

> EDITORIAL

Mycotoxins are naturally occurring hazards with severe toxic effects on humans and animals. Since this fact is generally agreed upon worldwide, responsible governmental bodies all over the world try to protect their population by setting regulatory limits for the most dangerous mycotoxins, such as aflatoxin. But, the regulatory limits differ greatly between countries and the limits do have complex effects on worldwide trade and local economies.

Harmonization of regulatory limits, introduction of quality control in agricultural production such as HACCP and establishing acknowledged test management would reduce trade barriers due to mycotoxin regulation.

Romer Labs, as an expert in mycotoxin testing, provides test systems world wide. Due to our expertise in many technologies, we offer mycotoxin tests suited for different situation, therefore covering mycotoxin testing of crops all the way from farm to fork.

The correct mix of low cost screening and high tech quantitative analysis based on good and practicable sampling plans can significantly reduce economic losses and is the only way to maintain the consumers trust in certain products.



Eva Wanzenböck



Mycotoxins such as Aflatoxins, Ochratoxin A and Fumonisin are health hazards that contaminate a wide variety of crops. Human and animal health can be at risk due to mycotoxin contamination. In order to reduce the risk associated with mycotoxin contamination, regulations and laws are enforced by the respective authorities.

Public health matters are only one aspect of this subject. How do regulations that are different from one country to the next influence the worldwide trade of agricultural commodities? What is the economic impact? Who benefits, who loses? Many questions occur once we look deeper into this matter. Romer Labs® asked opinion leaders in science and industry to share their view on this topic.

Impacts of Mycotoxin Regulations on World Trade

by Elisabeth Pichler

World wide regulation

The last survey of worldwide mycotoxin regulations was published by the FAO (Food and Agriculture Organization) in 2003. The number of countries setting regulatory limits for mycotoxins in food and feed is rapidly growing. By the end

of 2003 it reached a level of approximately 100 countries which regulated Aflatoxin B1 or total Aflatoxins. The trends observed in regards to mycotoxin regulation were:

- more mycotoxins in more commodities were regulated compared to earlier observations,
- limits remained or tightened,
- regulations became more detailed regarding e.g. sampling or analytical methodology,
- harmonization between countries belonging to economic communities occurred.

Still, the regulatory levels differ widely if we compare major economic communities: e.g. the European level for total aflatoxins in commodities like cereals for human consumption is five times lower than the U.S. level of 20µg/kg.

What are regulatory levels based on?

Many factors influence regulatory levels for mycotoxins⁽⁹⁾. The most important factor is the toxicity of a given mycotoxin. But whether the toxic effects are a real threat depends primarily on the exposure of the population to the toxin - which makes exposure another influential factor. The distribution of the toxin in contaminated crops should be considered as well as the availability of analytical methods to detect and quantify the mycotoxin at the intended regulatory limit.

Existing regulations in countries of trade partners play a role as well. An area of concern for regulatory authorities that



establish regulatory limits is ensuring that a guaranteed food supply will be available for the population. It does not and would not make sense to protect people from mycotoxin contamination by starving them. In this context a statement given by Kofi Annan, Secretary-General of United Nations, at the 2001 U.N. Conference on the least developed Countries in Brussels illustrates the broad effect of this issue very well: “A World Bank study has calculated that the European Union regulation on aflatoxins costs Africa \$ 670 million each year in exports of cereals, dried fruit, and nuts. And what does it achieve? It may possibly save a life of one citizen of the European Union in every two years [...] Surely a more reasonable balance can be found.”

Effect of mycotoxin regulation on price, trade and health status

In a paper recently published by Felicia Wu⁽¹⁰⁾, the complex effects of regulatory limits for mycotoxins on price, trade, public health, selling and purchasing decisions of nations was presented.

Developed countries face economic losses as a result of mycotoxin regulations. These losses are caused when disposing highly contaminated crops or by lower productivity of animal livestock due to chronic intoxication.

On the other hand the effects on the economy in developing countries are more indirect ones but far more dramatic for the population: The highest quality crop is exported to the developed countries while the lower quality is consumed locally. In combination with the wide spread malnutrition and the lack of health care this can lead to severe acute or chronic intoxication in those populations. But there is also a direct impact on the economy of developing countries: Due to a lack of monitoring at the export points, or – if monitoring is present – a lack of confidence in the existing test management, exported goods get rejected at the importing points of developed countries leading to pricing pressure.

Based on an empirical model developed and published by Felicia Wu⁽¹⁰⁾, the economic impact of different regulation scenarios can be determined. Two scenarios for the three biggest peanut exporters (US, China, Argentina) were assumed. In the first one, Wu based her calculations on the assumption that the US-Aflatoxin limit of 20µg/kg was adapted world wide, for the second she used the current EU limit of 4µg/kg.



