Greenpeace technical critique of EFSA Opinion on Monsanto's Roundup Ready Oilseed Rape, GT73[i]

1. Procedural concerns about the handling of the application

The three-tier risk assessment and public scrutiny of the application material set out in Directive 2001/18/EC is wholly dependent on the proper handling of the application by the country that received the notification, which in the case of GT73 are the Netherlands. However, the Dutch authorities have not met their obligations under the Directive, and this has severely hindered the entire subsequent risk assessment process.

According to article 13.1 of the Directive, "The competent authority [in the member state that receives the application] shall without delay examine whether the notification is in accordance with paragraph 2 and shall, if necessary, ask the notifier for additional information." The exact requirements to the application material are set out in Annex II, Annex III and Annex IV of the Directive.

Despite this responsibility, the Dutch authorities accepted a clearly incomplete and not updated application for GT73. Although several member states subsequently pointed out that the application was incomplete, the application process was still not suspended. The risk assessment cannot work as intended by Directive 2001/18 when incomplete applications are being considered. As highlighted by the example below (Compositional analysis – pooled data and significant differences), the application material received for GT73 was also of a generally poor quality.

According to article 25.3 of Directive 2001/18/EC, "The competent authority shall, after consultation with the notifier, decide which information will be kept confidential and shall inform the notifier of its decisions". Article 25.2 of the Directive clearly states that only information, "the disclosure of which might harm [the notifier's] competitive position" can be treated as confidential and that "verifiable justification must be given in such cases". However the Dutch authorities allowed a large part of the application to be kept confidential. This confidentiality is supposed to be applied to knowledge obtained through innovative research, it cannot possibly apply to the large part of the GT73 application material that the Dutch authorities allowed to be stamped confidential - no matter how unfavourable it is to the GMO.

The vast confidential section of the GT73 application even includes basic animal wholesomeness studies (Naylor 1994, Naylor 1995, Naylor 1996), which show abnormalities in rats fed with GT73. Such feed trials involve absolutely no secret know-how, and could therefore absolutely not qualify for confidentiality under article 25.2. Feed trials are part of the food safety assessment required by the Directive, which in turn is part of the environmental risk assessment detailed in Annex II. For the environmental risk assessment, and thus these feed trials, it is specifically emphasised in article 25.4 of Directive 2001/18/EC that this information "in no case may [...] be kept confidential". The Dutch authorities have thus in clear breach of the Directive impeded due public scrutiny of the application.

2. Technical critique

When describing the GE constructs in GT73, (Section 2.2.2) EFSA states "*The sequencing of 3' and 5' flanking regions revealed that 40 base pairs (bp) of parental (Westar) DNA is absent from GT73, and that GT73 contains 22 bp of DNA adjacent to the 5' insert/plant junction which is not present in Westar*". This means that there has been a small deletion of plant DNA in the GE plant and small extra fragment of DNA (it is not clear where this extra fragment originates from). The significance of these irregularities has not been examined in depth. EFSA should have initiated further studies, but instead it simply sates that there are no similarities between these sequences and known toxins and allergens. But these are not the only concerns from molecular irregularities. Are these fragments functional? What has been deleted from the plant, was a gene or regulatory sequence? These questions remain unanswered.

Compositional analysis – pooled data and significant differences

The EFSA detail (Section 3.2.2) the analysis performed "*Kernels from oilseed rape (GT73, Westar and other commercial varieties) were obtained from field trials in Canada (1992 [7 sites], 1993 [5 sites]), 1997 [4-19 sites per variety]) and Europe (1994 [3 sites], 1995 [3 sites]).*" But, in the dossier and further information, these data are pooled from the different locations. This is exactly one of the major criticisms of poor quality data that was made prior to the initiation of the EFSA. Pooling of data can mask any variations present. Therefore, such data cannot be submitted in support of compositional sameness.

Even though the data was pooled significant differences were noted: the level of linolenic acid was lower and, importantly, glucosinolate levels were higher in the GE oilseed rape. Why these levels are different has not been investigated further, the EFSA has simply accepted two possible explanations for the difference in glucosinolate levels from Monsanto as "*reasonable explanations*". These explanations include variation within the original cultivar and variation induced by tissue cultivation. This is not scientifically rigorous, the EFSA should have rejected the GE crop at this point, or at least asked for further studies to determine exactly why these differences exist. It is certainly not in keeping with the philosophy of substantial equivalence as a starting point, i.e. where significances are noted they should be investigated.

