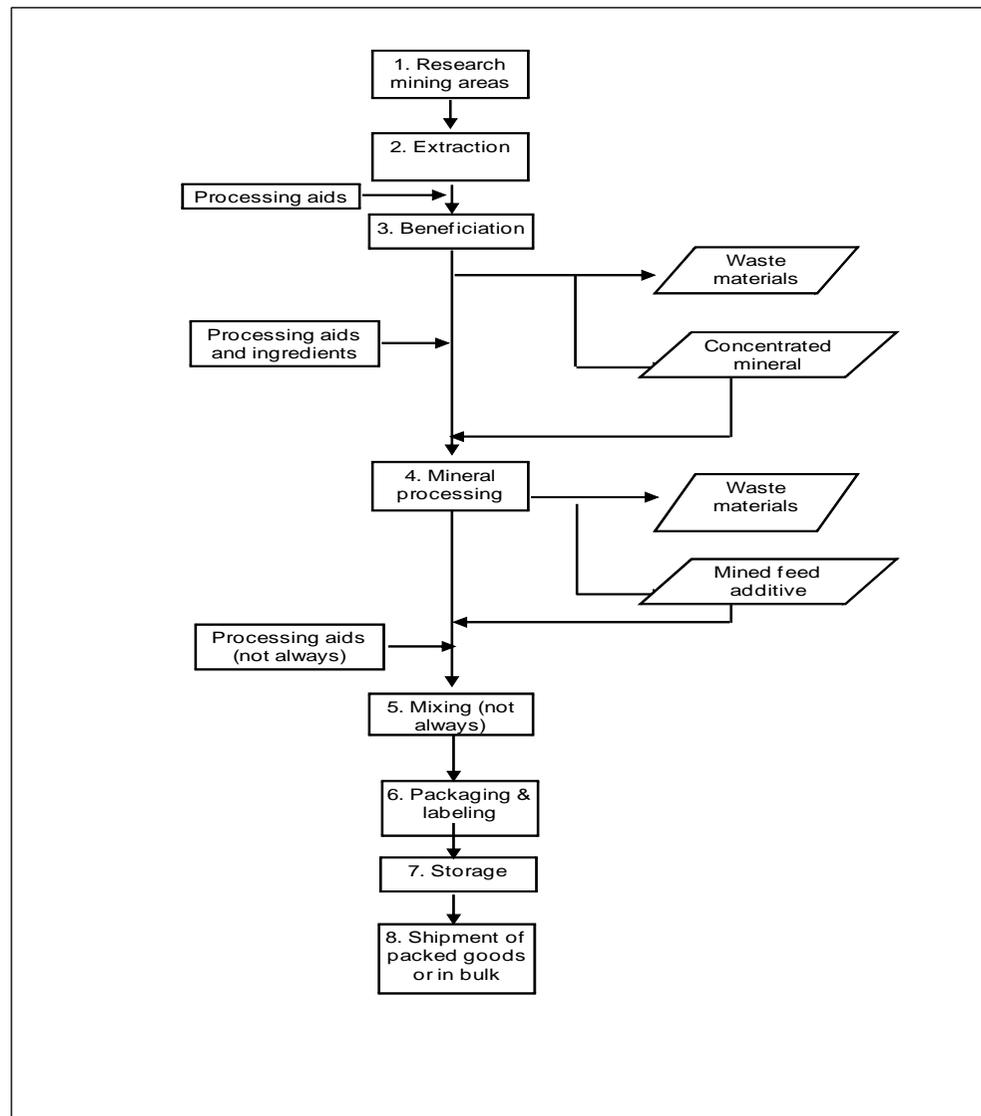
Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
<b>5. Shipment of packed goods or in bulk</b>	Packed goods			<ul style="list-style-type: none"> <li>• Contractual agreements with transporters</li> <li>• Inspection before loading /dedicated transport</li> <li>• Use only certified and registered transporters according to requirements</li> </ul>	
	Bulk shipment			<ul style="list-style-type: none"> <li>• Contractual agreements with transporters</li> <li>• Inspection before loading /dedicated transport</li> <li>• Info about previous load(s) and request for cleaning certificates</li> <li>• Use only certified and registered transporters according to requirements</li> </ul>	

**c) Risk assessment on mining process**

**Production characteristics**

Mining is the extraction of valuable minerals or other geological materials from the earth. Mineral processing (or mineral dressing) is mainly based in various mechanical means of crushing, grinding and washing that enable the separation (extractive metallurgy) of valuable metals or minerals from their gangue (waste material).

Flow chart of process →



## HACCP Analysis

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
1. Research in mining areas	Research in mining areas	Natural contamination of the ore with heavy metals, dioxins	C	<ul style="list-style-type: none"> <li>Follow processes to reduce the level of undesirable substances to an acceptable level</li> <li>Ensure compliance of the final product with legislation on undesirable substances</li> </ul>	
2. Extraction	Removal of rocks of diverse hardness and toughness from earth	<p>Oils, anti-freezes and greases spilled during the process by heavy machinery (bulldozers, drills, explosives and trucks)</p> <p>Contamination with foreign materials from machinery and operators like glass, metal parts, ropes, scoops, synthetic materials, tools, internal liners of equipment, insulation materials, wood, jewellery from operators</p>	CP	<ul style="list-style-type: none"> <li>Good hygienic practices</li> <li>Regular inspection of machinery, maintenance programme</li> </ul>	

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
<b>3. Beneficiation</b>	Operations to separate and concentrate the mineral values from waste through different physical and chemical techniques. This is typically performed by employing various crushing, grinding and froth flotation techniques	<p><b>Formation of contaminants and toxics due to inappropriate chemical reactions, high temperatures, residues of solvent, processing reagents, etc.</b></p> <p><b>Contamination with foreign materials from equipment and operators like: oils, greases, glass, metal parts, ropes, scoops, synthetic materials, tools, internal liners of equipment, insulation materials, wood, jewellery from operators</b></p>	CP	<ul style="list-style-type: none"> <li>• <b>Written and standardized protocols, good laboratory practices</b></li> <li>• <b>Downstream processes to remove by-products to an acceptable level</b></li> <li>• <b>Good hygienic practices</b></li> <li>• <b>Regular inspection and calibration of the equipment</b></li> </ul>	
<b>4. Mineral Processing</b>	Operations to destroy the physical structure of the mineral and modify its chemical composition into a more useful chemical form. Include techniques such as smelting, electrolytic refining and acid attack or digestion (most are indistinguishable from chemical and refining plants)	<p><b>Formation of contaminants and toxics due to inappropriate chemical reactions, high temperatures, residues of solvent, processing reagents, etc.</b></p> <p><b>Contamination with foreign materials from equipment and operators like: glass, metal parts, ropes, scoops, synthetic materials, tools, internal liners of equipment, insulation materials, wood, jewellery from operators.</b></p>	CP	<ul style="list-style-type: none"> <li>• <b>Written and standardized protocols, good laboratory practices</b></li> <li>• <b>Downstream processes to remove by-products to an acceptable level</b></li> <li>• <b>Good hygienic practices</b></li> <li>• <b>Regular inspection and calibration of the equipment</b></li> </ul>	

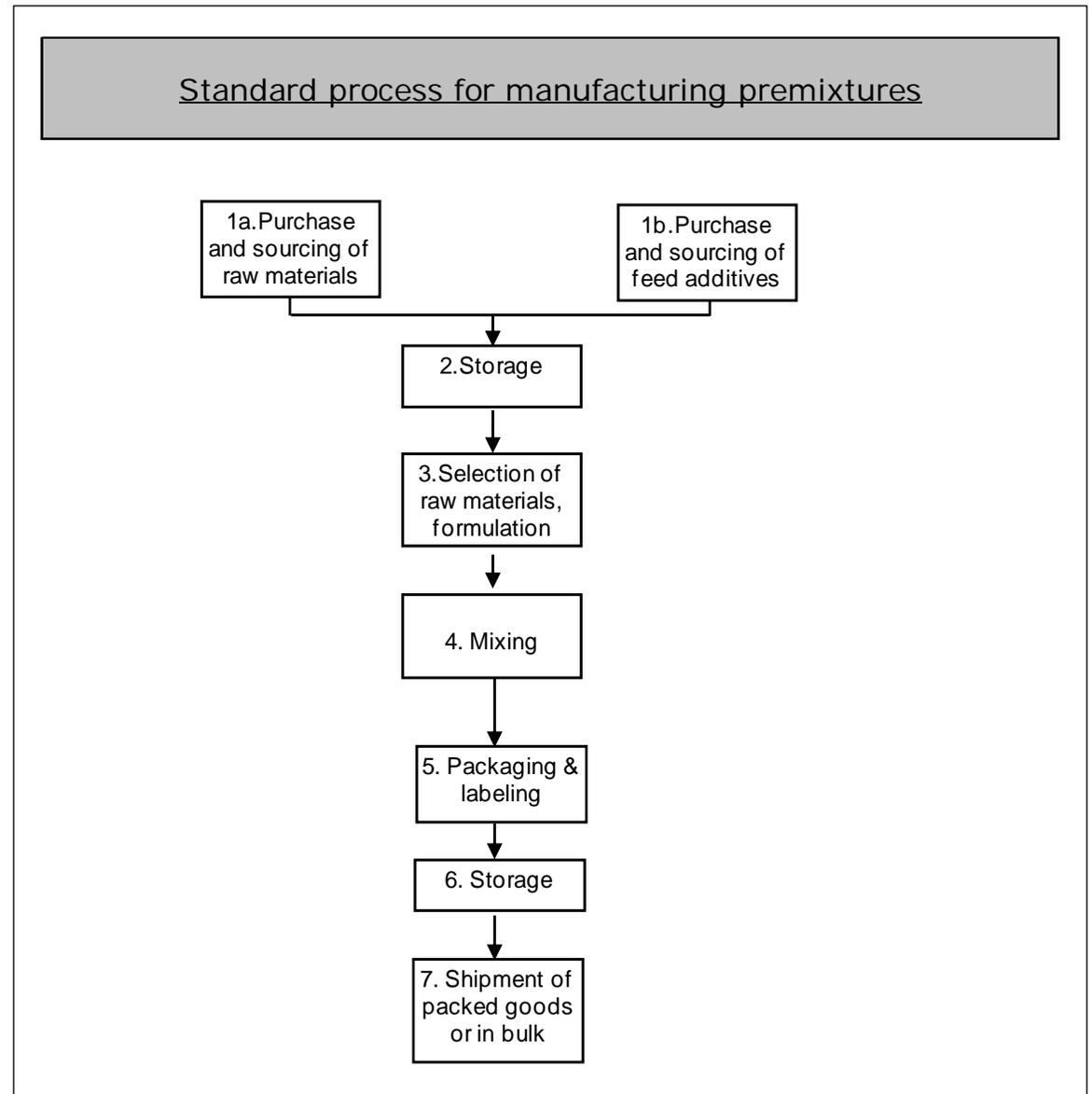
Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
5. Mixing Process		<p>Cross contamination</p> <p>Incorrect dosage</p> <p>Non-uniform distribution of ingredients</p>	CP	<ul style="list-style-type: none"> <li>Cleanliness of the mixer</li> <li>Written maintenance schedules for the examination of the mixer to ensure that wear of the equipment does not lead to build-up of residues when the mixer is emptied, or only use dedicated mixing</li> <li>Adequate dosing system</li> <li>Use of food grade oils and detergents</li> <li>Regularly test mixer efficiency</li> </ul>	
6. Packaging and Labelling	Packaging of the products in bags, boxes, drums, bigbags, IBC's etc.	Contamination via the packaging process	CBP	<ul style="list-style-type: none"> <li>Packaging via dedicated production lines and packaging machines</li> <li>Cleaning and inspection procedures</li> <li>Use of new and/or clean packaging materials</li> </ul>	
	Identify the products with the right label identification according to the applicable legislation and to enable traceability (where required)	Wrong labelling and identification of the product could lead to wrong usage and or inability to undertake appropriate levels of recall where required	CBP	<ul style="list-style-type: none"> <li>Appropriate labelling procedures</li> <li>Check on batch identification system</li> </ul>	
7. Storage	Storage and keeping of feed additives	<p>Exposure to rain and/or damp conditions</p> <p>Spoilage due to condensation and mould growth</p> <p>Cross contamination with other feed</p>	CBP	<ul style="list-style-type: none"> <li>Training and education of employees</li> <li>Weatherproof storage facilities.</li> <li>Effective segregation of different materials particularly when stored on floors</li> <li>Cleanout procedures between different types of products</li> </ul>	

