

## **THE MEDROXY PROGESTERON ACETATE (MPA)-CASE IN EUROPE: AN EXAMPLE OF THE WEAKEST LINKS IN THE QUALITY ASSURANCE SYSTEM FOR THE FEED INDUSTRY TO PRODUCE WHOLESOME FOOD FOR ALL**

**Tielen Martin J. M.**

*Em. Prof. University Utrecht, the Netherlands  
First Vice-President of the ISAH  
Vice President of the European Feed Manufacturers Federation (FEFAC)  
President Netherlands Feed Industry Association,  
P.O.Box 1732, 3000 BS Rotterdam, the Netherlands*

### **Summary**

Between May and August 2002 Europe was confronted with a contamination of Medroxy Progesterone Acetate (MPA) in the feed and food chain. The contamination was accidentally discovered through fertility problems in a sow farm. The MPA-concentrations in the kidneys of the sows were between 33 and 65 ppb. This concentrations were due to the liquid feed of the animals. Sixteen days after the last application of this feed the concentration were decreased to 2.5 – 6 ppb. Tracking and tracing through the Quality Assurance System for Animal Feed worked out that the MPA-contamination in feed and food was very extensively spread. The origin of the MPA-contamination was due to illegal activities in the waste processing of sugar water from a farmaceutic plant in Ireland. This sugar water was exported to a non-certified Belgium feed ingredient trader and purchased to two Dutch traders in liquid feed. There the spread of the MPA-contamination through the food chain started by supply of liquid feed to pig farms and supply of sugar syrup to the compound feed industry.

The presence of MPA in the feed and food chain is forbidden by the hormone ban of the European Union. MPA-concentrations in the feed and in the kidney's and meat of the animals showed, that there was no risk for human health by consuming the products. In spite of that, due to the hormone ban 60.000 pigs has to be culled. The MPA-affaire did cost the Dutch animal production chain about 130 million Euro.

The Quality Assurance System for Animal Feed (GMP+HACCP) was not able to prevent against this MPA- affaire. Lessons learned by this event where used to upgrade the system for the future.

### **INTRODUCTION**

MedroxyProgesterone Acetaat (MPA) is usually used as an anti concepticum in the human fertility regulation. During the production process the anti conception pill is coated with sugar water. The overflow of the sugar water has to be managed as waste due to contamination with MPA.

Based on the report of van Leengoed e.a. (2002) the case started in May 2002 when severe fertility problems occurred in an closed sow farm with 1200 sows.

Problems started with slow proceeding parturition and increased anoestrus. From 60 à terme sows only 3 sows started farrowing with a very slow parturition procedure. Six sows died after a pregnancy of 124 days. Weaned sows didn't became in oestrus again. Sixty percent of the sows developed cystic ovaries after weaning.

Suspected cause of the problems were expected in an anti-oestrogen factor in the feed.

Sows were fed with liquid feed containing beer by-product, wheat starch and potato steam shells. Analyses of the MPA concentration in the different feed ingredients of the liquid feed varied from 18000 to 43000 ppb. In the kidney fat from slaughtered sows fed with this liquid feed MPA-concentrations from 13 to 65 ppb were found. Kidney fat from sows examined 16 days after the last contaminated feed supply showed MPA concentrations from 2.5 to 6 ppb.

Further analyses worked out, that the MPA contamination was originated from a glucose syrup composed with the waste sugar water from a farmaceutic plant involved in the production of the anti conception pill. This glucose syrup was included in the liquid feed diet of the pigs. The discovery of the MPA in the glucose syrup was the begin of an extended spread of MPA contamination in the feed and food chain.

## **SPREAD OF MPA-CONTAMINATION**

After the discovery of the MPA-contamination in the glucose syrup a intensive survey started to track the use of this contaminated feed ingredient in the feed and food chain. It worked out, that the glucose syrup contamination was originating from an Irish farmaceutic plant who delivered the contaminated syrup to an waste processing company. This company exported the contaminated syrup to a non certificated Belgium trader with own storage, where the syrup was mixed to the glucose syrup mentioned before.

