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|  | **Australian Competition and Consumer Commission** |
| **Title** | **Hazard Analysis and Management Guidelines** |
| **Description** | These guidelines provide an overview of how Consumer Product Safety Branch staff identify consumer product safety hazards and the considerations that are relevant to managing them. |

## Hazard identification and analysis framework

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| --- | --- |
| Possible issues are identified | Proactively generated:   * International and Australian recalls * Media reports * Health system records * Professional literature * Coroner data   Reactive:   * Mandatory injury reports * Reports and complaints from consumers and competitors   Information may also be received from a state/territory regulator. |
| Appropriate regulator identified | * Many reports relate to consumer goods that are regulated by specialist regulators. These reports are referred to the relevant regulator. * Cooperative actions with these regulators occur when necessary. |
| Preliminary assessment occurs | * All reports have a preliminary assessment by ACCC staff. * An Assessment Matrix is used to conduct the preliminary assessment. * Decisions are subject to oversight by senior Consumer Product Safety Branch staff (the Product Safety Committee). |
| Initial assessment occurs | * Reports that gain a matrix score of *moderate* or above require an initial assessment to be conducted to determine the overall hazard. * Reports with an initial assessment score of *low* or below are closed requiring *no further action* * Reports with an initial assessment score of *moderate* or above require a detailed assessment. |
| Detailed assessments are undertaken and issues requiring risk management are identified. | * Initial assessments with a *moderate* or *high* score generate commencement of a detailed hazard assessment. * Trend analysis may also identify issues requiring detailed assessment. * A hazard assessment includes further research and analysis. * Detailed assessments resulting in a *moderate* or higher score are generally considered by the PSC and may be referred for further action within the Consumer Product Safety Branch or to another relevant line area, such as enforcement. |

**Risk Management Decision Making Framework**

**Step 1: Does the hazard assessment indicate that intervention is warranted?**

**Consider:**

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| How likely is it that an injury will occur? | * Are the hazard scenarios and steps leading to the injury realistic and complete? * Are they supported by any evidence? Does historic injury data suggest that there is a correlation between the injury and the product? * What is the exposure of consumers likely to be? |
| What is the severity of possible injuries? | * Are the injuries severe or at a persistent but lower level? * Are vulnerable consumers affected? |
| How likely are consumers to recognise the hazard? | * Could consumers see the hazard themselves (e.g. some chemicals contained within products cannot be detected by human senses)? * Is the nature of a hazard (such as drowning or hot surfaces) likely to be known to consumers? * Is the type of hazard related to a relatively new product (such as a strong magnet)? * Are vulnerable groups unlikely to recognise the hazard associated with the product (e.g. button batteries) or be attracted to a product that is not appropriate for them (e.g. child attractive products like small strong magnets)? |

**Conclude:**

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| --- | --- |
|  | |
| Yes | No |
| Consider what intervention might be possible (see step 2) | No further action required |

**Step 2: Are there acceptable, possible remedies that would allow the product to remain in the market?**

**Consider:**

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| --- | --- |
| * Who is being injured or may be injured? * How and why are injuries occurring or might they occur? | The central concern will have been identified through hazard assessment (step 1 above). The degree of precision that is available to understand the problem may be very important to the targeting and success of the solution. |
| How widely available is the product? | Availability may vary from rare to widespread. This information is important to the priority given to the problem and to the nature of the solution. A consumer product in widespread use warrants more consideration than a product in limited use. |
| Is there a hazard inherent to the product and can it be modified or performance requirements set? | * Is there something about the product that can be improved that will remove or minimise the hazard? * Can improvements be made to the structure and design of the product (the manufacture and production) or to its performance (its ability to meet a particular goal)? * Improvements might relate to performance, composition, contents, methods of manufacture or processing, design, construction, finish, packaging or testing. * To what extent do possible changes to the design or performance requirements mitigate the hazard? * Will the changes work? Can we establish a ‘safe’ level or measure a desired limit? |
| Is there a hazard related to a service associated with the product? | Many consumer goods need to be installed or maintained and the conduct of these services may impact on the hazards associated with the product.  Services might include the method of supply; the skills or qualifications of persons who supply such services; the materials used in supplying such services; the testing of such services; or the form and content of warnings, instructions or other information about such services. |
| Is the hazard associated with consumer behaviour? Can this behaviour be changed? | Is there a possibility that by providing consumers with a warning or education about the product and its intended use or inherent dangers, consumers may be able to avoid the hazard by changing their behaviour or product choices?  Information and warnings might be provided with, or on, the product or its packaging. For example it is possible to specify the form and content of markings, warnings or instructions that accompany consumer goods.  Education may be less direct: provided via government, community or industry education campaigns. |
| What is stakeholder/community hazard tolerance likely to be? | * Is the product widely in use, e.g. bicycles? * Are hazards reasonably evident and likely to be accepted? * Is there evidence of this? * Is political interest reflecting a perception of unacceptable hazard? * Are there substitutes or alternatives to the product or is it essential? * Is the level of injury higher than might be expected where a hazard is obvious? |
| Has voluntary or mandatory intervention been developed internationally? | * What is the international experience with the product? * Is a hazard assessment available? * Is there information about the reason a particular course of action was taken internationally? * Can the international action be replicated in Australia? |
| Are there unique Australian considerations? | Is there something about the culture, climate, demographics, history and economic situation of Australia that influences the perception of risk or risk tolerance? |
| Can possible interventions be implemented in an acceptable timeframe? | * Does the hazard require a particularly urgent solution? * Have there been sudden serious incidents or has something else changed in the environment that warrants the implementation of an urgent intervention? * Does this urgency suggest that a prohibition might be warranted? |
| Could there be unintended consequences? | * What may be substituted for the product or a component or feature of it? (For example a chemical used to soften plastic will need to be replaced if the softness of the plastic is important to the product). * Will these alternative arrangements be safer? |