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
		<p>materials</p> <p>Contamination with other non-feed materials such as chemicals, fertilizers</p> <p>Deterioration of the product due to poor stock rotation</p> <p>Products for different species and medicated and non-medicated feeds not adequately segregated.</p>		<ul style="list-style-type: none"> <li>• Separate storage areas for feed and non-feed materials</li> <li>• Proper stock rotation</li> <li>• Effective consolidation and sheeting of clamped forages</li> </ul>	
8. Shipment of packed goods or in bulk	Packed goods			<ul style="list-style-type: none"> <li>• Contractual agreements with transporters</li> <li>• Inspection before loading /dedicated transport</li> <li>• Use only certified and registered transporters according to the requirements</li> </ul>	
	Bulk shipment			<ul style="list-style-type: none"> <li>• Contractual agreements with transporters</li> <li>• Inspection before loading /dedicated transport</li> <li>• Info about previous load(s) and request for cleaning certificates</li> <li>• Use only certified and registered transporters according to the requirements</li> </ul>	

**d) Risk assessment on standard processes for the manufacture of premixtures****Production characteristics**

The typical production process consists of a dry blending of certain micronutrients like minerals, vitamins *etc.* with suitable carriers in multi purpose equipment.

Flow chart of process →



HACCP Analysis

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
2. Storage	Storage and keeping of ingredients and raw materials	<p><b>Exposure to rain and/or damp conditions</b></p> <p><b>Spoilage due to condensation and mould growth</b></p> <p><b>Cross contamination with other feed materials</b></p> <p><b>Contamination with other non-feed materials such as chemicals, fertilizers</b></p> <p><b>Deterioration of the product due to poor stock rotation</b></p> <p><b>Products for different species and non-medicated and non-medicated feeds not adequately segregated</b></p>	CBP	<ul style="list-style-type: none"> <li>• <b>Training and education of employees</b></li> <li>• <b>Weatherproof storage facilities</b></li> <li>• <b>Effective segregation of different materials particularly when stored on floors</b></li> <li>• <b>Cleanout procedures between different types of products</b></li> <li>• <b>Separate storage areas for feed and non-feed materials</b></li> <li>• <b>Proper stock rotation</b></li> <li>• <b>Effective consolidation and sheeting of clamped forages</b></li> </ul>	
3. Selection of raw materials, formulation	Selection of raw Materials for processing	<b>Selection of incorrect ingredient or incorrect raw material</b>	C	<ul style="list-style-type: none"> <li>• <b>Clear labelling</b></li> <li>• <b>Verification of checked ingredients</b></li> </ul>	
	Formulation	<b>Poor performance/ill health due to unsuitable premix design or formulation</b>	C	<ul style="list-style-type: none"> <li>• <b>Feed formulations produced or checked by qualified nutritionists</b></li> </ul>	

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
4. Mixing (see also annexes 4 and 5)	Mixing of additives with other additives, carriers	<p>Contamination from oils or cleaning agents</p> <p>Foreign body contamination at addition points</p> <p>Incorrect addition/dosage of ingredients</p> <p>Inappropriate mixing, non-uniform distribution of ingredients</p> <p>Presence of residues due to carry-over</p>	CBP	<ul style="list-style-type: none"> <li>• Only use dedicated mixer or have a verified cleaning procedures</li> <li>• Use of food grade oils and detergents</li> <li>• Regularly test mixer efficiency</li> <li>• Good house keeping, jewellery policy, etc</li> <li>• Sieve, metal detector</li> <li>• Preventive measures to control carry-over</li> </ul>	
5. Packaging and labelling	Packaging of the products in bags, boxes, drums, bigbags, IBC's etc.	Contamination via the packaging process	CBP	<ul style="list-style-type: none"> <li>• Packaging via dedicated production lines and packaging machines</li> <li>• Cleaning and inspection procedures</li> <li>• Usage of new packaging materials</li> </ul>	
	Identify the products with the right label identification according to the applicable legislation and to be able to track and trace the products in cases it is necessary	Wrong labelling and identification of the product could lead to wrong usage or unable to do a complete recall in case it would be necessary	C	<ul style="list-style-type: none"> <li>• Labelling procedures</li> <li>• Check on batch identification system</li> </ul>	

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
6. Storage	Storage and keeping of premixtures	<p>Exposure to rain and/or damp conditions</p> <p>Spoilage due to condensation and mould growth</p> <p>Cross contamination with other feed materials</p> <p>Contamination with other non-feed materials such as chemicals, fertilizers</p> <p>Deterioration of the product due to poor stock rotation</p> <p>Products for different species and medicated and nonmedicated feeds not adequately segregated.</p>	CBP	<ul style="list-style-type: none"> <li>• Training and education of employees</li> <li>• Weatherproof storage facilities</li> <li>• Effective segregation of different materials particularly when stored on floors</li> <li>• Cleanout procedures between different types of products</li> <li>• Separate storage areas for feed and non-feed materials</li> <li>• Proper stock rotation</li> <li>• Effective consolidation and sheeting of clamped forages.</li> </ul>	
7. Shipment of packed goods or in bulk	Shipment of packed goods	Contamination of stock that was stored in good condition by: damaged packaging at the point of loading or during shipment	CBP	<ul style="list-style-type: none"> <li>• Contractual agreements with transporters</li> <li>• Inspection before loading /dedicated transport</li> <li>• Use only certified and registered transporters according to the requirements</li> <li>• Notification of any problems during transport</li> </ul>	
	Shipment of Bulk	Contamination from: oils or cleaning agents, if the transporter is not dedicated to one product	CBC	<ul style="list-style-type: none"> <li>• Contractual agreements with transporters</li> <li>• Inspection before loading /dedicated transport</li> <li>• Info about previous load(s) and</li> </ul>	

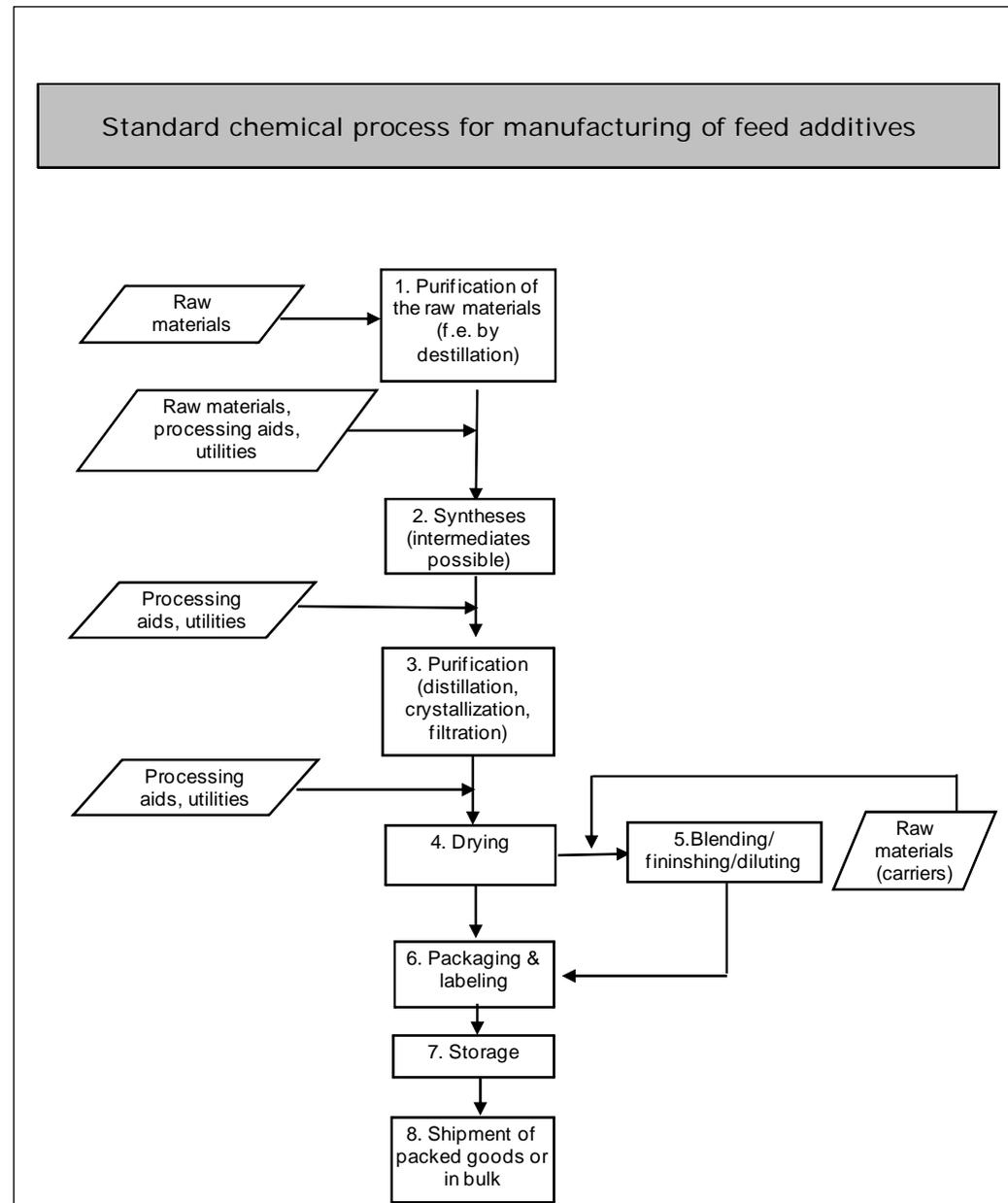
Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
				request for cleaning certificates • Use only certified and registered transporters according to the requirements	

**e) Risk assessment on chemical processes**

**Production characteristics**

The typical production process consists of a chemical reaction of organic and/or inorganic raw materials under defined conditions whereby organic and/or inorganic processing aids, steam, water, air and gas could be inserted into the process. After the synthesis the final product is purified by *e.g.* distillation/ crystallisation/ filtration and dried.

