Development and Implementation of a Policy and Regulatory Framework for Cultivation and Processing of Opium Poppies in South Australia

Discussion Paper

18 MAY 2016
Development and Implementation of a Policy and Regulatory Framework for Cultivation and Processing of Opium Poppies in South Australia

Information current as of 18 May 2016

© Government of South Australia 2016

Disclaimer

PIRSA and its employees do not warrant or make any representation regarding the use, or results of the use, of the information contained herein as regards to its correctness, accuracy, reliability and currency or otherwise. PIRSA and its employees expressly disclaim all liability or responsibility to any person using the information or advice.

All enquiries

Matthias Dengler
PIRSA Biosecurity SA
GPO Box 1671, Adelaide SA 5001
T 08 8207 7939
E Matthias.Dengler2@sa.gov.au
1. Introduction

The South Australian Government is establishing a regulatory framework which will permit the commercial cultivation of poppies in suitable growing regions of South Australia. This Discussion Paper provides the background and details of what is being considered in a poppy regulatory scheme.

A commercial licit poppy cultivation and processing industry will enable licensed South Australian producers to enter a new and slowly expanding agricultural industry. Australian poppy processing companies are pursuing opportunities to expand geographically, leading to potential employment and financial benefits for South Australian producers, supporting industries, the community and the State.

The regulatory framework to allow for the licit cultivation of poppy crops in South Australia is now under development with draft regulations released for consultation with stakeholders.

Australia is an international leader in the manufacture and export of opiate raw material, currently producing around half the world’s raw opiate supply for pharmaceutical manufacture and research. Licit cultivation of opium poppies in Australia has until recently been confined to Tasmania, under the terms of a Ministerial exchange of letters in 1971 between the Commonwealth and the States and Territories.

The demand for opiate-based pharmaceuticals and improved supply chain security of commercially produced opiate raw materials are cited as the main reasons for the planned geographic expansion, with increased cultivation areas needed to meet sustained demand in the market for licit opiates.

In August 2014, the Australian Government conditionally agreed to the geographical expansion of licit opium poppy cultivation outside Tasmania. The Australian Government is currently leading the development of an Agreement on Licit Opiate Cultivation and Production between the Commonwealth, States, and Territories that clearly defines roles and responsibilities of all parties, and a five year implementation strategy to ensure Australia continues to meet its international drug treaty obligations for the secure and safe supply of licit opiate materials.

In Australia, opium poppies are now grown in Tasmania, Victoria and the Northern Territory, for use in a wide range of painkillers, including morphine and codeine. Poppy straw is the raw material obtained from the poppy plant, from which the narcotics are extracted - morphine and codeine (used in the manufacture of pain relief medications), thebaine and oripavine (used in manufacture of pain relief and anti-narcotic abuse medications). Narcotic Raw Material (NRM) is obtained by extracting narcotics from poppy straw. See more at: [http://grdc.com.au/Research-and-Development/GRDC-Update-Papers/2014/07/An-overview-of-the-Tasmanian-poppy-industry](http://grdc.com.au/Research-and-Development/GRDC-Update-Papers/2014/07/An-overview-of-the-Tasmanian-poppy-industry)

New legislation to control opium poppy cultivation and processing was introduced in Victoria and the Northern Territory in 2014.

The growing of poppy crops in South Australia, particularly in the lower south-east region, presents a potentially viable and profitable rotational option for farmers who traditionally grow seed and other horticultural crops. The south-east presents an area with suitable climatic and soil conditions, with the added advantage of existing crop irrigation infrastructure.

The Controlled Substances (Poppy Cultivation) Amendment Bill 2015, introduced into the Legislative Council on 29 July 2015, was passed by both South Australian Houses of Parliament on 19 November 2015 and assented on 3 December 2015.

The amended Act establishes a regulatory framework for licit opium poppy cultivation and processing in South Australia, while ensuring effective controls are in place to protect the community from a crop that yields dangerous substances, and to prevent criminal infiltration of the industry.

The Victorian legislation was the basis of the South Australian Bill, and is considered appropriate to manage the risks associated with public safety and organised crime.
The key arrangements in place to manage the identified risks associated with the licit opium poppy industry include:

- requirements for appropriate fencing and sign-posting of crops,
- development of a risk management plan,
- ensuring licence holders and their associates are ‘fit and proper persons’, and
- that licence applications and renewals to cultivate and process poppies are also considered by the Commissioner of Police.

