

Australian Government

Department of Health

Tobacco Control Enforcement Policy

Legal Statement

This Department of Health (Department) Tobacco Control Enforcement Policy (the Enforcement Policy) contains general information only and should not be relied upon for the purposes of a particular matter. It does not provide legal advice and is not to be relied upon as a source of legal advice. It is provided as a general guide only and as such any person reading this Enforcement Policy should rely upon their own judgment and make their own enquiries including seeking relevant professional advice before entering into any arrangements, or making any commitment on the basis of any of the material in this Enforcement Policy. Nothing in this Enforcement Policy shall be taken in any way to replace the provisions of any legislative instruments made pursuant to tobacco control.

World Health Organization Framework Convention on Tobacco Control

Australia is a Party to the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC), which aims to protect present and future generations from the devastating health, social, environmental, and economic consequences of tobacco consumption and exposure to tobacco smoke. As a Party to the FCTC, Australia's objectives for tobacco control are guided by the principles of Article 4 of the FCTC, namely;

"Every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke and effective legislative, executive, administrative or other measures should be contemplated at the appropriate governmental level to protect all persons from exposure to tobacco smoke."

Under the FCTC, Australia must adopt and implement effective measures for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke. The FCTC also obliges Australia to take steps to protect its tobacco control policy setting and implementation from interference from the tobacco industry and its interests. This obligation comes from Article 5.3 of the FCTC, which states:

"In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law."

The Australian Government and the tobacco industry are pursuing conflicting goals – there is a fundamental and irreconcilable conflict between the tobacco industry's interests and the Australian Government's public health policy interests. For these reasons, and in line with the Australian Government's declaration to the Secretary General of the United Nations, public officials should interact with the tobacco industry only when, and to the extent strictly necessary, to achieve effective regulation and policy development.

To comply with Article 5.3, the Department makes public its interactions with the tobacco industry. The Department may also express its position on public health and tobacco control issues as appropriate. This may include informing the industry about specific tobacco products or circumstance considered to be non-compliant. The Department takes reasonable and necessary action to ensure compliance with relevant legislation. Further information regarding the Department's approach to further implementing Article 5.3 is available at: https://www.health.gov.au/resources/publications/guidance-for-public-officials-on-interacting-with-the-tobacco-industry.

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1. Purpose of the Enforcement Policy

The Enforcement Policy sets out the principles adopted by the Department in its enforcement of compliance with the *Tobacco Plain Packaging Act 2011* (TPP Act), the *Tobacco Plain Packaging Regulations 2011* (TPP Regulations), the *Tobacco Advertising Prohibition Act 1992* (TAP Act), and the *Tobacco Advertising Prohibition Regulation 1993* (TAP Regulation) (relevant legislation), which seek to improve public health and reduce the consumption of tobacco products and the harms associated with the use of those products.

The Australian Government recognises that consideration may need to be given to the range of enforcement options available and has developed this Enforcement Policy to explain the strategies and priorities that will guide decisions about enforcement actions.

2. Tobacco in Australia

Tobacco use was the leading risk factor of burden of disease for both males and females and contributed the most to fatal burden, with almost 20,500 attributable deaths (13% of all deaths) in 2018¹.

The report *Identifying the Social Costs of Tobacco Use to Australia in 2015/16* estimates the social costs of tobacco in Australia were \$136.9 billion in 2015/16. This comprises \$19.2 billion in tangible costs and \$117.7 billion in intangible costs. The report highlights that harms accrued from smoking in previous decades continue to have an impact today and there is a need to continue to invest in tobacco control strategies.

The Australian Government, together with state and territory governments, is committed to reducing the prevalence of smoking and its associated health, social and economic costs, and the inequalities it causes. In line with this commitment, the Australian Government has set targets to reduce smoking rates to below 10 per cent by 2025, and to 5 per cent or less by 2030.

