Extractas Bioscience

3 February 2021

The Hon Guy Barnett
Minister for Primary Industries and Water
Minister for Energy
Minister for Resources
Minister for Veterans' Affairs
SDN-1 Regulations
Agriculture and Water Division
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Dear Minister Barnett

Response to the Invitation to Comment on the Draft *Biosecurity (SDN-1 Modified Organism) Regulations 2020*

Thank you for the opportunity to provide comments on the draft *Biosecurity (SDN-1 Modified Organism) Regulations 2020.* Tasmanian Alkaloids Pty Ltd trading as Extractas Bioscience Pty Ltd (Extractas) has collaborated extensively with Poppy Growers Tasmania Inc (PGT) and Sun Pharmaceutical Industries Australia Pty Ltd (Sun Pharma) to provide this submission.

Crops genetically modified for pharmaceutical purposes and not intended for use as food or feed may be authorised for release to the Tasmanian environment for limited and controlled release or commercial purposes under the *Genetically Modified Organisms Control Act 2004.* On the surface, this would appear to exempt pharmaceutical poppies from the current Moratorium on commercial GMO production in Tasmania, however we are aware that this authorisation is subject to:

- Prior approval by the national OGTR as required;
- Assessment by DPIPWE of the likelihood of GMO entry into the broader environment, other than plants, or human and animal food supplies;
- Conditions as required.

Thus we feel that "real" exemption for non-food pharmaceutical crops from the *Genetically Modified Organisms Control Act 2004* and the proposed *Biosecurity (SDN-1 Modified Organism) Regulations 2020* is less certain than has been widely proposed. We are therefore of the view that we have a potential stake in the proposed changes to this legislation.

Further,

(i) A significant quantity of poppy seed is sold for culinary purposes on both the domestic and international markets. The sale of seed for culinary purposes would constitute use for food, which comes under the control of the proposed new regulations.

(ii) Extractas Bioscience and Sun Pharma are constantly looking for new production, processing, and extraction opportunities as part of their ongoing strategies of innovation, diversification and utilisation of core capacity and capabilities. Future opportunities may very well include food crops and products, and it is important that both companies have freedom to operate in the research and development space and maximum operational and development flexibility.

(iii) Extractas, Sun Pharma and PGT represent and collaborate with rural producers who are diversified in terms of crop production, including food production enterprises. We feel the need to take a wider view of our responsibility to our grower base including providing technical comments on changes to legislation and regulation that could potentially affect their livelihoods.

Extractas, Sun Pharma and the PGT have three broad concerns regarding the proposed new biosecurity regulations:

1. **Freedom to Operate and Ability to Access and Utilise and Important Research and Development Technology**

Site-Directed Nuclease-1 (SDN-1) is one of a suite of new breeding technologies which are being considered for use by innovation-based companies such as Extractas and Sun Pharma. Essentially SDN-1 is a mutation breeding technique. Mutation breeding seeks to develop new traits and breeding lines through the alteration of the nucleotide sequence of the genome of an organism. In conventional mutation breeding (CMB), propagules and parts of the organism (in our case generally seeds) are exposed to mutagenic chemicals (e.g. ethyl methanesulfonate or EMS) or radiation (generally x-rays, gamma rays or fast neutrons) which induce deletions in the nucleotide sequences of the target organism. Mutations occur naturally in organisms at about 10^{-4} to 10^{-6} per generation but with CMB this can be increased to 0.14-0.6%. CMB is a useful plant improvement tool and companies such as Extractas and Sun Pharma have used it very effectively to produce pharmaceutical poppies with distinct chemotypes and desirable traits such as significantly increased yield. That said, CMB does have a number of drawbacks. Large numbers of propagules need to be treated with mutagens to produce an effective population from which to select potentially useful breeding lines that occur with relatively low frequency. Mutagenesis with chemicals and radiation is generally not targeted and can result in undesirable traits, changes to multiple traits and physiological damage. Several generations of breeding may be required to stabilise useful mutations and remove deleterious ones and it may take many years to introgress these useful characteristics into commercial cultivars.

SDN-1, on the other hand, is a targeted technology which uses nuclease enzymes to cleave phosphodiester bonds between nucleotides of targeted nucleic acid sequences. This technique causes small deletions which then repair through natural cell processes. It is relatively quick and simple to use and free from many of the drawback associated with CMB. SDN-1 offers the prospects of a targeted plant breeding technology with a significant reduction in time to commercialisation for new cultivars. This technology does not use recombinant DNA and does not lead to the insertion of foreign DNA. As a result, SDN-1 has the potential to transform commercial plant breeding programmes and is of intense interest to Extractas, Sun Pharma and most other plant-based industries. In poppies, it may have potential to induce resistance to diseases such as systemic downy mildew, induce differential herbicide resistance to aid in the management of wild poppies and to develop novel commercially exploitable traits. Extractas is also interested in the potential of this technology for plant improvement in medicinal cannabis.