Flow chart of process →



## HACCP Analysis

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
1. Purification of raw materials	Distillation separates chemicals by the difference in how they vaporize. The two major types of classical distillation include continuous distillation and batch distillation	Contamination of the raw materials in case of incomplete distillation	C	<ul style="list-style-type: none"> <li>Check the temperature</li> </ul>	
2. Synthesis (intermediates possible)	More than one synthetic reaction is likely to take place. Probably the last reaction is where the "active molecule" is created and from this step onwards the feed hygiene requirements are followed	Besides the wanted substance some by-products are formed	C	<ul style="list-style-type: none"> <li>The downstream process removes the by-products to an acceptable level</li> </ul>	
3. Purification	Crystallization / recrystallization: Production of a purer sample of a substance by slow precipitation of crystals from a solution of the substance	Besides the wanted substance by-products precipitate	C	<ul style="list-style-type: none"> <li>Remove the by-products by elution</li> </ul>	
		Crack in cooling system → Contamination by non-potable drinking water	C/B	<ul style="list-style-type: none"> <li>Preventive maintenance program</li> </ul>	
		Leak of lubricant in speed reducer → Undesirable substances	C	<ul style="list-style-type: none"> <li>Man hole protection (edge)</li> <li>Speed reducer design</li> <li>Preventive maintenance program</li> <li>Food grade lubricant/grease</li> </ul>	
	Distillation: Distillation separates chemicals by the difference in how easily they vaporize	Contamination of the product in case of incomplete distillation	C	<ul style="list-style-type: none"> <li>Check the temperature</li> </ul>	

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
	Ion exchange: A method of separating ions from a solution by reversibly binding them onto a resin that has charged sites on its surface. Ion exchangers are used to remove metal ions from (drinking) water	<b>Microbial growth during the process</b>	B	<ul style="list-style-type: none"> <li>Perform a regular regeneration of the resin</li> </ul>	
	Filtration via activated carbon which is a porous form of carbon that acts as a powerful adsorbent, used to decolorize liquids, recover solvents, and remove toxins from water and air	<b>Reduced capacity of the activated carbon during the process</b>	C	<ul style="list-style-type: none"> <li>Exchange or recycle the carbon in regular terms</li> </ul>	
<b>4. Drying</b>	General drying processes	<p><b>Occurrence of harmful substances during the process</b></p> <p><b>Contamination by drying aids such as additives</b></p> <p><b>Formation of dioxins, NOx and PAHs during non-optimal burning process(es)</b></p> <p><b>Contamination of the product if cyclone dust is returned in the process</b></p> <p><b>Formation of CO and soot in case of incomplete burning</b></p> <p><b>Contamination with fly ash from drying gases</b></p>	CP	<ul style="list-style-type: none"> <li>Use of clean fuels</li> <li>Check on fuel quality where applicable</li> <li>Avoid use of pollutant drying aids</li> <li>Check of burners where applicable</li> <li>Avoid carry back of dust or ash</li> <li>Monitoring of CO levels where applicable</li> <li>Check on soot forming where applicable</li> <li>Flue gas cleaning before drying</li> </ul>	

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
5. Blending/ Finishing/ Diluting	Blending: Blending of small batches to a bigger batch or with the intention to homogenize the product	Contamination in case the blending line is not clean or not dedicated to these products	CBP	<ul style="list-style-type: none"> <li>Cleaning and inspection procedure of the mixing line</li> <li>Only use dedicated mixing</li> </ul>	
	Finishing: Homogenization, delumping, sieving	Contamination in case the finishing line is not clean or not dedicated to these products	CBP	<ul style="list-style-type: none"> <li>Cleaning and inspection procedure of the finishing line</li> <li>Only use dedicated finishing line</li> </ul>	
	Diluting: Blending the concentrated feed additive to a practical dilution, ready for use	Contamination in case the mixing line is not clean or not dedicated to these products	CBP	<ul style="list-style-type: none"> <li>Cleaning and inspection procedure of the mixing</li> <li>Only use dedicated mixing</li> </ul>	
6. Packaging and Labelling	Packaging of the products in bags, boxes, drums, bigbags, IBC's etc.	Contamination via the packaging process	CBP	<ul style="list-style-type: none"> <li>Packaging via dedicated production lines and packaging machines</li> <li>Cleaning and inspection procedures</li> <li>Usage of new and/or clean packaging materials</li> </ul>	
	Identify the products with the right label identification according to the applicable legislation and to be able to track and trace the products in cases it is necessary	Wrong labelling and identification of the product could lead to wrong usage or unable to do a complete recall in case it would be necessary	CBP	<ul style="list-style-type: none"> <li>Labelling procedures</li> <li>Check on batch identification system</li> </ul>	
7. Storage	Storage and keeping of feed additives	<p>Exposure to rain and/or damp conditions</p> <p>Spoilage due to condensation and mould growth</p> <p>Cross contamination with other feed materials</p> <p>Contamination with other non-feed materials such as chemicals,</p>	CBP	<ul style="list-style-type: none"> <li>Training and education of employees</li> <li>Weatherproof storage facilities</li> <li>Effective segregation of different materials particularly when stored on floors</li> <li>Cleanout procedures between different types of products</li> <li>Separate storage areas for feed and non-feed materials</li> </ul>	

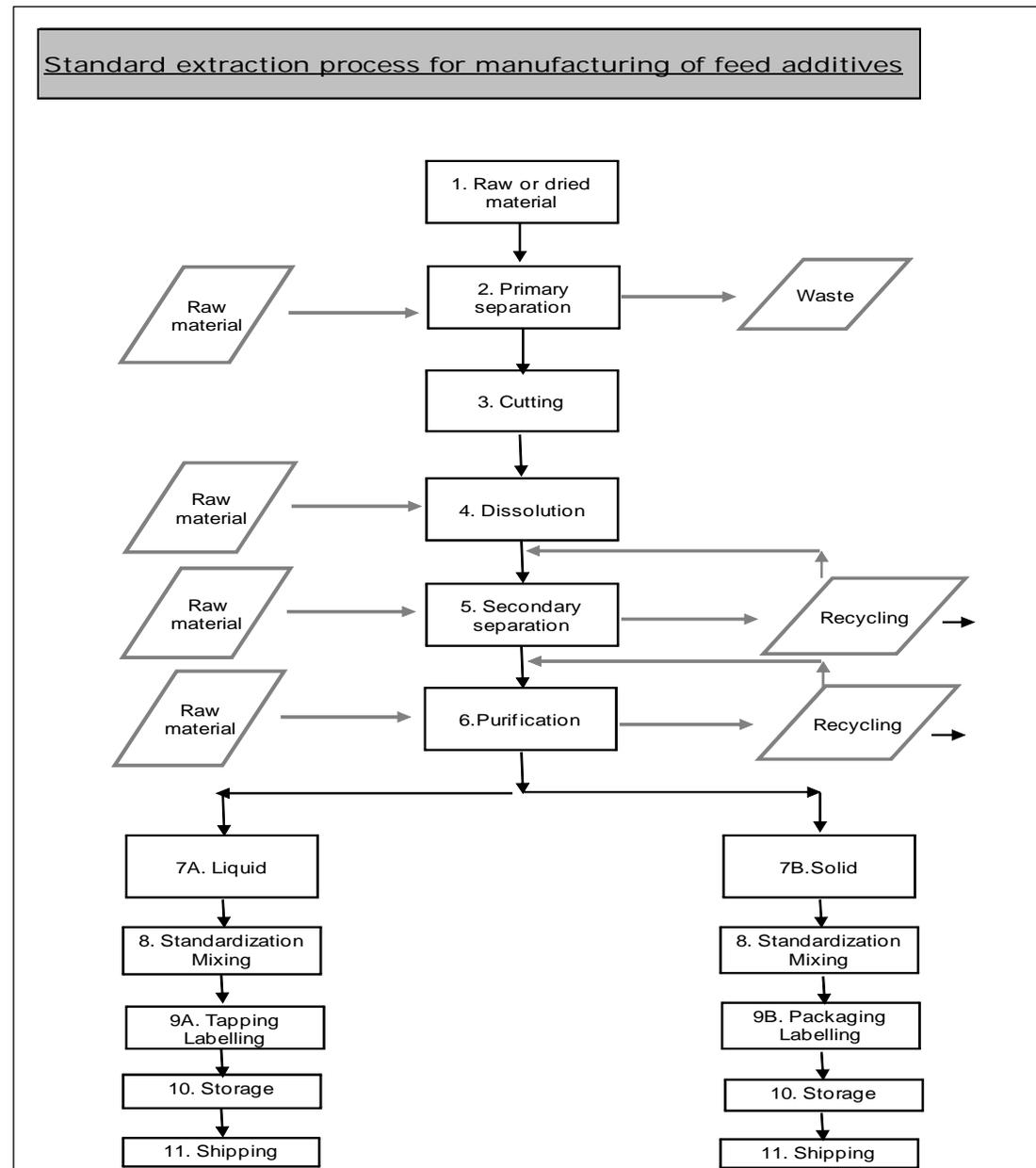
Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
		<b>fertilizers</b> Deterioration of the product due to poor stock rotation Products for different species and medicated and non-medicated feeds not adequately segregated		<ul style="list-style-type: none"> <li>• Proper stock rotation</li> <li>• Effective consolidation and sheeting of clamped forages</li> </ul>	
<b>8. Shipment of packed goods or in bulk</b>	Packed goods	Possible contamination with foreign materials, pests or other goods in case the packaging gets damaged	CBP	<ul style="list-style-type: none"> <li>• Contractual agreements with transporters</li> <li>• Inspection before loading /dedicated transport</li> <li>• Use only certified and registered transporters according the requirements</li> </ul>	
	Bulk shipment	Possible contamination by previous loads	CBP	<ul style="list-style-type: none"> <li>• Contractual agreements with transporters</li> <li>• Inspection before loading /dedicated transport</li> <li>• Info about previous load(s) and request for cleaning certificates</li> <li>• Use only certified and registered transporters according the requirements</li> </ul>	

**f) Risk assessment on an extraction process**

**Production characteristics**

Some thickening, colouring or flavouring additives may be produced from natural raw materials (botanical materials) by extraction methods, which mostly are executed either by aqueous solutions or by using organic solvents, or by a combination of both. The distinctive characteristics of such production methods are the combination of a series of dissolution and precipitation steps, pH adjustments, in order to refine and isolate the required molecule. The down-stream process(es) end with a drying step, followed by grinding and sieving, unless the final product is liquid.

