MANUAL FOR MANUFACTURING UNCOOKED COMMINUTED FERMENTED MEAT (UCFM) IN NSW







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Introduction

Uncooked Comminuted Fermented Meat (UCFM) is a comminuted meat product manufactured by a series of processes including fermentation and maturation (with smoking and/or heat treatment as optional steps). In addition, the final product has **not** had its core temperature maintained at 65°C for at least 10 minutes or an equivalent combination of time and higher temperature <u>during production</u>.

The range of UCFM products available covers a wide spectrum of water activity (a_w) and pH, ranging from the acidic, moist Mettwurst to the dry, high-pH Italian sausages. Examples of UCFM products commonly produced in NSW include salami, chorizo and pepperoni.

UCFM products are not cooked, so any harmful microorganisms present in the raw materials and/or the processing environment could survive and/or grow to cause illness.

Poor quality meat and uncontrolled manufacturing process can lead to a devastating result. For example, the Garibaldi incident in South Australia in 1995 – affecting 150 people, some with long-term health effects, and one death.

In NSW, businesses that manufacture UCFM products are classified as Priority 1 (P1) – which represents the highest food safety risk – under the Food Safety Risk Priority Classification Framework (RPF). Information on the Priority Classification System can be found on the NSW Food Authority's (Food Authority) website (www.foodauthority.nsw.gov.au).

Purpose and scope

All UCFM products for sale must be produced in accordance to Standard 4.2.3 of the Food Standards Code (the Code) and the NSW Food Regulation (2015).

This document aims to provide UCFM manufacturers with information on how to comply with the regulations in NSW. Food businesses must read this document carefully before making any UCFM product for sale. It is the <u>responsibility</u> <u>of food businesses</u> to produce safe and suitable products and to comply with all regulations in relation to the products made.

This document does not cover all requirements of the Code. For example, particular requirements relating to premises and equipment are not included within this document. Food businesses are advised to read the Code and ensure they meet all the requirements as they relate to their business.



Definitions

Term	Definition	
Audit	An activity to assess a business's food safety program and compliance with the program, as we as any other requirement of the relevant Food Safety Scheme set out in the Food Regulation.	
Batch	Product made using the same batter mix, process or packaged under the same conditions within a 24-hour period, i.e. products must have the same starter culture and curing agent, undergo the same processing steps (e.g. fermentation & maturation time & temperature) and have the same general characteristics (e.g. pH and water activity). For example, a kangaroo salami uses a different type of meat compared to a pork salami, so they must be considered as different batches.	
Batter mix	All the ingredients in the UCFM recipe that have been combined prior to filling a casing.	
Challenge study	A study designed to validate the effectiveness of the UCFM process in reducing or eliminating the microorganisms of concern. A challenge study involves inoculating a typical batter with known quantities of microorganisms of interest, followed by the monitoring of the level of their inactivation, through testing at a NATA accredited laboratory, throughout the fermentation and maturation stages and at the end of the process.	
Control	Any action or activity that prevents, eliminates or reduces a food safety hazard to an acceptable level.	
Date marking	The date mark indicates the length of time a food should keep before it begins to deteriorate or, in some cases, before the food becomes less nutritious or unsafe. In Australia, there are two types of date marking, 'best before' and 'use-by'.	
<i>E. coli</i> inactivation predictor	A mathematical formula used to provide an estimate of how much <i>E. coli</i> is inactivated under conditions which occur as a UCFM product matures.	
Food Safety Program	A systematic and documented approach to help businesses identify and manage hazards to food safety associated with the food handling activities of the business. Food safety program must: identify potential hazards that may occur in all food handling operations carried out in the business; identify where these hazards can be controlled; monitor these control methods; provide corrective actions when a hazard is found to be not under control; establish, document and verify detailed pre-requisite programs and; be regularly reviewed for adequacy (at least every 12 months).	