There is strong evidence that comprehensive public health strategies focusing on both the supply and demand of tobacco are most likely to achieve long-term health gains, prevent the uptake of smoking and reduce smoking prevalence. This comprehensive approach has led to historically low smoking rates in Australia, particularly among children and youth.

3. Tobacco Advertising Prohibition

3.1 Background

The first tobacco advertising restrictions were introduced in Australia in 1973, which phased out radio and television advertising for cigarettes in 1976, with exception for accidental and incidental broadcast. Further legislative amendments were introduced in 1989 which further prohibited tobacco advertising from appearing in print media at a national level.

The TAP Act was introduced in December 1992, which phased out the use of billboards and other outdoor signage, including at sporting events, art and cultural gatherings, festivals, and other public displays. Further amendments were introduced in 2012, which extended the prohibition of advertising tobacco products to the internet and social media.

¹ https://www.aihw.gov.au/reports/burden-of-disease/burden-of-disease-study-2018-key-findings/contents/about

The object of the TAP Act, as set out in section 3, is to improve public health by limiting the exposure of the public to messages and images that may persuade them to start or continue smoking, or to use or continue using tobacco products.

The TAP Act, with certain limited exceptions, makes it an offence to publish or broadcast a tobacco advertisement. The definition of a 'tobacco advertisement' means any writing, still or moving picture, sign, symbol or other visual image, or any audible message, or any combination of two or more of those things, that gives publicity to, or otherwise promotes smoking or the purchase or use of tobacco products.

3.2 Point of Sale

The application of the TAP Act does not apply within the point of sale where tobacco products may be purchased in person. Local state and territory restrictions or requirements apply to the point of sale. Where the Department receives information relating to a potential contravention of the TAP Act occurring at the point of sale, the Department will refer the information to the local state or territory jurisdiction for their consideration, as outlined under Engagement with other agencies.

3.3 Online and social media

The TAP Act restricts tobacco advertising on the internet, including social media platforms, and through other electronic media in Australia such as mobile phones and emails.

There are a limited number of exceptions to this prohibition which permit limited publication of a tobacco advertisement (including the brand names of tobacco products) at the point of sale on the internet. However, specific requirements, such as meeting strict formatting and information requirements, must be met for these exceptions to apply as specified in the TAP Regulation. Additional online advertising requirements or restrictions may also be applied by local, state and territory governments.

Due to the international nature of the internet, there are times where an advertisement may be viewed in Australia yet published outside of Australia. The Department will explore all avenues in investigating websites and social media that appear to not comply with the TAP Act regardless of origin. In instances of overseas advertisements, the Department will advocate for the removal of the advertisement where it is able.

4. Tobacco Plain Packaging

4.1 Background

In April 2010, the Australian Government announced that it would introduce world-first legislation to mandate the plain packaging of tobacco products. Alongside this measure, health warnings on tobacco products were also to be updated and expanded.

The TPP Act came into full effect on 1 December 2012, and from that date required that all tobacco products sold, offered for sale, or otherwise supplied in Australia must be in plain packaging and be labelled with the new and expanded health warnings.

The objects of the Act are stated in section 3 of the TPP Act, which aim to improve public health, and to give effect to certain obligations that Australia has as a party to the FCTC. The Australian Government pursued this objective by regulating the retail packaging and

appearance of tobacco products to reduce the appeal of the products to consumers, increase the effectiveness of health warnings on retail packaging, and reduce the ability of retail packaging to mislead consumers about the harmful effects of smoking.

4.2 Graphic Health Warnings

The Australian Government is responsible for mandating health warnings on the packaging of tobacco products sold in Australia. The health warnings were updated and expanded under the *Competition and Consumer (Tobacco) Information Standard 2011* (the Standard), which commenced on 1 January 2012. Under the Standard, from 1 December 2012, retail packaging of tobacco products must display the updated warnings.

The Department has policy responsibility for health warnings, while the Standard is administered within the Treasury portfolio and enforced by the Australian Competition and Consumer Commission, and state and territory agencies. The Enforcement Policy does not affect the enforcement of the Standard by those agencies.

