



Australian Government

Department of Health

**Tobacco Plain Packaging
Enforcement Policy**

May 2018

This Department of Health Tobacco Plain Packaging 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 the *Tobacco Plain Packaging Act 2011* (Cth), the *Tobacco Plain Packaging Regulations 2011* (Cth) or any other legislative instruments made pursuant to tobacco control.

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1. PURPOSE OF THE ENFORCEMENT POLICY

The Tobacco Plain Packaging Enforcement Policy (Enforcement Policy) sets out the principles adopted by the Department of Health (the Department) in its enforcement of the *Tobacco Plain Packaging Act 2011* and the *Tobacco Plain Packaging Regulations 2011* (together, the TPP legislation). The Department has responsibility to investigate and enforce the TPP legislation on behalf of the Commonwealth. The Australian Government is committed to the full enforcement of the TPP legislation. In doing so, it recognises that consideration may need to be given to the range of enforcement options available and has developed this Enforcement Policy to explain the options for enforcement of the TPP legislation and the strategies and priorities that will guide decisions about enforcement actions.

2. BACKGROUND

A. Tobacco Plain Packaging Act 2011

In April 2010, the Government announced that it would introduce 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 *Tobacco Plain Packaging Act 2011* (the 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 *Tobacco Plain Packaging Act 2011*, which aim to improve public health, and to give effect to certain obligations that Australia has as a party to the Convention on Tobacco Control. The Parliament intended to achieve 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.

B. Health warnings

The Australian Government is responsible for mandating health warnings on the packaging of tobacco products sold in Australia. The health warnings have been 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 new 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, in collaboration with the state and territory fair trading agencies. The

Enforcement Policy does not affect, in any way, the enforcement of the Standard by those agencies.

3. 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. By undertaking compliance and enforcement activities in line with the Act and the associated powers, the Department's primary aims are to ensure a high level of compliance with the Act and deter future non-compliance, to achieve the objective of the Act. The Department notes the principles of the Australian Government Investigations Standards (AGIS), and applies them to any compliance and enforcement activity where necessary and appropriate.

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 with regard to risk and priority, to ensure that Government investigative resources are allocated in the most efficient and effective manner. Complaints that are received as a result of 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* once having undergone risk and priority consideration, and the complaint may be closed on that basis.

A. 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 whether the non-compliance affects the consumer having access to the required health warnings and graphics. The Department also acknowledges that non-compliance with the Act in some cases is due to a misunderstanding of the Act (rather than deliberate contravention), and undertakes information visits to ensure industry knowledge of its obligations under the Act.

B. Transparency

Guidance material on compliance with the TPP legislation 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.

C. Consistency

A consistent national approach is taken in interpreting, applying and enforcing the TPP 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.

D. Confidentiality

Investigations are conducted confidentially and the Department will not comment on matters it may or may not be investigating. Further, the Department maintains the confidentiality of complainants when conducting its enquiries, and will not release this information to any parties outside the Department.

The Department complies with its obligations under the *Freedom of Information Act 1982*, Australian Privacy Principles under the *Privacy Act 1988*, and Article 5.3 of the World Health Organization Framework Convention on Tobacco Control. 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 supply chain about specific tobacco products it considers to be non-compliant. The Department takes reasonable and necessary action to ensure compliance with the Act, and this may be a necessary step in achieving compliance at all levels of the supply chain.

E. 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 a potential breach is identified.

Compliance and Enforcement Matrix

	Entity's Attitude to Compliance	Department's Compliance Approach
Tier 1	Perceived decision to not comply <ul style="list-style-type: none"> • Ambivalence to TPP legislation • Aware of requirements, but insufficient change to non-compliant behaviour. 	Enforcement Options <ul style="list-style-type: none"> • Civil Prosecution • Criminal Prosecution • Infringement Notice
Tier 2	Reluctant but willing to comply <ul style="list-style-type: none"> • Approach to compliance flouts the legislation • Long term interests in industry - necessary to achieve compliance 	Return to Compliance & Deter <ul style="list-style-type: none"> • Warning letter • Infringement Notice • Negotiated Compliance
Tier 3	Willing to be compliant <ul style="list-style-type: none"> • Unaware of TPP legislation • Belief that compliant, but non-compliance detected 	Compliance Options <ul style="list-style-type: none"> • Education • Warning Letter • Negotiated Compliance

4. AIMS OF COMPLIANCE AND ENFORCEMENT ACTIVITY

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

- ensure the highest level of compliance with the TPP 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 TPP legislation. The aim is to achieve the highest level of tobacco importer/manufacturer and supplier compliance, and the industry's understanding of the regulatory scheme.