2. Industry Overview

Today, legal poppy farming is restricted to a few countries such as Australia, France, Hungary, India, Spain and Turkey. The industry is controlled by the International Narcotics Control Board (INCB), which seeks to prevent opiates being refined into illegal heroin.

The poppy industry has been operating successfully in Tasmania for many years. The industry started in Tasmania in the late 1960s due to a global shortage of morphine, the desire for alternate manufacturing regions, beneficial crop cyclicality (fitting well with vegetable and crop rotations), climatic conditions, and geographic isolation (enhanced security). Poppy processing companies currently operating in Australia are industry leaders in production of high-alkaloid yielding poppy varieties and efficient manufacturing processes, driving competitiveness in the global industry. See more at: http://grdc.com.au/Research-and-Development/GRDC-Update-Papers/2014/07/An-overview-of-the-Tasmanian-poppy-industry

As the world’s largest producer of licit narcotic raw material, supplying around half of the world’s demand, Tasmania is a significant supplier to the international pharmaceutical market.

With a processing industry that yields in excess of $100 million per annum, and with farm gate returns to growers estimated at between $70 and $90 million in recent years, the Tasmanian poppy industry benefits not only farmers and processors, but the entire local economy. Approximately 1,000 licences to grow opium poppies are issued each year to over 750 Tasmanian poppy growers, who collectively grow up to approximately 30,000 hectares of opium poppies on contract to three licensed processors – Sun Pharma, Tasmanian Alkaloids Pty Ltd and TPI Enterprises Ltd.¹

According to the 2013-14 Annual Report of the Department of Justice, 913 licences were issued and 21,428 hectares of opium poppies were harvested in Tasmania during the reporting period. Growers are subject to ‘fit and proper person’ checks by Tasmania’s Police Force, and there has been no evidence of the industry having been infiltrated by criminal elements.

Growers’ licences are conditional on the grower having a contract with one of the three licensed processors. Each of the three processors determines the required quantities of opium poppies and then allocate specific growing targets to their contracted growers. The three processors provide the seed, assist in the growing process, arrange for harvesting and take the poppy capsules for processing.

Poppy growing is generally restricted to areas under irrigation, with high rainfall and cool climates.

¹ Tasmanian Government Submission to the Legislative Council Select Committee Inquiry into the Tasmanian Poppy Industry November 2012
3. Regulatory Framework

3.1 International

The opium poppy industry is highly regulated under international and domestic law. As a signatory to the United Nations’ Single Convention on Narcotic Drugs 1961 (the Convention), as amended by the Protocol Amending the Single Convention 1972, Australia is required to carefully control and supervise all stages of the growing and production of opium poppies as well as the import and export of narcotic material.

Implementation of the Convention is overseen by the International Narcotics Control Board (INCB), which determines annual quotas for the growing of narcotic plants based on estimates of worldwide production needs.

3.2 Commonwealth and State

International obligations, based on quotas determined by the INCB, are implemented through Commonwealth and state legislative frameworks which regulate the importation, possession, cultivation and processing of opium poppies. Commonwealth and state legislative frameworks impose separate importation and licensing requirements. While these processes operate concurrently, consultation processes between Commonwealth and state government agencies support a coordinated approach to importation and licence applications.

In 1971 a joint decision of Commonwealth and state governments restricted the growing of opium poppies to Tasmania for security reasons. Under Commonwealth law, opium poppies are a scheduled substance under the *Therapeutic Goods Act 1989*. Licensing requirements for the importation and manufacture of poppy materials and products apply under Commonwealth law under the *Narcotic Drugs Act 1967* (manufacturing) and *Customs (Prohibited Imports) Regulations 1956*. These requirements must be met before importation or manufacturing can occur.

In addition, separate licensing requirements must also be met under the respective state legislative frameworks before the possession, cultivation, manufacture or supply of narcotic substances is permitted. Strict public safety and security measures are required for opium poppy cultivation, and the transport and processing of product.

3.3 South Australian Regulatory Framework

The *Controlled Substances (Poppy Cultivation) Amendment Bill 2015* amended the *Controlled Substances Act 1984 (the Act)*, to include the new Part 4A - Licences to cultivate alkaloid poppies and to process poppy straw.

