Annexes to FAMI-QS CODE OF PRACTICE
GUIDANCE ON IMPLEMENTATION

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Annex 1: GUIDANCE ON THE IMPLEMENTATION OF HACCP

Introduction:

HACCP is a Hazard Analysis of Critical Control Points that helps an operator identify safety hazards and quantify the risk associated with their product and process. The system then enables the operator to document, control and verify the affect of these control measures.

General requirements:

Ensure you have a robust system in place to manage the daily tasks of good manufacturing practice (GMP or prerequisites). The prerequisites are the backbone of any quality or safety system and without them no management program will 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 prerequisites 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 verified and how it's audited. Remember, as far as an auditor is concerned, if its not written down it doesn't exist!

Specific requirements for HACCP – the 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 procedure 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 that will have responsibility for establishing, developing, maintaining and reviewing the HACCP system. It is vital this group has the full support of the operator's 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

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 the product raw materials, nutritional value and application of the finished product by your customers.

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

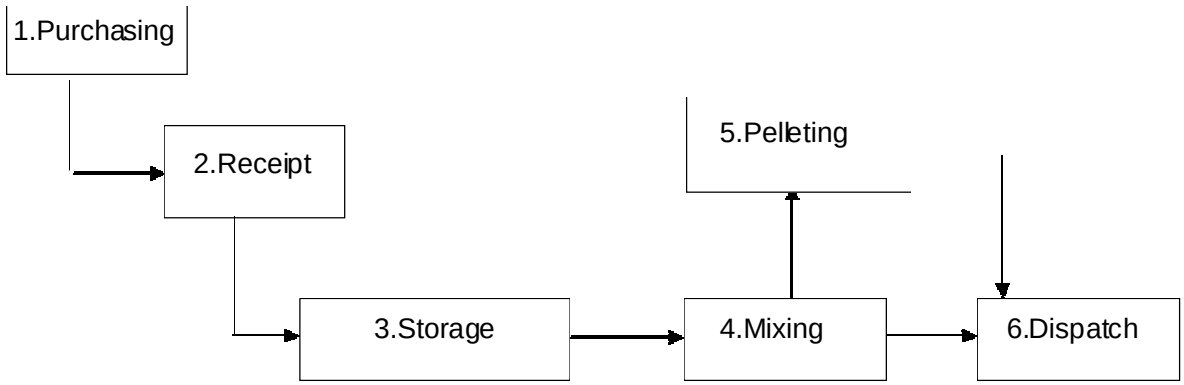
3. Identify the product's intended use

The product specification must detail the target groups for which it's 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 used 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



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 don't miss any steps.

6. Identify and analyse the hazards

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

- Chemical – Pesticides, lubricants, dioxins, heavy metals, cleaning agents etc.
- Biological – Undesirable microorganisms such as salmonella, E. coli etc.
- 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're 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 of the step into account.

For each risk, of each step, decide how severe the potential risk is and how likely it is to occur. If your study shows that it's a risk that needs a specific control and there is no point further down stream in the process that can control it; you have a Critical Control Point

(CCP)! If it's not a CCP then no control or the correct application of your prerequisite program will suffice. Useful questions to ask yourself when you're establishing CCPs are:

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

7. Determine the CCP and control measure/s

Once you have identified a hazard that needs a specific control you must identify the process step that will carry the control measure (CCP). Keep in mind that control 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.

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.

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 divide 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, 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 & verification
				What	How	When	Who			
4.Mixing	Any form of physical contamination	Physical	3 (3rd 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 its out of spec.	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 including the prerequisites, deviations and customer complaints. All records of this review should be in writing 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.

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

Annex 2: GUIDANCE ON THE IMPLEMENTATION OF BASIC HYGIENE RULES

Introduction:

This guidance provides assistance and gives practical examples to conduct and implement measures within manufacturing, storage and transport processes that are essential to comply with the requirements for feed hygiene.

The plant, buildings, facilities and equipment should be designed suitable for the intended use as well as to prevent contamination and to ensure the production of safe feed additives and premixtures. A maintenance system in place including cleaning program and pest control makes sure that appropriate hygiene standards are met at all times. Regular training of the personnel as well as evaluation of the applied programs for suitability and effectiveness are also very important and have to be documented.

1. Buildings and Facilities

- Design and construct all buildings and facilities for manufacture, packaging and storage according to its intended use in a manner that maintenance and cleaning is facilitated.
- Provide buildings and working spaces of sufficient size to allow orderly storage of equipment and materials.
- Construct floors, walls, ceilings and windows of smooth, easily cleanable surfaces.
- Construct ceilings, overhead fixtures and pipes so that the build up of dirt and condensation is minimised.
- Design and construct adequate drainage and waste disposal systems.

2. Personnel Hygiene Facilities

- Ensure that personnel hygiene facilities are suitably designated, located and maintained. They should include:

  a) adequate changing and washing facilities;
  b) adequate number of toilets;
  c) adequate facilities for hand washing and drying;
  d) a constant supply of potable water.

