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in

Brufau J. (ed.), Tacon A. (ed.).
Feed manufacturing in the Mediterranean region: Recent advances in research and technology

Zaragoza : CIHEAM
Cahiers Options Méditerranéennes; n. 37

1999
pages 145-154

Draft technical guidelines for good aquaculture feed manufacturing practice – A shortened working paper for discussion

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SUMMARY - The paper presents a review of the draft technical guidelines for good aquaculture feed manufacturing practice compiled by the author for the FAO Fisheries Department; the latter requested as an FAO authors contract in support of Article 9 of the Code of Conduct of Conduct for Responsible Fisheries (CCRF) concerning Aquaculture Development (FAO, 1997), and in particular in support of Article 9.4.3 of CCRF concerning the selection and use of feeds and additives. The draft technical guidelines cover a range of issues, ranging from ingredient purchasing, processing, bulk storage, handling, monitoring, and documentation, to issues such as employee training and safety, customer relations, and the delivery of finished goods to the farmer. However, issues relating to the handling and management of manufactured aquaculture feeds by farmers on the farm are not covered here, as these will be considered within separate guidelines to be produced at a later date concerning good on-farm feed management practices. This document is not a formal publication of FAO and the views expressed are those of the author.

Key words: Aquaculture, aquafeed, quality assurance, ingredients, purchasing, manufacturing, storage.

RESUME - *"Proposition de principes techniques pour une bonne fabrication d'aliments composés en aquaculture - un bref document de travail pour discussion". Cet article présente une proposition de principes techniques pour une bonne fabrication d'aliments composés en aquaculture, compilés par l'auteur pour le Département des Pêches de la FAO, dans le cadre d'un contrat avec la FAO, à l'appui de l'Article 9 du Code de Conduite pour une Pêche Responsable (CCPR) en matière de Développement Aquacole (FAO, 1997), et en particulier de l'Article 9.4.3 du CCPR concernant la sélection et l'utilisation d'aliments composés et d'additifs. La proposition de principes techniques concerne une vaste thématique, depuis l'achat d'ingrédients, la transformation, le stockage en vrac, la manutention, le contrôle, et les documents, jusqu'à des problématiques telles que la formation et sécurité du personnel, les relations avec la clientèle, et la livraison de produits finis à l'exploitant aquacole. Cependant, cet article ne considère pas les questions liées à la manutention et la gestion à la ferme par les exploitants des aliments aquacoles manufacturés, car elles seront envisagées dans un autre recueil de principes techniques à paraître à une date ultérieure, concernant de bonnes pratiques de gestion des aliments composés sur l'exploitation aquacole. Ce document n'est pas une publication officielle de la FAO et les points de vue exprimés n'engagent que l'auteur.*

Mots-clés : *Aquaculture, aliment pour aquaculture, assurance de qualité, ingrédients, achat, fabrication, stockage.*

Introduction

These guidelines for good aquaculture feed manufacturing practice have been prepared as a draft working paper for the Fisheries Department of FAO in support of Article 9 of the Code of Conduct of Conduct for Responsible Fisheries (CCRF) concerning Aquaculture Development (FAO, 1997), and in particular in support of Article 9.4.3 of CCRF concerning the selection and use of feeds and additives. The objective of these guidelines is to encourage adherence to Good Manufacturing Practice (GMP) during the procurement, handling, storage, processing, and distribution of compound aquaculture feeds or aquafeeds for farmed finfish and crustaceans. This paper briefly reviews these guidelines, and does not represent the complete document which is still in the process of being edited by FAO prior to distribution to the aquaculture feed manufacturing community and other interested parties for comment and/or modification/approval.

Statement of purpose

Feed millers must recognize their responsibility to provide quality products to their customers, and their intent should be to provide consistent quality products by implementing sound quality control procedures. Assuring quality is a direct responsibility of all feed mill employees, and each will be held accountable to follow accepted procedures to implement effective Good Manufacturing Practice (GMP) for aquaculture feeds. Management should realize that quality feed comes from quality ingredients and there is no way to make good feed from inferior, spoiled, or otherwise damaged or contaminated ingredients. The protection of human and animal health are, after all, the prime considerations in the production of aquafeeds.

Training and assistance are vital for both new and experienced employees in order to handle tasks and solve problems in a manner that assures the manufacture of consistent high quality feed products. Each mill employee should expend the effort necessary to implement this program because quality assurance is vital to the effectiveness of the aquaculture feed products being manufactured and, thereby, the company's success.