Term	Definition	
Hazard	A biological, chemical or physical agent in, or condition of, food that has the potential to cause an adverse health effect in humans.	
Monitoring	The act of regularly checking to see that food safety hazards are under control, procedures are being correctly implemented and food safety compliance is followed. It includes checking, observing, supervising and keeping record in order to maintain control.	
Pro forma	A documented description of the ingredients and processing steps used by a manufacturer to make a UCFM product.	
Starter culture	 A preparation of microorganisms prepared for the purpose of fermenting meat which – a) successfully competes for the nutrients in the meat medium; and b) produces microbial inhibitors; and c) is microbiologically safe; and d) produces a controlled reduction of the pH of the meat mix. 	
UCFM	A comminuted fermented meat which has not had its core temperature maintained at 65°C for at least 10 minutes or an equivalent combination of time and higher temperature <u>during production</u> . To avoid doubt, a UCFM includes comminuted fermented meat which has been heat treated. (editorial note: but under conditions less than 65°C for at least 10 minutes or equivalent).	
Validation	A study to obtain evidence to confirm that the control measure or combination of control measures is complete, effective and will deliver the expected food safety outcomes.	
Verification	The use of methods, procedures and tests in addition to monitoring to determine ongoing compliance with the food safety program.	

Steps for manufacturing UCFM for sale in NSW

A UCFM manufacturer must:

Step 1. hold a licence with the Food Authority.

Step 2. develop and implement a Food Safety Program (FSP).

Step 3. submit a pro forma and all relevant supporting documents to the Food Authority for assessment.

Step 4. receive a letter of approval before manufacturing UCFM products for sale.

Step 5. comply with the Regulation in relation to processing, labelling, and testing.

Step 1. A UCFM manufacturer must be licensed with the NSW Food Authority

Information on licensing can be found on the Food Authority's website.

If a business is found to be operating without a licence or appropriate licence permission, enforcement actions may be taken.

For new manufacturers of UCFM:

- A license application and a pro forma must be submitted to <u>food.licensing@dpi.nsw.gov.au</u>
- Once the letter of approval for making UCFM is received, the business can start making the UCFM products following the approved pro forma and the FSP.
- The products **cannot be sold** until the business has a licensing audit with a Compliance Officer from the Food Authority. This means that the fermentation, maturation and packing steps can take place, but the final products must be put on '**HOLD**'.
- Once an acceptable audit rating is received, products on 'HOLD' can be released and sold (both at retail and wholesale).
- A verification study is also required on the first five batches of UCFM product in order to verify that the production process does make a product that complies with the Code requirements.

At a minimum, this includes testing of final product for *E. coli*, pH and water activity.



Step 2. A UCFM manufacturer must have a Food Safety Program (FSP)

Food safety programs are designed to help businesses identify and manage hazards to food safety. A UCFM manufacturer **must** develop and implement a documented FSP. Information on food safety programs can be found on the Food Authority's website.

The business **must** identify all hazards that may be present in their products and establish control systems that focus on preventing or eliminating the hazards¹. The business **must not** rely solely on end-product testing. Some hazards in relation to UCFM products include (but are not limited to):

- Pathogenic bacteria may be present in UCFM if the process is not properly controlled. This may include Salmonella, Escherichia coli, Staphylococcus aureus, Clostridium botulinum, Listeria monocytogenes and parasites
- Chemical hazards may include excessive additives (including preservatives), allergens and other chemical contaminants
- Physical hazards may include plastic from packaging, metal staples or any other foreign objects from the external environment

During a product development phase, it is important to assess whether the new product can introduce new hazards which are not captured in the current FSP. For example, making a new type of salami with game meat might introduce new hazards such as parasites. It is important that the FSP is updated to capture the new hazards and controls.

All control measures must be documented in the FSP and be strictly followed for every batch of UCFM, because any deviation from established procedures may result in an unsafe product.

As there is not a cooking step to control the survival and/or growth of any pathogenic microorganisms, a combination of other hurdles are crucial in making a safe product. These hurdles include (but are not limited to):

- addition of nitrite or nitrate as curing agent and anti-microbial agent especially against C. botulinum,
- growth of competitive flora during fermentation by using a suitable starter culture,
- pH reduction by acid production during fermentation. A pH of 5.2 or lower within 48 hours is recognised as adequate protection against the growth of pathogens, and
- reduction of water activity through maturation process. Maturation reduces the water activity, and together with pH fall in fermentation, inactivates pathogenic bacteria.

¹ Read through the MLA's '*Guidelines for the Safe Manufacture of Smallgoods*' for more information on FSP and hazards relating to UCFM



Step 3. A UCFM manufacturer must submit a pro forma

Businesses that produce a UCFM product for sale **must** complete a documented description of the ingredients and processing steps used to make the UCFM product. This is called a pro forma.

