

## Comments to Bioteknologiradet

- Most of the members of the Biotechnology Advisory Board proposes that regulation of the GMOs should be divided into several levels, depending on the type of genetic change that has been made. Under Level 1, minor changes, in one or a few base pairs (point mutations), should initially be subject to a notification requirement with feedback requirement before allowing use and release in the environment. According to me, this argument is not strong enough because it assumes that small genetic changes have little risk, which may not be correct. There has been sufficient information in the scientific literature which shows that small genetic changes can lead to major consequences. The other argument could be that how many point mutations could be allowed to be classified as Level I GMO.
- According to me, one of the most important factor is the assessment of the consequences of allowing a GMO in respect to refusing it. The Act should provide clear guidelines on how to assess it and quantify the effects. It should also include guidelines to assess how the Norwegian society and the food production would be affected by a GMO.
- I believe that the Act should include guidelines that doesn't only require that a GMO should not be harmful to the society and the environment but also have a utility value for the society. It should also highlight the socio-economic cost-benefit analysis. The assessment shouldn't be only from the top-level but also the pros and cons for different groups and communities in the society should be assessed.

- I believe that there will be always be small uncertainty about the consequences of approving or banning a GMO. Therefore, it is important to assess the different uncertainties, and possible steps should be taken to reduce the uncertainty as far as possible.
- The regulations should assess that the GMO should be ethically sound, contribute to sustainable development and be socially beneficial. Though the regulations should assess the afore-mentioned factors, but they shouldn't be too excessively restrictive as it would then hinder scientific development in this field.
- Technological development, and the potential benefit of GMOs should not be limited by bureaucracy's ability to predict and assess its utility value. It is important that manufacturers prove that manipulation is not dangerous and harmful, as is currently the case in a thorough six-step assessment. A minority in the council proposed that there are requirements for sustainability, ethics and utility to be levelled. But this is too conservative in the long run. Developments in the field are taking place quickly, and technology such as CRISPR can have such a great positive potential that should not be ruled out when it is still at its initial stages.