Theme One: Technical Issues

1. What technological advances can be foreseen that might pose regulatory challenges for the Scheme? P19

The ASF believes that the current regulatory scheme, with some minor tweaking, is sufficiently robust to handle new technological advances. The Scheme has broad definitions, in combination with lists of exclusions that include certain technologies and/or organisms that do not pose new risks relative to those already existing. Mechanisms for the regular review and revision of these exclusion lists is key.

2. What are the potential impacts of the capability to make small edits in the DNA of an organism using no foreign DNA? P19

The capability to make small, precise edits in the DNA of plants using gene technology poses no unique or incremental risks different from those posed by crop varieties produced through natural genetic variation, and conventional breeding techniques including mutagenesis. Plant breeders have always used the creation of new variations of plant characteristics to provide solutions for resistance to plant diseases and pests, to increase tolerance to environmental stress, to improve quality and yields, and to meet consumer expectations. Plant breeding depends upon genetic variability within and across related species as a basis for developing new plant varieties with improved characteristics. To create a new plant variety, plant breeders have generally relied on two sources of genetic variation as a basis for new characteristics: the inherent diversity in a plant's gene pool and new, naturally occurring variants of existing genes.

Such genetic variation can be increased by mutations – changes in the DNA sequences of the plants. In plants, spontaneous mutation mechanisms and induced mutagenesis (e.g. chemical and irradiation) have long been exploited to introduce different types of mutations that confer desirable traits to breeding programs. Such mutations may range from point mutations, which include substitutions, insertions and deletions of one or a few DNA base-pairs, to larger changes including gene duplications and chromosomal rearrangements. Since the 1950s, well over 3200 crop varieties have been directly developed by mutation breeding. The capability of making small edits in the DNA of a plant is a more precise of such breeding technologies.

3. Under what circumstances might it be practical, efficient or appropriate to regulate gene editing under the GT Act when, from an enforcement perspective, it may not be possible to distinguish the products of gene editing from the products of conventional methods? P19

The ASF, as part of the international seed industry community, believes that an underlying principle for determining regulation should be that plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar to, or indistinguishable from, varieties that could have been produced through earlier breeding methods. We therefore propose that the Review consider that the genetic variation in a

final plant product should be excluded from regulation under the Gene Technology Act 2000 where:

a) there is no novel combination of genetic material (i.e. there is no stable insertion in the plant genome of one or more genes that are part of a designed genetic construct), or;
b) the final plant product solely contains the stable insertion of inherited genetic material from sexually compatible plant species, or;
c) the genetic variation is the result of spontaneous or induced mutagenesis.

This is why the ASF previously advocated for implementation of Option 4 of the Office of the Gene Technology Regulator's Discussion paper on options for regulating new technologies. This Option aligns completely with the our suggested criteria for regulating plant breeding innovations. We would also like to note that the OGTR's Discussion Paper focussed only on gene editing techniques, and did not address other new breeding platforms such as the cisgenesis and the proprietary Seed Production Technology (SPT). We would encourage the Regulator to also consider specific exclusion from regulation of these techniques for the same reasons.

4. Do these (emerging) applications of gene technologies present unique issues for consideration? If so, how might these issues be addressed by the Scheme? P20

The Consultation Paper refers to synthetic biology, human germline therapy and gene drives specifically for this question. The ASF does not agree with the definition of synthetic biology provided by the Consultation Paper, and global work in this space is still being undertaken. We would also note that experienced regulators engaged in work programs on synthetic biology under the Convention on Biological Diversity, and on risk assessment under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, have also yet to identify an example of an organism developed using "synthetic biology" that could not be assessed according to existing case-by-case regulatory approaches to risk assessment. The ASF therefore does not believe that these emerging applications of gene technologies present unique issues that cannot be addressed under the current regulatory framework. More regular technical reviews of the risk categories under the regulatory scheme, and flexibility to implement any changes quickly as knowledge increase, may help improve the scheme.

5. What are the potential implications of the release of a GMO targeting an invasive species in Australia? P20

Not relevant for ASF.

6. What are the technical issues to consider in the scenario of a GMO used to target an introduced plant, vertebrate or invertebrate pest? P20

Not relevant for ASF.

Theme Two: Regulatory Issues

1. What do you think is the most appropriate regulatory trigger for Australia in light of extensions and advancements in gene technologies? P23

As mentioned in relation to Theme 1, the ASF continues to believe that the most appropriate regulatory triggers for regulation in Australia in light of extensions and advancements in gene technologies are risk and enforceability. In particular, plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar to, or indistinguishable from, varieties that could have been produced through earlier breeding methods. We therefore propose that the Review consider that the genetic variation in a final plant product should be excluded from regulation under the Gene Technology Act 2000 where:

a) there is no novel combination of genetic material (i.e. there is no stable insertion in the plant genome of one or more genes that are part of a designed genetic construct), or;
b) the final plant product solely contains the stable insertion of inherited genetic material from sexually compatible plant species, or;
c) the genetic variation is the result of spontaneous or induced mutagenesis.