Flow chart of process →



## HACCP Analysis

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
<b>1. Raw or dried material</b>	Control of the botanical material (e.g. seaweed) as input in the process	Possible contamination with undesirable and unwanted substances as well as foreign objects	CB	<ul style="list-style-type: none"> <li>Specification and testing with regard to parameters which were not removed during downstream process(es)</li> </ul>	
<b>2. Primary separation</b>	To remove foreign material and process interfering substances	The natural material may contain ions which may affect the downstream process(es) but may not act on feed safety	None	None	
<b>3. Cutting</b>	Process step to achieve an acceptable particle size to support efficient dissolution	None	None	None	
<b>4. Dissolution</b>	Step to produce a solution	None	None	None	
<b>5. Secondary separation</b>	Precipitation and filtration to remove cell debris. This step may include precipitation in organic solvents	None	None	None	
<b>6. Purification</b>	Purification may include a series of steps, e.g. removal of solvent, pH adjustment, ultra filtration, diafiltration, carbon filtration, chromatography	<p>Residues of solvents</p> <p>Growth of microbes if process time is prolonged and temperature is in the microbial optimal range</p>	CB	<ul style="list-style-type: none"> <li>Controlled downstream</li> </ul>	
<b>7A. Liquid</b>	Continue to step 8	None	None	None	

Process steps	Process description	Hazard description	Cat.	Suggestion of control and preventive measures	Remarks
<b>7B. Solid</b>	Several possible steps: <ul style="list-style-type: none"> <li>▪ Spray-drying</li> <li>▪ Granulation and sieving</li> <li>▪ Precipitation, drying, grinding and sieving</li> </ul>	<b>Possible contamination from equipment</b>	P	<ul style="list-style-type: none"> <li>• Metal-detector downstream</li> </ul>	
<b>8. Standardization and Mixing</b>	Addition of substances in order to achieve the expected concentration or viscosity	<b>Possible contamination from added materials or from process</b>	PCB	<ul style="list-style-type: none"> <li>• Metal-detector or screen installed down-stream</li> <li>• Final product specification, including residues of organic solvents and microbial testing</li> </ul>	
<b>9A. Tapping and Labelling</b>	Tapping process is almost closed and covered	<b>Very little possibility of contamination with foreign objects</b>	P	<ul style="list-style-type: none"> <li>• Sieves and/or strainers are installed to hold back foreign objects and the equipment is checked for possible contamination</li> </ul>	
<b>9B. Packaging and Labelling</b>	Packaging process is almost closed and covered	<b>Very little possibility of contamination with foreign objects</b>	P	<ul style="list-style-type: none"> <li>• Sieves and/or metal detector are installed to hold back foreign objects</li> </ul>	
<b>10. Storage</b>	Storage in closed containers	<p><b>If needed, control of temperature to prevent microbial growth</b></p> <p><b>It cannot be excluded that deterioration of products may introduce an unhealthy molecule</b></p>	<p>B</p> <p>C</p>	<ul style="list-style-type: none"> <li>• See general section</li> <li>• See general section</li> </ul>	
<b>11. Shipping</b>	Bulk transport of outgoing products as well as packed products	<b>Possible contamination from previous loads</b>	CBP	<ul style="list-style-type: none"> <li>• See general section</li> </ul>	

## Annex 2: GUIDANCE ON THE IMPLEMENTATION OF A COMPLAINT HANDLING SYSTEM

### Introduction:

This guidance provides assistance to describe and implement a complaint handling system including in the case of non-conforming products. It highlights key areas which have to be covered to achieve an effective and efficient procedure for handling complaints by feed additive and premixture operators.

Area	Suggested Action
<p><b>1.</b> Make information visible to the customers on how and where to complain.</p> <p>Publicise the system to encourage the customers to voice their dissatisfaction and to make the good intentions of the operator apparent.</p>	<p>Publicise your complaints procedure system <i>e.g.</i></p> <ul style="list-style-type: none"> <li>• on company invoices;</li> <li>• in use and care instructions;</li> <li>• on product packaging and labelling;</li> <li>• on company internet home page.</li> </ul> <p>Prepare a form for the complainant (customer) to submit the details required to handle the complaint adequately (see Annex A: Form for complaints).</p>
<p><b>2.</b> Collect and record complaints</p>	<p>File the forms</p>
<p><b>3.</b> Acknowledge the receipt of the complaint to the customer immediately on receipt</p>	<ul style="list-style-type: none"> <li>• If possible by phone or in person</li> <li>• By e-mail or post, but avoid impersonal standard letters.</li> </ul>
<p><b>4.</b> Assess the complaint for validity and evaluate the cause for further handling</p>	<p>Categorise according to <i>e.g.</i></p> <ul style="list-style-type: none"> <li>• severity;</li> <li>• environmental, health and safety risks;</li> <li>• complexity;</li> <li>• impact;</li> <li>• immediate/urgent action needed;</li> <li>• immediate/urgent action possible.</li> </ul>
<p><b>5.</b> Assign the complaint to the person who is the best to deal with it</p>	<p>Allocate the responsibilities for the handling and ensuring all complaints are dealt with</p>
<p><b>6.</b> Resolve as soon as possible or further investigate the complaint</p>	<p>Investigate and analyse all the relevant circumstances and information in an objective manner by getting all sides of the issues raised in the complaint.</p> <p>Keep records of all findings.</p>
<p><b>7.</b> Make a prompt decision about what to do</p>	<p>Adopt a customer-focused approach.</p> <p><i>e.g.</i> correct the problem and put in place measures to prevent it from happening again</p>

Area	Suggested Action
<b>8.</b> Communicate the decision to the customer and evaluate the response	
<b>9.</b> If the customer accepts the proposed decision carry out the action timely and effectively	Keep records of the outcome <i>e.g.</i> according to the example described in Annex A
<b>10.</b> If the customer rejects the proposed decision give alternative internal and external options of recourse	Keep records
<b>11.</b> Monitor the progress of the complaint	Until all reasonable internal and external options of recourse are exhausted or the complainant is satisfied
<b>12.</b> Close the complaint	
<b>13.</b> Review complaints regularly Define the responsibility for review	A brief review <i>e.g.</i> each month helps to act upon any obvious issues that could be changed immediately  A more detailed annual review helps to identify any trends and thus to implement ongoing improvements of the product quality
<b>14.</b> Establish and implement an action plan for complaint prevention	Summarise corrective actions

Annex A: Form for complaints

**Annex A: Form for complaints**

Part 1: Information from the complainant

<b>1. Details of complainant</b>	
Name / Organisation	_____
Address	_____
Postal code, town	_____
Country	_____
Phone No.	_____
Fax No.	_____
E-Mail	_____
Details of person acting on behalf of complainant (if applicable)	
Person to be contacted (if different from above)	_____
<b>2. Product description</b>	
Reference number of product/order (if known)	_____
Description	_____
<b>3. Problem encountered</b>	
Date of occurrence	_____
Description	_____
<b>4. Remedy requested</b>	
yes <input type="checkbox"/>	no <input type="checkbox"/>
<b>5. Date, signature</b>	
Date	Signature
<b>6. Enclosure</b>	
List of enclosed documents	

Part 2: Complaint follow-up

<b>1. Details of complaint receipt</b>			
Date of complaint _____			
Name of recipient _____			
Complaint medium    phone <input type="checkbox"/> e-mail <input type="checkbox"/> internet <input type="checkbox"/> personally <input type="checkbox"/> postal mail <input type="checkbox"/> other <input type="checkbox"/>			
Reference number of complaint _____			
<b>2. Problem encountered</b>			
Date of problem _____			
Recurrent problem    yes <input type="checkbox"/> no <input type="checkbox"/>			
Problem category _____			
_____			
<b>3. Complaint assessment</b>			
Severity _____			
_____			
Complexity _____			
_____			
Impact _____			
_____			
Need for immediate action                  yes <input type="checkbox"/> no <input type="checkbox"/>			
Availability of immediate action                  yes <input type="checkbox"/> no <input type="checkbox"/>			
Likelihood of compensation                  yes <input type="checkbox"/> no <input type="checkbox"/>			
<b>4. Complaint resolution</b>			
Remedy requested                                  yes <input type="checkbox"/> no <input type="checkbox"/>			
Action to be taken _____			
_____			
<b>5. Tracking complaint</b>			
Action taken	Date	Name	Remarks
Complaint acknowledged to complainant			
Complaint assessment			
Investigation of complaint			

Information to complainant			
Correction			
Correction verified			
Complaint closed			

### **Annex 3: GUIDANCE ON TRANSPORT**

The transporter is responsible for maintaining product integrity during transportation.

The transporter should apply HACCP principles.

#### **Transport of packaged goods**

The chosen transport vehicle shall be designed to protect the packaged goods against adverse effects (*e.g.* humidity, scratches in package).

The transporter must implement preventive actions to avoid any risk of cross contamination with impurities coming from other goods loaded on the same vehicle at the same time or in a previous loading.

#### **Transport of bulk products**

The transporter will ensure that the container:

- can be effectively cleaned and maintained to avoid contamination of the feed. This applies in particular to materials and surfaces which come into direct contact with feed;
- is in good technical condition;
- is appropriate for the intended use and function;

When transport requirements are changed, the transporter must ensure that:

- relevant documents are amended;
- relevant persons including the operator's representative are made aware of the changes made and possibly associated requirements.

In case of subcontracted activities (*e.g.* cleaning, transport), the transporter must manage and communicate all applicable requirements in chapter 6.1 to the subcontractor(s).

Driver responsibility: The driver in charge of transport should:

- be aware of her/his responsibility in terms of product preservation during cleaning, loading, transport and unloading activities;
- if necessary, take preventive actions to avoid any kind of contamination during cleaning, loading, transport and unloading activities;
- inform the operator as agreed, directly or via own organization, of any non-conformity that could compromise the safety of the goods;

#### Contents/containers traceability

For each delivery the transporter should:

- record the loaded product information including associated container identification as well as any associated cleaning operations;
- keep the recorded information available for an appropriate period of time.

Before loading takes place, the container must be:

- empty;
- clean;
- odourless;
- dry (especially where solid or powdery product(s) is/are to be loaded);
- sealed / covered.

The discharge equipment must be clean, and this includes piping, hoses and pumps on vehicles where applicable.

### **Cleaning principles**

Four basic principles can be distinguished with respect to cleaning and disinfection. The choice of a minimum necessary cleaning regime is established on the basis of the characteristics of the previous product. If the loading compartment is not clean after the chosen cleaning regime, additional cleaning should take place and the choice of cleaning regime shall be reconsidered.

The four basic principles for cleaning are:

- A. Dry cleaning
- B. Cleaning with water
- C. Cleaning with water and cleansing agent
- D. Disinfection immediately or after one of the previous cleaning regimes (A, B or C)

#### A. Dry cleaning

In the case of transport of dry 'neutral' substances only, dry cleaning may be sufficient and beneficial both practically and microbiologically.

The general cleaning regime could be as follows:

- a. clean the means of transport by extraction, blowing out or sweeping;
- b. manually clean places which are difficult to reach;
- c. if there are still some dirt remaining after dry cleaning then use some wet cleaning.

In dry cleaning the preference is for suction cleaning as there is unlikely to be dust building up with hid cleaning method.

#### B. Cleaning with water

Cleaning with water is necessary after transport of, for instance, damp or sticky substances or possibly harmful chemicals.