3. Equipment

- Ensure that all equipment is kept clean and adequately maintained.
- Place equipment away from walls to allow easy access for cleaning and to prevent the infestation of pests.

4. Maintenance and Cleaning

- Ensure that all inside and outside areas, buildings, facilities and equipment are kept clean and in good state to function as intended and to prevent contamination
- Maintain grass areas regularly.
- Cleaning and / or disinfection should remove dirt and residues which may be a source of contamination.
- Cleaning can be carried out by e.g. physical methods like scrubbing and vacuum cleaning and chemical methods using alkaline or acidic agents and methods without the use of water.
- Where appropriate disinfection may be necessary after cleaning.

Cleaning program

Write and implement a cleaning program and specify the following items. Where appropriate consult experts to draw up the program.

a) areas, facilities and equipment to be cleaned
b) method and frequency of cleaning
- establish a schedule

c) agents used
- use and store according to the manufacturer's instruction
- ensure clear labelling of the containers
- store separate from raw materials and finished products
- apply properly so as not to contaminate raw materials and finished products

d) responsibilities for the tasks
e) inspection and evaluation
- perform periodic checks and verify the procedure for suitability and effectiveness

f) training of the personnel
g) record-keeping of all cleaning, inspections and evaluation

5. Pest control

- Ensure that all inside and outside areas, facilities and equipment are in an appropriate condition to avoid creating an environment conductive to pests.
- The following preventive measures can minimise the likelihood of infestation and thus limit the use of pesticides.

  a) check that exterior walls are free of holes
  b) keep doors to the exterior closed when not in use
  c) keep holes and drains sealed or close up with a mesh screen
  d) eliminate potential breeding sites
  e) remove trash daily and store in exterior dumpsters
  f) remove dead insects and spider webs
  g) inspect storage areas regularly for indications of infestation of pests

Pest control plan

Write and implement a pest control plan and specify the following items. Where appropriate consult experts to draw up the plan.

a) areas, facilities and equipment to be inspected
b) methods and / or preventive measures
- install rodent traps (interior) or rodent bait stations (exterior) and inspect regularly
- map the positions of traps and bait stations
- install flying insects defence traps and inspect regularly
- fit windows with removable and cleanable insect-proof screens

c) pesticides used
- check and record that they are suitable and comply with local regulations
- record details of used materials including safety data sheets
- store separate in a secured area

d) responsibilities for the tasks
e) inspection and evaluation
- perform periodic checks and implement corrective actions

f) training of the personnel
g) record-keeping of all applied methods and inspections

6. Waste and drainage

- Identify waste clearly and dispose in a manner which avoids contamination of raw materials and finished products.
- Ensure that drainage lines and sewage systems are watertight and of sufficient capacity.
- Store waste in closed or covered containers at defined waste accumulating areas
- Clean waste accumulating areas regularly.
- Waste containers should be clearly marked and designated for that purpose only.
- Dispose waste and sewage according to local regulations.

7. Personal Hygiene

- Provide workwear such as protective clothing and safety footwear and maintain in hygienic condition.
- If gloves are worn control that there is no risk of contamniation of the finished product.
- Establish clear rules on smoking and eating / drinking on site. If necessary provide separate facilities.

8. Storage

- Prevent cross-contamination by separate storage of raw materials and finished products
- Keep packaging dust-free.
- Store raw materials and finished products under cool and dry conditions to prevent the growth of mould. Control temperature and humidity.
- Keep temperatures as low as possible to avoid condensation.

9. Transport

Please refer to annex 4

10. Evaluation

- Check procedures and programms for suitability and effectiveness and implement corrective actions routinely.

11. Training

- Perform training programs of the personnel regularly and keep records.
- Train the staff that they are aware of their responsibility for feed safety and quality.

Annex 3: GUIDANCE ON THE IMPLEMENTATION OF A COMPLAINT HANDLING SYSTEM

Introduction:

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

Area	Suggested Action
1. Make information visible to the customers about how and where to complain. Publicise the system to encourage the customers to voice their dissatisfaction and to make the good intentions of the operator apparent.	Publicise your system e.g. • on company invoices • in use and care instructions • on product packaging and labelling • on company internet home page Prepare a form for the complainant (customer) to submit the details required to handle the complaint adequately (see Annex A: Form for complaints)
2. Collect and record complaints	File the forms
3. Acknowledge the receipt of the complaint to the customer immediately **4.** Assess the complaint for validity and evaluate the cause for further handling	• If possible by phone or in person • By e-mail or post, but avoid impersonal form letters Categorise according to e.g. • Severity • Environmental, health and safety risks • Complexity • Impact • Immediate action needed • Immediate action possible
5. Assign the complaint to the person who is the best to deal with	Allocate the responsibilities for handling and controlling the complaints
6. Resolve as soon as possible or further investigate the complaint.	Investigate and analyse all the relevant circumstances and information in an objective manner by getting both sides of the complaint. Keep records of all findings.
7. Make a prompt decision about what to do	Adopt a customer-focused approach. e.g. correct the problem and prevent it happening in the future
8. Communicate the decision to the customer and evaluate the response	
9. If the customer accepts the proposed decision carry out the action timely and effectively	Keep records of the outcome e.g. according to Annex A
10. If the customer rejects the proposed decision give alternative internal and external options of recourse	Keep records