5. Principles underlying this Enforcement Policy

The Department will exercise its enforcement powers in an appropriate manner using the principles of proportionality, transparency, consistency, confidentiality (where appropriate) and timeliness. The Department applies the Australian Government Investigations Standards (AGIS), which provide the minimum standard of conduct for entities conducting investigations into programs and legislation they administer.

In enforcing the provisions of the relevant legislation, the Department's primary aims are to:

- ensure the highest level of compliance with the relevant legislation;
- educate and inform tobacco suppliers of their obligations;
- deter future non-compliance;
- encourage reporting of non-compliance (including self-reporting where an error has been identified); and
- encourage the effective use of compliance systems.

To assist with these aims, it is necessary to ensure a balance between the appropriate use of resources and effective compliance with the relevant legislation.

The Department will consider all complaints and referrals of non-compliance, which will be assessed and progressed according to the principles below. Complaints will also be considered having regard to risk and priority, to ensure that resources are allocated in the most efficient and effective manner. Complaints that contain old or unreliable information (or if an inspection has been conducted since the date of the alleged non-compliance) may be treated as 'for information only'. The information will be assessed for risk and priority and may be closed or referred on that basis.

The Department will conduct information campaigns from time to time, aimed at proactively addressing certain trends, and improving education and compliance in areas identified as being of concern. Appropriate campaigns may be conducted, and may be determined based on data held by the Department, including but not limited to:

- geographic locations;
- store types;
- product names or types;
- emerging products and suppliers;
- systemic alleged or perceived non-compliance; or
- where a need appears to exist.

The Department also provides information on its website that assists entities in ensuring compliance with the relevant legislation. The website includes guidance documents, information kits, frequently asked questions pages and fact sheets that provide information on how to comply.

5.1 Proportionality

Any enforcement action undertaken will be proportionate to the seriousness of the non-compliance. Consideration is given to the risk to public health, the degree of risk associated with failure to comply, the reputation of the regulatory scheme, and the appropriate use of resources in pursuing compliance on a case by case basis. Appropriate consideration is also given to the efforts made by the non-compliant entity to comply with the relevant legislation. The Department acknowledges that non-compliance in some cases is due to a misunderstanding of the relevant legislative requirements, rather than deliberate contravention. The Department undertakes information visits and makes information available on its website to ensure industry knowledge of its obligations.

5.2 Transparency

Guidance material on compliance with the legislative requirements together with compliance policies and strategies are publicly available so that regulated entities understand what is expected of them, and how compliance will be enforced. Regulated entities, where appropriate, will be informed of decisions made, and the grounds for those decisions.

5.3 Consistency

A consistent national approach is taken in interpreting, applying, and enforcing the relevant legislation. The Department takes a systematic approach to ensure consistency in case management and quality control, and that no preferential treatment is given or perceived to be given to one entity over another.

5.4 Confidentiality

Investigations are conducted confidentially, and information is handled in accordance with the Department's obligations under the *Freedom of Information Act 1982*, the *Privacy Act 1988*, the WHO FCTC, the TPP Act and TAP Act.

Where the Department elects to release comments, statements or otherwise publish information in relation to a particular matter, the information released will be guided by the principles of AGIS, namely that the information should not:

- prejudice a person's right to a fair hearing or the legal process;
- impinge upon the privacy or safety of others involved in the investigation; or
- prejudice any actions taken or future actions of the agency or other agencies.

5.5 Timeliness

The Department will conduct all investigations as efficiently as possible to avoid costly delays and uncertainty. The Department focusses on the timeliness of progressing investigations following receipt of a complaint to ensure the enquiries are made as soon as reasonably practicable after non-compliance is identified.

6. Assessment and Investigation of alleged contraventions

As the agency responsible for the enforcement of the TPP Act and the TAP Act, where an alleged non-compliance may have occurred, the Department considers the appropriate course of action to achieve compliance, and where appropriate, address instances of non-compliance.