We understand that the current GMO legislation and proposed Biosecurity Regulation allow for the licensing of companies and organisations to use SDN-1 for research and development purposes. However, commercialisation of new varieties developed using SDN-1 will fall under the moratorium on GMOs for food crops in Tasmania and be subject to an approval process for non-food pharmaceutical crops. This approval process will presumably involve wider industry and/or community consultation with the very real chance that these varieties will not receive adequate support for approval for formal commercialisation. In such an uncertain regulatory and approval environment, companies such as Extractas and Sun Pharma may be unwilling to invest significant amounts of funding in R&D using this technology in Tasmania and may be forced to commercialise new varieties arising from the use of SDN-1 in mainland Australian states where the legislative environment is not as restrictive. Thus, in reality this technology will not be available for use by industry in Tasmania, and the Tasmanian economy will not benefit from the large potential gains available using this technology if this draft Biosecurity regulation is adopted by the Tasmanian Government.

2. **The Basis for the Proposal to Regulate SDN-1 in Tasmania and Potential Flow-on Effects**

In 2018, the European Court of Justice (ECJ) ruled that mutation breeding was a form of gene editing and was therefore regulated under the *2001 GMO Directive*. They further ruled that CMB (using chemicals and radiation) would be exempt from regulation on account of their history of safe use, but that new gene-editing technologies such as SDN-1 should remain regulated under the GMO Directive. Individual EU member countries are free to adopt these rulings, and 19 member states have currently adopted these

restrictions. It should be noted that these rulings have attracted wide international criticism from the international scientific community. Australia and the USA have officially decided not to regulate SDN-1 as

a GMO technology. It is difficult to separate "artificial" SDN-1 technology from natural cell processes and even more difficult to conceive of a credible safety risk from the use of this tool in plants. In reality, the European decision to regulate SDN-1 bears all of the functional attributes of a non-tariff trade barrier and it appears that it is being used in this regard in some European country markets. Extractas, Sun Pharma and PGT have additional concerns in addition to the lack of a robust scientific or safety rationale for regulating SDN-1 under GMO legislation.

For example, there are those politically active international groups including Greenpeace, Friends of the Earth Europe, BUND, GeneWatch, the Association of Food Without Genetic Engineering (VLOG) and the Corporate Europe Observatory who are seeking to ban or regulate all forms of mutation breeding. The ECJ has already ruled that mutation breeding is a form of gene editing and thus varieties produced in this way are subject to regulation as GMOs in this jurisdiction. These organisations are very influential in Europe and it is easy to envisage a situation in which some European countries move to ban products derived from all forms of mutation breeding, including CMB. This may prove problematic for the Tasmanian Government. Having made the decision to regulate SDN-1 organisms in Tasmania in an attempt to counter the decision of some EU countries to use the regulation of SDN-1 for restrictive trade practices, will the Tasmanian Government extend this to CMB should this too become regulated by European countries?

The Tasmanian poppy industry relies very heavily on poppy varieties that have been developed through CMB. Alkaloid poppies have a farm gate value of $60 million with a total annual value to the state of around $240 million and directly employing 250 FTEs with a further 250 FTEs indirectly benefiting. Should CMB crops become regulated in Tasmania, then the major commercial poppy companies may have no other option than to commercialise varieties produced though mutation breeding in mainland jurisdictions which are unencumbered by such restrictive regulation. This would have a significant negative effect on the Tasmanian economy.

3. Compliance, Regulation and Enforcement of SDN-1 in Tasmania

The 'Fact Sheet' on the proposed *Biosecurity Regulations 2020* states that the regulation will be administered and enforced through a registration system. Under this registration system persons or organisations intending to import, use, or create SDN-1 modified organisms in any commercial, scientific research or other activity will need to be registered with Biosecurity Tasmania. It further suggests that the regulation will be enforced through traceability. The scientific literature is quite clear that SDN-1 modified organisms are indistinguishable from natural mutations or CMB produced varieties. In the case of GMOs produced using recombinant DNA technology, modified varieties can be identified through laboratory analysis "exotic" genetic material such as promoters and terminators from *Agrobacterium tumefasciens*, cauliflower mosaic virus and nopaline synthase terminator (NOS), or the kanamycin resistance market gene, using PCR of LAMP analysis. No such tests exist for SDN-1 modified organisms as the technology does not insert foreign DNA or promoters and terminators. Thus, the proposed Tasmanian approach is a registration and traceability scheme but is not underpinned by any tangible means of enforcement. It is, in fact, an "honesty scheme" relying on the ethics and integrity of industries, organisations and individuals. This raises a number of issues for Extractas, Sun Pharma and the PGT:

(i) We are of the view that the burden of compliance will largely be borne by Industry and organisations such as Extractas and Sun Pharma. In a situation where the regulator cannot effectively enforce the regulation or indeed differentiate the 'regulated' material from natural or CMB produced material, then our concern is that the onus will fall on us to prove the unprovable. That is, that the material has or has not been produced by SDN-1. We are curious to know how the Tasmanian Government will deal with this when inevitably these cases proceed to legal determination.