Area	Suggested Action
11. Monitor the progress of the complaint	Until all reasonable internal and external options of recourse are exhausted or the complainant is satisfied
12. Close the complaint	
13. Review complaints regularly. Define the responsibility for review.	A brief review e.g. each month helps to act upon any obvious things 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.
14. 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

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

Part 2: Complaint follow-up

1. Details of complaint receipt

Date of complaint

Name of recipient

Complaint medium phone e-mail internet personally postal mail other

Reference number of complaint

2. Problem encountered

Date of problem

Recurrent problem yes ð no

Problem category

3. Complaint assessment

Severity

Complexity

Impact

Need for immediate action yes ð no

Availability of immediate action yes ð no

Likelihood of compensation yes ð no

4. Complaint resolution

Remedy requested yes ð no

Action to be taken

5. Tracking complaint

Action taken	Date	Name	Remarks
Complaint acknowledged to complainant			
Complaint assessment			
Investigation of complaint			
Information to complainant			
Correction			
Correction verified			
Complaint closed			

Annex 4: GUIDANCE ON TRANSPORT

Introduction:

Transportation of finished goods as well as goods received e.g. raw materials can be a major critical point. Impurities may get into the product that are hazardous to humans or animals. Thus measures must be taken to ensure that the transportation of goods is adequate and minimizes the risk of contamination. Goods received must be checked to find out whether they have been transported in a safe way.

Basically two major categories have to be considered: transportation of packed goods and transportation of loose bulk materials, either liquid or solid.

1. Packaged goods

- If goods are packed in appropriate durable containers they are well protected against the risk of cross contamination with impurities coming from other goods loaded on the same truck/container. This requires that the packaging material is strong enough. The package should provide adequate protection against deterioration of the product that may occur during transportation.
- In order to increase the safety level it is advisable to check transporters for cleanliness. Even though goods are packed there may be items like sharp edges or rusty nails that may damage the packaging.
- All products intended for the usage in the feed or food chain should not be loaded together with other goods that are hazardous. Dust, droplets or gases coming from such goods may contaminate the packaging of feed materials and when these are opened my get into the feed material itself. Thus feed additives or premixtures should be loaded, even if packed, only with goods that do not smell, color and are not hazardous to humans and animals.
- The above-mentioned aspects are to be considered for both, goods delivered and received. In both cases other goods loaded together with feed material and the condition of the transporter may have a serious effect on the integrity of the packaging and the safety of the product.

2. Bulk Transportation

- In case of transporting loose goods in bulk containers cleanliness of the container and loading or unloading equipment is very important.
- The clean status of the containers used can be assured by several steps. First of all ideally a haulier should have sufficient knowledge about handling feed materials. In the best case this is proven by a certification according to a quality standard which is good enough to cover feed transportation.
- Ideally only bulk transporters are used which specifically carry only safe feed ingredients. If this is the case, guaranteed by the container provider and verified by its user through spot checks of information about goods previously transported no other measures need to be taken.
- If a container may be used for transportation of goods hazardous to humans or animals the provider of the transporter shall have cleaning certificates and guarantee that the container is clean. Such cleaning certificates shall be dated and signed and state the method of cleaning. In addition knowledge of at least the previous load is required. It is even better to know the two or even three last loads.

- Equipment used to load or unload bulk transporters must be checked for cleanliness prior to usage. There could be residual amounts of other products in e.g. pipes that can contaminate the whole load.

3. HACCP

The process of selecting transporters as well as checking of carriers for cleanliness and goods for damage cause by transportation shall be included in the HACCP considerations of an operation. Appropriate steps must be taken to minimize the risk for the product safety due to transportation

Annex 5: GUIDANCE ON HOMOGENEITY

Introduction:

This example procedure can be used to determine the efficacy of blending procedures at producing a product within which all ingredients are uniformly distributed.

As a basic guide, homogeneity trials should carried out biannually. Frequency should be amended according to results. ie. Where mixing times have been adjusted following unacceptable results in a homogeneity trial, the frequency of testing should be increased. Where homogeneity has proven satisfactory over a long period of time frequency may be reduced, bearing in mind that the frequency of testing should always be in line with the frequency noted in quality policies and procedures.