The TAP Act and TPP Act contain monitoring and investigation powers to enable the Department to determine whether provisions of the TAP Act and TPP Act have been, or are being, complied with, and whether information given in compliance, or purported compliance, with a provision of those Acts is correct.

In assessing the seriousness of an alleged contravention, the Department takes a risk-based approach to the breach's effect on public health and the reputation of the broader regulatory scheme.

When making these assessments, these factors may include:

- the extent and reason for the alleged non-compliance;
- the efforts, if any, made to comply with the relevant legislation;
- history of non-compliance;
- previous provision of educational information;
- the likelihood of future non-compliance occurring;
- an apparent willingness to comply with the relevant legislation in the future; and
- any other matter the Department considers relevant.

Where more serious action should be considered, Authorised Officers will recommend appropriate steps to a decision maker (this may include the delegate of the Secretary where required). Further information about Authorised Officers is provided under item 6.1.

Where further education and communication is necessary to achieve compliance, a written warning may be issued. Alternately, where the Department considers that sufficient education has been provided and the risk is low, matters may be closed.

6.1 Appointment of Authorised Officers

The Secretary of the Department appoints Authorised Officers to conduct investigations under the relevant legislation. As required by the relevant legislation, Authorised Officers are

required to have suitable qualifications, training, or experience to conduct investigations. Authorised Officers must also be engaged by one of the appropriate entities as specified in the relevant legislation. Authorised Officers utilise powers provided under the relevant legislation to monitor compliance and investigate allegations of potential non-compliance that may be occurring.

Authorised Officers must report the findings of investigations to the Department with a recommendation on what next steps should be taken. The Department will consider the information and recommendation provided by Authorised Officers but will remain the ultimate decision maker on the appropriate next steps and outcomes in the investigation of a matter.

7. Compliance and Enforcement Action

The following table provides an indicative high-level matrix of the Department's compliance approach based on the perceived attitude to compliance by an entity.

Table 1 - Compliance and Enforcement Matrix

	Perceived Attitude to Compliance by Entity	Department's Compliance Approach
Tier 1	Perceived decision to not comply	Enforcement Options
High	Ambivalence to legislationAware of requirements, but unwilling to	Civil ProsecutionCriminal Prosecution
Risk	change non-compliant behaviour	Infringement NoticeInjunction
Tier 2	Reluctant but willing to comply	Return to Compliance & Deter
Medium Risk	 Superficial approach to compliance with the legislation Long term interests in industry - necessary to achieve compliance 	Warning LetterInfringement NoticeNegotiated ComplianceEnforceable Undertakings
Tier 3	Willing to be compliant	Compliance Options
Low Risk	Unaware of legislationBelief that compliant, but non-compliance detected	EducationWarning LetterNegotiated Compliance

7.2 Compliance and Enforcement Actions (Low to Medium Risk)

Where there is a low to medium level of non-compliance by a manufacturer, supplier or any other entity with an interest in tobacco products, proportionate enforcement actions will be taken to achieve the Department's compliance and enforcement objectives.

The Department is more likely to start with administrative and low-level enforcement actions in circumstances where:

- the conduct is considered lower risk;
- the entity is willing to accept the Department's position on the non-compliance, and a compliance outcome can be reached;

- there is a lower risk for future potential non-compliant behaviour; or
- the entity demonstrates a willingness to rectify non-compliance and take steps to achieve complete compliance moving forward.

In these circumstances, the Department may undertake one or more of the below actions.

7.2.1 Communications, information, and education

Measures such as communications, Authorised Officer visits, and the provision of information and educational material are designed to encourage compliance. The Department has undertaken a comprehensive communications and information strategy to ensure tobacco manufacturers and suppliers are aware of their responsibilities and obligations under the relevant legislation.

Education will continue to be an important feature of the Department's compliance and enforcement approach. The Department, however, has a reasonable expectation that manufacturers and suppliers continuously enhance their compliance mechanisms.