Two Dutch Liquid Feed traders received 250 ton of this syrup. Most of the syrup was delivered as mixed Liquid Feed (LF) to fattening pig farms. A small part of the syrup was delivered to the sow farm with the fertility problems mentioned before. An other part of the syrup was delivered to the compound feed industry.

One compound feed manufacturer purchased the glucose syrup direct from the trader. The rest of the glucose syrup was delivered to an big molasses trader, who used the glucose syrup to mix it with molasses for quality requirement reasons. This molasses was delivered to compound feed manufacturers to use it for the production of feed for cattle, pigs and poultry.

A part of the molasses was delivered to an alcohol fermentation plant, who used the molasses to produce alcohol. By-products of this production are wheat yeast concentrate and vinasse. This vinasse was delivered to compound feed manufacturers again to use it to produce feed for farm animals.

This affaire created by this way the following traces:

### **Track 1:**

59 fattening pig farms received liquid feed with MPA-contaminated glucose syrup. The MPA-concentrations in this liquid feed varied from 5- 237.341 ppb. All farms were blocked and controlled. Animal samples of 26 of these farms were positive on MPA. 60.000 pigs of this farms had to be killed and rendered.

### **Track 2:**

60.000 tons of the syrup was purchased by a feed ingredients trader who sold it in two ways. 3 ton of the glucose syrup was purchased straight to an compound feed factory who used in molasses to produce compound feed for 516 farms. After discovering of this trace all the compound feed was recalled. Samples of fat of the pigs and poultry where negative on MPA. All farms were set free again.

**Track 3a:**

59 ton of the glucose syrup was purchased by a molasses trader, who used it to mix up the molasses to the required quality standard. This contaminated molasses was delivered to 73 compound manufacturer's and traders. The MPA-concentrations from the compound feed were so low (3-38 ppb, see table I) that based on the composition of the feed and the animal consumption per day it was calculated, that there was no risk for the human health by consuming this products. Samples from 316 animals in this track fed with the contaminated feed didn't show detectable MPA-concentrations. Due to the EU-ban on hormones in products for animals a recall for the feed was requested. The farms were set free for production.

**Track 3b:**

Part of the molasses was delivered to an alcohol factory, who used wheat and molasses for alcohol fermentation. By-products of this process are vinasse and wheat yeast concentrate. Compound feed produced with the contaminated vinasse was supplied to 850 farms. The wheat yeast concentrate was delivered to 63 LF-pig farms. The MPA-concentrations in this liquid feed where 26-48 ppb (table I). The MPA-concentration in the vinasse were 44-193 ppb. There was a recall for the compound feed contaminated with the vinasse at the pig farms. This feed had a MPA-concentration of 3-38 ppb. After negative results of the control samples from 160 animals in this track all farms became free.

**Table I.** MPA-concentrations in the different ingredients and feed contaminated with MPA. (ER-Calux-assay).

<b>Product</b>	<b>MPA concentration (ppb)</b>	
	<b>Lowest</b>	<b>Highest</b>
Glucose syrup	1.4	4,750,000.0
Liquid feed with glucose syrup (track 1)	5.0	237,341.0
Pig kidney fat (track 1)	< 1.0	135.0
Molasses (track 2)		6,751.0
Compound feed (track 2)	9.0	286.0
Pig fat (track 2)		< 1.0
Glucose syrup (track 3a)	70.0	1,250,000.0
Molasses (track 3a)	38.1	4,487.0
Compound feed (track 3a)	3.0	38.0
Vinasse (track 3b)	44.0	193.0
Silage (track 3b)	3.0	33.0
Wheatyeat concentrate (track 3b)	26.0	48.0
Pig fat (track 3a, 316 samples)		< 1.0
Pig fat (track 3b, 160 samples)		< 1.0

It can be concluded, that the MPA-contamination was due to illegal acts of a waste processing company in Ireland and a feed ingredient trader in Belgium. That did make the MPA-contamination in the feed – and food chain unpredictable and unavoidable. The existing Quality Assurance Systems for feed where not able to detect the contamination in an early stage because there was no control on MPA in the monitoring system at all. The MPA-contamination showed

accidentally up through fertility problems in a sow farm. The Quality Assurance System for animal feed has to be adjusted to the lessons learned from the MPA-affaire.