The general cleaning regime could be as follows:

Dry-clean to remove as much residues from the previous load as possible

- a. pre-rinse with cold water, or warm water if necessary;
- b. manually clean hard to reach places if necessary;
- c. high-pressure clean with water;
- d. dry through ventilation and hot air dryer.

If chemicals need to be removed, warm water should be used at a temperature of at least 60°C, to dissolve the chemicals more easily. Places that are difficult to reach should, if necessary, be cleaned separately with additional means such as brushes. It is important that the water can be drained afterwards.

### C. Cleaning with water and cleansing agent

The general cleaning regime is as follows:

Dry-clean to remove as much residues from the previous load as as possible

- a. pre-rinse with hot water (max. 60 °C) and clean difficult places manually/by hand;
- b. use foam or gel with a cleaning agent for tippers open wagons or flush with CIP cleaning agent at 80 °C in the event of tank cleaning;
- c. rinse with water at approx. 60°C;
- d. if necessary, dry through ventilation and or hot air dryer.

If chemicals need to be removed, warm water should be used at a temperature of at least 60°C, to dissolve the chemicals more easily. Places that are difficult to reach should if necessary be cleaned separately with additional means such as brushes. It is important that the water can be drained afterwards.

Advice about cleaning regime C: A raised water temperature is required to remove fats more easily. This may however not be higher than 60°C to prevent the protein from coagulating and thereby sticking to surfaces. To facilitate the removal of protein and greases it is advisable to use a medium to strong alkaline cleansing agent, using the dosage prescribed/recommended by the manufacturer.

In open systems, it is best to use a foaming degreasing agent. In the case of cleaning of a tank with spray balls, no foaming agents may be used. It is then better to use a so-called Cleaning in Place (CIP) agent at a high temperature. In specific cases, such as the removal of calcareous substances, an acid cleansing agent may be preferable.

### D. Cleaning with water, cleansing agent and disinfection

Dis-infection is only necessary if preceding loads are microbiologically compromised (detectable signs of decay), or if it is known that they could have harboured micro-organisms that cause disease, such as Salmonella.

The general cleaning regime could be as follows:

- a) cleaning in accordance with cleaning regime A, B or C;

- b) dis-infection with a legally-permitted disinfectant (approved for the foodstuff industry) at a dosage indicated in the instructions for use;
- c) If necessary, wet rinsing should be employed;
- d) if necessary, drying should be through ventilation or hot air dryer.

*Advice about cleaning regime D:* Another form of disinfection (*e.g.* dry) may only be applied if its effectiveness has been established. A distinction can be made between disinfectants tested for bactericidal and fungicidal effect and those tested for bactericidal, fungicidal and virucidal effect. The latter may only be used in the livestock sector. For animal feed transport vehicles, use of a disinfectant approved for the food industry is the only other alternative.

Use of a combined cleansing and disinfecting agent containing active chlorine is only possible on smooth surfaces that are easy to clean, such as stainless steel. In all other cases, it is advisable to clean first and then disinfect afterwards, in which case, for the disinfection of open vehicles, disinfectants containing active chlorine are advised.

In some cases, it is not advisable to use a cleaning agent containing chlorine, such as for materials which corrode easily or after an acid cleansing due to the possibility for toxic chlorine gases to be formed. In this case quaternary ammonium compounds may be used.

For closed tankers, the use of acetic acid can be considered. Its advantage is that it is less reactive than chlorine. The penetrating odour and the harm it does to rubber are the disadvantage of using the acid.

Disinfectants must be given at least five minutes to take effect.

The food industry prescribes rinsing after disinfecting. In order to avoid the risk of residues, it is advisable to apply this to transport vehicles as well, unless it can be demonstrated that residues do not constitute a risk. In some cases, removing the disinfectant can lead to the development of surviving bacteria if the surface remains wet for too long.

After cleaning loads containing animal proteins, a check may be carried out for residues of components of animal origin in animal feeds according to the microscopic screening methods laid down in Directive 98/88/EC.

Other additional checks should be carried out to assess the effectiveness of the cleaning and/or disinfection method used. In order to assess the cleaning, ATP (Adenosine Tri Phosphate) measurements can be made. ATP is present in all animal and vegetable cells and can thus be used as an indicator for the extent of biological contamination left on surfaces. The ATP measurement itself is very easy and can yield a result within minutes.

The application of ATP is not useful in most cases of transport of chemicals. In order to verify the effectiveness of a particular disinfection technique in use, agar stamps can be used, which can determine the numbers of surviving micro-organisms.

This technique takes a day to produce results, which means that any necessary adjustments to the disinfection process can only be made afterwards.

More advanced methods may be used for checking on chemical residues and pesticides such as HPLC and Mass Spectrometry (MS).

## Annex 4: GUIDANCE ON HOMOGENEITY

### Introduction:

A homogenous mix is attained when all of the ingredients in a product are present, in the same ratios they were added, throughout the product. This is an important concept as a processing run that is not homogeneous may result in an overdose of additives in some instances and an under-dose in others, both of which can be dangerous to animals and the consumer.

To prevent ingredient segregation account must be taken of

- the particle size, shape and distribution;
- the design of the process line including extraction points and air lines;
- mixing time, overfill or apparatus failing to move ingredients through the mixing area such as gaps between mixing paddles and the mixer wall.

The above problems are all commonly found in most processes. Common areas where they occur are:

- equipment vibration;
- electrostatic hang up;
- changes in air pressure;
- free fall through or from equipment;
- angle of repose, funnelling;
- dust collection points.

Ways to overcome these problems:

- use ingredients with a uniform particle size and density;
- training to ensure there is no overfilling, good accuracy at addition points, weighing, calibrations, *etc*;
- adjustment of paddles to operate as close to mixer walls as possible and replacement of worn parts;
- changing the addition rates to re-blend fine ingredients and moving the addition point as close to the mixer as possible;
- reduce possibilities for further segregation between processing and packaging.

How to test for segregation:

- repeatedly sample the additive at the point of packaging;
- test for chemical characteristics that should be exhibited when well mixed (tracers can be used);
- the co-efficient of variation of samples should be less than 5%.

This is an example of a procedure that can be used to determine the efficacy of blending to ensure all ingredients are uniformly distributed.

Procedure:

	Instruction
1.	Determine the product to be tested. Use a product that has an ingredient that can be tested with a high degree of accuracy. Tracers such as Zn or Mn can be used.
2.	Take and test retention samples of each raw material before production commences.
3.	Mix the raw materials in accordance with normal procedure.
4.	When the mixing is completed and packaged (but not sealed) samples should be taken from throughout the batch to check for consistency. A sample must be taken from the first bag of product made and regularly thereafter.
5.	Each retention sample must be tested for the active ingredients and results recorded.
6.	The efficacy of the mixing process should be determined by calculating the standard deviation and coefficient of variation of the results.
7.	Records of testing should be maintained in accordance with documented procedures.

CALCULATION OF STANDARD DEVIATION:

The formula for calculating standard deviation is:

$$\sigma = \sqrt{\frac{\sum(x - \bar{x})^2}{n - 1}}$$

$\sigma$  = lower case sigma

$\Sigma$  = capital sigma

–

$\bar{x}$  = x bar

Lower case sigma = ‘standard deviation’

Capital sigma = ‘the sum of’

x bar = ‘the mean’

‘n’ = number of values

To calculate the Standard Deviation of a group of results, for example, 4, 9, 11, 12, 17, 5, 8, 12, 14:

$$\begin{aligned}
 1. \text{ Calculate the mean: } & \frac{(4 + 9 + 11 + 12 + 17 + 5 + 8 + 12 + 14)}{9} \\
 & = \frac{92}{9} \\
 & = 10.222
 \end{aligned}$$

2. Subtract the mean individually from each result and square the result.

x	4	9	11	12	17	5	8	12	14
$(x - \bar{x})^2$	38.7	1.49	0.60	3.16	45.9	27.3	4.94	3.16	14.3

3. Add the results in step 2.

$$\sum(x - \bar{x})^2 = 139.55$$

4. Divide by n-1.

$$\sigma = \frac{\sum(x - \bar{x})^2}{n - 1} = \frac{139.55}{8}$$

$$\sigma = 17.44$$

5. Square root:

$$\sigma = \sqrt{\frac{\sum(x - \bar{x})^2}{n - 1}} = 4.18$$

#### CALCULATION OF CO-EFFICIENT OF VARIATION:

1. Co-efficient of variation (CV) is the standard deviation expressed as a percentage of the mean.

In this example CV = 40%

As a guide, a CV of less than 5% is desirable with respect to homogeneity of additive mixes. Operators should establish an acceptable limit for CV based on scientific research and in consideration of specific mixers (refer to HACCP Principles).

## Annex 5: GUIDANCE ON CARRY-OVER

Carry-over is the contamination of a product with another material or product that originates from previous use of the same equipment.

Carry-over has to be controlled during the production process in order to minimize and avoiding it occurring, until an acceptable level of carry-over is reached. The operator should follow documented procedures and actions that have been taken to prevent carry-over.

In order to prevent carry-over, special attention should be paid to the following:

- Transport (contamination with previous cargoes)
- Dosage
- Transport through the circuits within the factory
- Mixing
- Delayed dust return
- Electrostatic hang up
- Residue in equipment lines, walls, moving parts
- Leaking valves/gates
- Poor cleaning/flushing
- Preparation and storage

Operators must ensure that formal systems are in place to minimize the risk of carry-over of feed additives and premixtures between them and/or with other products. Operators are required to take measures to avoid this carry-over by providing, among others:

- thorough and complete cleaning of all equipment used between batches;
- use of suitable sequencing and flushing techniques to prevent traces of restricted material entering the production line; and
- use of separate dedicated storage bins to store stock feed additives and premixtures, and to label each bin.

The operator should also be able to provide written procedures specifying:

- Control of the carry-over critical points;
- Sampling and analytical results;
- Cleaning of the equipment when changing to a product with different characteristics from the product previously manufactured;
- Verification of the adequate maintenance and cleaning of the equipment (verification of the mixer total opening, verification of the cleaning program, *etc.*);
- Record the corrective measures taken, including their efficiency, in order to prevent or eliminate carry-over.

### Practical example:

Carry-over of batches must be addressed via your HACCP program.

Where process lines may sometimes carry non-EU authorised products, this process must be used to demonstrate that there is no carry-over of this unapproved material into EU destined products.

Procedure:

	Instruction
<b>1.</b>	Determine product to be tested. Use a product that has a low inclusion rate of an ingredient that can be tested with a high degree of accuracy. Tracers such as Zn or Mn can be used.
<b>2.</b>	Retain samples of all raw materials to be used in the test.
<b>3.</b>	Batch A containing the selected active raw material/tracer, must be produced in accordance with normal production procedures.
<b>4.</b>	A sample of Batch A must be tested and retained.
<b>5.</b>	If a flush takes place between Batches A and B, samples of the flush material should be taken from the very beginning and end of the flush.
<b>6.</b>	When Batch B is completely mixed and packaged (but not sealed) representative samples should be removed from the batch. A sample must be taken from the first 25kg of product made.
<b>7.</b>	All samples (including samples of flush materials) must be tested in accordance with prescribed procedures.
<b>8.</b>	Batch B should not contain levels of the active ingredient contained in Batch A to an extent that it poses a risk to the end user. (Apply your HACCP principles!).
<b>9.</b>	Records of testing should be maintained in accordance with documented procedures

## Annex 6: GUIDANCE ON SAMPLING

### Introduction/General considerations

The sampling procedure must be adapted to the intended purpose, to the type of controls intended to be applied to the samples, and to the material to be sampled. The procedure should be described in writing. All operation related to sampling should be performed with care, using proper equipment and tools. Any contamination of the sample by dust or other foreign material is liable to jeopardize the validity of the subsequent analyses.