Education and compliance campaigns may also be undertaken to increase awareness of the relevant legislation, whereby Authorised Officers may conduct supply-chain site visits, centring on specific geographical locations, where information and trends suggest higher prevalence or risk of non-compliance.

7.2.2 Notice of Alleged Non-Compliance

Authorised Officers may issue manufacturers or suppliers a *Notice of Alleged Non-Compliance*, recording the nature of the activity alleged to be contravening the relevant legislation, and providing general guidance on rectification. Authorised Officers may revisit manufacturers or suppliers that have been issued with such a notice to ensure that the manufacturer or supplier is complying with the relevant legislation.

7.2.3 Written Warning Letter

In some circumstances it may be appropriate for the Department to issue a written warning letter. Authorised Officers may revisit manufacturers and suppliers that have been issued with a written warning to ensure that appropriate remedial action has been taken. Failure to comply following a written warning may lead to the issuing of an infringement notice or other enforcement action being undertaken against the manufacturer or supplier. Compliance with the relevant legislation is expected after a warning letter is issued, and it is the entity's responsibility to ensure its own compliance. The warning letter is not intended to address every aspect of non-compliance detected, and it may be of value to the entity to seek its own independent legal or compliance advice.

7.2.4 Infringement notices (TPP Act only)

Infringement notices may be issued when an Authorised Officer believes on reasonable grounds that a manufacturer or supplier has contravened a provision of the TPP Act which constitutes a strict liability offence. For a strict liability offence, it is not necessary to prove fault, or that the manufacturer or supplier intended to contravene the relevant legislation, only that the manufacturer or supplier did commit the prohibited act.

The Department may use infringement notice/s to address suspected contraventions, the seriousness of which requires a more formal sanction than a written warning or a Notice of Alleged Non-Compliance. For example, an infringement notice may be appropriate where:

- there is prima facie evidence of a contravention;
- non-compliance has not been sufficiently addressed where non-compliance was detected and identified to the manufacturer or supplier; and/or
- an infringement notice is a reasonable and appropriate penalty in the circumstances.

An infringement notice will include details of the alleged contravention, amount payable under the notice, payment due date and method for payment. A person may choose not to pay the amount; however, the Department may consider civil or criminal proceedings against the entity in relation to the alleged contravention if the infringement is not paid. The payment of an infringement notice does not imply an admission of guilt for the alleged contravention.

A person who receives an infringement notice may seek withdrawal of an infringement notice or an extension to pay an infringement notice by applying in writing to the Secretary. An application for an extension to pay an infringement notice, or the withdrawal of an infringement notice is not considered to be accepted until confirmed by the Secretary (or Secretary's delegate) in writing.

7.2.5 Enforceable undertakings

The Department may use enforceable undertakings where an investigation finds non-compliance, and the responsible entity is willing to rectify the issue and take proactive steps to prevent non-compliance occurring in the future.

Generally, an enforceable undertaking will include:

- acknowledgement by the responsible entity that non-compliance has occurred;
- agreement by the responsible entity to remedy the situation; and
- commitment by the responsible entity to introduce measures that will reduce the risk of future non-compliance occurring.

Where an Authorised Officer considers the responsible party has breached an undertaking, the Department may apply to a relevant court to make an order including to direct the responsible party to comply with the undertaking, to pay the Commonwealth amounts of any financial gain obtained because of the breach, or to compensate any persons who have suffered loss or damage as a result of the breach.

7.3 Compliance and Enforcement Actions (Medium to High Risk)

Where administrative and low-level enforcement actions have been undertaken and there still remains a medium to high level of non-compliance by a manufacturer or supplier of tobacco products, high-level enforcement action will be taken if, having regard to all the circumstances, the Department considers it is the most appropriate way to achieve its compliance and enforcement objectives.