Procedure:

	Instruction	Guidance
1.	Determine product/raw materials to be tested.	Minerals are suggested as an appropriate active ingredient as they are easily assayed and subject to relatively narrow limits of variation.
2.	Take and test retention samples of each raw material before production commences.	
3.	Mix the raw materials in accordance with normal procedure	Mixing times should reflect those used in the normal course of production
4.	When the product 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 and regularly thereafter.	For example, were product packaged into 40 x 25Kg bags, samples should be taken from the first bag and every fifth bag thereafter, (ie every 125Kg) and labelled in accordance with the bag they were removed from, ie, 1, 5, 10, 15, 20, 25, etc.
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.	Standard deviation measures the spread of data about a mean (average) value. The formula is given below. The Coefficient of Variation is the standard deviation expressed as a percentage. Each statistic gives us an impression of how much the distribution of product varies from the mean value. Formula is given below. Quality procedures must define an acceptable limit of variation for Coefficient of Variation.
7.	Records of testing should be maintained in accordance with documented procedures.	

CALCULATION OF STANDARD DEVIATION:

The formula for calculating standard deviation is:

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

σ = lower case sigma

Σ = 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

1. Calculate the mean: $\frac{(4 + 9 + 11 + 12 + 17 + 5 + 8 + 12 + 14)}{9}$

$$= \frac{92}{9}$$

$$= 10.222$$

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.

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

4. Divide by n-1.

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

$\sigma = 17.44$

5. Square root:

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

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 10% 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!). Where the CV is greater than the limit set by the operator, corrective action should be implemented. This may include increasing mixing time, looking for worn equipment or overfilling of mixer, or amending the order in which ingredients are added to the mixer.

Annex 6: GUIDANCE ON CARRY-OVER

Introduction:

This example procedure can be used to determine the efficiency of production procedures at preventing the passage of raw materials from one batch of product to subsequent batches of product, such that the efficacy, safety and specification of either product it is not threatened.

Carry-over and cross contamination 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.

The basis of this procedure is the production on one production line of a batch of material containing a traceable, easily tested active ingredient, (Batch A) followed by the production of a second batch of product (Batch B), which does not contain the same active ingredient.

This procedure should reflect the actual practices in place on the production line. For example, where it is customary for a flush to take please in between production of batches, this should take place as usual.

Procedure:

	Instruction	Guidance
1.	Determine materials to be used to test	Minerals are suggested as an appropriate active ingredient as they are easily assayed and subject to relatively narrow limits of variation.
2.	Retain samples of all raw materials to be used in the test.	Retention samples to be used in production of Batch B should be taken before production commences and labelled with product name and batch number.
3.	Batch A containing the selected active raw material, must be produced in accordance with normal production procedures.	For example, blending times should reflect normal blending times. Where a flush is normally carried out between batches of production, this should be completed as normal.
4.	A sample of Batch A must be tested and retained.	
5.	If a flush takes place between Batches A and B, samples of the flush material should be taken from the first 25 Kg of flushed product and from the last 25Kg.	For example, were 100 Kg of flush material used and packaged into 25Kg bags, samples should be taken from the first bag and from the fourth bag. Labelling of the samples should identify their source bag.

6.	When Batch B is completely mixed and packaged (but not sealed) representative samples should be removed from the batch. Samples should be taken from the first 3rd and 5th bags. A sample must be taken from the first 25Kg of product made.	Assay each sample individually for the target material. Use your HACCP system to consider if there is a significant risk to the end user, from any one of these results.
7.	All samples (including samples of flush materials) must be tested in accordance with prescribed procedures.	
8.	Batch B should not contain levels of the active ingredient contained in Batch A to an extent that poses a risk to the end user. (Apply your HACCP principles!).	Should Batch B test positive for levels of active ingredient to an extent that causes concern, procedures should be reviewed. For example, procedures for flushing between Batches A and B or production scheduling procedures.
9.	Records of testing should be maintained in accordance with documented procedures	

NOTE: This is a basic example and is intended as guidance only. As the operator, you know your machinery and its limitations better than anyone.

Use results in conjunction with your HACCP program to demonstrate product safety.

Annex 7: GUIDANCE ON SAMPLING

Introduction: (General considerations)

The sampling procedure must be adapted to the purpose of sampling, 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.

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.

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.

1. 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 should be avoided, since it can mask quality problems.

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

2. 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.

Sampling on receipt (for acceptance):

1. Raw materials

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.

Sampling plans for raw materials and finished products:

From a practical point it is not prudent to open all containers for sampling.

The number of units depends on different assumptions following the three plans.

2. 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 place 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.

3. 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.

4. 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 subject to testing. If the results are concordant the r samples are pooled for the retention sample.

Annex 8: GUIDANCE ON BIOLOGICAL HAZARDS

1. Microorganisms

The growth of microorganisms is depending on temperature, pH and the media (nutrients).

A special group of microorganisms are the zoonotic pathogens which are the major part of food borne diseases. Therefore, it is important to eliminate those microorganisms in the feedingstuffs, including additives and premixtures. The zoonotic microorganisms are mostly found in the animals' digestive tract and from there transferred to humans via meat, raw milk and eggs. Therefore, the risk of zoonotic microorganisms should be avoided in the manufacture by designing process steps which limit or prohibit growth, kill or remove the organisms.