## **QUALITY ASSURANCE SYSTEM FOR ANIMAL FEED**

### *Feed Safety*

It has become clear by some food safety crisis like BSE and MPA in the past years, that animal feed has to be considered as one of the potential sources for human health risks. We therefore have to take care for a high feed quality. In this regard "feed quality" does mean "feed safety".

Experiences learned that food safety crises related to feed safety provoked problems, especially for the dairy, eggs and meat processing industry. Quality of milk, meat and eggs is all the more important for the Dutch agriculture, because about 60% has to be exported. For an undisturbed export the product safety have to be irreproachable. If this would not be the case, the results are:

- stagnation of sales
- a beating of the public confidence in food safety
- financial damage for a lot of companies
- increasing need of safety requirements by politics and retail.

The animal feed industry, including the feed ingredient suppliers, forms an important part of the food production chain, with a considerable responsibility for product safety.

Especially retail wants that the safety of products is safeguarded in the whole production chain in a demonstrable way, including the animal feed industry. This has to contribute to improve and maintain the retailers' and public confidence in food safety.

These requirements are not from recent time. To comply with the demands of the following partners in the chain, already in 1992 the Netherlands Feed Industry established a quality assurance policy with the following main objectives:

- to produce, deliver and feed animal feed materials which are safe for consumers of animal products, for animals as such and for the environment
- in a trustworthy way for all stakeholders, that are the chain partners, the consumers and the politics

The second objective means that safeguarding has to be demonstrable and transparent. We are very glad to notice that our approach runs parallel with the White Paper on Food Safety of the European Commission (January 2000), which is based on the same principles. That should result in the application of this approach in the entire European Union within several years.

### *GMP Animal Feed*

For these reasons, in 1992 the Product Board Animal Feed elaborated the so-called GMP (Good Manufacturing / Managing Practice) for animal feed suppliers. GMP means careful production, delivery and feeding of animal feed. Since that time it has been improved and extended on the basis of experience and ongoing insight.

Participation is voluntary, but this quality assurance scheme is part of the Integral Quality Control programs, applied in the meat, eggs and dairy chains. Livestock farmers, participating in

these quality control programs, are obliged to purchase feed materials only from GMP-recognised suppliers.

More than 95% of the Dutch animal feed suppliers (compound and straight feeding stuffs) to livestock farmers is GMP recognised. In June 1999 the Product Board Animal Feed decided to enhance the GMP quality assurance system for animal feed by choosing for:

- A pro-active, risk analytical approach in the entire production chain for feed materials with hazard analysis at chain level and HACCP (Hazard Analysis & Critical Control Points) at the individual company's level.
- Extension of the quality assurance system to the suppliers of feed ingredients
- Development of an early warning system (EWS) for incidental unacceptable contamination situations.