**Conclude:**

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|  | |
| Yes | No |
| Consider the costs and benefits of the intervention (Step 3 [a]) | Consider the costs and benefits of prohibiting the product or implementing an education campaign (Step 3[b]) |

**Step 3[a]: Are the costs to the industry or an expected increase in the price of the product warranted in light of the perceived hazard and risk tolerance?**

**Consider:**

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| * Will an intervention change the cost of the product? | * Will the change in the cost of the product be minimal or is it likely to significantly increase the cost? * Will an increased cost be accepted by the community in light of the hazard assessment and perceived risk tolerance? |
| Will a potential change impose costs on industry? | * Will industry be able to sell existing stock? * Will the required changes necessitate costly new plant or equipment? * Does the hazard assessment warrant particularly urgent action that might limit suppliers’ ability to minimise the cost of the change to them? |

**Conclude:**

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|  | |
| Yes | No |
| Consider whether the outcome can be achieved voluntarily or whether regulation is required. (Step 4) | Repeat Step 2 – looking for a less costly (and possibly less effective) measure that might be acceptable.  OR  Issue a Safety Warning Notice  OR  Conclude that no intervention is warranted. |

**Step 3 [b]: Should the product be prohibited?**

**Consider:**

|  |  |
| --- | --- |
| Is the assessed hazard extremely high? | Are there elements in the hazard assessment that are particularly concerning? |
| Will the community accept the removal of the product? | Does the risk tolerance considered in the previous step suggest that the community would accept the removal of the product from the market? |
| Has the product been prohibited in other countries? | * Has the product been prohibited elsewhere? * Is there anything about the Australian market that makes it different to international markets where action has been taken? |
| What is the cost to industry (e.g. loss of stock, jobs, income) | * What information is available about the nature of suppliers and the size of the market? * Are these costs warranted by the hazard associated with the product? |

**Conclude:**

|  |  |
| --- | --- |
|  | |
| Yes | No |
| Consider whether the prohibition can be achieved voluntarily or whether regulation is required. | Develop an education strategy (this may include issuing a Safety Warning Notice).  OR  Do nothing. |

**Step 4: Can the desired outcome be achieved voluntarily?**

**Consider:**

|  |  |
| --- | --- |
| Is industry willing and able to implement the change? | * Does the industry have a relatively small number of identifiable suppliers? * Is there a representative and active industry body? * Is the product restricted to a narrow range of products sold in only a few stores? * Is the industry willing to implement change? |

**Conclude:**

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| Yes | No |
| Implement voluntary arrangements and monitor outcome.  Voluntary remedies will depend on the amount of product affected and the size of the industry, but might include recalls, development of guidelines, adoption of a code, changes to the product or its packaging, improved labelling.  These options are generally considered by the Product Safety Committee and referred for further action within the Consumer Product Safety Branch. | Propose a regulation.  Complete prohibitions are usually achieved through the implementation of a product safety ban.  Product requirements and performance specifications would ordinarily be achieved through a standard (but a banning notice may also be used). |

## Hazard identification

### On which products and services might the ACCC take action?

The product safety provisions of the Australian Consumer Law (ACL) apply to the supply of consumer goods in trade or commerce and services related to the supply of such goods.

