Analysing change in assessed risk across package releases
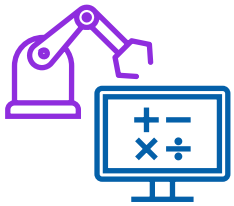
Bríd Roberts, Principal Statistical Programmer

R Validation Hub
20th August 2024

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Introduction

Principal Statistical Programmer with Novartis

Member of the Automation group, within Statistical Programming function

Working with the Scientific Open Source (SOS) team at Novartis
- Manage and execute the risk assessment process for R validation

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Overview

Risk assessments across releases

Determine risk assessment impact for packages with and without version changes across releases

Causes and impact of these changes to risk assessment

Resulting actions our team is taking

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Risk Assessment at Novartis

- Classify the risk level of each package as low, medium, or high

- Utilise internally developed R package Brave

R package
admiral

Brave

Classification Criteria
Low
Medium
High

Risk Rating
Low
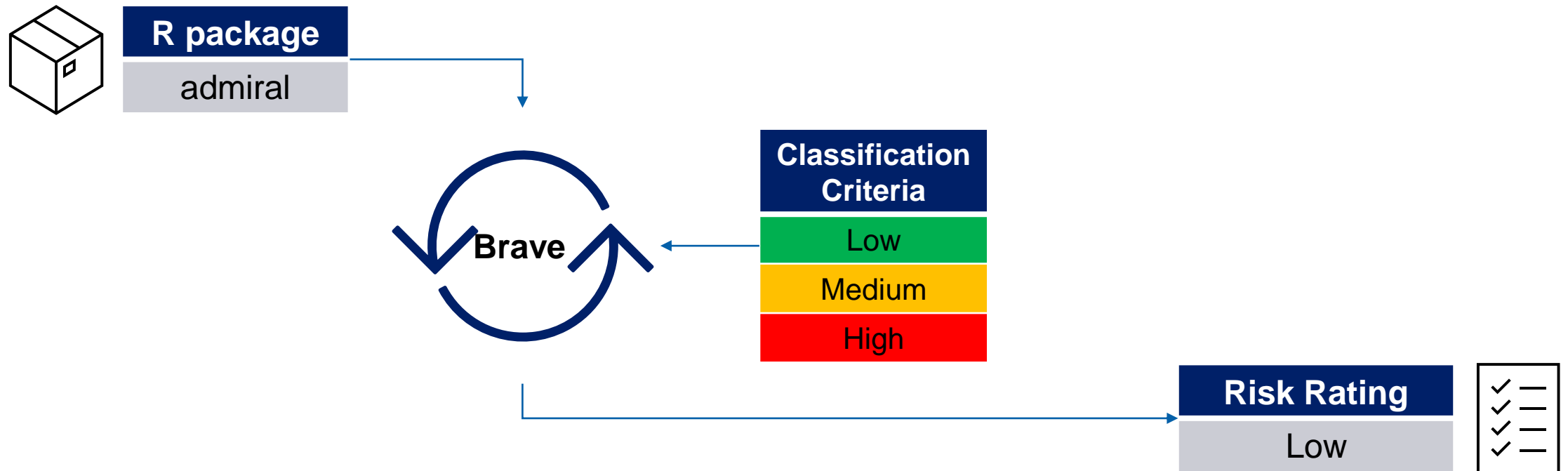
Setting up the analysis

Step 1

Create a master package list

Package
admiral
shinytest2
PowerTOST
plyr
...

Setting up the analysis

Package
admiral
shinytest2
PowerTOST
plyr
...

Step 1

Create a master package list

Step 2

Analyse change in risk assessment for this master list of packages across two releases

RELEASE 1

Package	Risk Assessment
admiral	Low
shinytest2	Low
PowerTOST	Low
plyr	Low
...	...

RELEASE 2

Package	Risk Assessment
admiral	Low
shinytest2	Medium
PowerTOST	High
plyr	Low
...	...