Critical information collected in the pro forma is used to determine if a UCFM production process inhibits the growth of *C. botulinum* and is effective in reducing the numbers of *E. coli* to a safe level and to ensure that the process complies with other requirements outlined in Standard 4.2.3 of the Code.

Filling in a pro forma

A blank pro forma can be found on the Food Authority's website.

To fill in the pro forma, the business needs to make a trial batch (**not for sale**) to obtain the following information:

- Product details
- Raw meat supply & quality i.e. raw meat supplier details, meat temperature on receipt
- Ingredients i.e. type (meat species) and amount of meat; type and amount of fat; amount of salt, curing mix, acidifiers, sugar, other ingredients
- Starter culture i.e. brand, name (as stated on the label) and amount
- Temperature and length of fermentation
- Temperature and length of maturation
- Temperature and length of smoking or heat treatment (if applicable)
- Process monitoring frequency e.g. pH, time and temperature, end product testing
- Criteria for judging when the product is ready for sale
- Packaging and labelling, including shelf life and storage condition

A trial batch must be clearly labelled so there is no confusion with the products made for sale.

A guidance document has been developed to help businesses fill in the pro forma. Please see Appendix 1 - '*UCFM* pro forma guide'.



- One pro forma **must** be filled in for each distinct product.
 - This helps the Food Authority's Officer to identify the products during an audit or investigation.
- It is the responsibility of the UCFM manufacturer to submit a pro forma for any UCFM products made on behalf of someone else (a sub-contract agreement).
- The pro forma **must** be filled in by a person with the skills and knowledge (as per Standard 3.2.2 of the Code) of the UCFM manufacturing process.
- The pro forma **must** be signed by the Licensee or their proxy (someone with the authority to represent the Licensee).
- A new pro forma **must** be filled in and sent to the Food Authority for approval if there is a change in the following:
 - the type of meat, or
 - the diameter of the product, or
 - the type of casing, or
 - the type of curing agent (nitrate/nitrite), or
 - the amount of curing agent (nitrate/nitrite), or
 - the amount of salt, or
 - the starter culture, or
 - the ingredients (e.g. different dried spices for seasoning, addition of cut olives, truffles, cheese), or
 - the fermentation & maturation time or temperature (and any other process like smoking or heat treatment).
- A completed pro forma with signed declaration and required supporting documents (as listed in the pro forma template) **must** be emailed to <u>food.sciencesupport@dpi.nsw.gov.au</u>

For new UCFM manufacturer, send the license application and pro forma to <u>food.licensing@dpi.nsw.gov.au</u>

Validating the UCFM process

A business **must** validate its process to make sure that the number of pathogenic bacteria at the end of the process complies with the Regulation and a safe UCFM product is produced.

Validation must be done for each type of product or group of products² with the same characteristics (e.g. same starter culture, pH, water activity, percentage weight loss during production). Validation is usually only done when developing a product or a process. It must be repeated if a change is made to the product or process (e.g. change of ingredients other than the dried spices for seasoning, change of starter culture, change in fermentation or maturation process time or temperature).

There are two methods which can be used to validate the process.

² Group of products: products which only differ in dried spices used for seasoning and casing type.



1. Predictive modelling

The *E. coli* in fermented meats predictor developed by the University of Tasmania (UTAS) is used by industry and regulators to provide an estimate of how much *E. coli* is inactivated under conditions which occur as a UCFM product matures.

The predictor can be accessed at http://www.foodsafetycentre.com.au/fermenter.php.

To use the Predictor, the following information is needed:

- Temperature of the batter,
- Temperature of fermentation,
- Length of fermentation (hours),
- Temperature at each stage of maturation (and/or smoking or heat treatment, if applicable), and
- Length of each stage (hours).

When the temperatures and times at each stage of fermentation and maturation are entered into the Predictor, an *E. coli* inactivation prediction for the process will be produced.

A guidance document has been developed to help businesses to use the Predictor. Please see Appendix 2 - '*E. coli Inactivation Predictor Guide*'.