2. What factors need to be taken into account in the design of a product-based or a hybrid process/product regulatory scheme? P23

The ASF believes that the Scheme should continue to be risk-based, and should look to combine elements of both a process and a product-based system – as it already does to a large extent – but with more flexibility for the Regulator to regulate or exclude according to risk. As mentioned in relation to Theme 1, the current Scheme allows for technical reviews of the Gene Technology Regulations, resulting in additions to the exclusion lists in Schedules 1 and 1A. However, this has not been used to its full potential to enable innovation. Exclusion lists should be reviewed and updated at more regular intervals, e.g. every two years, as technology advances and more risk knowledge is gained about technologies and/or organisms. To support quick implementation of the results of these reviews, the Scheme should also permit the Regulator to regulate through the use of legal instruments capable of being amended in a timely manner at the discretion of the Regulator (acting with advice of the GTTAC) – such as Determinations. Such an outcome was also a Recommendation of the 2011 Review of the Gene Technology Act.

3. Are there any 'fixes' the scheme needs right now to remain effective?

It is the ASF's view that the current restrictions on the transport of GM seed and grain through South Australia (SA) by the SA Government are imposing a logistical constraint on the operations of its members who are involved in this market sector, including significant additional costs being imposed on members who are actively working to supply the seed for sowing market nationally. The South Australian Government maintains a total ban on the transport of GM seed and grain through the State. This ban applies even to those products –

including GM herbicide tolerant canola – that has been approved for legitimate commercial release in Australia by the Gene Technology Regulator, and would seem inconsistent with the spirit of the Intergovernmental Agreement on Biotechnology. We would therefore ask that the Review consider whether the transport of GM crops approved for general release in Australia could be something that the Regulator could consider excluding as a dealing under the Scheme, and whether it can look to regulate the field in this respect in order to provide the certainty and flexibility needed by the seed industry in order to meet the legitimate demands of growers. Without this fix, the path-to-market is not clear - which acts as a disincentive to investment and innovation.

4. How would you streamline the existing scheme? P24

Not relevant for ASF.

5. What efficiencies could be gained through adjusting the interface between the Scheme and other regulators? P24

One area of concern for the seed industry when it comes to interactions between the Scheme and other regulators is that of certification/accreditation of nursery facilities undertaking plant breeding work with GMOs both under the Scheme and under Australia's quarantine legislation. The requirements of both regulators are relatively similar and yet require ongoing auditing and sign-off from both. Mutual recognition of certification under either scheme would significantly reduce the regulatory burden and confusion in this space.

6. What support exists for a regulatory framework providing for tiered risk? P25

The ASF is supportive of the Decision Tree provided by CropLife Australia in its submission to Phase One of this Review, which is consistent with a tiered approach to risk-based regulation. Certain exclusions (SDN-1, SDN-2, ODM, cisgenesis, null segregants) should immediately be made to the Scheme, but the Regulator should also have the ability to undertake more streamlined risk assessments where:

a) The GMO is well characterised (i.e. an OGTR Ecology and Biology document already exists); OR

b) The genetic modification results in the same or a substantially similar protein to one previously approved in Australia; OR

c) The GMO has been approved for cultivation in another country with a 'recognised' biosafety regulatory system (i.e. one that follows the OECD or Codex Risk Assessment Guidelines).

This will certainly assist plant breeders in bringing innovation to growers more quickly.

7. What examples exist of licence applications to the Regulator that could be 'fast-tracked', under a risk tiering system, with evidence of scientific and technical integrity that the aims of the Scheme (protection of human health and the environment) will be delivered? P25

Not relevant for ASF.

8. Under a regulatory framework to tier risk for environmental release, what efficiencies might be delivered to regulated stakeholders? P25

Not relevant for ASF.

9. How could efficiency gains to the Regulator be quantified? P25

Not relevant for ASF.

10. What justification is there to regulate animals, plants or microbes differently? P25

The ASF believes that the Scheme already regulates different organisms and applications differently. For example, contained dealings involving knockout mice require a PC1-level facility, whereas GM plants require a PC2-level facility and certain microorganisms even higher containment. It is appropriate that the level of regulation is commensurate with risk.

There is a lot of experience with plants that makes dealings with these systems less risky. For thousands of years, plant breeders have always used the creation of new variations of plant characteristics to provide solutions for resistance to plant diseases and pests, to increase tolerance to environmental stress, to improve quality and yields, and to meet consumer expectations. Plant breeding depends upon genetic variability within and across related species as a basis for developing new plant varieties with improved characteristics, and these processes are well understood.