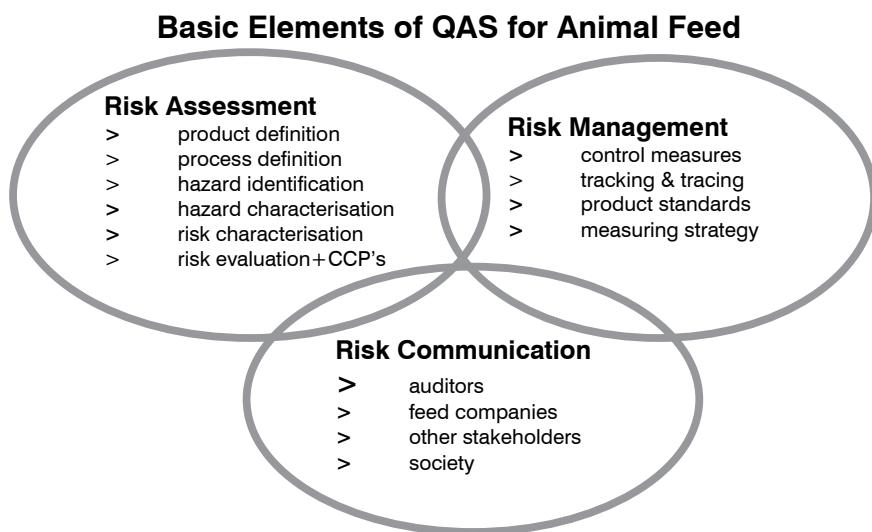
Essential in this approach is the systematic working method and the acting beforehand. It may also contribute to avoid emotional reactions and uncontrolled decisions.

One very important part of the GMP is the extension of safeguarding to the supply of all feed ingredients.

From 1 October 2000 GMP recognised suppliers of compound and straight feeding stuffs are obliged only to buy feed ingredients from suppliers who are able to safeguard the product safety in a demonstrable way. All Dutch ingredient suppliers must have a certified quality system that comply with the GMP requirements, by way of a GMP-recognition or an equivalent ISO 9002 or HACCP certification. By way of exception suppliers of recycled frying fats have already to be GMP-recognised since 1 April 2000. Since 1 January 2002 all suppliers of raw material to Dutch GMP+ compound feed producers have to demonstrate a Quality Control System certified by an external certification body.

#### *Risk analysis*

The bases for a Quality Assurance System has to be a scientific risk analytical approach. This contains three components: risk assessment, risk management and risk communication.



Risk assessment is carried out by scientific advice and information analysis; that means hazard identification and characterisation, exposure assessment and risk characterisation. This risk assessment forms the basis for risk management and risk communication.

#### *European Benchmark Standard*

On an equal way the feed industry in different Member States started to set up Quality Assurance Systems to prevent against optional risks for feed safety. Optional risks has to be determined through scientific based analyses and translated in risk management and risk communication. This QAS systems should be based on Hazard Analysis Critical Control Point (HACCP) systems. Based on risk analysis each feed manufacturer has to describe the procedures and to control the critical control point in this procedure regularly to the QAS. This self control system has to be externally controlled by an independent control organisation. The system has to give assurance to the government and the consumer about the required quality of the feed. Suppliers of the feed ingredients all over the world have to be included in this HACCP system too. It is very important for mutual recognition and equality that the different national codes will meet the requirements of EU-legislation. Therefore European Feed Manufacturers Federation (FEFAC) decided to develop a benchmark standard for feed quality assurance systems who can be used for the certification of the national codes on equality. Certification of the individual feed manufacturers have to take place by accredited independent certification bodies. That can be the bases for European suppliers organisations to adapt there codes of practice to the FEFAC-benchmark standard to realise a EU wide acceptation.

#### **CLOSING REMARKS**

- Feed safety has a high priority in the whole European Union to produce wholesome food for all. The animal feed industry, including the ingredient suppliers, is part of the food chain and is responsible for the safety of its products.
- HACCP type quality assurance systems are a pro-active approach which links up the feed chain with the food chain and has to be the standard for all steps in animal production.
- Demonstrable and transparent quality assurance systems are the 'licence to produce' and has to be based on certification by independent certification bodies.
- Production of feed and food should only take place with materials, ingredients and products with well known origin from QAS-certificate participants.
- Home mixers has to be included in the QAS certification
- Control, monitoring and certification audits should be especially focused the critical points in the production.
- The QAS should include severe sanctions in case of avoidable failures
- The MPA-contamination in the feed production chain was unpredictable and unavoidable due to illegal activities.

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