Analysis over two releases
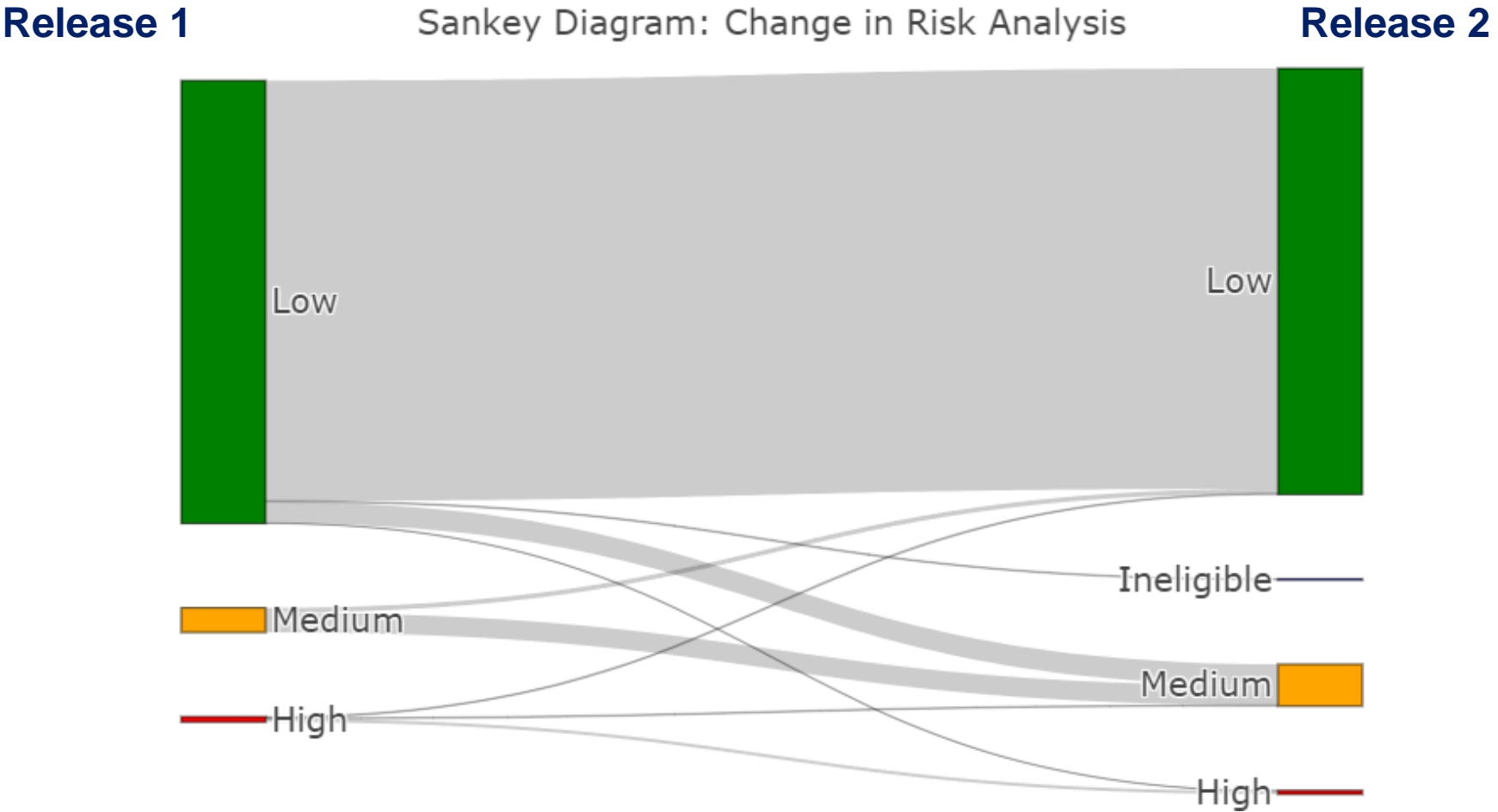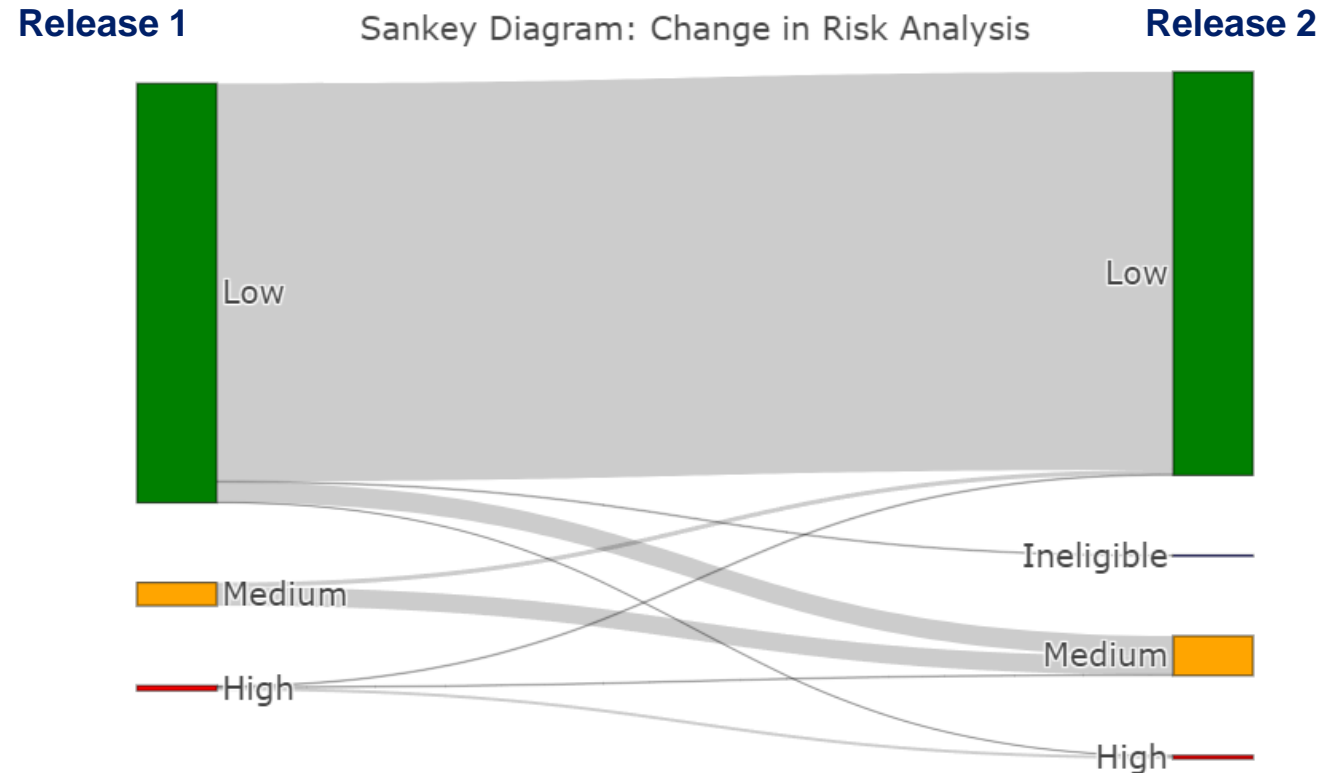
