

June 2019

Item C10  
FSANZ78

Subject	New breeding techniques: regulatory options and implications
Paper presenter	Dr Scott Crerar  General Manager Science and Risk Assessment
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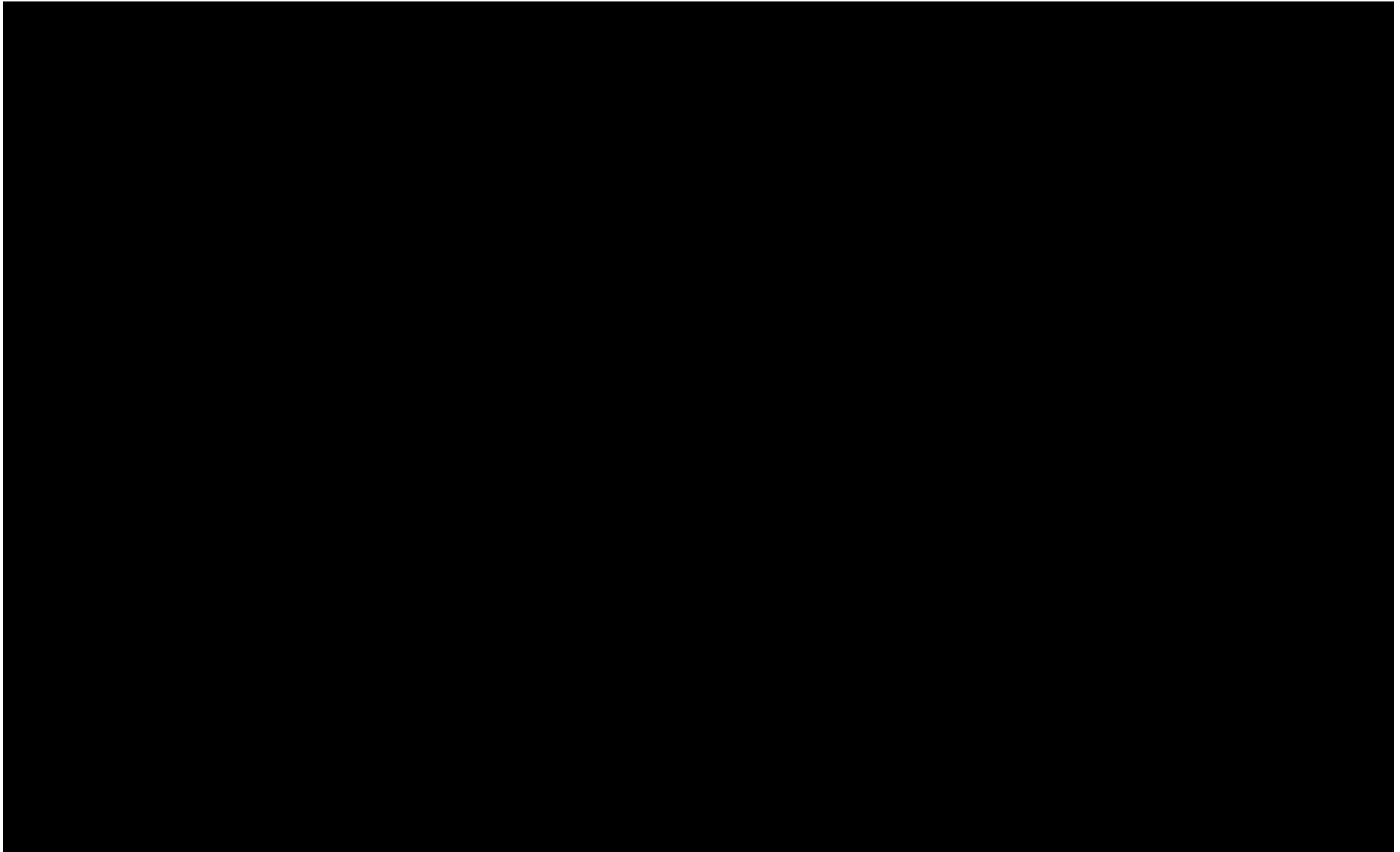
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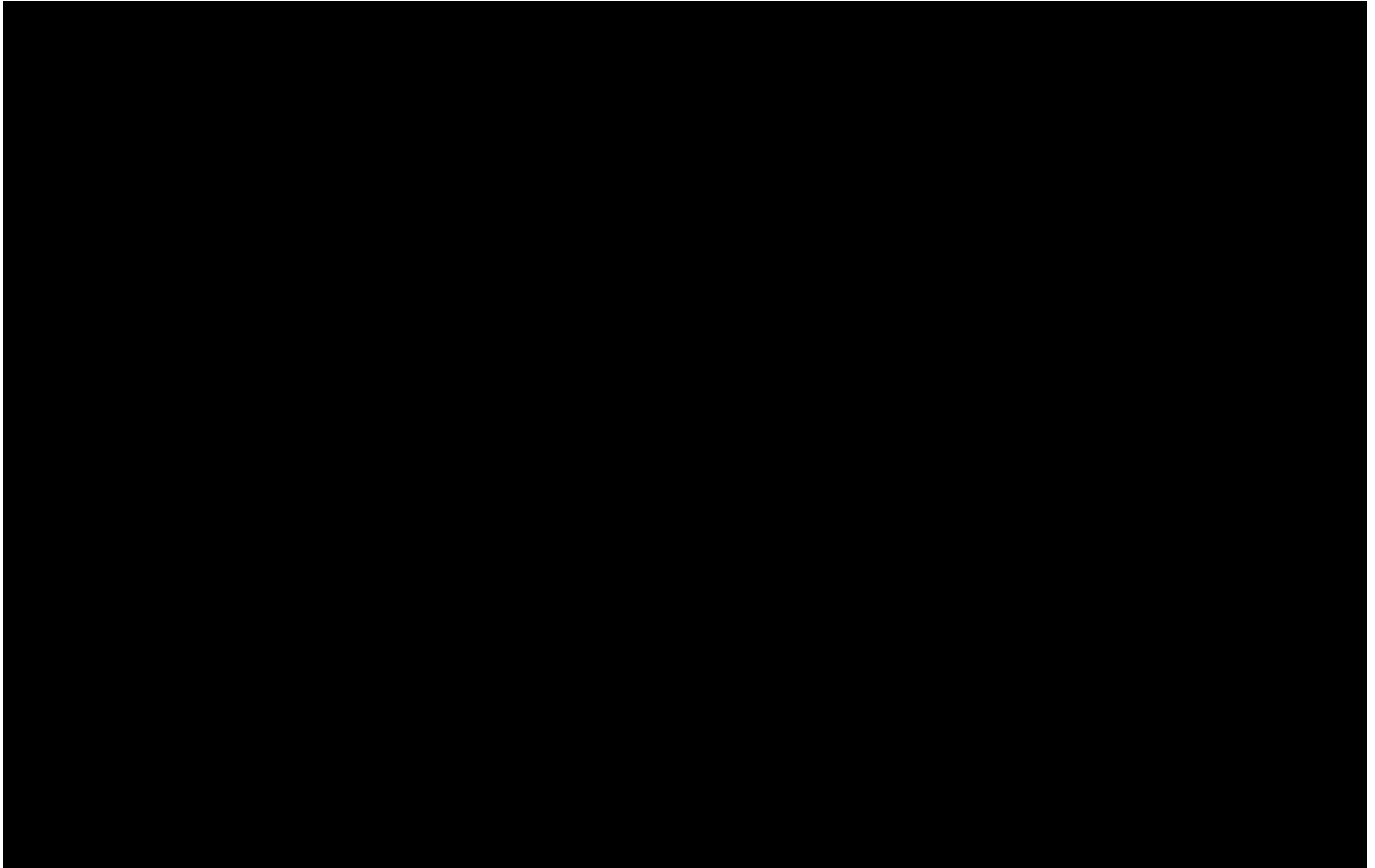