(ii) We have concerns regarding the potential for non-compliance with this regulation. Within Tasmania, ethical organisations such as Extractas, Sun Pharma and the PGT will clearly agree

to follow the regulations including registration and enforceability. However, SDN-1 technology offers significant opportunities for innovative R&D and large potential economic returns. Thus, it is conceivable that registered and unregistered facilities within Tasmania could decide not to declare SDN-1 derived varieties or report on SDN-1 R&D and it would be very difficult for Tasmanian government agencies to ensure compliance. The proposed legislation may in fact cause the use of this technology to go "underground" in some circumstances disadvantaging those companies which operate ethically, and which operate within the spirit of the legislation.

(iii) We have concerns regarding the importation of SDN-1 modified organisms from interstate and overseas. Biosecurity will be relying on importers to declare SDN-1 modified organisms which are indistinguishable from natural mutations and CMB-induced organisms. There may be organisations and individuals that are tempted to import SDN-1 modified varieties as natural or CMB-induced varieties. The experience with PBR natural mutations such as those which occurred with the hundreds of bud sports in Red Delicious apples highlights the difficulties in determining provenance in this type of material and thus legal enforcement. Biosecurity Tasmania may try to enforce this by requiring importers to prove the provenance of imported varieties, but will this survive legal challenge in an environment where there is no definitive scientifically accepted test of origin?

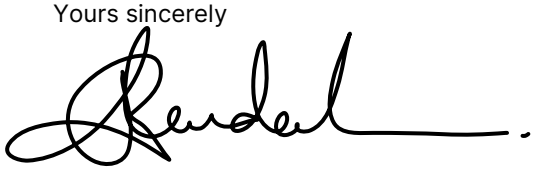
(iv) Extractas and Sun Pharma import significant quantities of germplasm from overseas. This is currently particularly so in the case of medicinal cannabis varieties which are being sourced to establish a wide genetic base for varietal development in Australia. Extractas obtains material from reliable and well-established sources, however we rely on the integrity of the supplier for the provenance of this material, and we have no way of checking to ensure that material has not been developed using SDN-1 technology. The proposed legislation will place the onus for certification and compliance on Extractas and we will not be able to provide the required certifications for imported plant material with any certainty. In such an uncertain operating environment Extractas management may decide not to invest further in importing additional commercially important germplasm into Tasmania. This may have adverse commercial impacts for Extractas and the Tasmanian economy and ultimately reduce our ability to compete with mainland medicinal cannabis producers who are not encumbered by such legislation.

(v) The fact that SDN-1 induced organisms are indistinguishable from natural or CMB-induced material is widely known. Given that the proposed *Biosecurity Regulations 2020* may very well be unenforceable logistically or legally, that unregistered laboratories may be able to operate within the state, and that SDN-1 varieties may be able to be introduced from mainland Australia and overseas, will the Tasmanian scheme be acceptable to overseas countries who prohibit imports products produced from SDN-1 varieties? How will the Tasmanian Government defend the integrity of the Tasmanian scheme and will it help Tasmanian producers to overcome a potentially serious non-tariff barrier in some markets as proposed?

Extractas, Sun Pharma and PGT understand that some Tasmanian producers and companies are adversely affected by the bans on products from SDN-1 varieties imposed by some European countries. That said, we are of the view that the Tasmanian Government has a responsibility to consider the implications of the proposed Biosecurity Legislation for the wider agricultural production and value adding in Tasmania. We note that policy and economic analyses of the proposed changes did not accompany the documentation regarding the Biosecurity regulations, and we would be very interested in receiving copies of these when they become available.

We therefore urge the Tasmanian Government to seriously reconsider the regulation of SDN-1 technologies in Tasmania and the effects that the *Biosecurity Regulations 2020* may have on Tasmanian industries and the government's target for the value of agricultural production reaching $10 billion by 2050. We would welcome the opportunity to meet with you to further discuss PGT, Extractas, and Sun Pharma's concerns regarding the proposed regulation of SDN-1 in Tasmania or to provide additional information to support our concerns.

Yours sincerely



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