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Ministry of Health
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To the Chairman
DG-AGRI
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Object: Observations and suggestions to set up rules on the concentration of Fusarium-toxins in cereals and its derivatives.

INTRODUCTION.

If we take a look at the Italian productive situation, the problem of contamination by Fusario-toxins in cereals is mainly related to the presence, in the corn, of Fumonisine.

The figures which have been recently shown at the meetings held by the operators involved in the corn production chain and the researchers of the agro-industrial sector show that in the unprocessed corn, more than 50% of the examined samples (in certain cases 75%) present a concentration of Fumonisine which is higher compared with the limits currently under discussion at the EU (1500 µ/kg). The same analytical results have underlined a significant percentage of samples whose values of Fumonisine are 4-6 times higher compared with the above mentioned limits.

Even though these figures are the result of a not heterogeneous and not well-coordinated exam, it stands to reason that a vast amount of work (in terms of research and spreading of information) has to be carried out in order to take the cultivation of corn within the limits of Fumonisine expressed by DG-Sanco Committee; particularly, apart from the actions which have to be carried out, the expected result, however, will not be achieved by the prescribed time (April 2007), because the extent of the phenomenon together with the high concentrations of mycotoxins is too wide.

Indeed, a great amount of work is needed for a **coordinated testing** in order to establish the production protocols suitable for each specific corn environment, this without taking in consideration the time that is needed to disclose the correct production methods among the various operators in this field.

In the light of what the considerations are, as a result of the analysis on the current situation in this sector, even though we acknowledge the undelayable need of setting up rules for the presence of this contaminant in our cereals, we ask that the related regulation (expected to be issued by April 2007) is planned in order to protect this important production whose income is the basis for the survival of a relevant number of agricultural and agro-industrial companies in our country.

In order to give a hint for identifying the possible solutions, here below you will find some suggestions.

1 – Audit of the limits under discussion

The Scientific Committee on Food (SCF), as quoted in the document SANCO/0006/2004-rev 2, expressed the maximum daily intake quantities (Total Daily Intake – TDI) related to the different Fusarium-toxins.

Starting from the fixed TDI levels for fumonisins (TDI = 2 µg/kg b.w.), we have planned chart no.1, here below. The aim of this chart is to examine which are the limits for the quantities of product intake, without exceeding the TDI limits.

Particularly, the figures in the chart have been calculated by considering the fact that the maximum daily intake quantity of toxins for an adult of 75 kg. is equal to 150 µg. The column for the limits proposed by law, shows the values for each category as in the document SANCO/0006/2004-rev 2. The last column shows the results of the calculations for the quantities of food intake, without exceeding the TDI limits, by assuming to have ingested food highly contaminated whose values are allowed by the actual suggested regulation.

Tab.1 Maximum limits under discussion for total fumonisins (TDI=2 µg/kg b.w.)

	Suggested limits (µg/kg) as DG - SANCO rev.2	Maximum quantities of product intake without exceeding the TDI (g) limits fixed by law
2. Food ingredients		
2.1 Maize grits	500	300
2.2 Maize meal and flour	1000	150
3. Final consumer products		
3.1 Maize based foods for direct consumption	500	300
3.2 Maize based breakfast cereals	200	750

We would like to remark that, for what concerns the fumonisine, the maximum intake quantity for a product, in accordance with the limits fixed by law allows an adult to have a daily intake of 300 g (adult of 75 kg.) of products with maize based foods (this product only can be contaminated by fumonisine). The average European consumption for maize based foods has been estimated between 8.8g/day (data from Joint Expert Committee on Food Additives – JEFCA, 2001) and 19g/day (data from Nutritional Data – Food Balance Sheets FAO, 2001). If we take into consideration an adult of 75 kg, the TDI is equal to 2 µg/kg. b.w. which corresponds to a safety limit equal to an intake of 300g/day; this value proves to be from 34 to 16 times superior compared with the average intake quantities which have been appraised by JEFCA and FAO. Even though we consider a person whose weight is equal to 15 kg., the safety limit intake of 60g/day proves to be from 7 to 3 times superior compared with the actual European average consumption.

As a consequence, we would suggest that a limit of 3000 µg/Kg. for the unprocessed maize is fixed.

