



## **GMP Fee Model Review**

February 2018

# Background - Cost Recovery

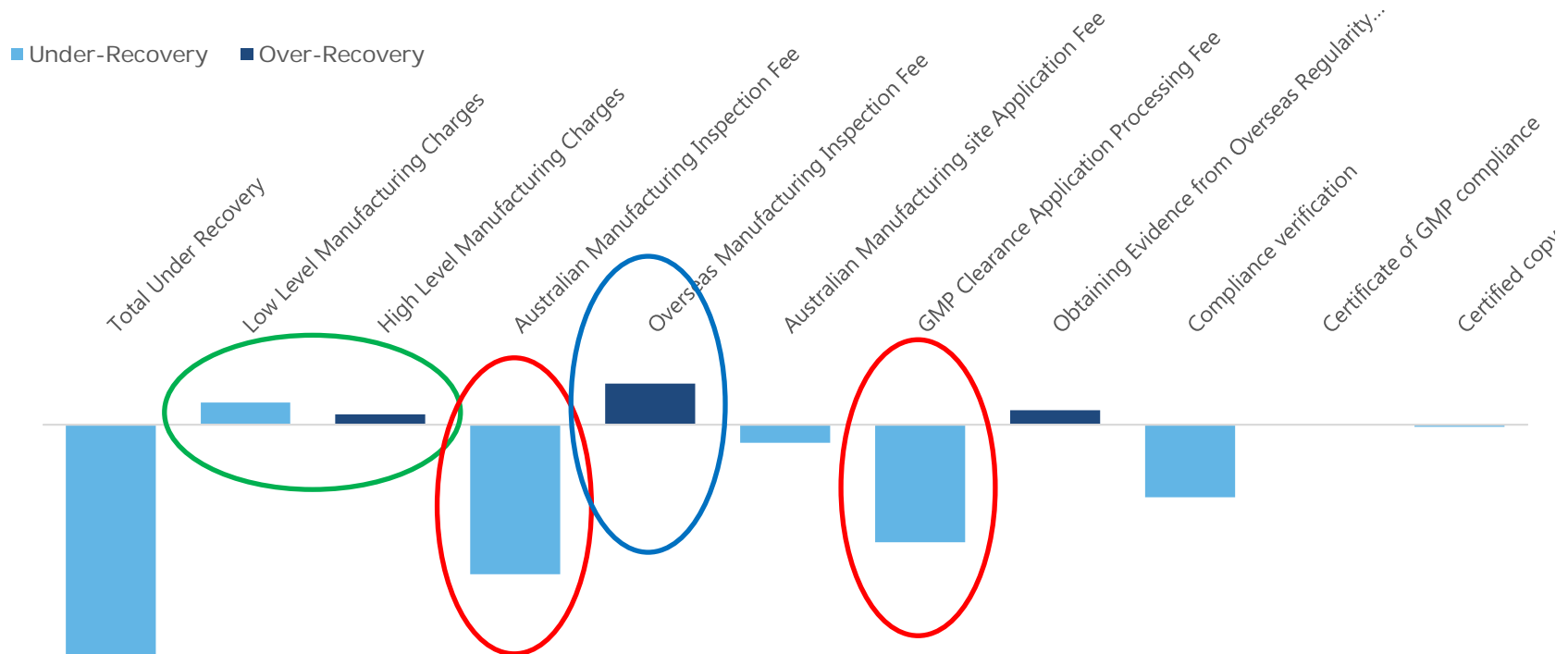
- TGA operates on full cost-recovery (different to some O/S regulators)
- Cost recovery should align costs incurred with costs recovered
- Cost recovery mechanisms should:
  - optimise demand for activities
  - improve efficiency and responsiveness of government activities and accountability for those activities

# Purpose of this Review

- Simplify the structure of fees and charges
- Improve transparency
- Address material under-recovery

	2013-14 \$m	2014-15 \$m	2015-16 \$m	2016-17 \$m	Average \$m
Revenue	12.1	12.1	11.2	10.0	11.3
Spend	13.5	12.9	13.2	14.4	13.5
Under – Recovery	-1.4	-0.7	-2.0	-4.4	-2.1

# Analysing the under-recovery



**Explanatory note (this was spoken at the presentation – not part of the original slide)**

*This chart shows a scaled depiction of the level of under and over recovery based on the initial TGA Activity Based Costing. We focussed on the two large under-recoveries – because of their scale.*