The feed miller recognizes that dedicated employees committed to quality will produce quality products. The importance of adequately and fairly representing the quality products produced by the firm is paramount. It is the feed miller's responsibility to instruct the farmer, through labelled instructions, the correct method of application of the feed for the particular species for which it is intended. Therefore, guarantees, disclaimers, cautions and warranties should be limited to technical and scientific content (AAFCO, 1996).

The company should be dedicated to its customers and employees in stating its commitment to good manufacturing practices and carrying out an on-going programme to improve feed product performance and to minimize environmental impacts. To the extent practicable the manufacturer should work with producers (farmers) not only to enhance production, but also to improve aquacultural practices which may have adverse environmental or other impacts.

Definitions

Additive: An ingredient or combination of ingredients, other than a premix, added to the basic feed mix or parts thereof to fulfil a specific need. Usually used in micro-quantities and requires careful handling and mixing (McEllhiney, 1994).

Complete feed: A nutritionally adequate feed for animals other than man: by specific formula is compounded to be fed as the sole ration and is capable of maintaining life and/or promoting production without any additional substances being consumed except water (McEllhiney, 1994).

Compound feed: A mixture of products of vegetable or animal origin in their natural state, fresh or preserved, or products derived from the industrial processing thereof, or organic or inorganic substances, whether or not containing additives, for oral feeding in the form of a complete feed (Anonymous, 1992; see also formula feed).

Concentrate: A feed used with another to improve the nutritive balance of the total and intended to be further diluted and mixed to produce a supplement or a complete feed (McEllhiney, 1994).

Feed (feedstuff): Any substance, whether processed, semi-processed or raw, which is intended for animal consumption (McEllhiney, 1994).

Food: Any substance, whether processed, semi-processed or raw which is intended for human consumption, including drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of 'food' but excluding cosmetics, tobacco and substances used only as drugs.

Formula feed: Two or more ingredients proportioned, mixed and processed according to specifications (McEllhiney, 1994; see also compound feed).

Hazard: A biological, chemical or physical agent in, or a property of, feed which may have an adverse effect (FAO/WHO, 1995).

HACCP: Hazard analysis critical control point.

Ingredient: A component part or constituent of any combination or mixture making up a (commercial) feed (McEllhiney, 1994).

Medicated feed: Any feed which contains drug ingredients intended for the treatment or prevention of disease of animals other than man. (*N.B.* Antibiotics used as growth promoters are considered to be 'feed additives'; McEllhiney, 1994).

Premix: A uniform mix of one or more micro-ingredients with a diluent and/or carrier. Premixes are used to facilitate uniform dispersion of micro-ingredients in a larger mix or a mixture of additives, or a mixture of one or more additives with substances used as carriers, intended for the manufacture of feed (McEllhiney, 1994).

Straight feedstuff or straights: A vegetable or animal product in its natural state, fresh or preserved, and any product derived from the industrial processing there of, and single organic or inorganic substance, whether or not it contains any additive, intended as such for feeding (Anonymous, 1992).

Supplement: A feed used with another to improve the nutritive balance or performance of the total and intended to be: (i) fed undiluted as a supplement to other feeds; (ii) offered free choice with other parts of the ration separately available; or (iii) further diluted and mixed to produce a complete feed (McEllhiney, 1994).

An overview of aquaculture feed manufacturing

Although aquaculture dates from the earliest parts of human history in Asia, Europe and in the Pacific Islands, it is only in the last few decades that aquaculture has begun to catch up with the rest of animal agriculture in terms of the science of feed milling and nutrition, as well as the management of pond and/or raceway systems to optimize the production of aquatic vertebrates and invertebrates. Aquaculture represents the fastest growing component of the feed milling industry with major international efforts underway to renovate older mills plus the building of dozens of modern new mills, particularly in mainland Asia. World-wide feed tonnages for aquaculture have been growing at an average rate of 9% *per annum*. This growth is expected to continue as both the world population increases and the demand increases for formula feeds to replace feed for aquaculture species currently cultured with food, farm and other organic wastes.