The operator is responsible for evaluating if other microorganisms may show a risk to feed and food safety, depending on the manufacturing methods, the use and the animal species.

The following zoonotic microorganisms show the major risks linked to feeding of domestic animals:

- **Salmonella-**Characteristics:
  - Normal occurrence in the digestive tract in warm-blooded and poikilothermal animals.
  - Growth optimum at 37°C (range 5-46°C).
  - Does not survive pasteurization
  - Relative resistant to freezing processes.
  - pH optimum at 6,5 – 7,5 (range 4,5 – 9,5)
  - Water activity a_w below about 0,95 eliminates growth.
  - ***In general, a food hazard from eggs, poultry, swine, and possible but seldom in cattle.***

- **Campolybacter-**Characteristics:
  - Normal occurrence is the digestive tract in warm-blooded animals, including birds.
  - May be found in surface water due to fecal contamination from animals, birds and humans, or from canals leading from fields fertilized with slurry.
  - In general, no growth below 30°C, and not above 43-34°C.
  - Does not grow in products stored at cool temperatures.
  - Sensitive to heating, dehydration, and concentrations of salts above 0.5%.
  - Growth optimum at pH 6,5 – 7,5.
  - ***In general, a food hazard from cattle and poultry.***

- **Yersinia enterocolitica**
  - Characteristics:
  - Frequent occurrence is in swine.
  - Can grow at low temperature like 0°C and salt concentrations below 5-7%.
  - Growth optimum at pH 7,2 – 7,2 (range pH 4 – 9).
  - ***Swine are healthy carriers, and therefore pork meat presents a food hazard.***

- **E. Coli, verotoxin-producing (O157)-**Characteristics:
  - E. Coli is a normal bacteria in the digestive tract in humans and most warm-blooded animals.
  - The verotoxin-producing E.Coli is found in cattle, sheep and deer.
  - Growth optimum at 8-45°C, but survive cooling and freezing temperatures almost without decimation, but temperatures above 75°C are killing.
  - Lower limit for growth is pH 4 – 4,5, but speciel species may grow at pH 2.
  - ***An uncommon food hazard from cattle.***

2. Viruses

Viruses are linked to materials of animal origin. Such raw materials should not be part of feed additives or premixtures.

3. Pests

Rodents and insects should be controlled, and excluded from access to production areas. An efficient preventive pest control program should be in place.

Annex 9: 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 FAMI-QS Code:

- Section 6.1 Product Requirements
- Section 6.1.1 Determination of Requirements
- Section 6.1.2 Compliance.

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 come on top of the EU ones, but this is expected to be rather limited as the feed additives and premixtures legislation is a highly integrated area.

1. Products

In the European Union the placing on the market of feed additives and premixtures is ruled by Regulation 1831/2003/EC. The coverage of the FAMI-QS code is restricted to the additives and premixtures (as defined in Art. 2 of Reg. 1831/2003/EC) that are allowed to be put on the EU market.

1.1. Authorised additives

Only the additives that have been duly authorised by the EU Commission and included in the Register mentioned in Article 17, i.e. the EU Positive List, can be put on the market, at the exclusion of any other additive.

Further to be included in the Register, the additives shall fit to the

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

This has to be considered as requirements at the level of the operator.

Although Reg. 1831/2003/EC is in force, the additive legislation is in practice currently in a transition phase between Directive 70/524/EEC and Regulation 1831/2003/EC. All the information mentioned above may not yet have been included in the Register, because they were not necessarily part of the original authorisation. The lacking information in the Register shall progressively be completed through the re-authorisation process, 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

The operator shall ascertain 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 this documentation in order to adapt to the evolution of the Register and so the requirements of the product, 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 1831/2003/EC, premixtures[1] of additives do not require specific product authorisation. They can be manufactured and put on the market, provided they only contain additives duly authorised, and carriers that comply with the EU legislation[2]. The operator shall document that he complies with these requirements.

2. Undesirable substances.

Beside the criteria included in the authorisation of an additive under Regulation 1831/2003/EC, 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, and 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[3] 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.

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1 Definition on premixtures, see FAMI-QS Code of Practice.
2 See guidance on carriers, the Annex is under preparation.
3 Definition on export, see FAMI-QS Code of Practice.

4. Products intended for import

Products manufactured by any EU member state can freely be transferred from one state to another, provided compliance with Community regulation.

In accordance with Regulation 183/2005/EC, an operator may import[4] products from third countries provided that

- the country appears on a list, drawn in accordance with Article 48 of Regulation 882/2004/EC
- the establishment of dispatch appears on a list, drawn up and maintained by the third country in accordance with Article 48 of Regulation 882/2004/EC
- the feed was produced by the establishmert of dispatch
- the feed satisfies the requirements laid down in Community legislation, or those conditions recognised by the Community to be at least equivalent thereto, or where a specific agreement between the Community and the exporting country exists.