The Department is more likely to proceed to high-level enforcement action in circumstances where:

- the conduct is brazen, reckless and /or clearly not in line with the intention of the relevant legislation;
- the entity maintains its opposed view to the Department's position on the non-compliance, and a compliance outcome cannot be reached;
- there is reason to be concerned about future non-compliant behaviour; or
- the entity fails to demonstrate a willingness to achieve complete compliance.

In these circumstances, the Department may undertake one or more of the below actions.

7.3.1 Injunction

An application for an injunction may be made to restrain a manufacturer or supplier of tobacco products from engaging in further conduct, if the manufacturer or supplier has, is, or is proposing to engage in conduct that would constitute an offence under the relevant legislation. An injunction may be applied for where the offence, and/or the impact of the offence is serious.

7.3.2 Civil penalty (TPP Act only)

The Department may apply to a relevant court to enforce the imposition of a civil penalty on an entity for contravening a provision of the TPP Act which a civil penalty applies. This is undertaken through civil court proceedings rather than criminal court proceedings. A civil penalty is a purely monetary penalty and does not result in any criminal conviction.

The Department is likely to commence civil proceedings where prior enforcement actions have not led to rectification of non-compliance, or where there is reason to be concerned about future non-compliance.

7.3.3 Criminal prosecution

The Department will refer an alleged contravention to the Commonwealth Director of Public Prosecutions (CDPP) for prosecution where there is sufficient prima facie evidence that an offence has been committed and one or more of the following applies:

- public interest considerations support prosecution action;
- other enforcement options are not appropriate, or have been employed but proved to be ineffective in achieving compliance;
- the alleged contravention is of such significance that a strong disincentive to potential offenders is warranted, and prosecution is an appropriate enforcement action; or
- the compliance history of the non-compliant manufacturer or supplier demonstrates a high risk of ongoing or future non-compliance.

The decision to prosecute rests with the CDPP who will assess the information and determine if there is a reasonable prospect of conviction based on admissible, substantial, and reliable evidence. The CDPP guidelines on prosecutions is available at: https://www.cdpp.gov.au/prosecution-process/prosecution-policy.

8. Engagement with other agencies

8.1 Information sharing and referrals for external investigations

The Department notes that some complaints are multi-jurisdictional and that at times, related offences are more appropriately dealt with by another Australian Government or state and territory agency. Where the situation involves a breach of more than one regulatory scheme (e.g. as with the import of illicit tobacco products, and appropriate involvement of law enforcement agencies) it may be appropriate for another agency to take the lead.

Cases may be referred to other agencies without notice to a person or entity. Case investigations commenced by the Department may continue to be investigated in conjunction with another agency, or matters may be referred in their entirety. Matters that do not fall within the remit of the Department are likely to be referred to another agency with the appropriate jurisdiction.

Information and referrals by the Department are completed in accordance with the requirements of the Australian Privacy Principles under the *Privacy Act 1988*.

8.2 Providing assistance to other agencies

Where requested, the Department may provide assistance to other agencies in their investigations. This may be through providing formal or informal advice or general information, data relevant to a particular matter that may be under investigation, the provision of formal witness statements, giving evidence in court, or providing assistance to inspect a product or premises, including in the execution of a search warrant.

8.3 Requesting assistance for investigations

Where appropriate, the Department may seek assistance from other agencies in conducting their enquiries and investigations. The Department may request:

- formal or informal advice or general information, data relevant to a particular matter that may be under investigation;
- the provision of formal witness statements;
- giving evidence in court; and/or
- assistance to inspect a product or premises, including in the execution of a warrant.

In situations where technical or professional expertise beyond the reasonable scope of the Department or other agencies may be required, the Department may engage with other entities that provide specialist assistance. This may include activities such as laboratory testing, information technology data forensics, or specialist legal advice.

9. Annual Reporting

Under s34A of the TAP Act, the Minister is required to prepare a report outlining the contraventions of the past calendar year. This report is tabled in Parliament by the Minister.

Under s108 of the TPP act, the Minister is required to prepare a report outlining the contraventions for the past financial year. This information is published in the *Department of Health Annual Report*.