* Consumer goods are defined in the ACL as goods for personal, household or domestic use and explicitly extend to such goods that have become fixtures.
* The price of the goods is an irrelevant consideration for the product safety provisions; non-consumer goods such as industrial or workplace goods are not included.
* The private sale of consumer goods is also excluded, since this is not considered supply in trade or commerce.

The ACCC frequently liaises with other regulatory agencies that may have responsibilities in relation to a particular product we are assessing, and often seeks the advice of experts (including those within regulatory agencies) in relation to emerging hazards we are assessing.  Contact with other regulatory agencies and experts—from the earliest stages of assessment and onwards—is routine, appropriate and necessary to our work.

For example, food safety issues are addressed by the food safety regulators at Commonwealth, State/Territory and local government levels and the safety of therapeutic goods such as medicines is addressed by the Therapeutic Goods Administration (TGA). Similar arrangements exist for registrable motor vehicles, electrical and gas appliances, industrial chemicals, radiation protection, veterinary products and pesticides.

Sometimes the scope of these specialist regulatory regimes is limited and their enforcement activities may be poorly resourced. In general, the specialist regulators will take a lead role in safety investigations of the products they regulate, with the support of the ACCC.

Consumer goods can sometimes be used primarily in industrial, commercial, agricultural or healthcare settings. Where this occurs, safety issues are generally addressed by agencies with specific roles in those areas (such as workplace health and safety, building products, pesticides and veterinary goods).

### What is the process for determining the need for ACCC involvement?

* **Clearinghouse overview**

Reports, complaints, media articles and professional assessments relating to consumer goods which have been associated with injuries or potential injury are recorded in the ACCC’s Consumer Product Safety Clearinghouse database. These reports and information are received from several different sources. The majority are mandatory reports received from suppliers, as required by sections 131 and 132 of the ACL. Other reports are made voluntarily, often by consumers or competitors and by staff proactively monitoring foreign and domestic recalls, media reports, health system records, professional literature and other sources.

Staff assess this information and actively monitor and identify potential emerging hazards.

## Hazard analysis

* **Preliminary Assessments**

The Assessment Matrix process applies the Injury Severity Rating and the number of reported injuries or near misses[[1]](#footnote-1) to Clearinghouse reports assessed by the ACCC to determine the overall assessment rating.

**Assessment Matrix**

Injury

Severity

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| HSC | HSC | HSC | HSC | HSC | HSC |
| 4 | M | H | H | H | H |
| 3 | L | M | H | H | H |
| 2 | L | L | M | H | H |
| 1 | L | L | L | M | H |
|  | 0 | 1 or 2 | 3 - 5 | 6 - 20 | 20+ |

Number of injuries  
or near misses

Index: Action for Reports of injury, potential injury or near misses

|  |  |
| --- | --- |
| HSC | Further Action including Detailed Assessment triggered by High Stakeholder Concern |
| H | Further Action including Detailed Assessment |
| M | Complete the Initial Assessment Checklist and send supplier letter |
| L | No Further Assessment |

When assessing a report, staff interrogate the Clearinghouse database and other sources to determine the number of reported injuries or near misses associated with the consumer product and then apply the assessment matrix. If the matrix score is *low* the matter is closed as requiring *no further action*.

Reports that achieve a *moderate* or higher matrix score are progressed to the ‘initial assessment’ stage of the assessment process.

*High Stakeholder Concern* *(HSC)* recognises that there may be other external factors that require a Detailed Assessment be undertaken for a matter that would normally be assessed as *no further action* or *moderate*.

* **Initial Assessments**

Those cases that achieve a Matrix score of *moderate* or higher are progressed to the initial assessment stage. The initial assessment stage involves clarifying details of the product or injury with the stakeholder who reported the incident, and with ensuring the quality and integrity of the record. **See Attachment 2.**

The Initial Assessment Checklist includes a hazard assessment that ranks the hazard posed by the product as being *low, moderate* or *high*. The assessment produces this ranking by determining:

1. **the maximum potential injury**: death, critical, severe, serious, moderate, minor. The injury severity is assessed using a reference table developed by the EU for its risk assessment methodology, which is known as RAPEX (**Attachment 1**)
2. **the probability of the hazard occurring**: remote, unlikely, possible, probable, highly probably, almost inevitable
3. **the hazard recognition** (how likely is it that consumers will recognise the hazard): highly improbable, improbable, possible, probable, almost inevitable
4. **the product availability**: rare, limited, general, widespread.