Aquaculture feed manufacturing presents special challenges to the traditional feed milling concepts due to the size and variety of animals being cultivated. For example the animals are typically smaller than their terrestrial counterparts, such as pigs, poultry and cattle. Feed for aquatic species requires a higher degree of precision be it the particle reduction of ingredients to sizes ranging from 50 to 2000 microns, or the precise mixing of as many as four dozen ingredients in a feed which is of minute size in comparison to its terrestrial counterpart. These are the compelling reasons why many new feed mills are dedicated to aquatic feeds and often employ human food standards in production. Along with the higher standards of production come more expensive and higher quality standards for the ingredients used to prepare feeds for what are often very sensitive production animals.

The principles of the Hazard Analysis and Critical Control Point (HACCP) procedure may have application in aquaculture feed milling if they are genuinely cost effective in terms of providing scientifically sound protection to animal and human health. Critical control points will have to be identified and in this regard FAO's Draft Code of Hygienic Practice for the Products of Aquaculture (FAO, 1996) provides a model for possible adaptation. Current Good Manufacturing Principles (CGMP) are represented in the balance of procedures outlined in this manual, and it is this use of CGMP employed world-wide which has proven successful in production of wholesome and effective

feeds. As a result, adverse health impacts on humans or animals from compound feeds has been negligible. While cleanliness of ingredients is important, ultimately the wholesomeness of feeds will depend upon the quality of ingredients as well as the application of a treatment or process to eliminate disease producing organisms (i.e., *Salmonella*) and to prevent possibility of recontamination after pelleting or extrusion is completed (Beumer and van der Poel, 1997). It is on-farm management (husbandry) of cultured species which has the greater impact on product wholesomeness, including health of the animals and the human consumers. Pathogen destruction and reduction of toxicants involves a partnership at all levels of production from field, to feed mill, to farm, to packer and processor, as well as care in preparation by the final consumer. Research is needed to demonstrate management benefits of quality assurance (Q/A) programs and pathogen negative feed. Tests for pathogens are typically too slow to make HACCP practicable for aquafeeds. Indeed, while CGMP may not meet the entire definition of HACCP, parts of CGMP do meet some of the criteria for an overall HACCP programme, and it is important that aquafeed feed millers continue to use a programme which will minimize adverse animal and human health effects while continually improving feed production. Contamination of feed after processing, by birds and rodents in particular, may be the single greatest hurdle to overcome (Fedorka-Cray and Lautner, 1996).

Much work remains to be done in terms of determining, scientifically, the precise nutrient demands for each of the wide variety of cultured aquatic species (NRC, 1993; Lovell, 1997). As this information comes available mill design and mill processing changes are inevitable, and they are likely to develop very quickly. For that reason the aquatic feed miller of today must maintain flexibility within their mills and an awareness that changes are taking place as these guidelines are being written. An example of feed requirements and good management for shrimp can be found in Akiyama (1989).

Site location of the manufacturing facilities

The design and location of a feed mill should be guided by the customers it is to serve with important consideration given to soil conditions and whether or not an area is prone to flooding. It is important that the mill be located so that any impacts from wet conditions are minimized and the area kept free of heavy undergrowth and bushes. Equally, it is important that local transportation infrastructure be utilized to the extent that railroad spurs, wharves, and highways are considered for receipt of raw ingredients and also for the ease and cost-effectiveness with which the farmers are to receive their feed. Areas prone to flooding, tidal inundation, and fire should be avoided if at all possible. It is important to remember that if the mill cannot deliver feed on schedule due to flood or other natural disaster the feed miller is not the only one at risk, but it may put the farmer at risk as well. It is important to locate the plant such that future expansion of mill facilities can be accomplished cost-effectively. Initially, the mill equipment should be sized and designed to allow for expansion and easy change of equipment as new techniques in milling evolve and/or the species mix fed changes. Flexibility in the mill design is vital if one is to remain competitive. The property should be configured to contain and/or manage any spills or runoff from the mill site. In wet areas elevator and receiving pits should have drains (and/or sump pumps) to prevent flooding (McEllhiney, 1994). It is important, too, that the plant be a good commercial neighbour, that by design it is inoffensive and a positive force in the community, complying with local health, safety, and environmental regulations and always presents a clean and neat appearance. Regular inspections by management are important to assure the good outward appearance and a high standard of cleanliness, as well as to be certain that all equipment is performing to specification.