Due to interim measures, derogation from the above mentioned requirements is feasible provided that:

- the establishments in the third countries have a representative based within the Community
- the representatives submit to the competent authority in the relevant Member State where they are located:
  - § a declaration which ensures that the establishment in the third country fulfils the conditions laid down in the current Feed Hygiene Regulation 183/2005/EC[5].
  - § if the appropriate representative is exercising this activity for the first time, the declaration must be accompanied by a commitment to maintain a register of the imported products.

5. Authorised operators.

The Regulation 183/2005/EC on feed hygiene imposes all feed business operators either to be approved or registered prior to the placing on the market of their products.

All additive or premixture operators have to be covered by one or more of the regime as described below and document that they are duly approved or registered.

[4] Definition on import, see FAMI-QS Code of Practice.
[5] Before the appearance of Regulation 183/2005/EC the conditions were provided in Directive 95/69/EC.

5.1. Activities requiring approval of the establishment:

Categories	Functional groups	Products
Additives re Regulation 1831/2003/EC		
Nutritional additives	(a)	Vitamins, pro-vitamins, 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)	Colorants, but only carotenoids and xanttophylls
Products re. Directive 82/471/EEC		
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
Premixtures containing certain additives		
Nutritional additives	(a)	Vitamins, pro-vitamins, 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
Additives re Regulation 1831/2003/EC		
Technological additives	(a)	Preservatives
	(c)	Emulsifiers
	(d)	Stabilisers
	(e)	Thickeners
	(f) (g)	Gelling agents Binders
	(h)	Substances for control of radionucleide contamination: Substances that suppress absorption of radionucleides or promote their excretion
	(i)	Anticaking agents
	(j)	Acidity regulators
	(k)	Silage agents
	(l)	Denaturants: Substances which, when used for manufacture of processed feedingstuffs, allow the identification of the origin of specific food or feed material
Premixtures containing certain additives		
Categories not requiring approvals	Any functional group	Premixtures containing any feed additive, excluding - vitamin A and D - copper and selenium

References:

List of EU legislation related to this guidance:

- 183/2005/EC Regulation laying down requirements for feed hygiene
- 1831/2003/EC Regulation on additives for use in animal nutrition
- 2002/32/EC Directive on undesirable substances in animal feed
- 82/471/EEC Directive concerning certain products used in animal nutrition
- 70/524/EEC Directive concerning additives in feeding-stuffs

Annex 10: GUIDANCE ON CARRIERS FOR PREMIXTURES

Introduction

This guidance provides assistance to operators to comply with the requirements of FAMI-QS Code regarding the safety of carriers[6].

For a better understanding, take into account the following concepts:

- Carrier suppliers are feed business operators included in the scope of Regulation 183/2005/EC, and consequently the establishments must be approved or registered by the competent authorities. Written declaration from the supplier of compliance with the Regulation 183/2005/EC will be required.
- The risk assessment for carriers is linked to the production process and consequently under the responsibility of the supplier.
- The operator of premixtures must evaluate and ensure that the incoming material is suitable for the purpose.
- Carriers are handled as feed materials, and belong to a group that covers a wide variety of materials of different nature[7].

Carriers are incoming materials and must comply with the specific requirements as detailed in FAMI-QS Code of Practice, sections 6.4 “Incoming materials” and 6.5.3 “Identification and traceability”, including:

- Maintain a procedure on how to approve new suppliers
- Maintain a list of approved suppliers and approved establishments (Regulation 183/2005/EC). The list should include the name, address and products they supply.
- Maintain records of conformity statements
- Maintain records of material specifications
- Maintain documents on production process description, including risk assessment, listing potential hazards of the material, control measures and corrective actions, as required in the annex of the “Recommended International Code of Practice General Principles OF Food Hygiene” of the Codex Alimentarius, CAC/RCP 1-1969, Rev. 4, 2003.

The operator has to check that the products provided by the supplier are in compliance with the EU Directive 96/25/EEC and not comprised by the prohibited materials as laid down in the Decision 2004/217/EC.

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6 **Definition on feed material**: Various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof. Organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such, or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures.

7 **List of feed materials:** The Annex Part A of the Directive 96/25/EEC contains general provisions, e.g. a list dividing feed materials into 12 subgroups. This official list is copied to this guidance, see Annex I. The Annex part B of the Directive contains a non-exclusive list of the main feed materials by listing the number, name, description and compulsory declaration.

The feed safety of the carrier must be verified when entering the operators' premises according to section 6.4.2 "Verification of incoming materials" by:

- Inspection of the incoming carrier
- Registration of
    - o Name of the supplier
    - o Supplier's name of the carrier
    - o Supplier's lot/batch number and expiry date
    - o Delivery data (quantity, date)
- Approval of the delivery
- Inspection and archival of the supplied documents.

The operator must evaluate the risks and CCPs introduced by the supplier of a carrier in order to ensure feed safety of the premixtures.