- Unless a business is conducting a challenge test, the business **must** use the Predictor before submitting the pro forma.
- The proposed process must result in a **minimum predicted** *E. coli* reduction of 2-log. If the process does not achieve a 2-log reduction, adjust the time and temperature of the fermentation and/or maturation stage of the process until a predicted 2-log reduction is achieved.

Increasing the time or temperature of fermentation and/or maturation will generally increase the log reduction achieved.

• A copy of the *E. coli* inactivation predictor result **must** be submitted with the pro forma.

<u>NOTE</u>: The report "*Predicting E. coli inactivation in uncooked comminuted fermented meat products*" is also available from the UTAS website. The report provides information explaining the scientific basis for the model and an extensive review and analysis of published and unpublished studies of the UCFM process and the inactivation of *E. coli* during processing.

From these studies, it was concluded that once the fermentation process starts, the combined effects of temperature and time are responsible for most of the observed death of *E. coli*. The amount of salt, acid and nitrite are important for setting up conditions in UCFM products so that *E. coli* are killed and this information is used in the Food Authority's assessment of the process.



2. Challenge testing

The process conditions (time and/or temperature of fermentation and/or maturation) of a new product may need to be changed to achieve the required minimum 2-log reduction of *E. coli*. This may lead to a product with undesired characteristics or mouthfeel. For example, small diameter sausages may become too dry when the times and temperatures required by the model are applied to the product to achieve the minimum of 2-log reduction. Therefore, instead of using the predictive model to validate the process, a business may choose to undertake a challenge test.

Challenge testing involves inoculating a typical batter with known quantities of microorganisms of interest, followed by monitoring of the level of their inactivation, through testing in a NATA accredited laboratory, throughout the fermentation and maturation stages and at the end of the process.

Challenge testing can be considered as the ideal method for validation because it gives results that are specific to a particular product, its characteristics and the process. However, it can be expensive and it requires a high level of technical competency.

If a business wishes to undertake a challenge testing, the business **must** consult a food technologist expert or a laboratory experienced in doing challenge testing in food.

Determining the shelf life of a UCFM

All food for sale must have a date marking on the label (Standard 1.2.5 of the Code). It is the manufacturer's responsibility to determine the appropriate shelf life for its product. Reliable 'use-by' or 'best before' dates cannot be determined by guesswork or by copying the shelf life of a competitor's product.

For more information please refer to '<u>Shelf-life testing</u>' on the Food Authority's website.



Step 4. Letter of approval and starting the manufacture of a UCFM for sale

The assessment of a pro forma will be completed once all information has been reviewed. An incomplete or incorrectly filled in pro forma will result in the delay of the assessment and approval.

The information provided in the pro forma is used to assess the following:

- Compatibility of the starter culture and the fermentation temperature,
- Salt in moisture content,
- Appropriate level of nitrate and/or nitrite input,
- pH drops (pH at 24 hours and 48 hours),
- Final characteristics of the product (pH, water activity or weight loss), and
- E. coli inactivation.

Applicants will be advised of the assessment outcome in writing.

Timeline:

- For traditional products using beef or pork, the approval process will be completed within **one month** after <u>all</u> information is received.
- For products using other types of meat, the approval process will be completed within **6 months** after <u>all</u> information is received. This is to allow time for a risk assessment to be conducted.
 - A business **must not** commence manufacturing for sale until a letter of approval for a product is issued to the licensee by the Food Authority.

If a business is found to manufacture an unapproved product, appropriate enforcement actions will be taken.

NOTE: It is recommended that the business write the pro forma number on the product tags during the manufacturing process to help the Food Authority's Officer to identify which product relates to which pro forma during an audit or investigation.

- The licensee **must** comply with the conditions set out in the approval letter.
- The approval letter and each pro forma **must** be kept onsite at the manufacturing facility together with the Food Safety Program. The documents **must** be available to be examined during a compliance audit.
- Once approved, the licensee **must** submit one sample from each of the first two batches to the Food Authority. It will be tested for *E. coli*, pH and water activity. The cost of testing is covered by the Food Authority and the testing results will be communicated back to the business.

Please notify the Food Science team by email <u>food.sciencesupport@dpi.nsw.gov.au</u> to schedule the delivery of these samples.

Do not send the products to the Food Authority until you have received confirmation from the Science team that the samples can be submitted.