Selection and purchasing of raw ingredients; ingredient quality control

Quality feed begins with quality ingredients and it is the manufacturer's responsibility to make sure that the ingredients used within their feeds are wholesome and safe. To this end the manufacturer's buyer should have a set of standards for ingredients to be purchased and only purchase from reputable ingredient sellers who will comply with the mill's purchasing standards. Ideally the commodity merchants, and supplement companies from which feed ingredients are purchased, should provide the buyer with specifications of exactly what is to be bought. To insure the ingredients are meeting specifications, the miller should conduct periodic sampling to verify the ingredient specifications are being met. (See Sampling Methods and Analyses.) In addition to the nutritional and

analytical characteristics of the feeding stuffs, the specifications ought to include: origins and sources; any pre-processing details; hazards or limitations; miscellaneous information including moisture, possible non-hazardous contaminants (stones, grit, etc.). All incoming ingredients should be inspected and tags/labels should be read for medications, trace minerals and other additives.

In the event the analysis indicates that an ingredient does not meet mill specifications, and the supplier continually transports substandard ingredients, that supplier should be removed from the mill's supplier list. To become reinstated, a supplier must demonstrate that positive action has been taken to correct the deficiencies.

Grain or feedstuffs used in the manufacture of aquaculture feeds which are mouldy, treated/dyed or otherwise discoloured should not be used for any feed or food. Brightly coloured grain usually indicates seeds which are treated for use as rodenticides, or other pest control; these can be highly toxic to aquatic animals and man. Mycotoxins found in mouldy feedstuffs may, even at very low concentrations of a few parts per billion, have detrimental effects on aquatic species (Li *et al.*, 1994; Meronuck and Concibido, 1997).

Receiving of ingredients

All incoming ingredients should be verified for correct: (i) labelling of product; (ii) purchasing specification; (iii) cargo destination; (iv) lot numbers/date; and (v) regulatory compliance, as appropriate, especially for medicated feeds.

Before acceptance and unloading procedures begin, the following factors should be considered: (i) colour of the product; (ii) odour of the product; (iii) presence of any foreign material; (iv) presence of any insect infestation; (v) granulation, texture; (vi) density of the product; (vii) moisture; (viii) weight; and (ix) other appropriate factors (including temperature).

A visual comparison should be made to a known sample of the ingredient. The contents of the carrier should be inspected for load depressions which could indicate leakage. Before or during unloading of all bagged ingredients (i.e., premixes, minerals, medications, etc.), a physical count should be taken and compared with delivery tickets and bills of lading. Any bag count variances or damaged products should be noted on receiving documents and on the bill of lading. The variances must be reported to the mill manager as well as the purchasing manager so that a claim can be made to the supplier and/or carrier.

Refusal of a load can be a very difficult choice, especially if the mill is short of the particular ingredient which should be refused due to contamination, failure to meet specifications or other valid reason. It is very risky to all customers and the financial stability of the mill if contaminated ingredients are allowed into the mill system. It may be very difficult and costly to remove the contamination, depending upon the nature of it.

Documentation allowing a "paper trail" or chain of custody should be maintained which may include: (i) type of ingredient received; (ii) date received; (iii) shipper; (iv) supplier; (v) unloading assignment; and (vi) other appropriate information, including lot number of drug shipments received.

Both bulk and bagged ingredients should be used in a manner such that first-in, first-out rotational procedures occur.

Storage and handling of ingredients and finished goods

Feed ingredients which are dry before processing should be kept dry and cool and used on a first-in, first-out basis. As a general rule the moisture percentage should be less than 13% particularly in humid and/or tropical areas. The tanks in which these ingredients are commonly stored should be cleaned monthly, or as indicated by experience, to prevent the build-up of dust and fragments of feedstuffs. Such build-up creates habitat for mould (and therefore the possible production of mycotoxins) and insects which will quickly destroy the food value of the products being stored; heat is

also produced by these organisms and spontaneous combustion resulting in serious ingredient losses, and possible property losses may occur. The elevator legs, other conveying equipment and spouting should also be routinely inspected and cleaned out for the same reasons. While processing may dilute or kill concentrations of mould and insects, keeping equipment and storage free of dust and build-up of old feedstuffs will prevent or at least reduce the possibility of contamination of the finished feed. Liquid ingredients such as tallow, amino acids, and molasses should be stored in accordance with manufacturers' recommended procedures to protect freshness. Fats and oils may need to be heated for ease of handling and/or have antioxidants added (to prevent lipid peroxidation and control off-flavours in food animals) to maintain quality. In general aquaculture feeds are composed of some highly perishable (and expensive) ingredients and care must be taken to keep both the feed ingredients and the finished feed away from contamination including heat and light, as well as biological factors such as mildew, insects, birds and rodents. Propionic acid and other antifungal agents may be used during processing, but these chemicals may adversely affect palatability and efficacy of the feed. Both the feed miller and the farmer/end user of the feed need to remember that heat, light, and moisture can damage feed and that sacked feed should be stored off the ground on pallets, out of direct sunlight due to the damaging effects of ultraviolet rays (New *et al.*, 1995).