Analysis over two releases – Discussion
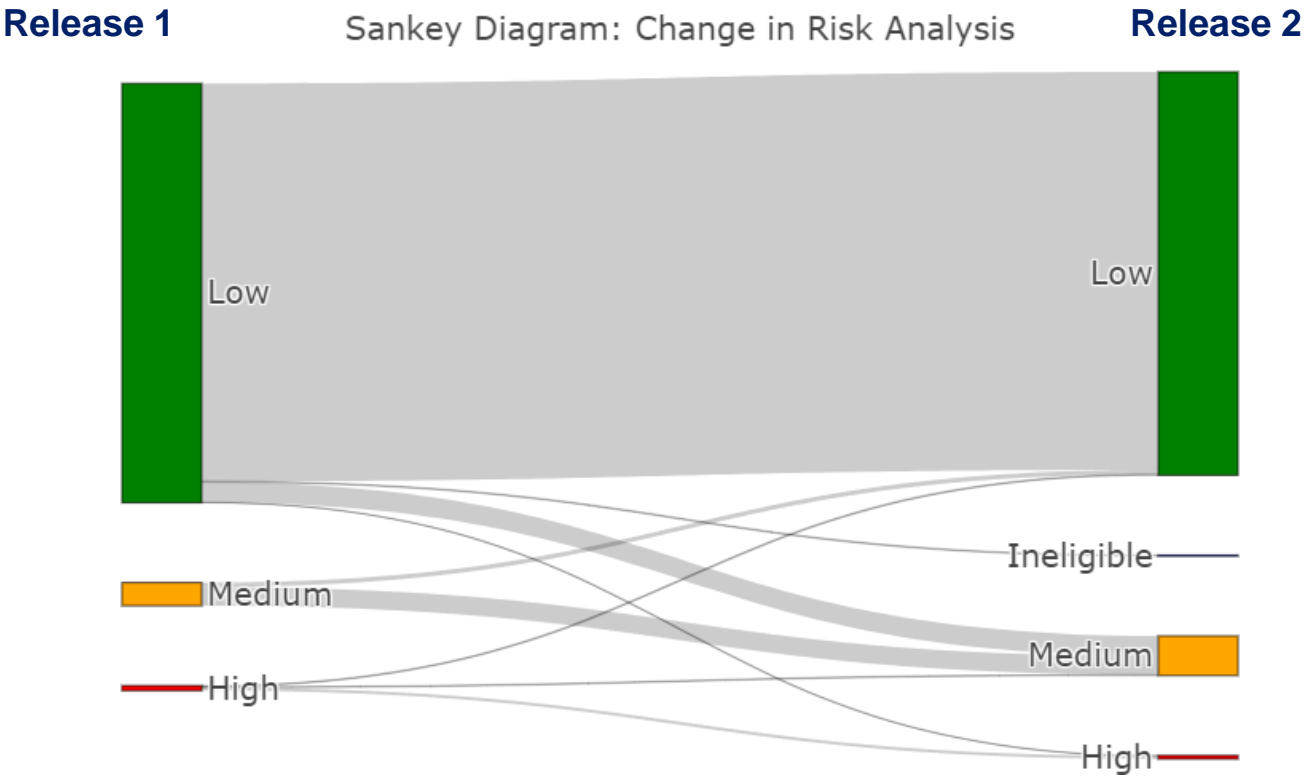
Total number of packages: 892

