

## **Key Background to the High Court Ruling**

What the EPA was asked to decide: In 2012, crown research institute Scion asked the Environmental Protection Authority (EPA) whether organisms created using two new breeding techniques are genetically modified organisms (GMOs), and so subject to the regulatory conditions for GMOs. The new techniques are called zinc finger nuclease 1 (ZFN-1) and transcription activator-like effectors (TALEs).

The process the EPA used: Scion's request was made under a special procedure for determining whether something is a new organism and a GMO under the law. This process (set out in section 26 of the Hazardous Substances and New Organisms Act 1996 (HSNO)) is called a 'determination' and allows a committee appointed by the EPA board to make that decision. The process does not require the EPA to consult anyone beyond government departments but the Sustainability Council was invited to comment in this case.

**How the law defines a GMO:** There are two criteria for deciding whether a plant or animal is legally a GMO:

- 1. Whether the organism meets the definition of a GMO in section 2 of the Act.
- 2. If it does, whether the organism is expressly excluded by regulations made under the HSNO Act. A regulation issued in 1998 lists all the techniques considered not to produce GMOs.

**What the Committee decided:** In 2013, the three-person EPA committee decided 1) that ZFN-1 and TALEs organisms do meet the definition of a GMO but 2) are "similar to" a technique excluded from the Act under regulations. As a result, the Committee concluded that ZFN-1 and TALEs organisms are not GMOs.

**The Sustainability Council's appeal:** The Sustainability Council appealed that decision in the High Court, stating that:

- The EPA committee had overstepped its legal authority because ZFN-1 and TALEs are not excluded under a proper reading of the HSNO regulations; and
- Only the Government has the authority to decide which techniques are to be excluded from regulation and the Act defines a process for this that is outside EPA control.

What the High Court ruled: The High Court ruled that the EPA had misinterpreted the law it administers and quashed the determination. The following points emerged from the judgment:

- The EPA was wrong to conclude that ZFN-1 and TALEs are not covered by the Act because they share similarities with a technique listed as not being GM. Only those techniques specifically named in the regulations are excluded from HSNO. (para 73)
- Parliament had made clear in the Act that decisions about what techniques are GM are to made by the government, and where there is doubt about what the law covers, "a more cautious approach" would be to leave any change of coverage to a change of regulation by government. (para 69)
- The EPA decision "did not sit well" with the overall purpose of the HSNO Act. In particular, the EPA failed to apply a precautionary approach. The court dismissed the regulator's argument that it is not required to do so for decisions of this nature. The court said that the techniques are novel and no evidence had been presented that demonstrated an understanding of their environmental safety. (para 68)