*We also focussed on the annual licence charge over-recovery because we had very good data and it would be administratively simple to fix.*

*The initial data suggested an over-recovery in Overseas Manufacturing Inspections but more detailed analysis showed it was close to even – with an hourly cost of \$1338 matching closely to the current hourly rate of \$1330 - hence no change proposed.*

# Possible Approaches

- Spread the load but no structural change
- Minimalist structural change
- Moderate structural change
- Complex structural change

# Summary of Options

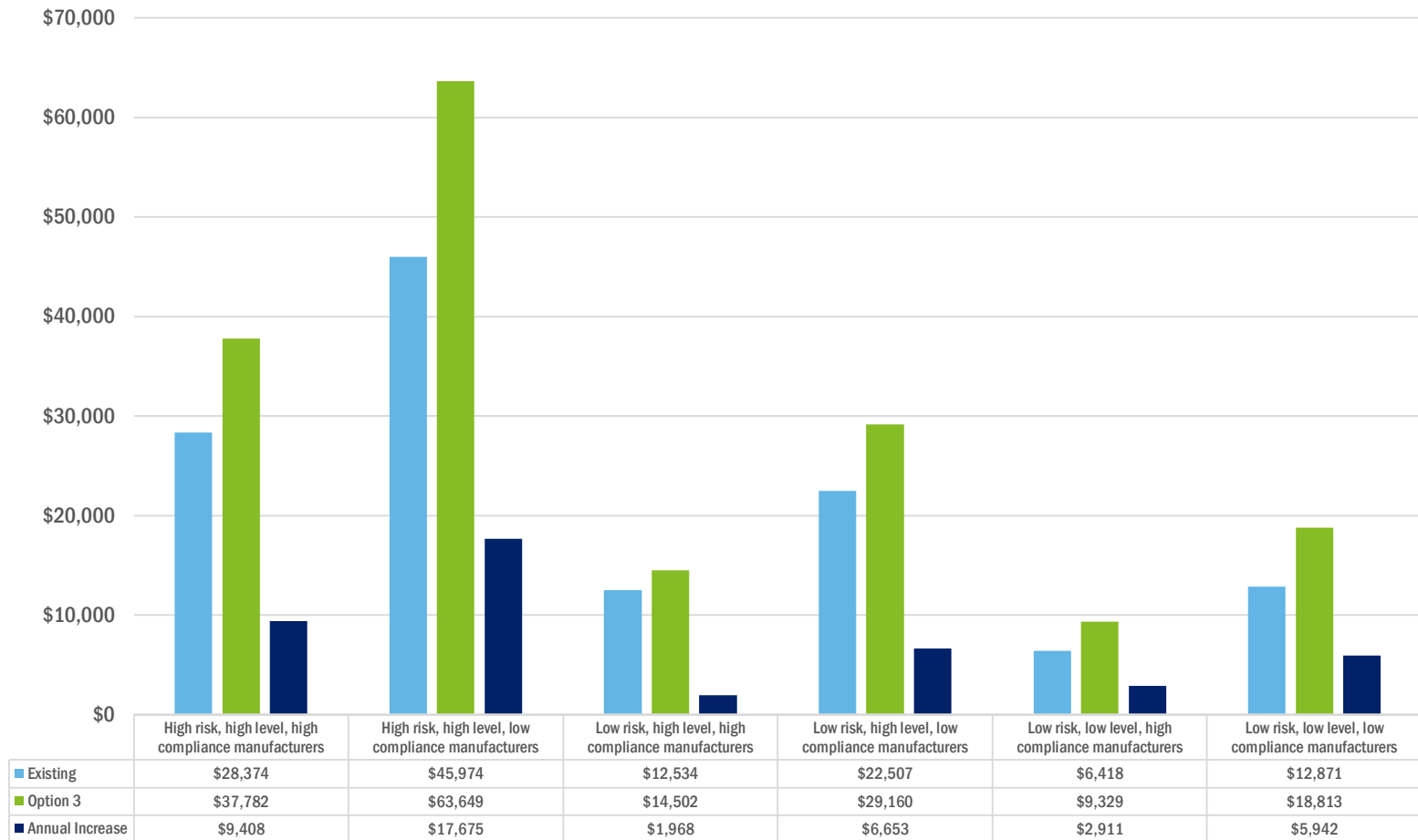
	Current State	Option One	Option Two	Option Three
Uniform Increase of all fees & charges	☒	✓	☒	☒
Fully Recover Inspection Hours	☒	☒	✓	✓
Merge Low & High Annual Licence Charge	☒	☒	✓	✓
Licence Variation Application Fee	☒	☒	☒	✓
Increase GMP Clearance Application Processing Fee	☒	☒	☒	✓