---

2 Tasmanian Government Submission to the Legislative Council Select Committee Inquiry into the Tasmanian Poppy Industry November 2012
3 Tasmanian Government Submission to the Legislative Council Select Committee Inquiry into the Tasmanian Poppy Industry November 2012
Administrative responsibility for Part 4A of the Act lies with the Chief Executive of the Minister responsible for regulation of the Agricultural and Veterinary Chemicals (South Australia) Act 1994, which is the Department of Primary Industries and Regions South Australia (PIRSA). The amended Act requires for:

- licensing of growers and processors;
- growers to have a growing contract with a licensed processor;
- licences to be issued subject to conditions;
- growers and processors to maintain a risk management plan;
- a register of licensed growers and processors to be established and maintained; and
- licensed growers and processors to be assessed on their respective arrangements including their risk management plan.

The amended Act also describes the offences against the Act regarding poppy cultivation and processing and establishes a process for review of decisions of the Chief Executive by a tribunal.

The Act provides for the making of regulations to ensure appropriate requirements are in place to control alkaloid poppy cultivation and processing in South Australia.

The proposed regulations will provide the regulatory framework to support the Act and will enable South Australia to comply with Australia’s international obligations under the Narcotic Drugs Act 1967 (Commonwealth) to control the growing of opium plants and the processing of narcotic drugs.

The proposed regulations will establish a stringent framework to control every stage of poppy production, including transport, storage and processing, to require that poppy cultivation and processing licences are only issued to prescribed persons of good standing and to protect the South Australian community, by restricting access to toxic crops and preventing access to narcotic substances for criminal purposes.

A regulatory framework will generate costs associated with cultivation and processing licence applications and monitoring compliance with licence conditions. Prescribed fees will be collected for recovery of the administrative costs of maintaining relevant registers, assessing the suitability of applicants and associates, issuing and renewal of licences and for compliance activities.

Penalties will be attached to prescribed offences under the regulations.

Do you have comments about the South Australian legislative framework regarding poppy cultivation?

- Controlled Substances Act 1984 – See section 6, reference 9
- Controlled Substances (Poppy Cultivation) Amendment Bill 2015 - See section 6, reference 9
4. Accreditation/Licensing

4.1 Contracts

Prospective poppy growers must have a valid contract with a poppy processing company. Contracts will need to be provided to PIRSA when applying for a licence as evidence that the cultivation of poppies is for the purposes of undertaking a bona fide commercial activity.

4.2 Fit and Proper Person Requirements

For the purposes of preventing criminal activity in the cultivation of poppies and the processing of poppy straw, every cultivation and processing licence application and renewal application will be assessed against fit and proper person criteria. The criteria will examine whether:

- applicants and/or associates of applicants have been found guilty of a serious offence (in or outside South Australia) within the last 10 years;
- the applicant and their associates are suitable persons to be connected with the cultivation or processing of poppies;
- the applicant’s property will be suitable for the growing or processing of poppies or poppy straw in respect of location, facilities and security arrangements; and
- the applicant meets any prescribed arrangements.

Further consideration may also be given to:

- the applicant’s and associates character, honesty and integrity;
- the applicant’s and associates history of non-compliance with the Act;
- whether in the case of an application to renew a cultivation licence, the licensed grower or any associate has been found guilty by a court (in or outside South Australia) of any offence within the last 3 years;
- whether in the case of an application to renew a processor licence, the licensed processor or any associate has been found guilty (in or outside South Australia) of any offence within the last 12 months;
- whether the applicant has a satisfactory ownership, trust or corporate structure in place, where an applicant is not a natural person; and
- whether the applicant is of sound and stable financial background.

It is proposed that applications for a poppy cultivation and processing licence may be made for the purposes of a commercial enterprise and also for research.

Applications will be required to be accompanied by supporting documentation, such as:

- the proposed risk management plan;
- evidence verifying either a proposed bona fide commercial or research activity;
- National Police checks for applicant and associates;
- certificate of registration of business name (if applicable);
- current company ASIC extract (if applicable);
- credit history report; and
- any other information reasonably required to assist in assessing the application.