11. In what way might different applications be treated differently (e.g. medical, agricultural, industrial, environmental, etc)? p25

As we have mentioned previously in relation to Question 6, consideration of a streamlined risk assessment process would enable different application to be treated differently.

12. How might the Scheme accommodate the DIY-biology movement? P26

Not relevant for ASF.

13. What measures might be warranted to identify potential long-term or 'downstream' effects of gene technologies on humans and the environment? P26

Not relevant for ASF.

14. What opportunities are there for principles-based regulation in the Gene Technology Scheme? What advantages could be gained from doing this? What drawbacks are there from such an approach to regulation? P26

Not relevant for ASF.

15. Are there any non-science aspects that would enhance the object of regulation, that do not place unnecessary burdens on the regulated community? How might these be considered? P26

The gene technology regulatory scheme should remain firmly focused on science and risk-based regulation. Non-science aspects, such as trade and marketing, and socio-economic considerations, have no place in this scheme given the Scheme's overall Object is to protect the health and safety of people, and to protect the environment, while providing an efficient and effective regulatory system for the application of beneficial gene technologies.

16. What are the potential impacts on market access for exporters of animal or plant derived food products? P27

ASF members are committed to market choice and are confident that Australian industry has the capacity to deliver such choice. This capacity is provided by industry stewardship programs, commercial practises, processes and protocols addressing marketing and technical requirements, the import/export processes and the supply chain mechanisms. Australia's experience with GM canola – with no loss of market access resulting from the commercial use of this technology – is evidence of this fact. Indeed, the ASF was an endorsing organisation of the grain industry's 'Delivering market choice with GM canola' report, and plays an important role in ensuring that end products such as grain meet market requirements.

We would still encourage the Australian government to participate in international initiatives to address asynchronous approvals and the regulation of new plant breeding innovations in order to harmonise requirements as much as possible, to provide certainty, and to facilitate trade.

Theme Three: Governance Issues

1. What will reassure the Australian public and regulated communities of the integrity of the Scheme? P29

Not relevant for ASF.

2. What mechanisms could address the challenges that making changes in the Scheme might entail:

- Domestically – across a federated government system experiencing different political agendas and community sentiments?
- Internationally – relating to other agreements, trade agreements, and harmonised regulatory approaches? P29

Not relevant for ASF.

3. What principles should guide the level at which a decision is made within the Scheme? P30

Not relevant for ASF.

4. Does reviewing the Scheme every five years best address the needs of the Scheme? Is there a preferable option? P30

Reviewing the Scheme every five years only makes sense if you are going to implement the Recommendations that result from such reviews. The ASF notes that lmited progress has been made in this space to date, especially in addressing new technologies. We do recommend more regular technical reviews of the delegated legislation, perhaps every 2 years, so that the exclusion lists and scope of regulatory oversight keep pace with technological developments and knowledge gained about technologies and/or organisms.

5. Is the existing role of the Forum the most suitable way of providing oversight and guidance for the Scheme? P30

Not relevant for ASF.

6. What criteria should be used to determine what legislative amendments are minor and could be progressed without going to the Forum? P30

Not relevant for ASF.

7. What evidence is there to support economic and trade advantages of GM moratoria – or indeed, the absence of GM moratoria? P30

It is the ASF's view that the current restrictions on gene technology dealings in South Australia are imposing a logistical constraint on the operations of plant breeders who are involved in this market sector, including significant additional costs being imposed on members who are actively working to supply the legal seed for sowing market nationally. The South Australian Government maintains a total ban on the transport of GM seed and grain through the State. This ban applies even to those products – including Roundup Ready canola – that have been approved for legitimate commercial release in Australia by the Gene Technology Regulator.

This ban is affecting the industry's ability to source seed from production areas in Eastern Australia in a timely manner to meet the increasing needs of Western Australian farmers.

This situation effectively means that GM canola approved for planting in Australia cannot be transported directly by truck across Australia, and must be either sent by road around to WA via the Northern Territory, shipped via sea around South Australia, or air freighted. All of this adds time and costs, and has led to requested seed not being available for planting. Quality testing of seed has also been affected, with seed companies now having to send GM seed to testing labs further afield for results. This is affecting ASF members' economic bottom line and puts us at a disadvantage trade-wise as grower orders and reacting to market demand.

The ASF therefore supports the recommendation in the Final Report of the Productivity Commission's Inquiry into the Regulation of Australian Agriculture in November 2016 that "the New South Wales, South Australian, Tasmanian and ACT Governments should remove their moratoria on GM crops.re transport."

8. How could regulated stakeholders access the benefits of a national scheme, whilst ensuring jurisdictions are able to effectively trade in the international context? P30

Not relevant for ASF.

9. What other mechanisms could be utilised in order to realise the outcomes currently achieved through moratoria? P30

Not relevant for ASF.