### Definitions specific to this annex

**Consignment:** A specified quantity of finished product or raw material; dispatched or received at one time. (Edited from EN ISO 6497:2005)

**Sampled Portion:** A quantity of product constituting a unit, and having characteristics presumed to be uniform, (Regulation (EC) No 152/2009), for example a Lot of finished product.

**Incremental sample:** A quantity taken from one point in the sampled portion (Regulation (EC) No 152/2009)

**Aggregate sample:** An aggregate of incremental samples taken from the same sampled portion (Regulation (EC) No 152/2009)

#### **1. Purpose of sampling**

Sampling may be required for different purposes such as: acceptance of consignments, batch release testing, in-process-control, special controls, deterioration, adulteration, obtaining retention sample, *etc.*

#### **2. Sampling facilities**

Where possible, sampling should be performed in a defined area. Sampling from large containers of starting material or bulk products can present difficulties. Whenever possible this work should be carried out within the warehouse in order to reduce the risk of contamination by dust of either the sample or the remaining material in the container, or cross-contamination.

#### **3. Qualification of the sampler**

Everyone called upon to take samples should be trained in the practical aspects of sampling and should have sufficient knowledge of the materials or products to execute the work effectively and safely. A conscientious approach, with meticulous attention to detail and cleanliness, is essential. The sampler must remain alert to any signs of contamination, deterioration or tampering.

#### **4. Health and safety**

It is the responsibility of the sampler to read the relevant health and safety information i.e. Material Safety Data Sheet before sampling the material or product. The information must include necessary safety precautions and requirements for both the sampler and the environment. The sampler must wear appropriate protective clothing for the task.

#### **5. Sampling process:**

For the sampling of products the sampler should have at his/her disposal all the tools needed to open the packages, barrels, containers, *etc.* and material to re-close the packages as well as labels to indicate that a part of the contents has been removed from the package or container. Cleaning of containers due to be sampled should be performed prior to sampling if necessary. All tools and implements should be made of inert materials and kept clean. After use, or before re-use, they should be thoroughly washed, rinsed and dried. They must be stored in clean condition. The use of disposable sampling materials has distinct advantages.

#### **6. Examples of apparatus for manual sampling of solid feedingstuffs**

Flat-bottomed shovel with vertical sides (Regulation (EC) No 152/2009)

Sampling spear with a long split or compartments. The dimensions of the sampling spear must be appropriate to the characteristics of the sampled portion (depth of container, dimensions of sack, *etc.*) and to the particle size of the feed (Regulation (EC) No 152/2009)

#### **7. Examples of apparatus for mechanical sampling of solid feedingstuffs**

Approved mechanical apparatus may be used for the sampling of moving feedingstuffs, for example pneumatic apparatus (EN ISO 6497:2005)

Sampling of products in motion at high flow rates can be performed by machines with manual control (EN ISO 6497:2005)

#### **8. Examples of apparatus for sampling solid liquid or semi-liquid feedingstuffs by manual or mechanical means**

Agitator, sampling bottle, zone sampler and dipper, of an appropriate size (EN ISO 6497:2005)

#### **9. Sampling operation and precautions**

The sampling procedure should be such that any non-uniformity of the material can be detected. Signs of non-uniformity include differences in shape, size or color of particles in crystalline, granular, or powdered solid substances, moist crusts on hygroscopic substances, deposits of solid material or stratification in liquid products. Such changes, some of which may be readily reversible, can occur during prolonged storage or exposure to extreme temperatures during transportation. Non-homogeneous portions of the material should be sampled separately from the rest of the material that has a normal appearance. Compositing of the samples from the different portions in this case should be avoided, since it can mask quality problems.

Labelling of samples should indicate appropriate details such as product name or identification code, batch number, quantity, date of sampling, storage conditions, handling precautions, container number, *etc.* Labels should be applied at the time of sampling.

#### **10. Storage and retention**

The container used to store the sample should not interact with the sampled material nor allow contamination. It should also protect the sample from light, air, moisture *etc.* as required by the storage conditions. Any headspace should be kept to a minimum in case of any degradation through oxidation. Adequate storage conditions must be ensured for the rooms where samples are stored. Samples should be retained for the shelf life of the material as a minimum.

#### **11. Raw materials**

Sampling on receipt (for acceptance):

If the material of a consignment can be regarded as uniform the sample can be taken from any part of the consignment. If, however, the material is not physically uniform special sampling tools may be required to withdraw a cross-sectional portion of the material. In some instances, however, an attempt can be made to restore the uniformity of the material before sampling, based on information concerning the subsequent handling and manufacturing steps. Thus, a stratified liquid may be stirred, or a solid deposit in a liquid may be dissolved by gentle warming and stirring. Such interventions should not be attempted without adequate knowledge of the properties of the contents and appropriate discussions with owner of the goods.

All partially processed natural products should be treated as intrinsically non-uniform. Special procedures requiring considerable practice are used to prepare representative samples from such consignments.

In relation to the control of undesirable substances or products likely to be distributed non-uniformly throughout the feedingstuff, such as aflatoxins, rye ergot, *etc.*, a number of aggregate samples should be compiled throughout the batch taking care to mix thoroughly and note the origin of each aggregate sample. The quantity of aggregate samples should vary with the size of the batch, degree of confidence in the product source and likelihood of contamination in line with the product risk analysis.

## **12. Sampling plans for finished product and raw materials**

The quantity, frequency and location of sampling should be based on the criteria below and a statistical approach may be followed where deemed appropriate. Examples of statistical plans are given in section 13.

- expected uniformity of the material;
- parameters to be tested;
- packaging unit size or volume;
- confidence in the product source;
- manufacturing processes employed;
- product risk analysis.

## **13. EXAMPLE: Statistical sampling plans for raw materials and finished products:**

### **The n-plan (Assuming a uniform material from a recognized source where there is a high degree of confidence in the source) \***

Samples can be withdrawn from any part of the container; usually from the top layer. The n-plan is based on the formula  $n = \sqrt{N} + 1$ , where N is the number of sampling units in the consignment. The value of n is rounded up to the next higher integer. According to this plan samples are taken from n sampling units selected at random and these are subsequently placed in separate sample containers. The control laboratory inspects the appearance of the material and tests the identity of each original sample according to the relevant specification. If the results are concordant the original samples are pooled into a final sample from which the analytical sample is prepared, the remaining part being kept as a retention sample.

**The p-plan (Assuming a uniform material from a recognized source with the main purpose to check identity) \***

The p-plan is based on the formula  $p = 0.4\sqrt{N}$ , where N is the number of sampling units. According to this plan samples are taken from each of the N sampling units of the consignment and placed in separate sample containers. These original samples are visually inspected and tested for identity by a simplified method. If the results are concordant, p final samples are conformed by pooling of the original samples.

**The r-plan (Assuming the material is non-uniform and/or from a source that is not well known) \***

The r-plan is based on the formula  $r = 1.5\sqrt{N}$ , where N is the number of sampling units. Samples are taken from each of the N sampling units of the consignment and placed in separate sample containers. These original samples are transferred to the control laboratory and tested for identity. If the results are concordant r samples are randomly selected and individually subjected to testing. If the results are concordant, the r samples are pooled for the retention sample.

*\* Source of the statistical plans: 'WHO GUIDELINE FOR SAMPLING OF PHARMACEUTICALS AND RELATED MATERIALS'*

## **Annex 7: GUIDANCE ON BIOLOGICAL HAZARDS**

The website of the Panel on biological hazards (BIOHAZ) of the European Food Safety Authority gives useful information on biological hazards:

[http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa\\_locale-1178620753812\\_BIOHAZ.htm](http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa_locale-1178620753812_BIOHAZ.htm).

## **Annex 8: GUIDANCE ON COMPLIANCE WITH THE EU LEGISLATION ON FEED ADDITIVES AND PREMIXTURES FOR PRODUCT REALISATION**

### **Introduction**

This guidance provides assistance in order to assure compliance of the products with the EU legislation as generally required under the FAMI-QS Code:

- Section 6.1 Product requirements
- Section 6.1.1 Determination of requirements related to the product
- Section 6.1.2 Compliance of the product to the requirements
- Section 6.4.1 Sourcing of incoming materials

This document highlights the aspects that have to be covered in order to achieve compliance with statutory and regulatory requirements related to the products as well as to the establishments.

It is important to notice that definitions are found in relevant legislative documents and must be understood before working with this guidance. A collection of the most important definitions are also found in the FAMI-QS Code of Practice.

In some countries, some specific statutory or regulatory requirements may apply in addition to the EU ones, but this is expected to be rather limited as legislation across the Community on the feed additives and premixtures is highly harmonised.

### **1. Products**

In the European Union the placing on the market of feed additives and premixtures is ruled by Regulation (EC) No 1831/2003. The coverage of the FAMI-QS Code is restricted to the additives and premixtures (as defined in Art. 2 of Regulation (EC) No 1831/2003) that are allowed to be placed on the EU market.

#### **1.1. Authorised feed additives**

Only additives that have been duly authorised by the European Commission and included in the Register mentioned in Article 17 of Regulation (EC) No 1831/2003, can be placed on the EU market.

In addition to the inclusion in the Register mentioned, additives should meet the requirements concerning:

- definition;
- specifications and purity criteria;
- labelling requirements; and
- conditions of use that are defined in the authorisation of the additive:
  - category and functional group of the additive;
  - animal categories for which the additive is authorised, and

- use levels

These have to be considered as requirements at the level of the operator.

Although Regulation (EC) No 1831/2003 is in force, the additive legislation is in practice currently in a transitory phase between requirements in Directive 70/524/EEC and Regulation (EC) No 1831/2003. Therefore some or all of the information mentioned above may not yet already be in the Register. It is intended that these outstanding information in the Register shall progressively be completed as soon as the re-authorisation process commences, and at latest by November 2010.

The Community Register of Feed Additives is available at the following address:

[http://europa.eu.int/comm/food/food/animalnutrition/feedadditives/registeradditives\\_en.htm](http://europa.eu.int/comm/food/food/animalnutrition/feedadditives/registeradditives_en.htm)

The operator shall ensure and document through a list of additives manufactured, held or managed on the premises, that the additives covered under the FAMI-QS process are only those authorised in the EU. This shall also imply regular update of the said list in order to adapt it to the evolution of the entries in the Register and so the requirements concerning the product such as those listed above including *e.g.* more precise definition of the additive, change of specifications, *etc.*

The applicant for an authorisation or his representative shall be established in the Community.

