Advice on a request to vary the consent conditions for the deliberate release of a GMO for research and development purposes

Applicant: Wild Bioscience Ltd

Application: To study the effect on agronomic performance of the expression of regulators of photosynthesis under conditions that differ from those specified in the original consent issued to Wild Bioscience in 2022.

Reference: 22/R55/01 (variation)

Date of advice: February 2024

Advice of the Advisory Committee on Releases to the Environment (ACRE) to the Secretary of State under section 124 of the Environmental Protection Act 1990

ACRE considers that the trial management measures it recommended in its advice on the original application (<u>ACRE advice: application for a field trial of genetically modified wheat (22/R55/01) - GOV.UK (www.gov.uk)</u> are appropriate for this variation. These measures are:

To minimise the likelihood that GM wheat from this trial will enter the human food or animal feed chains, the applicant should:

- 1. Ensure that the 20 m surrounding the trial site is planted with a non-cereal crop and that cereal volunteers are controlled (prior to flowering) in this area during the trial.
- 2. Plant a wheat pollen barrier, of 3 m width, to flower at the same time as the GM wheat as an additional precautionary measure.
- 3. Control *Elytrigia repens* (Couch Grass) using a glyphosate herbicide and hand weeding, if necessary, within the trial site and the surrounding 20 m, before flowering and for the duration of the trial.
- 4. Ensure that any GM or non-GM wheat plant material remaining in the area of release at the end of the trial is disposed of appropriately.
- 5. Ensure that following harvest, the area of release is lightly tilled twice (once after harvest and again in the following spring) to a depth of 5 cm to stimulate germination of any wheat plant volunteers. The release areas should be left fallow and monitored for wheat plant volunteers for 2 years following harvest.
- 6. Record the number of wheat plant volunteers that germinate before destroying them with an application of glyphosate herbicide or hand pulling them prior to flowering.

- 7. Ensure that suitable measures (such as those described in Wild Bioscience's application) are put in place to keep birds (and animals) out of the trial area and that the efficacy of these measures are kept under review.
- 8. Ensure that machinery used on the site is cleaned thoroughly onsite, including between using it with GM and non-GM material, and that clothing and equipment such as vehicles used by personnel on the site are also cleaned thoroughly before leaving the site.

Comment

ACRE notes that the main elements of the requested variation are the addition of two trial locations (one in Cambridgeshire and one in Norfolk) and that the maximum area allowed to be trialled is increased from 500 square meters to 6000 square meters. A further request is to alter the consent such that other GM cereal crops may be grown within the trial plots, which must be at least 20 meters from non-trial cereal crops. The GM cereals would be covered by different consents. This would allow GM cereal trials to be conducted simultaneously within the same trial plot so long as Condition 4(2) of the existing consent (which requires the presence of a pollen barrier) is met for all GMOs.

ACRE notes that Wild Bioscience is not planning to amend the management measures it is currently required to adopt for the expanded trials and the 2 additional locations (Norwich and Cambridge) and that the GM wheat and non-GM wheat grown in this trial will not be put into the human food chain or fed to livestock.

ACRE considered whether its existing advice is appropriate for the variation Wild Bioscience has applied for, including whether the 20 m separation distance remains appropriate for a greater area of GM wheat grown within a single 'exclusion zone'. Wheat pollen is relatively heavy so that dispersal by wind is only likely over short distances. Furthermore, it remains viable only for a short period of time which further reduces the likelihood of out crossing. Thus, evidence demonstrates that out-crossing may occur at frequencies that diminish significantly with relatively short distances (Gatford et al 2006; Gaines et al 2007). Other factors that may influence the level of out-crossing include humidity, wind speed and direction, topography and differences in relative times and durations of anthesis. Overall, ACRE concluded that its originally proposed risk management measures, including the 20-meter separation distance, will minimise the likelihood that unauthorised GM material from the trial could enter the human food or animal feed chain (under the varied consent conditions).

Regarding the request for an option to include GM cereals authorised under different consents within the same trial site, ACRE followed the same risk assessment process and concluded that if the same risk management measures are in place, the likelihood that unauthorised GM material from this trial will enter the human food or animal feed chain will be minimised.

However, ACRE also notes that the potential for out-crossing between GM lines covered by different consents within the trial site would mean that the resulting progeny could possess a combination of transgenes that is not covered by either consent. ACRE

reminded Defra that the growing of harvested material from such trials in future trials would require the consent holder to ensure that non-consented transgenic 'hybrids' were not present (or were covered by a separate consent).

In reconsidering its original advice, ACRE identified an error relating to the following paragraph:

"The relatively small scale of the trial is reflected by the fact that GM plants are being planted by hand as seedlings into the release site and that harvesting will also be undertaken by hand".

The consent holder has since clarified that it intends to use small plot drill cassettes for sowing the wheat seeds and that harvesting will be carried out by a plot harvester. ACRE did not consider that these amendments had any material impact on the conclusions of the risk assessment or necessitated any changes to the risk management measures.