The latter resulted in an export loss⁽¹⁾ of 450 million dollars annually while adopting the US limit globally would only cause an export shortfall of 92 million dollars annually. Interestingly this model shows a linear relation between mycotoxin regulations and export loss.

Current discussion and efforts of harmonization

There are lively discussions about this issue among different stakeholders and at different occasions. At the recent World Mycotoxin Forum (WMF) in the Netherlands, a panel discussion was organized where representatives of the USDA, the EU and of various industries debated about mycotoxin hazards and regulations. Not all conclusions of the discussion were new and quite a few points had been published previously⁽¹¹⁾:

According to the Joint FAO/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) which is the scientific body that develops advisory international standards on food additives and contaminants for the Codex Alimentarius Commission, reaching consensus on maximum levels for aflatoxin (and other mycotoxin) standards is complicated by the fact that: Levels of contamination of foodstuffs vary tremendously around the world, and with respect to trade, the perspectives of delegations differ profoundly. Those representing countries in which aflatoxin contamination is not prevalent want low standards because they do not wish to see the quality of their food supply degraded. Those delegations from countries in which aflatoxin contamination is a problem because of their climatic

conditions naturally wish to have standards in which higher levels of contamination are permitted so that they can sell their products on world markets with greater ease.

Regulatory limits...

One of the questions referred to very low regulatory limits like those in the European Union. Romer Labs® asked people if they feel that these limits overprotect the EU citizens on the expense of third world countries. Ms Bao Lei, who is working for Qingdao Entry-Exit Inspection and Quarantine Bureau in China, stated that low limits are a problem and cause large uncertainties in the aflatoxin determination. Mr. Baldi, Chief Quality Control Manager at Louis Dreyfus in Argentina was convinced that: *“Mycotoxin regulations can cause the loss of markets which are hard to retrieve because you have to solve a problem which can't be managed by the company. From my point of view Mycotoxin regulations are another form of protecting a market.”* And he added: *“In my opinion most of the Mycotoxin issues of imported grain in the EU are a result of inadequate storage measures within the European countries.”*

On the other hand Dr. Goto, Professor of Food Safety in Nagano, Japan, said: *“Countries have their own historic and social background and have right and duty to protect their people from any kind of problems. However, if their regulation is too strict from the view of international standards, not a view from one strong country, those countries must pay the cost.”*

Dr. Roland E. Poms, Secretary General of the International Association for Cereal Science and Technology (ICC) is aware of the fact that *“the currently tolerated maximum levels of mycotoxins in crops in the EU are already one of the lowest in the world [...]”* but also admits that *“[...] there always remains a statistical risk, no matter how low the legal limits might be.”* Finally Dr. Poms referred to the World Bank study and pointed out that *“Even one life lost to disease that could be saved is one too many, but at the same time many lives lost to hunger in third world countries that could be saved are far too many.”*

Import – Export...

Another inquiry addressed the problem, that shipments sometimes get rejected at import points even though they were tested at the point of export. All experts we contacted agreed that sampling and the lack of good

⁽¹⁾ “A nation’s total export loss of a particular food crop, given a particular internationally imposed mycotoxin standard, can be calculated as the product of the price of the food crop per unit volume on the world market, the total volume of that crop exported by a particular nation, and the fraction of that nation’s food export crop that is rejected as a result of a worldwide mycotoxin standard.”



sampling methods are most likely responsible.

Dr. Morales from the world's largest Tortilla producer in Mexico, added *"Sampling is such an important matter that determines the success or failure of a result, the meaning or the meaningless of a series of data. I consider sampling the most underestimated part of the analysis, and the most important one. Heterogeneous distribution of mycotoxins is overcome using appropriate techniques of sampling. Appropriate tests and methods are now easy to get contacting the right supplier."*

Dr. Poms pointed out that *"The main problem for both sampling and analysis is that there is often no consensus on the methodology and the protocols for analytical monitoring and control of crops. Even though there are some relevant ISO, CEN, ICC, AACC... standards for quality and safety control available, every country has its own legal requirements, which often do not correspond to Harmonised International Standards - if existent at all - and are not always mutually recognized. Even in the Western World these differences exist and often lead to trade disputes between the USA and the EU."*

Mr. Baldi from Louis Dreyfus Argentina agreed with the sampling problem and continued that *"... also the insufficient knowledge of regulations when it comes to sales contracts can cause serious problems at the import point."*

Impacts...