### **1.2. Premixtures**

According to Regulation (EC) No 1831/2003, premixtures of additives do not require specific product authorisation. They can be manufactured and placed on the market, provided they only contain additives duly authorised, and carriers that comply with the EU legislation. The operator shall document that he/she complies with these requirements.

## **2. Undesirable substances**

Beside the criteria included in the authorisation of an additive under Regulation (EC) No 1831/2003, some additives are also covered by the provisions of Directive 2002/32/EC on undesirable substances. The operator shall document the relevance or non-relevance of these requirements and, as the case may be, document compliance. This evaluation shall be included in the HACCP analysis.

## **3. Products intended for export**

An operator may manufacture and hold products that are not in compliance with the EU requirements and not intended for the EU feed market, but for export only. In that case, the operator shall maintain a list of those products that are not intended for the EU market, or intended for other applications.

## **4. Products intended for import**

Products manufactured by any EU Member State can freely be transferred from one state to another, provided they comply with Community legislation.

In accordance with Regulation (EC) No 183/2005, an operator may import products from third countries provided that:

- the third country appears on a list, drawn up in accordance with Article 48 of Regulation (EC) No 882/2004;
- the establishment of dispatch appears on a list, drawn up and maintained by the third country in accordance with Article 48 of Regulation (EC) No 882/2004;
- the feed was produced by the establishment of dispatch or by another establishment appearing on the list mentioned above;
- the feed satisfies the requirements laid down in Community legislation, or those conditions recognised by the Community to be at least equivalent thereto, or the conditions specified in a specific agreement between the Community and the exporting country.

Due to some interim measures still in place, all and or some of the above may not apply provided that:

- the establishments in the third countries have a representatives established within the Community;
- the representatives have submitted to the competent authority in the relevant Member State where they are located:
  - a declaration which certifies that the establishment in the third country fulfils the conditions laid down in the current Feed Hygiene Regulation (EC) No 183/2005.
  - And if the representative is exercising this activity for the first time, the said declaration accompanied by a commitment to maintain a register of the imported products.

## 5. Authorised operators

The Regulation (EC) No 183/2005 on feed hygiene requires most feed business establishments to be approved or registered prior to the placing on the market of their products.

All additive or premixture operators covered by one or more of the regimes as described below should document that they are duly approved and or registered.

**5.1. Activities requiring approval of the establishment:**

Categories	Functional Groups	Products
<b><i>Manufacture and/or placing on the market of additives re. Regulation 1831/2003/EC</i></b>		
Nutritional additives	(a)	Vitamins, pro-vitamins and chemically defined substances having a similar effect
	(b)	Compounds of trace elements
	(c)	Amino acids, their salts and analogues
	(d)	Urea and its derivatives
Zootechnical additives	(a)	Digestibility enhancers: substances which, when fed to animals, increase the digestibility of the diet, through action on target feed materials
	(b)	Gut flora stabilisers: micro-organisms or other chemically defined substances, when fed to animals, have a positive effect on the gut flora
	(c)	Substances which favourably affect the environment
	(d)	Other zootechnical additives
Technological additives	(b)	Antioxidants with a fixed maximum content in feed only, like propyl gallate, octyl gallate, dodecyl gallate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), ethoxyquin
Sensory additives	(a)	Colourants: carotenoids and xanthophylls only
<b><i>Manufacture and/or placing on the market of products re. Directive 82/471/EEC</i></b>		
Proteins	-	Proteins obtained from micro-organisms belonging to the group of bacteria, yeasts, algae, lower fungi: all products in the group (except for subgroup 1.2.1 of Directive 82/471/EEC)
Co-products	-	Co-products of the manufacture of amino acids by fermentation
<b><i>Manufacture and/or placing on the market of premixtures containing certain additives</i></b>		
Nutritional additives	(a)	Vitamins, pro-vitamins and chemically defined substances having a similar effect
	(b)	Compounds of trace elements
Zootechnical additives	(d)	Other zootechnical additives: antibiotics, coccidiostats and histomonostats, growth promoters

## 5.2. Activities requiring registration of the establishment:

Categories	Functional Groups	Products
<b><i>Manufacture and/or placing on the market of additives re Regulation 1831/2003/EC</i></b>		
Technological additives	(a)	Preservatives
	(b)	Other antioxidants not subject to maximum permitted levels
	(c)	Emulsifiers
	(d)	Stabilisers
	(e)	Thickeners
	(f)	Gelling agents
	(g)	Binders
	(h)	Substances for control of radionucleide contamination: Substances that suppress absorption of radionucleides or promote their excretion
	(i)	Anti-caking agents
	(j)	Acidity regulators
	(k)	Silage agents
Sensory additives	(l)	Denaturants: Substances which, when used for manufacture of processed feedingstuffs, allow the identification of the origin of specific food or feed material
	(a)	Colourants other than carotenoids and xanthophylls
	(b)	Flavouring compounds
<b><i>Manufacture and/or placing on the market of products re. Directive 82/471/EEC</i></b>		
Bio-proteins ('certain products') not subject to approval		Urea and its salts, ammonium salts, amino acids and their salts, analogues of amino acids
<b><i>Premixtures containing certain additives</i></b>		
Categories not requiring approvals	Any functional group	Premixtures containing any feed additive, excluding <ul style="list-style-type: none"> <li>- vitamin A and D</li> <li>- copper and selenium</li> </ul>

## 6. Labelling

Regulation (EC) No 1831/2003 on additives for use in animal nutrition (and in general terms article 16 of Regulation (EC) No 178/2002) lays down the rules for the labelling of feed additives and premixtures. Labelling provisions are described in Article 16 of this Regulation 1831/2003/EC.

### References:

Some EU legislation (as amended) considered while putting together this guidance:

- Regulation 1831/2003/EC Regulation laying down requirements for feed hygiene
- Regulation 882/2004/EC Regulation on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
- Regulation 1831/2003/EC Regulation on additives for use in animal nutrition
- Regulation 178/2002/EC Regulation laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
- Directive 2002/32/EC Directive on undesirable substances in animal feed
- Directive 98/88/EC Directive establishing guidelines for the microscopic identification and estimation of constituents of animal origin for the official control of feedingstuffs
- Directive 82/471/EEC Directive concerning certain products used in animal nutrition
- Directive 70/524/EEC Directive concerning additives in feedingstuffs
- Regulation 152/2009/EC Regulation laying down the methods of sampling and analysis for the official control of feed

## **Annex 9: GUIDANCE ON PRODUCT RECALL AND CRISIS MANAGEMENT**

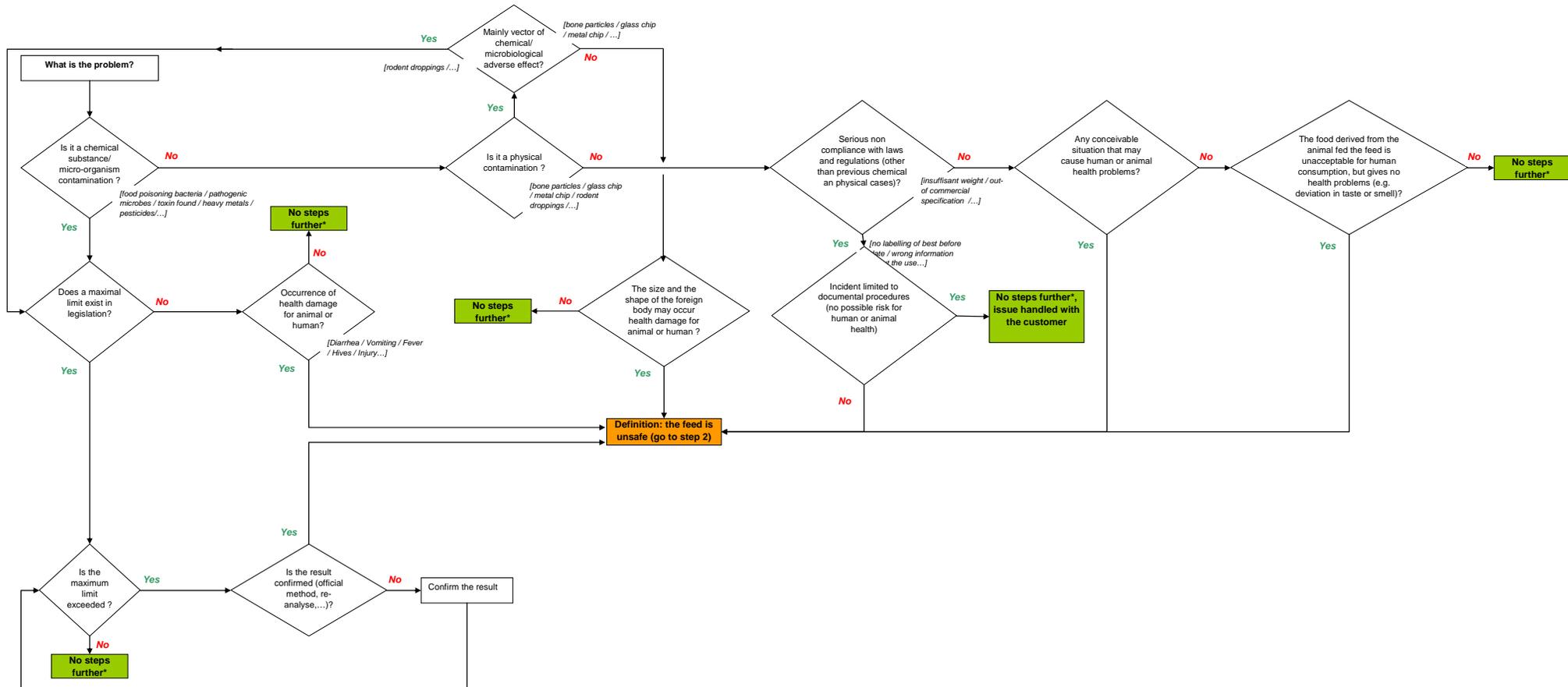
### **Introduction**

This section of the guidance outlines the elements of a product recall plan and the actions to take when unsafe feed additives and premixtures must be removed from the feed and/or food chain in the event of a crisis.

The objective of this guidance is to protect public health by informing authorities and consumers (when necessary) of the presence on the market of potentially hazardous feed additives and premixtures, and to facilitate a rapid identification and removal of these products from the production and distribution chain.

As an example only, please find below a flowchart that might help you establish an action plan in case you suspect an unsafe feed has been placed on the market.

Step 1: Use the crisis tree to decide whether the feed is unsafe



**Step 2: Define the status of the product**

The following definitions are relevant:

- a. The defined amount of the product is no longer under the control of the operator through:
  - being held at distributors with a view to sale;
  - being used by a customer;
  - being held at a customer with a view to use; or
  - being transported and complete control is questionable.
- b. The defined amount is still under complete control of the operator by either
  - having not left the operator’s premises;
  - being transported but complete control is manageable.

**Step 3: What to do**

According to Article 20 of Regulation (EC) No 178/2002, laying down the general principles and requirements of food law, it is the responsibility of the feed business operators to take the immediate and necessary actions in order to prevent a feed safety crisis to spread.

