Organisation: none
City: Barcelona
Country: Spain
Type: Individual
Public: Yes

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a. Assessment:
6. Labelling proposal

En ymmärrä kysymyksiänne kunnolla. Kansalaisen on joskus vaikea vaikuttaa omalla äidinkielellään. En näe syytä, miksi manipuloitu puuvilla pitäisi päästää EU:n markkinoille missään muodossa. Jos EU kokee saavansa siitä hyötyä taloudellisesti, voidaan minusta miettiä, onko se sen väärti.

Translation

a. Assessment:
6. Labelling proposal

I do not properly understand your questions. A citizen has sometimes difficulties to influence by using his own native language. I do not see any reason why manipulated cotton should be released on the EU markets in any form. If EU thinks to benefit by it economically, to my mind it is pertinent to ask whether it is worth of that.

Organisation: Genetic Rights Foundation
City: Rome
Country: Italy
Type: Others...
Public: Yes

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a. Assessment:
Molecular characterisation

The Documentation on the molecular characterisation of LLCotton25 is accurate and can be consulted in its entirety, there is nothing incongruous.

Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

The compositional analysis per site shows that there are several statistically significant differences in some compounds between the LLCotton25 and the conventional one used as control. In particular, the differences about the free gossypol levels fell outside the natural ranges reported in the literature. The applicant showed that such differences in the gossypol levels are nonexistent when analysed over the total field trials tested. It must be considered that these compositional modifications may be due to some change in the biochemical pathway of the GM cotton. Therefore it seems necessary a deeper evaluation of the characteristics of this product, with the aim of excluding the presence of currently unknown or unconsidered or not adequately examined metabolytes. This is particularly necessary in consideration of the toxic nature of gossypol.

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b. Food Safety Assessment:
Toxicology

No additional safety studies on the whole GM food/feed were made, yet data from compositional analysis show no equivalence between LLCotton25 and traditional counterpart. When the GM plant undergoes substantial modifications, EFSA provides the obligation for toxicity tests to be done using the whole GM food/feed, not only the new constituents. Particularly, it is required a 90-day study on rodents. Therefore it seems necessary to asses the possible presence of new and unexpected constituents, other than the PAT protein. A 14-day different dose feeding study conducted in rats with the PAT protein (lyophilized powder) encoded by the pat gene was provided. The study shows statistically significant increases in blood cholesterol levels and phospholipid. Since such modifications are also in one of the control groups, modifications are not considered as toxicologically relevant. A thourough scrutiny of the experimental results leads to point out that data provided are not trustworthy; the experiment should thus be repeated with a better experimental design.

Allergenicity

The potential allergenic effects are still evaluated only on deductions. LLCotton25 and its counterpart are not equivalent and an evaluation about potential toxicological effects of the whole plant (as EFSA requires) is not carried out. Therefore, we believe that more in depth analysis (experimental analysis) should be conducted to check the real absence of allergological risk of the whole GM plant.

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3. Environmental risk assessment

The environmental risks arising from the commercialization of LLCotton25 are limited to both unintentional events and intentional, even though illegal, through the release into the environment of GM cotton seeds.

Should they occur, however, in cotton growing areas of Mediterranean Europe (e.g.: Sicily, Spain, Greece), the spontaneous growth of feral LLCotton25 plants and cross-pollination with conventional cotton varieties would be likely outcomes.

In our opinion, these undesirable effects need to be controlled by means of a plan of specific monitoring.