Risk assessment:

As introduced before, there is a wide variety of products and it is not a priori possible to assume that a carrier is safe or not. The supplier should provide compelling evidence that he has conducted a throughout risk assessment analysis of its product in the perspective the intended feed use, and bring enough information to identify the specific hazards of each carrier. This assessment should demonstrate that risk is under control and allow us to identify CCPs.

The following basic risks need to be considered in a HACCP study by the supplier:

1. Biological and microbiological risks
2. Chemical risks
3. Physical risks

1. Biological and microbiological risks

1.1. Contamination with microorganisms

Potential critical control points are the control of the microorganisms documented in the supplier specification, e.g. salmonella, campylobacter.

2. Chemical risks

2.1. Contamination with undesirable substances originating from raw materials (including pesticides, dioxins, heavy metals, etc)
2.2. Contamination with impurities, originating from the downstream process

Potential critical control points are the control of the chemical contamination documented in the supplier specification.

3. Physical risks

3.1. Contamination with foreign materials (particles, pest infestation, tools etc.)
3.2. Particle size of the carrier

This is a generic risk which applies to most other processes as well. Potential critical control points are filters, sieves, metal detectors as well as maintenance and packaging procedures.

4. Critical control points

The potential critical control points shall be evaluated. The conclusion being, that they are covered either by the prerequisite control program (feed hygiene procedures) or controlled as a Critical Control Point (CCP) with defined acceptance limits.

ANNEX I

Introduction to subgroups of feed materials

For the full understanding, it is important to look into the Directive 96/25/EC and amendments

1. Cereal grains, their products and by-products
2. Oil seeds, oil fruits, their products and by-products
3. Legume seeds, their products and by-products
4. Tubers, roots, their products and by-products
5. Other seeds and fruits, their products and by-products
6. Forages and roughage
7. Other plants, their products and by-products
8. Milk products
9. Land animal products
10. Fish, other marine animals, their products and by-products
11. Minerals[8]
12. Miscellaneous

[8] **Minerals** are in everyday usage also referred to as macrominerals to distinguish from trace elements. When consulting the Annex Part B, chapter 11, it is obvious what is included in the subgroup minerals.

Annex 11: GUIDANCE ON RISK ASSESSMENT IN PRODUCTION

a) Production of feed additives by extraction processes

Introduction

Some thickening, coloring or flavoring additives may be produced from natural raw materials (botanic 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 series of solution and precipitations steps, pH adjustments, in order to refine and isolate the required molecule. The down-stream process ends with a drying step, followed by grinding and sieving, unless the final product is liquid.

Risk assessment

The following basic risks need to be considered in a HACCP study for extraction processes:

1. Biological and microbiological risks
2. Chemical risks
3. Physical risks

1. Biological and microbiological risks

1.1. Contamination with microorganisms
1.2. Contamination with virus
1.3. Contamination with parasites

Potential critical control points are raw material specifications and quality of water.

2. Chemical risks

2.1. Contamination with impurities originating from natural raw materials (including pesticides, dioxins, heavy metals, etc)
2.2. Contamination with pesticide chemicals
2.3. Contamination with impurities, originating from the downstream process

Potential critical control points are raw material specifications, up-concentration of impurities in the down-stream process, and re-circulation process steps.

3. Physical risks

3.1. Contamination with foreign materials (particles, pest infestation, tools etc.)

This is a generic risk which applies to most other processes as well. Potential critical control points are filters, sieves, metal detectors as well as maintenance and packaging procedures.

4. ***Critical control points***

By using the decision tree, the potential critical control points shall be evaluated. The conclusion being, that they are covered either by the prerequisite control program (feed hygiene procedures) or controlled as a Critical Control Point (CCP) with defined acceptance limits.

b) Production of feed additives by fermentation processes

Introduction

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

Risk assessment

The following basic risks need to be considered in a HACCP study for fermentation processes:

1. Biological and microbiological risks
2. Chemical risks
3. Physical risks

1. Biological and microbiological risks

1.1. Contamination with (living) microorganisms originating from waters treatment, equipment clogging, dead area of circuits etc

Potential critical control points are, control of quality of water and air used in the process, sterilization process in seed and main fermentation and downstream processing, in particular separation of biomass from target molecule.

2. Chemical risks

2.1. Contamination with impurities like pesticides, dioxins, heavy metals originating from raw materials, ingredients, processing aids
2.2. Contamination with toxins and impurities deriving from microorganisms during fermentation
2.3. Contamination with impurities originating from the downstream process (potential degradation)
2.4. Contamination with impurities originating from lubricants, greases used in equipment

Potential critical control points are incoming materials control procedures, control of physical parameters in the fermentation process like temperature, pH and aeration, control of parameters in the downstream process, in particular purification steps like crystallization etc.

3. Physical risks

3.1. Contamination with foreign materials originating from maintenance activities, sampling and cleaning activities, internal liners of equipment, screws and bolts, joints, packaging residues, pest infestation etc

This is a generic risk which applies not only to fermentation, but also to chemical processes, formulations and other techniques. Potential critical control points are filters, sieves, metal detectors as well as maintenance, packaging, cleaning and loading control procedures.