Step 5. A UCFM manufacturer must comply with the Regulations

All UCFM manufacturers in NSW **must** comply with the requirements outlined in the Code, Food Act 2003 (NSW) and Food Regulation 2015. Products **must** be processed exactly as described in the approved pro forma using the processes in the FSP.

Food Standards Code

1. Production and Processing Standard for Meat (Standard 4.2.3)

All UCFM manufacturers **must** comply with *Standard 4.2.3 – Production and Processing Standard for Meat*. Divisions 1 to 3 are applicable to all meat and ready-to-eat meat producers and Clause 5 of Division 3 sets out additional requirements for UCFM manufacturers.

Additional requirements for UCFM

- A UCFM must be produced in accordance with a food safety management system (FSP in NSW) which has been verified and audited to ensure the number of *E. coli* organisms in the final UCFM product complies with the microbiological limits in Standard 1.6.1 of the Code and demonstrates that the production process handles the variations of *E. coli* contamination in the ingoing raw meat ingredients.
- 2. As part of the validation or verification requirements of the FSP, the number of *E. coli* organisms must be recorded for the raw meat ingredients used to make a UCFM and in the product after fermentation and any other subsequent process.
- 3. During UCFM production the following must be monitored and recorded at suitable frequencies:
 - the pH of a fermenting UCFM; and
 - the temperature and time of fermentation of UCFM; and
 - the temperature and time of maturation/drying of UCFM; and
 - the temperature and time of smoking of UCFM; and
 - the weight loss or water activity
- 4. The measurements recorded must be kept for 12 months after the use-by date or best-before date of a UCFM.
- 5. The fermentation of a UCFM must be initiated through the use of a suitable starter culture.
- 6. A previously fermented or fermenting meat must not be used as a starter culture or an ingredient in a UCFM.
- 7. Meat and batter mix used in the preparation of a UCFM must, if stored by the manufacturer, be stored at 5°C or below prior to fermentation.

The pH of a fermenting UCFM must be measured in accordance with the Method outlined in Standard 4.2.3.



2. Labelling (Standard 1.2)

All packaged food for sale must have a label. Please refer to Standard 1.2 and Standard 2.2.1 of the Code for more detailed information.

Standard	Labelling requirement	Comments	
1.2.2	Name of the food	A name or description sufficient to indicate the true nature of the food.	
1.2.2	Lot identification	A unique code to be used for traceability.	
1.2.2	Name and address of the supplier	The business address in NSW. Not a PO Box number.	
1.2.3	Advisory statements, warning statements and declaration	If the product or ingredients contain any of the most common food allergens, they must be declared. Declaration can be made either in the ingredient list (bold font) or a separate statement such as 'contains peanut'. • gluten (if using wheat flour), • crustaceans, • eggs, • fish, • milk, • peanuts, • soybeans, • sesame seeds, • tree nuts, • lupin.	
1.2.4	A statement of ingredients	A statement of ingredients must list each ingredient (including food additives) in descending order of ingoing weight.	
1.2.5	Date marking information	Either a 'use-by' or 'best before' date of the product. Refer to the ' <i>Shelf-life testing</i> ' document on the Food Authority's website.	
1.2.6	Storage conditions and directions for use	The conditions at which the product is required to be stored to ensure that the product will keep until the 'use-by' or 'best before' date.	

At a minimum, the following information is required to be on the label of a UCFM:



Standard	Labelling requirement	Comments
1.2.7	Information relating to nutrition, health and related claims	Standard 1.2.7 sets out the claims that may be made on labels about the nutritional content of food (nutrition content claims) and the claims that may be made on labels about the relationship between a food or a property of a food and a health effect (health claims).
1.2.8	Nutrition information	The label must have a Nutritional Information Panel (NIP). It must include: the number of servings in the package, serving size (in grams), average quantity per serving and average quantity per 100 grams for: • energy • protein • total fat • saturated fat • carbohydrate • sugars, and • sodium. If a product has any nutrition content claims, the NIP must include the required additional declaration as per the Code.
1.2.10	Information about characterising ingredients and characterising components	Characterising ingredients or components means an ingredient or component of the food that is mentioned in the name of the food, or is usually associated with the name of the food by a consumer, or is emphasised on the label of the food in words, pictures or graphics. The proportion of a characterising ingredient or component must be declared as a percentage. For example: Product name: Truffle beef salami. Ingredient list: beef (99%), truffle (1%), etc