Depending on the status of the product: a or b (step 2)

Follow the steps marked with X in the sequence up-down.

Steps marked with -- do not need to be followed.

<b>Status of the product:</b>	<i>a</i>	<i>b</i>
Segregate existing stock	X	X
Initiate a recall process	X	X
Inform the competent authorities (Art. 20)	X	--
Inform the competent authorities (Art. 20) in case other Feed Business Operators could have potentially similar problems with their imported, produced, processed, manufactured or distributed feed.	X	X
Cooperate with the competent authorities in respect of handling the crisis, <i>e.g.</i> <ul style="list-style-type: none"> <li>• Information on names of suppliers/customers</li> <li>• Destruction or reprocess of the batch/batches, lot/lots or consignments/consignments</li> <li>• Other information needed to support the Rapid Alert System</li> </ul>	X	--
Conduct necessary corrective and preventive actions	X	X

## Annex10: TABLES OF REFERENCES OF FAMI-QS REQUIREMENTS WITH THE CORRESPONDENT LEGAL TEXT

**TABLE 1: Code transferred to regulatory requirements**

FAMI-QS Code Sections		Regulatory references		
#	Section	Regulation (EC) No 178/2002	Regulation (EC) No 183/2005	Regulation (EC) No 1831/2003
<b>1.</b>	<b>Introduction</b>			
<b>2.</b>	<b>Scope</b>	Art. 15 Art. 17	Art. 1, Approval of establishments Art. 20 Art. 22 Art. 2 Art. 5 (6) Art. 23	Art.1 Art. 3 Art. 17
<b>3.</b>	<b>Terms and definitions</b>	Art. 3	Art. 3	Art. 2
<b>4.</b>	<b>Management System</b>			
4.1	General requirements	Art. 17 Art. 4	Art. 4 (1) Art. 5 (4) Annex II: Quality control	Art. 5 Art. 7
4.2	Management principles	Art. 5 Art. 6	Art. 6 Art. 7	Art. 7
4.3	General documentation requirements	Art. 6	Art. 7 Annex II, Quality control (3) Art. 5 (3) Annex II: Production (2)	Art. 7
<b>5.</b>	<b>Management responsibility</b>			
5.1	Management commitment	Art. 17	Art. 4 Art. 5	./.
5.2	Quality and safety policy	Art. 6 Art. 15 Art. 17	Art. 4 Art. 5	./.
5.3	Responsibility, authority and communication	Art. 17	Art. 6 Art. 7 Annex II: Production (1) Annex II: Quality control (1)	./.
5.4	Management representative	./.	./.	./.
5.5	Management review	./.	./.	./.

FAMI-QS Code Sections		Regulatory references			
#	Section	Regulation (EC) No 178/2002	Regulation (EC) 183/2005	No	Regulation (EC) No 1831/2003
<b>6.</b>	<b>Resource management</b>				
6.1	Provision of resources	./.	Annex II: Facilities and equipment Annex II: Personnel Annex II: Production Annex II: Quality control		./.
6.2	Human resources				
6.2.1	Personal hygiene	./.	./.		./.
6.3	Infrastructure				
6.3.1	Basic requirements	./.	Annex II: Facilities and equipment		./.
6.3.2	Requirements for facilities, production areas and equipment	./.	Annex II: Facilities and equipment Annex II: Production		./.
6.3.2.1	Facilities and production areas	./.	Annex II: Facilities and equipment Annex II: Production		./.
6.3.2.2	Equipment	./.	Annex II: Facilities and equipment Annex II: Production		./.
6.4	Maintenance and control of monitoring and measuring devices	./.	Annex II: Production		./.
6.5	Cleaning	./.	Art. 6 (2) (a)		./.
6.6	Pest control	./.	Annex II: Facilities and equipment Art. 6 (2) (a)		./.
6.7	Waste control	./.	Annex II: Facilities and equipment Annex II: Production		./.
<b>7.</b>	<b>Product realisation</b>				
7.1	Product requirements				
7.1.1	Determination of requirements related to the product	Art. 17	Art. 5		Art. 3
7.1.2	Compliance of the product to the requirements	Art. 15 Art. 12	Art. 5 Annex II: Quality control Art. 25		Art. 3

FAMI-QS Code Sections		Regulatory references			
#	Section	Regulation (EC) No 178/2002	Regulation (EC) No 183/2005	No	Regulation (EC) No 1831/2003
7.1.3	Customer communication	./.	./.		./.
7.2	HACCP program	Art. 6	Art. 6 Art. 7		./.
7.3	Design and development				
7.3.1	Development of new production processes	Art. 6 Art. 15	./.		./.
7.3.2	Change control	Art. 15	Art. 6 (3) Annex II: Personnel		./.
7.4	Handling of incoming materials				
7.4.1	Sourcing of incoming materials	Art. 18 Art. 11 Art. 24	Annex II: Production Annex II: Quality control Art. 23		./.
7.4.2	Verification of incoming materials	Art. 18	Art. 1 Annex II: Quality control Annex II: Record-keeping		./.
7.5	Production of finished goods				
7.5.1	Quality control and production	./.	Annex II: Production Annex II: Quality control Annex II: Storage and transport Annex II: Record-keeping		Art. 16
7.5.2	Verification of processes for production	./.	Art. 6 (2f); (3)		./.
7.5.3	Identification and traceability	Art. 18	Art.1 (b) Annex II: Quality control Annex II: Record-keeping Annex II: Production		./.
7.5.4	Preservation of product	./.	./.		./.
7.6	Transport				
7.6.1	General requirements	Art. 4 Art. 17 Art. 18 Art. 20	Annex II: Production		
7.6.2	Transport of packed goods	./.	Annex II: Storage and transport		./.
7.6.3	Transport of bulk products	./.	Annex II: Storage and		./.

FAMI-QS Code Sections		Regulatory references		
#	Section	Regulation (EC) No 178/2002	Regulation (EC) No 183/2005	Regulation (EC) No 1831/2003
			transport	
<b>8.</b>	<b>System review</b>			
8.1	General requirements	Art. 17	./.	./.
8.2	Internal audits	Art. 17	./.	./.
<b>9.</b>	<b>Control of non-conforming products</b>			
9.1	General requirements	Art. 20	Annex II: Quality control	./.
9.2	Complaint handling system	./.	Annex II: Complaints and product recall	./.
9.3	Recall	Art. 15 Art. 20 (1) Art. 20 (2)	Annex II: Complaints and product recall	./.
9.4	Crisis management	Art. 15 Art. 20 Art. 50	Annex II: Complaints and product recall Art. 29	./ .
<b>10.</b>	<b>Statistical techniques</b>	./.	./.	./.

**TABLE 2: Regulatory requirements transferred to the Code**

*Regulatory references:*            *Headings and first column*

*FAMI-QS Code sections:*        *Cells*

#	Regulation (EC) No 178/2002	Regulation (EC) No 183/2005	Regulation (EC) No 1831/2003
1	./.	2: Scope 7.4.2: Product realisation 7.5.3: Product realisation	2: Scope
2	./.	2: Scope	3: Terms and definitions
3	3: Terms and definitions	3: Terms and definitions	2: Scope 7.1.1: Product realisation 7.1.2: Product realisation
4	4.1: Management system 7.6.1: Product realisation	4.1: Management system 5.1: Management responsibility 5.2: Management responsibility	./.
5	4.2: Management System	2: Scope 4.1: Management system 4.3: Management system 5.1: Management responsibility 5.2: Management responsibility 7.1.1: Product realisation 7.1.2: Product realisation	4.1: Management system
6	4.2: Management system 4.3: Management system 5.2: Management responsibility 7.2: Product realisation 7.3.1: Product realisation	4.2: Management system 5.3: Management responsibility 6.5 : Resource management 6.6 : Resource management 7.2: Product realisation 7.3.2: Product realisation 7.5.2: Product realisation	./.
7	./.	4.2: Management system 4.3: Management system 5.3: Management responsibility 7.2: Product realisation	4.1: Management System 4.2: Management System 4.3: Management System
8	./.	./.	./.

#	Regulation (EC) No 178/2002	Regulation (EC) No 183/2005	Regulation (EC) No 1831/2003
9	./.	./.	./.
10	./.	./.	./.
11	7.4.1: Product realisation	./.	./.
12	7.1.2: Product realisation	./.	./.
13	./.	./.	./.
14	./.	./.	./.
15	2: Scope 5.2: Management responsibility 7.1.2: Product realisation 7.3.1: Product realisation 7.3.2: Product realisation 9.3: Control of non-conforming products 9.4: Control of non-conforming products	./.	./.
16	./.	./.	7.5.1: Product realisation
17	2: Scope 4.1: Management system 5.1: Management responsibility 5.2: Management responsibility 5.3: Management responsibility 7.1.1: Product realisation 7.6.1 : Product realisation 8.1: System review 8.2: System review	./.	2: Scope
18	7.4.1: Product realisation 7.4.2: Product realisation 7.5.1: Product realisation 7.6.1 : Product realisation	./.	./.
19	./.	./.	./.
20	7.6.1 : Product realisation 9.1: Control of non-nonforming products 9.3: Control of non-nonforming products 9.4: Control of non-nonforming products	2: Scope	./.
21	./.	./.	./.
22	./.	2: Scope	./.

#	Regulation (EC) No 178/2002	Regulation (EC) No 183/2005	Regulation (EC) No 1831/2003
23	./.	2: Scope 7.4.1: Product realisation	./.
24	7.4.1: Product realisation	./.	./.
25	./.	7.1.2: Product realisation	./.
26	./.	./.	./.
27	./.	./.	./.
28	./.	./.	./.
29	./.	9.4: Control of non-conforming products	./.
30	./.	./.	./.
31	./.	./.	./.
32	./.	./.	./.
33	./.	./.	./.
50	9.4: Control of non-conforming products	./.	./.
<b>Annex</b>			
Facilities and equipment	./.	6.1: Resource management 6.3: Resource management 6.6: Resource management 6.7: Resource management	./.
Personnel	./.	6.1: Resource management 7.3.2: Product realisation	./.
Production	./.	4.3: Management system 5.3: Management responsibility 6.1: Resource management 6.3: Resource management 6.4 : Resource management 6.7 : Resource management 7.4.1: Product realisation 7.5.1: Product realisation 7.5.3: Product realisation 7.6.1 : Product realisation	./.
Quality control	./.	4.1: Management system 4.3: Management system 5.3: Management responsibility 6.1: Resource management 7.1.2: Product realisation 7.4.1: Product realisation	./.

#	Regulation (EC) No 178/2002	Regulation (EC) No 183/2005	Regulation (EC) No 1831/2003
		7.4.2: Product realisation 7.5.1: Product realisation 7.5.3: Product realisation 9.1: Control of non-conforming products	
Storage and transport	./.	7.5.1: Product realisation 7.6.2 : Product realisation 7.6.3 : Product realisation	./.
Record-keeping	./.	7.4.2: Product realisation 7.5.1: Product realisation 7.5.3: Product realisation	./.
Complaints and product recall	./.	9.2: Control of non-conforming products 9.3: Control of non-conforming products 9.4: Control of non-conforming products	./.