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**Table 4: Examples of NBT products where there is a clear rationale for exclusion under revised definitions**

Technique	Example of products with no new DNA and no novel food characteristics
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Genome editing	<i>Heat tolerant beef cattle<sup>22</sup></i>  Genome editing was used to introduce a single nucleotide deletion into the prolactin receptor gene of Angus cattle. This results in cattle with the SLICK trait – a short, sleek hair coat that enables them to better tolerate heat. The mutation to the prolactin receptor gene occurs naturally in a number of existing cattle breeds. No new DNA is present in the final animal used for food. Other than an altered hair coat, genome edited SLICK Angus cattle are identical to other Angus cattle already in the food supply.
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<sup>22</sup> Genome edited SLICK cattle are intended for commercialisation in South America

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## 2. *Update on recent developments – domestic and international*

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### 2.2 *International developments*

A number of developments have occurred since an update was last provided to the Board (December 2018).

#### 2.2.1 *South America*

Both Argentina<sup>32</sup> and Brazil<sup>33</sup> have been making decisions under their new regulatory frameworks for NBTs, both of which rely on case by case consideration of whether an organism or product comes within their respective GM regulations.

The Argentine approach applies the Cartagena Protocol<sup>34</sup> definition for *living modified organism*, where products are captured according to the outcome of a specific technique, specifically whether it results in a novel combination of genetic material. Using this approach, Argentina has ruled that a number of genome edited organisms are not GMOs, including polled Holsteins, Waxy corn, heat tolerant cattle, and fast growing Tilapia. Exclusion from the GM regulations do not exempt the products from other food regulations that may apply.

The Brazilian approach is slightly different although still outcomes based. It considers whether introduced genetic material is absent as well as the risk classification of the modified organism. Their regulation also includes a list of specific techniques that may result in a product not considered to be GM. Using this approach, Brazil has recently ruled that the polled Holsteins, Waxy corn, as well as a genome edited yeast, are not GMOs.

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<sup>32</sup> Resolution 173/2015, adopted in 2015; applies to plants, animals and microorganisms

<sup>33</sup> Normative Resolution 16, adopted in January 2018; applies to plants, animals and microorganisms

<sup>34</sup> The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international agreement on biosafety and is a supplement to the Convention on Biological Diversity effective since 2003.  
<https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf>

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