

### **BAYER CROPSCIENCE**

## SUBMISSION FOR THE REVIEW OF THE NATIONAL GENE TECHNOLOGY SCHEME 2017

## PHASE TWO CONSULTATION

#### INTRODUCTION

Bayer CropScience, a division of Bayer AG which recorded annual consolidated sales of € 46.7 billion in 2016, is one of the world's leading innovative crop science companies in the areas of seeds and traits, crop protection and non-agricultural pest control. The company has a global presence in over 120 countries and has operated in Australia for nearly 90 years. Bayer's Crop Science division in Australia has a long history of leading innovation in sustainable agriculture and a strong focus on sales and research and development (R&D) in Australia.

Bayer CropScience welcomes the opportunity to provide input into Phase Two of the review of the national gene technology scheme ("review" and "Scheme" hereinafter). This submission should be consulted in conjunction with Bayer's previous submissions for Phase One of this review, and for the technical review of the Gene Technology Regulations ("technical review" hereinafter). Bayer also supports submissions made by CropLife Australia for this review, both Phases One and Two, and for the technical review.

#### **THEME ONE: TECHNICAL ISSUES**

# **1.** What technological advances can be foreseen that might pose regulatory challenges for the Scheme?

Technological advancement is a constant, and not a recent phenomenon in biotechnology as emphasised in this review. While the Scheme commenced in 2001, its evolution began in the mid-1970s following the emergence of "recombinant DNA" technologies. It has since provided efficient, effective, robust, and most importantly, science-based regulation of any resulting genetically modified organisms (GMOs). However, today the Scheme only provides certainty for some longestablished gene technologies that result in well-known outcomes and needs modernisation. Technologies that have emerged since its inception, but have already existed for at least a decade, are still labelled as "new", e.g. site directed nucleases (SDN-1, SDN-2, SDN-3) and oligo directed mutagenesis (ODM) which were the subject of the technical review. These "new" technologies challenge the Scheme today because it is not sufficiently reactive to technological change.