# Options – Fee Table

Fees and Charges	Current Fee (\$)	Option 1 (\$)	Option 2 (\$)	Option 3 (\$)
Annual Manufacturing Charges	-	-	6,000	4,590
Low-Level Manufacturing Charges	6,260	7,352	-	-
High-Level Manufacturing Charges	12,200	14,328	-	-
Australian Manufacturing Hourly Inspection Fee	660	775	1,150	970
Overseas Manufacturing Hourly Inspection Fee	1,330	1,562	1,400	1,330
GMP Licence Application Fee	1,000	1,174	1,000	770
GMP Licence Variation Fee	-	-	-	770
GMP Clearance Application Processing Fee	390	458	390	790
Obtaining Evidence from Overseas Regularity Authority	680	799	680	680
Compliance Verification	2,030	2,384	2,030	2,030
Certificate of GMP Compliance	170	200	170	170
Certified Copy	60	70	60	60

# Industry Impact

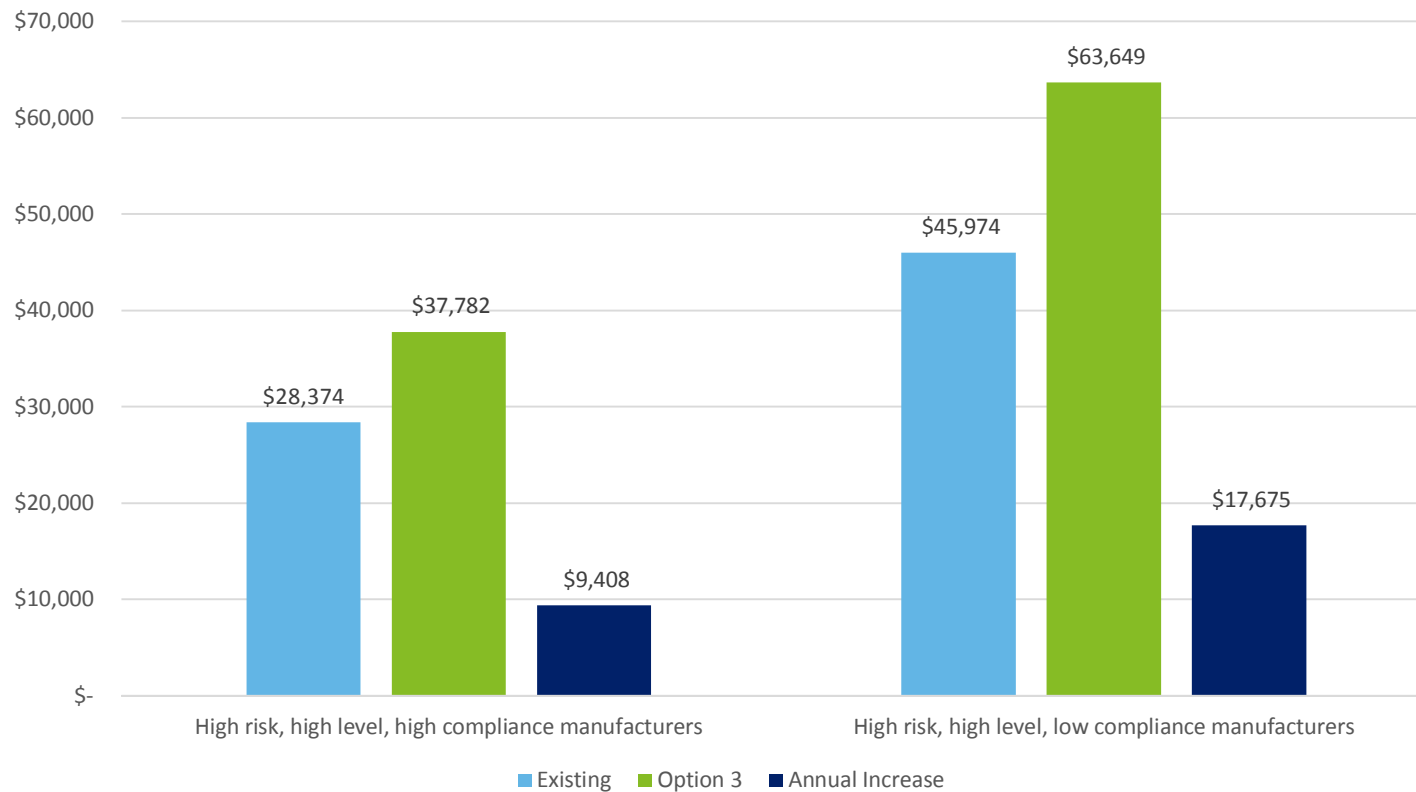
- We modelled the impact on 6 groups





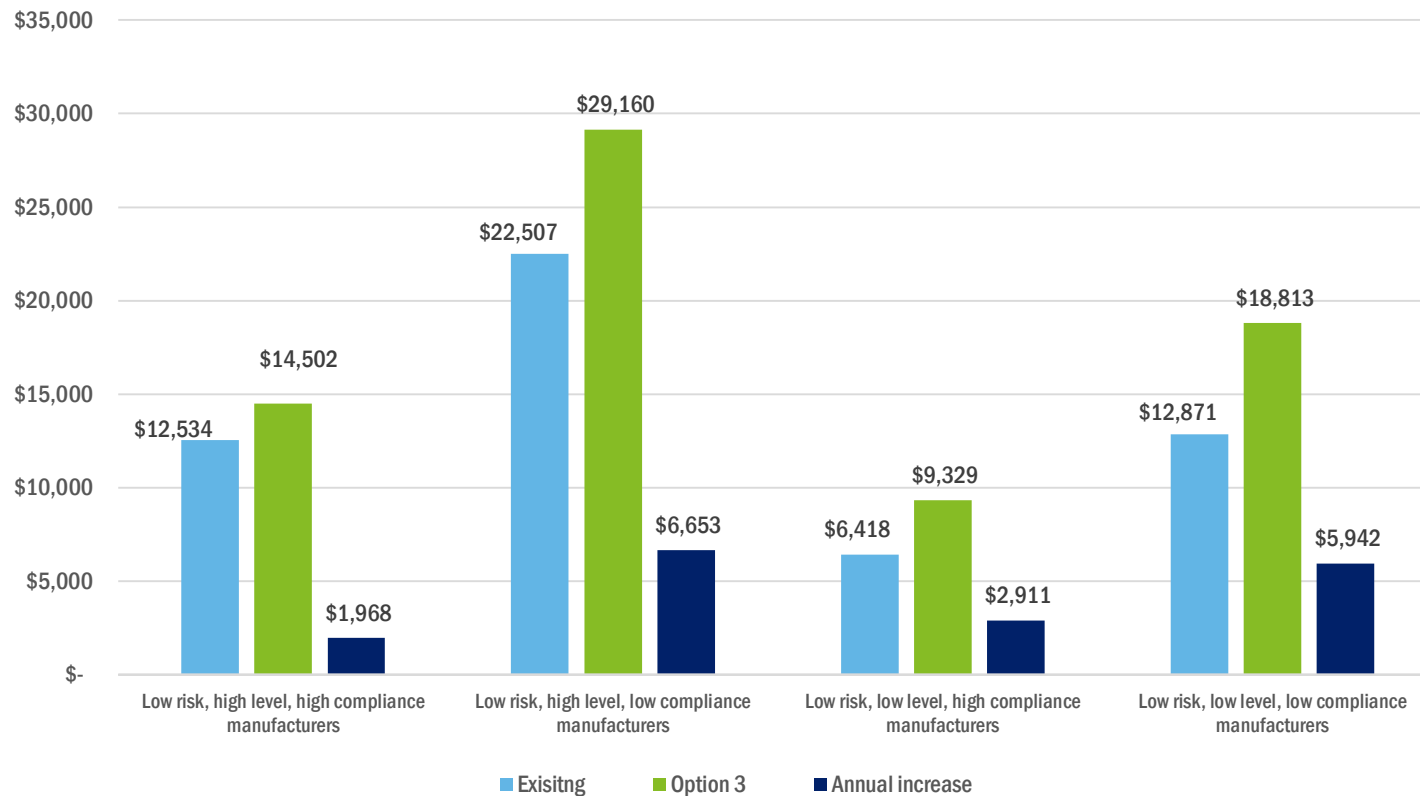
# Industry Impact

- High Risk Manufacturers



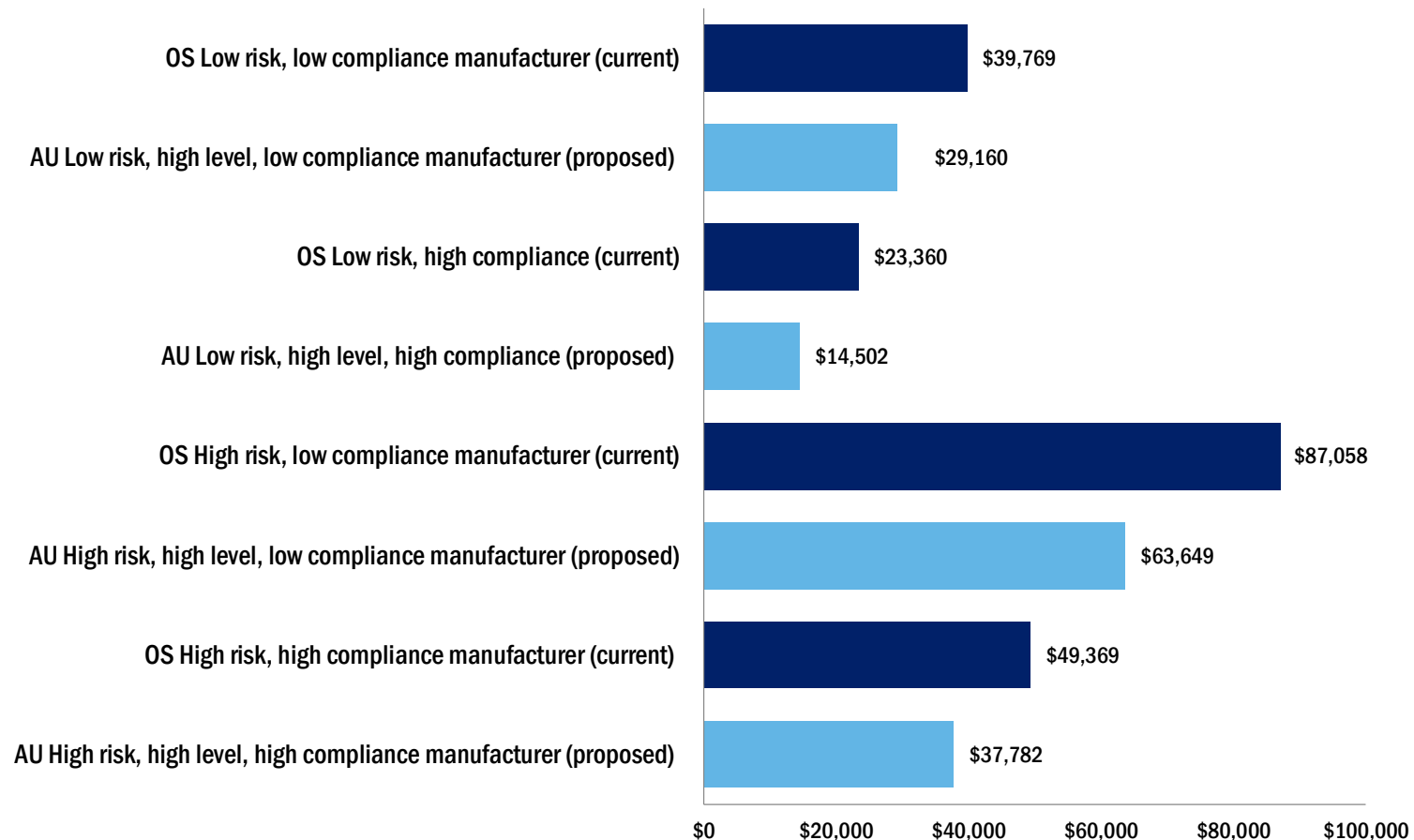
# Industry Impact

- Low Risk Manufacturers



# Industry Impact

- Australian vs Overseas Manufacturers



# Recap: Options

	Current State	Option One	Option Two	Option Three
Uniform Increase of all fees & charges	☒	✓	☒	☒
Fully Recover Inspection Hours	☒	☒	✓	✓
Merge Low & High Annual Licence Charge	☒	☒	✓	✓
Licence Variation Application Fee	☒	☒	☒	✓
Increase GMP Clearance Application Processing Fee	☒	☒	☒	✓

# Recap: Fee Table

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# End of Presentation

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