Question(s) for consideration:

- Do you consider fit and proper assessment requirements to be comprehensive enough in the context of the proposed South Australian regulatory framework for the purpose of preventing criminal infiltration?
4.3 Processing Applications

Once received, PIRSA will process poppy cultivation or processing licence applications within 60 days of receipt. A separate site assessment will be undertaken as part of determining the suitability of an application.

As part of the assessment process, every application will be referred to the Commissioner of Police for inquiry and advice. The Act requires that the Commissioner of Police advise of his or her decision to support or oppose the issuing of a licence and to provide the reasons for the decision within 28 days of receiving the application from PIRSA.

If PIRSA is notified that the Commissioner of Police opposes the application for or renewal of a poppy cultivation or processing licence, PIRSA must not issue or renew the relevant licence.

A set fee will apply for each application, and will cover the costs of reviewing the application against the criteria listed above.

4.4 Licences and Licence Conditions

Licence Conditions for Growers

Each poppy cultivation licence will be issued for a period not exceeding 3 years and will only relate to a specified premises. The licence will be subject to the licensed grower employing suitable persons, complying with the risk management plan and any other prescribed terms, conditions, limitations and restrictions of a licence. A poppy cultivation licence is also subject to the condition that a licensed grower, whilst carrying out an activity under the licence, must hold a contract with a licensed processor, with the contract to be registered on PIRSA’s Alkaloid Poppy Register.

Licence Conditions for Processors

Each poppy processing licence will be issued for a period not exceeding 12 months, will only relate to a specified premises, and must specify the maximum quantity of alkaloid poppies that may be processed by a licensed processor. A poppy processing licence is subject to the licensed processor employing suitable persons, and complying with the risk management plan and any other prescribed terms, conditions, limitations and restrictions of a licence. A poppy processing licence is also subject to the condition that a licensed processor, whilst undertaking an activity authorised by the licence, must hold a current Commonwealth licence to manufacture or export.

Prescribed Minor Licence Conditions for Growers and Processors

The prescribed licence conditions for growers and processors will include requirements such as:

- security of fencing and gates;
- restricted access to poppy crops;
- signage around crops/premises;
- destruction of harvest residue;
- destruction of volunteer poppy plant;
- keeping of records and other documents;
- provision/reporting of information and records within specified timeframes;
- notification of employee changes; and
- any changes to the risk management plan.

Non-Compliance with Licence Conditions

Non-compliance by growers or processors with licence conditions will attract penalties for prescribed offences under the Act and the Regulations.
4.5 Risk Management Plan

On application and renewal of licences, both growers and processors will be required to submit a Risk Management Plan outlining how they propose to deal with the risks relating to poppy production/processing and to comply with the conditions of their licence. These plans must be approved by PIRSA before a licence is granted. Compliance with the plan will be monitored by PIRSA through regular inspections of grower and processor operations and premises. Plans must be kept current during the growing season and any updates must be approved by PIRSA.

<table>
<thead>
<tr>
<th>Question(s) for consideration:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• What other licence conditions could be considered for growers and processors in the context of the proposed South Australian regulatory framework?</td>
</tr>
<tr>
<td>• Are the proposed security measures sufficient to protect public health and the environment?</td>
</tr>
</tbody>
</table>

5. Administration/Ongoing Management

PIRSA’s Chief Executive is the responsible authority for the administration of Part 4A of the Controlled Substances Act 1984 and the Controlled Substances (Poppy Cultivation) Regulations 2016.

PIRSA, through Biosecurity SA, will assess licence applications, consult with SA Police, issue grower and processor licences, and maintain a poppy licence register.

Each cultivation licence will be subjected to compliance monitoring by PIRSA through regular inspections of grower and processor operations and premises. Operations and premises will be assessed and inspected against licensing conditions, including the requirements for security (fencing, gates, advisory signs), and the approved risk management plans.

Prescribed fees will be collected for the recovery of administrative costs of assessing licence applications, renewals, and amendments and conducting related site assessments; conducting inspections of grower and processor operations and premises; conducting further background screening of applicants and their associates by SA Police; and the ongoing management and administration of the scheme.
6. References

1) Primary Industries and Regions South Australia (PIRSA) - http://www.pir.sa.gov.au/
2) International Narcotics Control Board (INCB) - https://www.incb.org/
4) Sun Pharma - http://www.sunpharma.com/
6) TPI Enterprises - http://tpienterprises.com/