The differences in glucosinolate levels could be important

The glucosinolate levels are important because they are known antinutrients. As the EFSA states, the EC maximum allowable for this type of oilseed rape is 25 ìmol/g seeds (9 % moisture content). But Monsanto haven't even given the concentration of glucosinolate in seeds, they have only estimated that they are below the threshold by converting this maximum into alkyl glucosinolates/g of defatted meal, which have been measured. However, no indication of moisture content is given and the estimates are just rough calculations. Much of the analysis on these glucosinolate levels is from samples pooled from different locations and most of the data are from GE oilseed rape that hasn't even been sprayed with Roundup (the herbicide that would be used with the GE oilseed rape). Analysing for glucosinolate levels in seeds is routine analysis – if would be easy for EFSA to ask for further studies on the glucosinolate levels but instead, they simply conclude "*The glucosinolate levels* *reported are thus clearly below the maximum content set by the European Commission*".

No environmental considerations of GT73 oilseed rape imports

It is not clear why EFSA do not consider the environmental implications of imports of oilseed rape, as environmental considerations are supposed to be part of their remit. Whilst the application is for the import of GT73 grain for food/feed purposes only, seeds may escape into the EU environment, e.g. during processing and transport. As feral populations of oilseed rape are widespread in Europe, it is highly possible, indeed likely, that escaped seeds could germinate, flower and potentially cross-pollinate with oilseed rape crops, feral populations or wild relatives in Europe. The assumption that populations of oilseed rape that result from losses during transport, storage and processing (the so called "volunteers") "*are easily displaced by other weeds*" cannot be made, as the results of several studies have shown[ii]. Pessel et al. (2001), Pessel and Lecomte (2002)[iii] show that relict plants of oil seed rape persisted for at least 8 years after their last cultivation, most probably in the soil seed bank, that feral populations persisted also by local recruitment, and that the spatial distribution of feral populations is partially related to the transport traffic at harvest from the field to the silo. Eastham & Sweet (2002)[iv] reported feral rape populations existing for at least 10 years. Feral (non cultivated) populations of oil seed rape and GE oilseed rape volunteers have been found from trials in the UK[v] producing populations for up to the three years (the entire length of the study). Control of feral populations, e.g. with herbicides, could adversely affect biodiversity in hedgerows, roadside areas, railway banks which may also be a haven for wildlife.

Also the proposition that oilseed rape (OSR) roadside populations are "*often prevented from reaching maturity by mowing or by chemical treatment*" is highly questionable. This most certainly would not apply to railway lines. Who is going to control these volunteer plants? And how? By use of other, less benign herbicides?

There is the potential for gene transfer from GT73 to other Brassica species. For example, it has now been demonstrated that *B. napus* can hybridize and pass on the GE trait to *B. rapa*, a wild relative of *B. napus* occurring in Europe and which readily produces hybrids[vi].

The energy costs associated with herbicide resistance in *Brassica napus* are probably negligible[vii], therefore they are as fit to survive in the environment as conventional oilseedrape. Even if the gene is neutral (as opposed to conferring a benefit), evolutionary theory predicts that the gene frequency will persist. It is a misconception that only beneficial genes will persist[viii].

Such populations may also act as a reservoir of GE constructs for feral or planted conventional oilseed rape, which would compromise co-existence requirements. In addition, there is the possibility of gene stacking, as has happened in Canada, where escapes have led to multiple herbicide resistance, leading to the increased use of other, less benign herbicides as reported by English Nature[ix].

In summary, spillage of GE herbicide tolerant oilseed rape grain could result in feral populations, which could compromise cultivation of conventional oil seed rape. The persistence of oilseed rape seeds and feral populations is problematic for the control of any volunteers arising from a spillage, and raises the possibly of adverse effects on wildlife through herbicide applications on non cultivated land. There are clear issues of biosafety, coexistence and liability, which are not currently addressed.

Conclusions on GT73

- **Irregularities in the molecular characterisation have not been studied further.**
- **Compositional analysis has been performed on samples pooled from different sites.**
- **Significant differences in composition have been found, but have not been investigated further.**
- **There is no environmental consideration of oilseed rape imports, in particular no consideration of the fact that import of GT73 can result in feral GE oil seed rape populations**

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