Where the Initial Assessment Checklist achieves a ranking of *moderate* or lower, no further action is required. Where the Initial Assessment Checklist achieves a score of *high* or above a Detailed Assessment is conducted.

The initial assessment process culminates in a decision to either close the matter or undertake a detailed assessment. These decisions are subject to oversight by senior managers of the Consumer Product Safety Branch (as the Product Safety Committee).

* **Detailed assessments**

Clearinghouse reports, generating a matrix score of *high* or *HSC* or an initial assessment rated as *high*, will progress to the detailed assessment stage of the process.

Detailed assessments review the product details, examine the circumstances associated with the injury under consideration and may include consultation with relevant stakeholders.

This work involves gathering injury data from various health systems such as Poisons Information Centres, Injury Surveillance Units (i.e. QISU or VISU), children’s hospitals, burns units, professional academic literature or other sources. Details about the product and the hazard are also researched and the nature of different models and variants are also determined. This generally involves internet searches, locating and purchasing samples and more extensive market surveys when warranted. The Consumer Product Safety Branch’s Inspections, Audit and Cases section, located across Australia, is utilised for larger market surveys and can assist with market intelligence data relevant to the product. If necessary, third party testing or assessment of the product is arranged.

Detailed assessments are often strategic in nature – working with the relevant stakeholders in order to develop a solution that may not be immediately apparent at the start of the project. Each detailed assessment results in a submission to the Product Safety Committee. The Product Safety Committee makes a decision about actions to address product safety concerns

The outcome may involve the development of a voluntary safety standard, industry guideline or international collaboration to address the problem. In some instances, the outcome may involve working with other specialist regulators. This work is undertaken by relevant specialist teams within the Consumer Product Safety Branch.

**Risk Management**

Risk management is the approach to setting the best course of action under conditions of uncertainty by identifying, understanding, acting on and communicating the risk.

The assessment process (described above) allows Consumer Product Safety Branch staff to understand the nature of the hazard:

* who is at risk of injury?
* what factors contribute to the occurrence of injury incidents?
* how the injury is occurring?

A range of factors considered in the risk management process is set out below. Guiding principles in considering these factors are:

* designing the hazard out of the product is the most desirable outcome as it minimises or removes the risk of harm while allowing consumers to enjoy the benefit of the product
* prohibitions should only be used when design improvements, warnings and education do not sufficiently mitigate the hazard
* voluntary action is preferred to regulatory action, where it is likely to effectively address the problem.

Possible outcomes resulting from action essentially fall into 3 categories:

* prohibit/remove from sale/retrieve or recall the product
* modify the product by designing the problem out or establish voluntary performance standards
* educate/warn the consumer so that they understand the hazard and how to avoid injury.

**Risk management options**

* **Product Bans**

A ban prohibits the supply of a product. A permanent ban is recommended by the ACCC when it believes that suppliers will be unable to ‘design out’ the hazard and/or effectively mitigate against the hazard through other means including warning labels or consumer education campaigns.

The greatest distinction between a standard and a ban is the speed with which it can be implemented.

The ACL enables the Minister, in certain circumstances, to implement a ban with immediate effect. However, bans are legislative instruments and are therefore subject to the same requirements as the development of standards, including the need for consultation, and potentially the development of a Regulation Impact Statement (RIS),

Bans can be used to very quickly stop the sale of a product. They have immediate effect and their use is the strongest method available to the Minister to address an urgent and serious product safety hazard.

* **Recalls**

A recall is used to quickly remove an unsafe product from the marketplace and from consumers. Historically recalls have been used where appropriate safety parameters (such as a ban or mandatory safety standard) are established (and have not been complied with) or where an unexpected problem with a supplier’s product has arisen. To date, recalls have not been used to accompany a new ban or standard, although such an approach might be possible. However, it should be noted that such an approach may pose practical problems where there are numerous suppliers; would significantly increase the cost to suppliers; and would effectively impose a new requirement retrospectively. Full details of the recalls process are available on the Recalls website.[[2]](#footnote-2)

* **Mandatory standard**

A mandatory standard is a minimum set of criteria or requirements that must be met for a product to be legally sold. The requirements can be about the performance, composition, contents, method of manufacture or processing, design, construction, finish, packaging, testing, warnings and more. The relevant provision is s. 104 of the ACL and the legislative test is that the standard consists of requirements reasonably necessary to prevent or reduce the risk of injury to any person.

A mandatory standard is used when it is possible to ‘design out’ the hazard so the product can be used safely.