In the chart no. 2, different limits are proposed. These limits have been identified by considering the following:

- ✍ The maximum quantities of maize products intake, calculated without exceeding the TDI of fumonisine, are much superior if we compare them with the European per capita consumption.
- ✍ If we take into consideration a contaminated grits with 2000 ppb of fumonisine, the processing from grits maize to corn flakes admits a dilution in the concentration of fumonisine so that the limit of 400 ppb can be respected.
- ✍ If the maize meal and flour manufactured and retailed for a direct consumption are included in the category of “final consumer products – maize based foods for direct consumption”, we must note that they cannot have the same limit suggested for corn flakes because, unlike the latter, they are not been directly consumed but are to be used as ingredients to prepare other foods (for example polenta – maize porridge – representing only 25% of weight).

As a fact, this type of use requires a dilution. Besides, maize flours do not undergo the same processing like for the corn flakes, therefore, the same limit cannot be adopted.

For these reasons, regarding maize meal and flours for direct consumption, we suggest a value of 2000 µg/Kg.

Tab.2 Maximum limits under discussion for total fumonisine (TDI=2 ? g/kg b.w.)

	Suggested limits (? g/kg) as DG - SANCO rev.2	Maximum quantities of product intake without exceeding the TDI (g) limits fixed by law
2. Food ingredients		
2.1 Maize grits	2000	75
2.2 Maize meal and flour	2500	60
3. Final consumer products		
3.1 Maize based foods for direct consumption	2000	75
3.2 Maize based breakfast cereals	400	375

2 – Audit to fix a date for the limits to become effective

Since the toxicological risk related to the fumonisine is lower (compared with other mycotoxins) and because of the peculiar situation present in our country, the gradual achievement of the limits, today under discussion, can be assumed; this should also allow to develop a “new culture about quality” among the operators of this field, avoiding a dramatic and sudden collapse in the quantity of marketable corn kernel.

A similar strategy has been already adopted in order to limit the use of copper for phytoiatric use, in biological cultivations (Reg. CE 473/2002 dated 15/3/2002). In that occasion, lawmakers, by considering the lack, for certain cultivations in the biological field, of another option, acknowledged the fact that the quantities of copper put into the environment had to be diminished; at a first stage, they allowed a maximum level for the first 4 years (maximum limit of 8Kg/ha/year, valid until 2006), afterwards, a subsequent reduction (6 kg/ha/year from 2006 on) had to be carried out. This decision was taken to allow a research for studying the possible solutions and for giving the manufacturers the possibility to adapt themselves to the new limits.

As a consequence, concerning the unprocessed maize, we could suggest to gradually reach the amount of 3000µg/Kg by following two steps, as shown here below:

By July 1st 2005 (prior to what proposed by the Committee):

	Maximum level (? g/kg) fumonisins	
1. Unprocessed maize	4000	
2. Food ingredients		
2.1 Maize Grits	2000	
2.2 Maize Meal and Flour	2500	
3. Final consumer products		
3.1 Maize based foods for direct consumption with the exception of 3.2 and 3.3	2000	
3.2 Maize based breakfast cereals	400	as proposed by the Committee
3.3 Processed maize-based food for infants and young children	150	as proposed by the Committee

By July 1st 2009

	Maximum level (? g/kg) fumonisins	
1. Unprocessed maize	3000	
2. Food ingredients		
2.1 Maize Grits	1500	
2.2 Maize Meal and Flour	2000	
3. Final consumer products		
3.1 Maize based foods for direct consumption with the exception of 3.2 and 3.3	1500	
3.2 Maize based breakfast cereals	400	as proposed by the Committee
3.3 Processed maize-based food for infants and young children	150	as proposed by the Committee

What has been suggested, should be considered in terms of a national project (Mycotoxin National Plan) which ought to commit our country by undertaking initiatives in order to limit the phenomenon. Such initiatives and the related results will be explained to the Committee so that there will be a control, within the two prescribed deadlines, of the achieved progress due to the actions engaged.

The participants of the present document confirm their commitment to pursue the above explained intentions and confide that the observations and suggestions they made, will be taken into consideration.

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