The use of the word 'suppliers' in the Enforcement Policy is, for the purposes of the Enforcement Policy, intended to include all wholesale and retail suppliers of tobacco products, but shall not include importers/manufacturers of tobacco products or related entities of manufacturers involved in the distribution or supply of tobacco products to arms-length wholesale or retail suppliers.

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. Campaigns will be determined by the Department or the Enforcement Committee, 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.

5. ENFORCEMENT OPTIONS

Not every contravention of the TPP legislation must be prosecuted, or attract an enforcement outcome. A range of compliance and enforcement options are available, including:

- communication, information and education;
- notice of alleged non-compliance;
- written warning;

- infringement notice;
- civil penalty; and
- criminal prosecution.

A. Enforcement Committee

The Tobacco Plain Packaging Enforcement Committee (Enforcement Committee) has been established, comprising representatives from the Department and the National Measurement Institute (NMI).

The NMI, through its authorised officers, undertake compliance and enforcement activities across Australia on the Department's behalf and report potential contraventions to the Enforcement Committee.

The Enforcement Committee considers NMI's field visit reports, and decide what actions, if any, should be taken in relation to potential contraventions of the TPP legislation. The Enforcement Committee may recommend compliance action through use of administrative mechanisms (as set out in section 5B below), or recommend to the Department that consideration be given to the commencement of civil or criminal proceedings (as set out in section 5C below). Where the Enforcement Committee considers that more serious action should be taken, the Committee will recommend that action to the appropriate decision maker.

Alternatively, the Enforcement Committee may consider that education already provided by NMI's authorised officers is sufficient, and recommend closure of the matter. Where further education and communication is necessary to achieve compliance a written warning may be issued to the entity.

In assessing the seriousness of the contravention, the Department takes a risk based approach to the breach's effect on public health and the reputation of the broader regulatory scheme, by considering:

- the extent and reason for the alleged non-compliance;
- the efforts, if any, made to comply with the tobacco plain packaging laws;
- any history of non-compliance;
- previous provision of any educational information;
- any likelihood of future non-compliance;
- any apparent willingness to comply with the plain packaging laws in the future; and
- any other matter it considers relevant.

B. Administrative enforcement

1) Communications, information and education

Measures such as communications, authorised officer visits, 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 TPP legislation.

Education will continue to be an important feature of the Department's compliance and enforcement approach. However, the Department is progressively shifting its focus to more direct forms of compliance activity as the tobacco industry's understanding of TPP legislation requirements continues to develop, and it is reasonable to expect manufacturers and suppliers to continuously enhance their compliance mechanisms accordingly.

Education and compliance campaigns may also be undertaken to increase awareness of TPP legislation, whereby authorised officers will conduct supply-chain site visits, centring on specific geographical locations, where information and trends suggest higher prevalence of non-compliance.

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 TPP legislation, and providing general guidance on rectification. Authorised officers may re-visit manufacturers or suppliers that have been issued with such a notice to ensure that the manufacturer or supplier is complying with the TPP legislation.

3) Written Warning Letter

In some circumstances it may be appropriate for the Department to issue a written warning letter. Authorised officers may re-visit 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 TPP 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.

4) Infringement notices

Infringement notices may be issued when an authorised officer has reasonable grounds to believe that a manufacturer or supplier has contravened a strict liability offence under the Act. A strict liability offence does not require proof that the manufacturer or supplier intended to contravene the TPP legislation, only that the manufacturer or supplier did commit the prohibited act.

An infringement notice may be issued where there has been a suspected contravention of the Act, the seriousness of which requires a more formal sanction than a Notice of Alleged Non-Compliance or a written warning. For example, an infringement notice may be appropriate where:

- there is prima facie evidence of a contravention;
- non-compliance has not been sufficiently addressed following an inspection where non-compliance was detected and identified to the manufacturer or supplier;
- there have been no previous infringement notices for similar contraventions; and/ or
- an infringement notice is a reasonable and appropriate penalty in the circumstances, taking into account the Department's preference for escalating compliance measures.

Where an authorised officer has reasonable grounds to believe that a manufacturer or supplier has contravened a strict liability offence, the officer will refer the breach to the Enforcement Committee, recommending that an infringement notice is issued.

An infringement notice will include details of the amount payable under the notice, the time for payment and how payment is to be made. A person may choose not to pay the amount, however payment of the amount within the specified time will mean that civil or criminal proceedings will not be brought against the entity in relation to the alleged contravention. The payment of an infringement notice does not imply an admission of guilt for the alleged contravention.

An infringement notice must be given within 12 months after the day on which the contravention is alleged to have taken place.