* **Negotiating voluntary industry action**

The Consumer Product Safety Branch sees minimising risk as the key goal of product safety. Sometimes this can be achieved through negotiated industry action rather than the use of regulatory powers. Such action might include the adoption of voluntary guidelines, the development of an industry code, agreed use of warning or changes to packaging. Where voluntary action can solve a problem it is preferred to regulation. This is in keeping with government requirements, but is also a more efficient use of available resources and can achieve a faster outcome.

* **Safety Warning Notice**

A Safety Warning Notice is a Notice issued by the Minister warning the public about the hazards associated with a product or type of product. Safety Warning Notices are published on the internet (s. 129 of the ACL).

The notice may announce that an investigation into the product is underway. If that investigation does not lead to a proposed recall or ban, the Minister must also publish the results of the investigation on the internet.

A Safety Warning Notice is recommended by the ACCC when it is deemed necessary to quickly alert the public and industry to a potential safety hazard.

* **ACCC alert/media release**

The ACCC has a range of mechanisms to alert the public to a product safety issue. For example, the ACCC may:

* issue a media release
* publish a news item or statement on the Product Safety Australia website or the ACCC website
* use social media channels to promote a particular message.

As an independent statutory authority, the ACCC does not require Ministerial or Departmental approval for its communications. Consumer education is another tool to address a safety concern and may accompany regulation or voluntary industry action to address risks.

There are some instances where the ACCC will work closely with the Minister’s office in relation to the operation of Ministerial decision-making under the Australian Consumer Law.

* **Search and seizure**

An ACCC Inspector (a formal appointment) is able to enter premises and exercise search-related powers and/or (if the search is being executed under a warrant) seize consumer goods. These powers are established under s. 135 and s. 154 of the CCA with the legislative test for search powers being that an Inspector has reason to believe that the goods (or a reasonably foreseeable misuse of the goods) will or may cause injury.

State and Territory regulators have similar powers.

**Attachment 1 – EU RAPEX Injury Severity Table**



**ATTACHMENT 2 – Initial Assessment Checklist**

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1. **Check the data entry**











1. **Is the product covered by a mandatory standard or ban?**[See lists of ACCC-managed [mandatory standards](http://www.productsafety.gov.au/content/index.phtml/itemId/970773#h2_45) and [bans](http://www.productsafety.gov.au/content/index.phtml/itemId/970715#toc3)]







1. **Was this assessment triggered by a mandatory report?**[CHR Source = ‘Mandatory Report’. The consent checkbox is found on the Mandatory Reporting tab of the CHR]







1. **Is the product available in Australia?**[Email/phone supplier for confirmation as well as internet searches]







1. **Is the product typenormally handled by a specialist regulator?**[These include: 240V electrical products, a gas appliance, a registrable motor vehicle or boat, medicine or therapeutic devices, a food or beverage, pesticide or veterinary medicines]





1. **Has the product (or similar products) been assessed before?**[Search Clearinghouse, TrackIT matters and TrackIT projects]







1. **Has the product been recalled?**  
   [Instigated by recall, or recalled independently, in Australia or overseas – check [recalls.gov.au](http://www.recalls.gov.au/)]







1. **Are there any other reports?**

[Such as media, research reports, extranet posts]







1. **Maximum potential injury**

[See [D12/11590](http://doris/Default.aspx?urilist=7696911,) for guidance]

Select one Explain why you chose this rating:

|  |  |
| --- | --- |
|  |  |

1. **Probability of hazard occurring**

[See section 5.2 on page 6 of [D11/7536](http://doris/Default.aspx?urilist=5285839) for guidance]

Select one: Explain why you chose this rating:

|  |  |
| --- | --- |
|  |  |

1. **Hazard recognition**

[See section 5.3 on page 7 of [D11/7536](http://doris/Default.aspx?urilist=5285839) for guidance]

Select one: Explain why you chose this rating:

|  |  |
| --- | --- |
|  |  |

1. **Hazard (Initial risk assessment)**

[Based on sections 7 to 9]



1. **Availability**

[See section 5.4 on page 8 of [D11/7536](http://doris/Default.aspx?urilist=5285839) for guidance]

Select one: Explain why you chose this rating:

|  |  |
| --- | --- |
|  |  |

1. **Risk (Final risk assessment)**

[Based on sections 7 to 10. Use this risk rating in CHA]



1. ‘Near Miss’ is a term that recognises that injuries are not always a true or sole indicator of risk. It recognises that where there is evidence that foreseeable use or misuse of a product may cause injury, action to address that possibility may be supportable. [↑](#footnote-ref-1)
2. <https://www.recalls.gov.au/content/index.phtml/itemId/1000105> [↑](#footnote-ref-2)