Standard	Labelling requirement	Comments
2.2.1	Meat and meat products – labelling of fermented comminuted processed/manufactured meat	 The prescribed name for fermented comminuted processed meat is: (a) if the meat has not been heat treated or cooked – 'fermented processed meat – not heat treated'; and (b) if the meat has been heat treated – 'fermented processed meat – heat treated'; and (c) if the meat has been cooked – 'fermented processed meat – cooked'. The prescribed name for fermented comminuted manufactured meat is: (a) if the meat has been heat treated or cooked – 'fermented manufactured meat is: (b) if the meat has been heat treated or cooked – 'fermented manufactured meat - not heat treated'; and (c) if the meat has been heat treated or cooked – 'fermented manufactured meat - not heat treated'; and (b) if the meat has been heat treated – 'fermented manufactured meat - heat treated'; and (c) if the meat has been cooked – 'fermented manufactured meat - heat treated'; and (c) if the meat has been cooked – 'fermented manufactured meat - heat treated'; and



3. Food Additives (Standard 1.3.1)

The amount of additives in the final UCFM product must comply with the maximum permitted levels specified in Standard 1.3.1 and Schedule 15 (section 8.3) of the Code.

INS	Description	Maximum Permitted Limit (MPL) – mg/kg	
	Additives permitted at GMP	See Schedule 16	
	Colourings permitted at GMP	See Schedule 16	
160b	Annatto extracts	100	
220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium 500 sulphites		
234	Nisin 12.5		
243	Ethyl lauroyl arginate 315		
249 250	Nitrites (potassium and sodium salts)	125	
280 281 282 283	Propionic acid and sodium and potassium and calcium propionates	GMP	
432	Polyoxyethylene (20) sorbitan monolaurate	500	
200 201 202 203	Sorbic acid and sodium, potassium and 1500 calcium sorbates		
235	Pimaricin (natamycin)	1.2 mg/dm2	
251 252	Nitrates (potassium and sodium salts) 500		

Food Regulation 2015

Part 9 of the Food Regulation 2015 outlines the specific requirements related to the meat industry.

Testing requirement

Division 8 Clause 116 states that the holder of a license that authorises the operation of a meat processing plant or meat retail premises must, at the holder's own expense, ensure that samples of ready to eat meat products that are handled in the course of the operation of the processing plant or premises and are required by the NSW Food Safety Schemes Manual to be analysed in accordance with this clause.

Non-compliance to the testing requirement will result in an enforcement activity with a maximum penalty of 25 penalty units.



The NSW Food Safety Schemes Manual specifies the following testing for UCFM products.

Product to be tested		Test to be conducted, the limit and frequency
		E. coli
		Not exceeding 3.6 cfu/g
Uncooked comminuted fermented meat (UCFM)	Finished product	Every batch

The Food Authority **must** be notified if any sample analysed fails to meet the standard set out in the Food Safety Schemes Manual:

- verbally within 24 hours after becoming aware of the result, and

- in writing within 7 days after becoming aware of the result. The Notification of pathogen detection form must be used. It can be found on the Food Authority's website.

Australian Standards

The operation of a meat processing plant must comply with the following Standards:

(a) in relation to a meat processing plant at which the processing of meat (other than poultry meat, rabbit meat, ratite meat or crocodile meat) is authorised by the relevant license – the standard specified in Australian Standard AS 4696 – 2007, *Hygienic production and transportation of meat and meat products for human consumption,* as in force from time to time,

(b) in relation to a meat processing plant at which the processing of poultry meat is authorised by the relevant license – the standard specified in Australian Standard AS 4465 – 2006, *Construction of premises and hygienic production of poultry meat for human consumption*, as in force from time to time,

(c) in relation to a meat processing plant at which the processing of crocodile meat is authorised by the relevant license – the standard specified in Australian Standard AS 4467 – 1998, *Hygienic production of crocodile meat for human consumption*, as in force from time to time,

The operation of meat retail premises must comply with the standards specified in the publication titled *New South Wales Standard for Construction and Hygienic Operation of Retail Meat Premises* published by the Food Authority.



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Standards Australia. https://www.standards.org.au/



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