10. Are existing mechanisms, when used effectively, sufficient to ensure the emerging health, environmental and manufacturing benefits of gene technology that were not anticipated at the establishment of the Scheme, can be harnessed for Australians? P31

Not relevant for ASF.

11. Should other policy principles be developed that are tailored to horizon technology management? P31

Not relevant for ASF.

12. What other factors could be considered in the regulatory decision? P31

The ASF believes that factors such as detection/enforceability, and whether products resulting from gene technology are similar to, or indistinguishable from, varieties that could have been produced through earlier breeding methods, should be considered in making regulatory decisions.

13. What data sets are required to assist the regulator to consider benefits in addition to the risks? P31

Not relevant for ASF.

14. What aspects of gene technology would benefit from greater policy position clarity? P32

One aspect of gene technology that would benefit from greater policy position clarity is low level presence of GMOs in seed. Currently under the Scheme, situations of low level presence (where a trait approved in another country is detected in Australia) must be dealt with through emergency licences, with a view to complete removal of the unapproved trait. It is the ASF's position that a better policy for addressing LLP in seed needs to be introduced into the Scheme. In agriculture, as with all biological systems, 100 per cent product purity is impossible and as agricultural biotechnology continues to be rapidly adopted around the world and trade in GM grains and seed increases, Australia's current legislation which imposes 'zero tolerance' to LLP will be unsustainable.

A national seed LLP policy that incorporates both thresholds based on industry practices and existing varietal purity standards, coupled with the recognition of safety assessments from other countries, will provide both industry and the Regulator with a comprehensive policy that maintains safety standards while at the same time being proactive, transparent and science-based. The use of familiarity – including a history of safe use, availability of data and safety assessments – could be incorporated into such a policy to allow for a proactive approach to specify situations where or if a safety assessment is required.

15. What other mechanisms would provide suitable policy clarity that would enhance the Scheme and support compliance? P31

As previously mentioned, the ASF believes that more regular review of the technical exclusions under the Scheme will help to provide early clarity and certainty for plant breeders as new breeding techniques become available.

16. What are the pressure points at the boundaries between regulatory schemes that are caused by regulatory gaps or overlaps? P32

Not relevant for ASF.

17. How can existing coordination functions be utilised more effectively to support the Scheme to be agile and facilitate transitions across regulatory framework boundaries? What other activities would enhance this? P32

Not relevant for ASF.

18. What amendments to the funding model would support an agile Scheme that will cope with increased future activity? P32

Not relevant for ASF.

19. How could some aspects of the Scheme be funded through other mechanisms that will support innovation and competition in gene technology, whilst retaining public confidence in the Scheme? P32

Not relevant for ASF.

Theme Four: Social and Ethical Issues

1. How do we help the community to best understand the benefits and risks of a complex, science-based technology? P35

Not relevant for ASF.

2. Where does the community have confidence in the gene technology regulatory scheme? How can this be maintained? P35

Not relevant for ASF.

3. Where is there a lack of community confidence in the gene technology regulatory scheme? Why might this be, and how can confidence be built? P35

Not relevant for ASF.

4. What does the public need to know? P35

Not relevant for ASF.

5. Who is best placed to provide that information? P35

Not relevant for ASF.

6. What does the public need in order to accept the increasing availability and range of use of gene technologies? P36

Not relevant for ASF.

7. What does the public need in order to determine whether to provide social licence for the adoption and embedding of gene technology into the culture, lifestyle, economy and health sector? P36

Not relevant for ASF.

8. What are the ethical considerations for enabling access to medical treatments? P36

Not relevant for ASF.

9. How do we ensure that information is available to the community on the value of GM and what it can do? Who is responsible for providing this, and why? P36

Not relevant for ASF.

10. Is the Scheme putting up barriers to research and development and commercialisation of agricultural applications? P36

The ASF certainly believes that the current scheme is putting up barriers to research and development. Australian plant breeders have investigated the applications of several new breeding technologies in their breeding programs but the current lack of regulatory certainty prevents the implementation of these techniques in their programs - resulting in a substantial reduction in innovation. The ASF notes, for example, that the US Department of Agriculture (USDA) has determined that some applications involving the use of techniques such as TALEN and CRISPR/Cas are not considered regulated articles by USDA. Food Standards Australia New Zealand has similarly reviewed several these techniques and reached similar conclusions. Again, we would like to see exclusions that are both process-based (SDN-1, SDN-2, ODM, cisgenesis used in plants) and product-based (null segregants) from the scope of regulatory oversight as we believe this will provide the certainty plant breeders need to proceed with this next step in innovation.

As mentioned previously in the submission as well, State moratoria on commercial cultivation of GM crops also present significant barriers to both R&D and commercialisation of new agricultural applications. Transport across Australia, and the ability to invest in the full Australian market, is being severely hampered by these decisions. Repealing the ability of the States to impose these moratoria must be a priority of this review.