Depending upon the source and nature of bulk feedstuffs ingredient cleaning may be necessary. Most feed mills have grain cleaning systems, designed to remove broken seed, tramp metal, and other foreign materials which contaminate inbound ingredients from time to time. It is wise for the buyer to specify that dust (fines) and other contaminants shall not exceed a certain level. Inbound ingredients should be subject to rejection if contamination levels exceed specification. Aquatic animals are particularly sensitive to low levels of, for example, fumigants, and possibly mycotoxins, and for that reason great care must be taken in the choice, sourcing and handling of feed ingredients for aquaculture.

Tanks, warehouses, and ingredient handling systems should be designed so that moisture, rodents, birds and other pests are denied access. Regular cleaning of storage facilities will go a long way toward assuring a high quality finished product. One of the main components of receiving and storing is proper scheduling of the arrival of ingredients so as to minimize storage time and handling of the ingredients. Quality of ingredients, be they sacked supplements and/or medications, or bulk corn, or soybean meal, for example, may lose nutrient value or efficacy from excessive handling. Handling also invites problems with shrink.

Misformulated, damaged or returned feed must be stored such that it cannot contaminate other feeding stuffs. Confirming analysis should be made to determine if such waste feed can be reprocessed, or must be destroyed. Here again a paper trail is important, especially for medicated feeds.

Feed ingredient processing

Processing refers to equipment which is used to reduce or enlarge feedstuffs so that manufacturing, handling, and feeding are economically practical. Such pieces of equipment include hammer mills, roller mills, attrition mills, aspirators, screeners, pellet mills, extruders, mixers and other equipment, including baggers and ancillary equipment. The operators of these pieces of equipment must be properly trained, and training records kept. Routine checking of ingredients and feed must be made to assure product is to specification.

Feed formulation and manufacturing

Aquaculture feeds should be manufactured according to a formula recommended by a competent nutritionist and should be specific for the aquatic species being fed and intended farm production system. While most temperate freshwater diets may be largely based upon the use of plant protein and energy sources, and cold water marine diets largely based upon the use of fishmeal and other fishery by-products, there can be regional differences which reflect optimal use of available and/or least-cost formulation of ingredients. In most existing feed mills the coarse grains and possibly other

ingredients will be ground in a hammer mill, roller mill or otherwise prepared by appropriate means to allow uniform mixing of the ingredients to formula specifications and further processing by pellet mill or extrusion to the cooled and finished product. The feed, properly cooled and dried after processing, is then ready for sacking or bulk delivery to the farm.

The particle size(s) of the ingredients may be limited by the type of process equipment available in an old mill. In aquaculture feeds particle sizes are typically smaller, some as small as 50 microns to allow proper mixing and pelleting (AFMA, 1982) or extrusion of the feed. The important thing is the conditioning and cooking process of the mash, whether it is to be pelleted or extruded (or a system which employs the principles of both), the starch must gelatinize so that the feed is digestible and maintains its integrity in water. This will assure that the feed nutrients are consumed by the fish or invertebrates and do not end up as fertilizer or pollutants for the intended farm production system. Generally, pelleting is less expensive than extrusion and may be cost-effective depending upon a variety of factors including the type and behaviour of the species being cultured, types of ingredients available, and resources of the feed miller. Newer hybrid machines which combine the best attributes of both pellet mills and extruders may be an exciting development for aquaculture (AFIA, 1996, 1997). For specific details on the different types of manufacturing processes which may be employed for the production of animal feeds, including aquaculture feeds, readers should consult McEllhiney (1994) and Pipa and Frank (1989).