C. Court enforcement

Where there is a moderate to high level of non-compliance by a manufacturer or supplier of tobacco products, legal action will be initiated 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 litigation in circumstances where:

- the conduct is brazen and /or clearly not in line with the intention of the Act;
- 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 following actions.

1) Injunction

An application for an injunction may be made to restrain a manufacturer or supplier of tobacco products from further conduct that may or would constitute an offence under the Act. An injunction may be applied for where the offence, and/or the impact of the offence, is serious.

2) Civil penalty

A civil penalty is imposed by proving a contravention through a civil court procedure rather than through the criminal court process. 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 the conduct is brazen, where prior enforcement actions have not led to rectification of non-compliance, or where there is reason to be concerned about future non-compliance.

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 ineffective;
- the alleged contravention is of such significance that a strong disincentive to potential offenders is warranted, and prosecution is considered to be an appropriate enforcement action;
- 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>.

6. ENFORCEMENT APPROACH

As stated at the beginning of this Enforcement Policy, the use of the word 'suppliers' is, for the purposes of the Enforcement Policy, intended to include all wholesale or retail suppliers of tobacco products, but shall not include manufacturers or related entities of manufacturers involved in the distribution or supply of tobacco products to arms-length wholesale or retail suppliers ('manufacturers').

A. Suppliers

1) Substantial compliance with minor or anomalous non-compliance

Where a tobacco supplier is substantially compliant with the plain packaging laws but has committed a relatively minor or anomalous contravention, the Department will consider a range of compliance actions including the provision of education and information to the supplier, the issue of a Notice of Alleged Non-Compliance, and/or a warning letter. Authorised officers may re-visit the supplier at a later date to ensure compliance.

2) Sale of a tobacco product with a non-compliant appearance (e.g. cigarette sticks)

The Department recognises that, it will be difficult in some cases for suppliers to confirm that the contents of tobacco packaging (e.g. cigarette sticks) comply with the TPP legislation. In the event that suppliers contravene the legislation in relation to the appearance of tobacco products contained in otherwise compliant external packaging, the Department may seek to educate suppliers. Authorised officers may revisit the supplier at a later date to ensure compliance.

3) Significant non-compliance

Suppliers selling, or offering for sale, tobacco products in non-compliant packaging will be issued a Notice of Alleged Non-Compliance and will be provided with education material on site. This is likely to be followed up with a warning letter. Where ongoing non-compliance is detected, the Enforcement Committee may recommend that infringement notices be issued, or that court action be initiated against the supplier, depending on the circumstances.

Factors to be taken into account in deciding the appropriate enforcement approach include the seriousness of the contravention, and the supplier's knowledge of the contravention. Previous education and/or compliance activity will form a significant part of this consideration.

4) Informing a conglomerate head office to inform of non-compliance under their name

Due to the structure of many tobacco retailers being under the banner of a conglomerate (by franchise or other arrangement), the Department may determine that a need exists to inform that conglomerate head office of any non-compliance detected, as in some situations, the conglomerate may be implicated directly or indirectly by the non-compliant activities of a retailer. The Department may consider this a reasonable and necessary step in achieving compliance with the Act in certain circumstances.

B. Manufacturers

Manufacturers who are non-compliant with the TPP legislation for any reason may be issued with a Notice of Alleged Non-Compliance, a warning or an infringement notice, or court action initiated against the manufacturer. The Department will consider each instance of alleged non-compliance on a case-by-case basis.

The TPP legislation does not currently contain enforced recall provisions, however a voluntary return of stock can be initiated by the manufacturer separate from the Department's intervention. The Enforcement Committee may give consideration to a manufacturer taking voluntary steps to achieve compliance by removing all non-compliant stock from the market within a reasonable period, and the Department encourages self-reporting to achieve compliance.

A manufacturer's efforts to ensure compliance by facilitating the removal of non-compliant stock from the market within a reasonable period will be taken into account by the Enforcement Committee when deciding what enforcement action may be appropriate. The Enforcement Committee will consider various factors, including the ongoing risk to public health, and any necessary industry deterrence to be leveraged by certain enforcement options.

7. REFERRAL TO ANOTHER AGENCY

The Department notes that some complaints are multi-jurisdictional and that at times, related offences are more appropriately dealt with by another Commonwealth or state /territory agency. Policy, resourcing, and complaints related to other cases may make it appropriate for another agency to take the lead 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). Cases may be referred to other agencies without notice to a person or entity.

Cases investigated 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 jurisdiction of the Department (non-Plain Packaging offences) are likely to be referred to another agency with the appropriate jurisdiction.