There are many assertions made, and scientific conclusions drawn, about how agriculture, including fish farming, horticulture and forestry, should develop over the next half century. The purpose of this development must be to provide adequate food for an increasing population without increasing, and if possible, decreasing, greenhouse gas (GHG) emissions and without decreasing biodiversity.

A major function of this Journal is to make an independent assessment of reliable scientific and economic evidence presented in a rational and objective way concerning these issues, whereas assertions are of little value without the backing of reliable evidence for their suppot.

Reliable scientific research has led to the production of many novel chemicals and genetically relevant crop varieties that have allowed the adoption of cultivation methods which save fuel and time and decrease costs of production, so that GHG production is also reduced.

These systems, as stated elsewhere here (Areal *et al* pp.19-22); Brookes & Barfoot (pp. 35-40), have been adopted by millions of farmers on millions of ha of land throughout the world without apparent interference with health and well-being. Nevertheless, their safety must be assured in comparison with the risks attached to continuing with traditional methods as populations increase and climates change.

Many technological developments have led to adverse criticism in western cultures by individuals and organisations, viewed at a distance “sitting in cosy arm chairs” of the well- nourished west. This is not to say there could be long term, chronic, adverse consequences of some of these developments that will be worse than the consequences for the systems they replace. Such adverse effects, if any exist, must be detected and the systems modified so that they are not transferred to general practice.

Has there been conclusive evidence, or even preliminary but sound evidence, for major adverse consequences over periods of up to 15 years to justify the criticisms of glyphosate, or of the recent genetic modification of maize? Our problem in assessing major adverse evidence is that, to our knowledge, none of any consequence has been published in peer-reviewed journals, except for a recent publication by French scientists (Séralini, G.-E. *et al*., 2012).

Yet this paper has received damning criticism from the official EU watchdog (BfR-Opinion 037/2012, 1st October, 2012). The French scientists state that the adverse effects they observed could have been caused by hormonal effects of Roundup and by specific constituents of the genetically modified maize.

The Federal Institute for Risk Assessment (BfR) has evaluated the study in terms of its relevance for the evaluation of the health risk of genetically modified glyphosate-tolerant maize NK603 and for the evaluation of the health risk of the glyphosate-containing formulation.

On the basis of the French publication, the BfR has concluded that the authors’ main statements are not sufficiently corroborated by experimental evidence, owing to deficiencies in the study design and in the presentation and interpretation of the study results.

Therefore, the main conclusions of the authors are not supported by the presented incomplete data. The study does not comply with internationally recognised standards for long-term carcinogenicity studies.

The rat strain used shows a relatively high spontaneous tumour rate, especially for mammary and pituitary tumours, and the number of animals used was too small and insufficient for assessing the claimed differences between the test groups and the control group.

The authors’ hypothesis that the observed effects could result from adverse effects on the endocrine system is not sufficiently supported by the data presented. Furthermore, the BfR criticises that the glyphosate dose administered was not determined in the studies with the glyphosate- containing plant protection product Roundup.

In summary the German Federal Institute for Risk Assessment is of the opinion that the experimental data do not support the main statements in the publication. Further, due to shortcomings in the study design as well as in the presentation and

interpretation of the data, relevant conclusions drawn by the authors are not comprehensible.

Our additional criticisms of the study are based on the evidence available to us:

1) There were only10 rats per treatment group; but for the measurement of non-monotonic responses of tumours there should be a minimum of 50 per treatment group. We understand that half the controls also presented with tumours.

2) The statistical analysis was inappropriate and inadequate. Also if the rats were not caged individually, but in groups the experimental unit would be the cage and not the rat and if any of the statistical analyses were carried out with the animal as the experimental unit that analysis would be invalid.

3) Feed intake was *ad libitum* and apparently not measured and so the dose was apparently unknown. Whereas, the rats should have been fed individually a defined amount daily. It is well established in both rats (1) and in women after menopause (2) that breast cancer (especially that of oestrogen receptor negative type) is correlated with obesity and with glycaemic load in French studies (3) and with glycaemic index in Danish studies (4). These effects in rats would be related to feed intake and if more was consumed by the experimental groups than by the control groups, this fact alone could account for the earlier deaths of the rats given glyphosate-tolerant NK603 maize. So the effects attributed to the experimental maize would be accounted for, entirely, by differences between groups in feed consumption and not by any direct relation between genetic manipulation on tumour growth.

4)The maize used was not tested for the presence of mycotoxins frequently found in maize: e.g. zearalenone and aflatoxin, that is a cause (author's evidence) of hepatic cancer in both rats and in humans world-wide, and fumonisins, produced by the mould, *Fusarium moniliforme* (fumonisin B1 has a world-wide distribution and is present in a majority of maize samples from 0.4-3.5 mg/kg) (5). At higher concentrations it causes leukoencephalomalacia in horses and cancer (mainly of the throat) in humans (author's evidence). A 30 day study in female rats showed it produced severe renal damage (6) and over 2 years it is a hepatocarcinogen in male rats (7). Contrary to the inference indicated in the French paper the evidence is that GM Bt crops, in particular, have decreased the incidence of moulds and mycotoxin presence, especially in products of those crops derived from developing countries. It is unfortunate that the French scientists presented their preliminary data from this inadequate experiment, as if those data provided reliable evidence. The data are at variance with all other reports, and although that is no reason of itself not to publish, it is a reason to question one's evidence to determine whether there are alternative explanations for it. In its present state the French report will provide no enlightenment on this topical and important subject. Yet it may stimulate other groups of scientists to carry out further two year studies with the same and different rat strains together with methods of measuring other potential long term effects, including those on biodiversity and GHG production. In the meantime those

individuals and organisations highly critical of scientific developments in agriculture, but with access to the popular media, will use these French data to further give concern and confusion of thought to the general public. World Agriculture looks forward to the receipt of reliable evidence on this important subject. We appreciate that many noble and legitimate groups opposed to the innovations discussed do, in fact, have the same objectives as many supporting the developments stated in the first paragraph above. It is a great pity that there are also “bigots in the pot” so that the general public receives mixed messages on this important subject.

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Figures

Figure 1.
GM Maize

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Comments