4. Critical control points

By using the decision tree, the potential critical control points shall be evaluated. The conclusion being, that they are covered either by the prerequisite control program or controlled as a Critical Control Point (CCP).

c) Production of feed additives derived from the mining industry

Risk assessment

The following basic hazards need to be considered in a HACCP study for products derived from or produced in the mining industry:

1. Biological and microbiological risks

1.1. Contamination with (living) microorganisms.
In general, microbiological hazards are not very important in a mine.

- At places where humidity is high, e.g. during drilling of a mine, special attention must be given, e.g. to the microbiological quality of the water. It is important to look for condensation, or leaking water lines.
- Where conveyors, storage or transport is open to the outside air, bird droppings are a microbiological risk.

2. Chemical risks

2.1. Contamination with mineral oil or diesel fuel because of over greasing conveyors or leaking engines used in the mines. It is important to look at maintenance systems and use of food grade oil, where possible and needed.

2.2. Contamination with mercury, from e.g. thermometers. Sometimes mercury thermometers are used in the mines.

2.3. Contamination with dioxin, heavy metals, PAH, or asbestos from the soil. Regular analyses/monitoring needs to be done to show that there is no contamination. If drying is done with direct dryers risks for PAH or Dioxin may be higher.

3. Physical risks

3.1. Contamination with foreign materials

- Glass contamination, from windows, measuring instruments, lights, mirrors etc
- Wood, from cleaning equipment, pallets etc
- Metal, from equipment, tools etc
- Jewelry, from operators
- Tape, used to quick fix leakages
- Physical contamination in general due to uncovered product during production, transport, storage e.g. from dust, dirty shoes etc.

3.2. General Hygienic conditions

- Eating, smoking drinking
- Condition of chemical toilets in the mine

- Hand washing
- Pest control

4. Critical control points

Above mentioned hazards can either be controlled by defining Critical Control Points, (CCP's) or by implementing Pre-Requisite Programs (PRP's). A well motivated risk analyses must show how a potential risk must be controlled.

5. Traceability

Traceability in a mine is in general not very well organized. Especially in mines, or sensitive products from the mines, with many, or high risk hazards, traceability is very important, and needs to be investigated by the auditor.

d) Production of feed additives by mixing (premixes)

Introduction

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

Risk assessment

The following basic risks need to be considered in a HACCP study for fermentation processes:

1. Biological and microbiological risks
2. Chemical risks
3. Physical risks

1. Biological and microbiological risks

1.1. Contamination with microorganisms
1.2. Contamination with toxins deriving from microbiological contamination during fermentation (eg. aflatoxins)

Potential critical control points are raw material specifications and the efficiency of cleaning procedures applied.

2. Chemical risks

2.1. Contamination with impurities originating from (natural) raw materials (including pesticides, dioxins, heavy metals etc)
2.2. Contamination with components from the previous blending operation
2.3. Wrong composition of the premix

Potential critical control points are raw material specifications, efficiency of cleaning procedures applied, sequencing of the premixes, control of scales, batch records and final product.

3. Physical risks

3.1. Contamination with foreign materials (particles, cleaning agents, tools etc.)

This is a generic risk which applies not only to blending, but to many other processes and techniques. Potential critical control points are filters, sieves, metal detectors as well as maintenance and packaging procedures.

4. Critical control points

By using the decision tree, the potential critical control points shall be evaluated. The conclusion being, that they are covered either by the prerequisite control program or controlled as a Critical Control Point (CCP).

e) Production of feed additives by chemical synthesis

Introduction

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.

Risk analysis

The following basic risks need to be considered in a HACCP study for production processes by chemical synthesis:

1. Biological and microbiological risks
2. Chemical risks
3. Physical risks

1. Biological and microbiological risks

1.1. Contamination with microorganisms

Potential critical control points are the quality of the water used in the process, the specification of organic raw materials and the control of the final product.

2. Chemical risks

2.1. Contamination with impurities, like heavy metals, dioxins, non-dioxin like PCBs etc, deriving from raw materials and processing aids of organic and inorganic origin
2.2. Contamination with impurities deriving from lubricants and cleaning agents

2.3. Contamination with impurities generated during synthesis

Potential critical control points are raw material specifications, processing aid specifications, the control of the specifications by analysis, the control of process parameters, the control of intermediates, the control of the final product and cleaning procedures.

3. Physical risks

3.1. Contamination with foreign materials like particles, packaging residues, tools, dust, pest infestation etc

This is a generic risk, which applies not only to chemical processes, but also to fermentation processes, formulations and other techniques. Potential critical control points are filters, sieves, metal detectors as well as maintenance, packaging and cleaning procedures.

4. Critical control points

By using the decision tree, the potential critical control points shall be evaluated. The conclusion being, that they are covered either by the prerequisite control program or controlled as a Critical Control Point (CCP).