Packaging and labelling

The function of packaging is to protect the finished feed from light and moisture and other environmental contaminants. Together with labelling, it should tell the farmer the identity of the manufacturer and the type of feed it is. The feed label describes the contents of the sack or package and the species for which it is intended. For bulk feed, that which may be delivered in quantity as by truck, or sea container, the label and instructions for application of the feed should be attached to the invoice. If the feed is medicated, warnings should be clearly evident along with specific instructions for the species being fed.

Warehousing and shipping

Up to this point in feed production great care has been taken in the manufacturing and materials handling of aquaculture feeds. Similar care must be taken in the warehousing and shipment of the final product. Sacked feeds must be stored in the warehouse off the ground on pallets away from sunlight with approximately one third of a meter between pallets to assure good air circulation. Storage should always be on a first-in, first-out basis. Storage of finished feeds must be carried out with the protection of the target species and human health as primary considerations. By meeting these objectives the feed miller should insure customer satisfaction.

Sampling methods and analyses

Sampling of raw ingredients and the finished products of aquaculture feed milling should be conducted routinely so as to be certain that the raw materials going into the feed and the finished feed itself meet formula specifications (Bates *et al.*, 1995) and do not contain any defects which could be harmful to the farmer's crop or the human consumer. For additional information and details see AOAC (1990) and McEllhiney (1994).

Recalling defective or mislabelled product

Most feed manufacturers use a broad range of ingredients, and there is a chance that a product recall could be necessary if there were sufficient evidence of a feed quality or labelling error. Not only may there be a potential violation of government regulations and a danger to aquatic animals and/or consumers, but the continuing healthy relationship with the farmer must be maintained. To this end an efficient and successful product recall procedure involving products manufactured by the mill is

necessary and should reduce or save a serious liability claim against the manufacturer and maintain a helpful relationship of trust with the customer.

Plant cleanliness and worker safety; housekeeping

The feed milling company should be committed to maintaining a quality housekeeping programme that provides a safe and healthy environment for its employees and the community. The intent is to maintain mill properties in a manner that minimizes loss to persons or property and maximizes product quality assurance. Housekeeping is a direct responsibility of all employees, and each should be held accountable to do the things necessary to implement an effective housekeeping programme.

Plant maintenance and repair

The plant maintenance program is vital to consistent production of high quality feeds and no less important to cost control and assurance to the customer that their feed will arrive on time and to formula specification. Equipment breakdowns are bad enough as they impede aquaculture feed production, but at least as bad is machinery which is not working to design which may, through short weighing, or improper mixing, produce a defective feed. Such defective feed may, at the least, hurt the farmer's production and at worst create a serious crop failure. Also possible is a threat to human health. Keeping motors, scales, pellet dies, conveyors and all other components of the mill in proper working order is as important as formulation or the quality of ingredients which go into the finished feed. Mechanical or electronic failures may occur from time to time in a complex system like a feed mill, but proper attention to preventive maintenance will minimize down time and the prospect of the customer's receiving feed which is out of specification. The latter may cause a costly recall of feed or possibly compensation for damages to the customer's crop, if the error is not found in a timely way. A good preventive maintenance programme should provide adequate maintenance at reasonable cost.

Personnel

Quality aquafeeds can only be made by knowledgeable and trained personnel. Training is an on-going process mentioned in various sections above, and can be summarized as follows: General management should have formal training in feed technology, sufficient to assure the competent purchase and handling of quality ingredients, correct manufacture, storage and handling of finished feeds. In addition to assuring that the feed manufactured meets the intended specifications for the species to be fed, the manager must maintain documentation of the process sufficient to allow accurate tracing of the ingredient sourcing and manufacturing events of a finished feed. This will include a record of who received the feed, and any other pertinent details including medications. Personnel should receive refresher training on a regular basis, or additional training on new equipment and/or processes to be employed. There will be a particular emphasis on regular safety meetings where employees will make known any safety problems (violations) in need of correction. A log or journal of safety meetings should be kept. Particular attention must be given to record keeping as it relates to animal health products; these should always be stored separately from other ingredients to avoid any possibility of cross contamination.

Documentation

Documentation must be both adequate and systematic and relate both to the manufacturing process and to quality assurance (UKASTA, 1997). Its main purpose is to define the system of control required to reduce the risk of error. This must include defining and mastering the critical points in the manufacturing process and establishing and implementing the quality control plan. It is also designed to ensure that personnel are instructed in the details of the necessary procedures and to permit investigation and tracing of defective products. The system of documentation should be such that the history of each batch, blend, or run of product may be determined.

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