Mycotoxin regulations have an increasing impact in all the different areas and businesses the contacted experts work in. But the impacts vary a lot, what is positive for one business is a threat in the other. Prof. Krska, expert in mycotoxin analysis, noted that: *"Regulations for mycotoxins have indeed increased the awareness for these secondary metabolites of fungi. As a result the number of activities in determination of mycotoxins, e.g. for standardization of analytical methods, have increased considerably. The number of nationally funded research projects in the area of mycotoxin analysis has gone up which was unfortunately not the case for European Commission funded projects."*

Mr. Mike Arcinas, Quality Control Manager for the Feed Business in San Miguel Foods, Philippines, commented on the positive developments due to the high awareness: *"On the positive end, for more than two decades we have been closely following developments in this field, we have seen tremendous improvements in the manner by which the food industry has tackled the mycotoxins issue. Indeed, food products are a lot safer today than ever before. This is the case even for third world countries. The heightened awareness, availability of new information & technology and the development of quick, easy and cheaper tests have allowed us to effectively manage the potential risks and negative effects of mycotoxin contamination."* But as Quality Manager of one of the largest conglomerates of the Philippines he also sees the threats: *"The bigger challenge today, I believe, is how less developed countries (like the Philippines), especially those in the "wet" tropics, will be able to cope and participate in world trade, in light of ever tightening regulations. The inherent climactic disadvantage is aggravated by the lack of infrastructure and state support. The Philippines is a unique case, in that, though standards pertinent to mycotoxins for internal and external trade of food commodities approximate those of developed countries, trade regulations are set up in a manner that will ensure the survival of local producers, who for their part, can hardly meet the standards. I believe that ultimately, it is the consumer or end-customer who will dictate what the standards should be. After all, sophistication will not come "free of charge". For many third world countries, food security and affordability is of the highest priority. There is the question of "having", not "having the best"."*

Dr. Morales, Mexico summarized: *"Of course, the cost impact of analysis, rejects, qualified personnel, etc., is high. However, we consider it as the way of guarantying safety to our costumers in this regard."*

Trade barriers...

Finally, Romer Labs® asked how the problem of trade barriers due to mycotoxin regulation could be solved. Ms. Bao Lei wanted to “encourage the export industry to improve their technique of aflatoxin prevention and management.” She added: “Furthermore, Bio control studies may be another research topic to solve the aflatoxin contamination pre-harvest.”

Prof. Krska was confident that: “The best approach to solve trade barrier is to increase confidence in analytical measurement results. Mycotoxin analysis needs comparability through traceability! This can be achieved by the use of certified reference materials incl. certified standards and calibrants, proficiency testing, accreditation and harmonized procedures as e.g. standardized methods and the compulsory application of recovery factors.” And Dr. Poms added that a “[...] general agreement on testing procedures and the implementation of (certified) standard methods and protocols may not solve all trade barriers but at least may ease the problem and improve international trading relations.”

Conclusion

Evidently, this issue is highly complex. Many contrary arguments like consumer protection, free trade, costs but also protection of local markets become important. No easy or rapid solution is in sight but from the point of view of a mycotoxin testing company it seems obvious to agree with the OECD report „The impact of regulations on Agro-food trade“^(IV) where it is mentioned that regulatory limits are not only a hindrance for exporters in developing countries because they can not reach the limits or because their products were not safe. It is mainly because they lack in infrastructure of monitoring, testing and certification. Without this infrastructure they can not demonstrate compliance of their products with the regulation of the importing country.

Consequently, a major leap forward would be to install area-wide testing management, certified by acknowledged bodies. These testing systems must be based on harmonized criteria regarding the major steps in mycotoxin testing like sampling, sample preparation, detection and interpretation of results. E.g. if the same method of detection is used in the harbor of the exporting country and by the authorities of the importing country, if the labs are certified by acknowledged bodies it should be possible to reduce the number of rejected goods together with the costs for shipment or even destruction significantly.

Developing countries are not left alone with the food safety issue. Certain international bodies offer financial and advisory help. E.g.:

Sixth framework programme Priority 5 Food quality and safety – specific support action^(V):

The present SSA proposal aims to implement the outcome of a wide range of European research projects in the area of mycotoxins and toxigenic fungi by supporting, stimulating and facilitating the participation and co-operation with countries having signed bilateral scientific and technological co-operation agreement with the EU.

The **Special Programme for Food Security (SPFS)**^(VI) is FAO's flagship initiative for reaching the goal of halving the number of hungry in the world by 2015. Since 1995, US\$ 770 million from donors and national governments have been invested in FAO-designed food security programmes. The SPFS initiative helps to achieve food security in two ways: through assisting national governments to run focused, well-planned *National Food Security Programmes* and through working closely with regional economic organizations to develop *Regional Programmes for Food Security* which optimize regional conditions for attaining food security in areas like trade policy.



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General Secretary

International Association for Cereal Science and Technology (ICC)

"ICC will be the pre-eminent international association in the field of cereal science and technology committed to the international cooperation through disseminating information and developing standard methods for the well-being of all people."

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San Miguel is one of the largest conglomerates in the Philippines dealing in highly diversified business.

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Central Lab Manager

GRUMA Mexico

World largest Tortilla producer

Lic. Jorge **BALDI**

Chief Quality Control Manager

Louis Dreyfus Argentina

One of the world largest commodity trading companies with global sales per year of more than 20 billion USD.

comparison of maximum tolerated levels of mycotoxins in foodstuffs:

country	commodity	Afla B1, B2, G1, G2 [g/kg]	Afla B1 [g/kg]
China *)	maize and maize products, peanut and peanut products, peanut oil, irradiated peanut		20
	rice, irradiated rice, edible vegetable oil		10
	soya bean sauce, grain paste, other grains ...		5
	infant formula-soybean based, infant formula "5410", formulated weaning foods, weaning supplementary foods		non-detectable
European Union *)	groundnuts, nuts and dried fruit and processed products thereof, intended for direct human consumption or as an ingredient in foodstuffs	4	2
	groundnuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	15	8
	nuts and dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	10	5
	cereals, with the exception of maize, to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	4	2
	cereals and processed products thereof intended for direct human consumption or use as an ingredient in foodstuffs	4	2
	maize to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	10	5
	spices	10	5
Japan *)	all foods		10
Mercosur *) **)	cereals and products	20	
	corn flour for tortillas	12	
United States of America *)	All foods except milk	20	

*) source: I Worldwide regulation...; list of commodities were shortened in some cases.

**) Mercosur member states: Argentina, Brazil, Paraguay and Uruguay



POINTS OF TESTING - ROMER LABS' OFFER

Interesting products for all industries:

- **Romer Analytical Sampling (RAS®) Mill**
- **Romer Series II® Subsampling Mill**
- **Other Equipment (TLC Autospotter, Romer Evap® System...)**

FIELD



Fast qualitative tests - **AgraStrip™**
A rapid lateral flow assay test which is:

- fast (5 min)
- user friendly
- rugged
- USDA/GIPSA approved

STORAGE



Fast quantitative tests for single tests

- **FluoroQuant™**

The fastest quantitative Test Kit in the market

- USDA/GIPSA approved

HARBOUR
(export point)



Quantitative methods, reference methods
HPLC/GC/TLC using
MycoSep®/MultiSep® clean up columns or StarLine™ immunoaffinity columns and biopure standards

FEED INDUSTRY

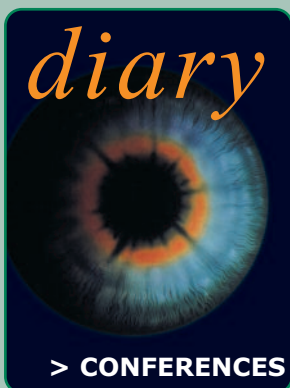
Fast quantitative tests for multiple tests
AgraQuant™ELISA



FOOD INDUSTRY

Quantitative methods, reference methods
HPLC/GC/TLC using
MycoSep®/MultiSep® clean up columns or StarLine™ columns and biopure standards



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The 28th Mykotoxin Workshop 2006 is organized by the Institute of Biology and Environmental Protection, Kazimierz Wielki University in Bydgoszcz (Poland) and the Society for Mycotoxin Research and Stockmeyer Stiftung.
It will be held from 29th – 31st May 2006.

V Latin American Congress of Mycotoxicology

The conference will take place in Florianopolis, Brazil.
It will be held from 18th to 21st June 2006.

The 2006 Mycotoxin and Food Allergen Symposia

The conference will take place in San Francisco, California USA.
It will be held from 11th to 13th September 2006.

9th European Fusarium Seminar (EFS9)

It will take place in Wageningen, The Netherlands.
It will be held from 19th to 22nd September 2006.

Mycoglobe International Conference 2006

From 27th to 30th September 2006 will be held in Bari (Italy) the Mycoglobe International Conference entitled "Advances on genomics, biodiversity and rapid systems for detection of toxigenic fungi and mycotoxins"

> Literature

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⁽²⁾ Wu, F. "Mycotoxin Risk Assessment for the Purpose of Setting International Regulatory Standards"; Environmental Science & Technology Vol. 48 No. 15; 2004

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⁽⁴⁾ The impact of regulations on Agro-food trade; 2003
OECD, Paris, 2003

⁽⁵⁾ <http://mycoglobe.ispa.cnr.it/>

⁽⁶⁾ <http://www.fao.org/spfs/>

⁽⁷⁾ <http://www.icc.or.at>

> IMPRESSUM

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