Analysis over two releases – Discussion
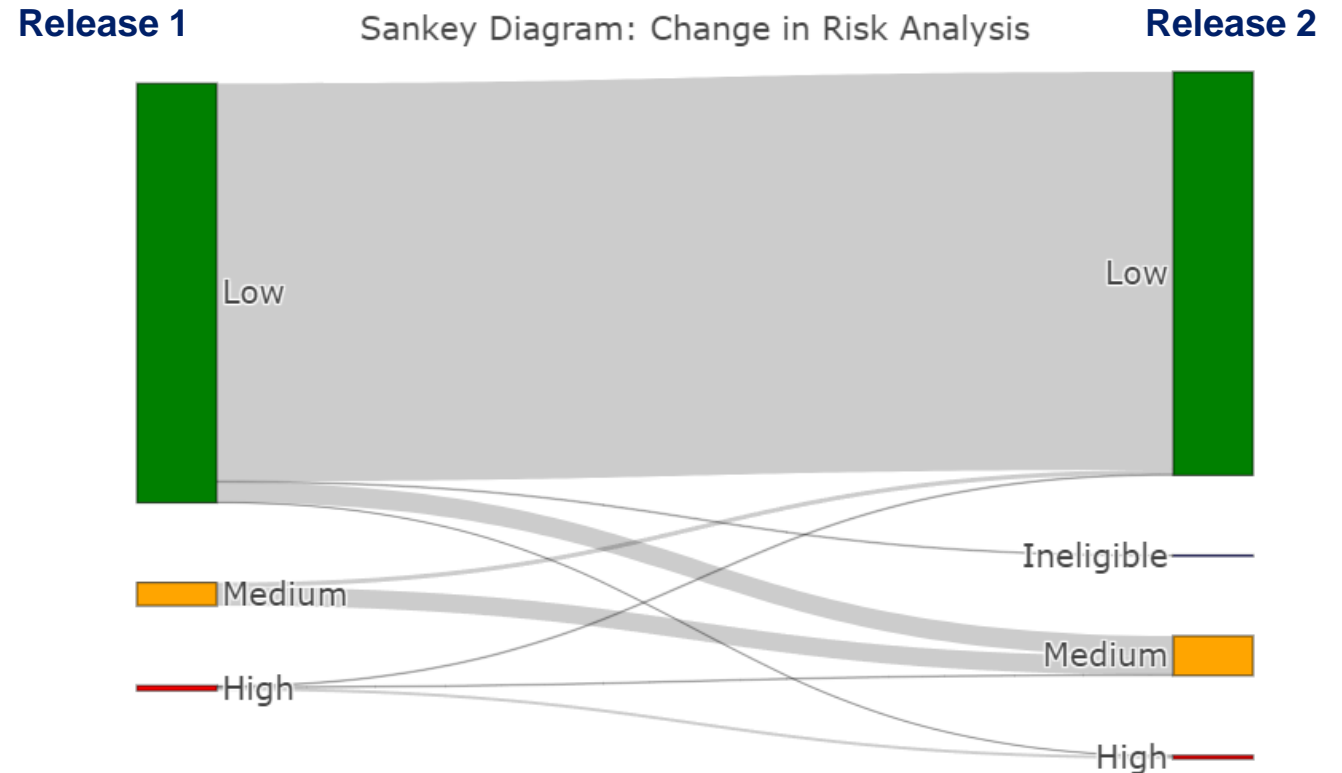
Total number of packages: 892

- Risk assessment unchanged: 836 **(93.7%)** packages

Sankey Diagram: Change in Risk Analysis

Release 1 ... Release 2

Low, Medium, High → Low, Ineligible, Medium, High

Analysis over two releases – Discussion

Total number of packages: 892

- Risk assessment unchanged: 836 **(93.7%)** packages

- Risk assessment changed: 56 **(6.3%)** packages

Sankey Diagram: Change in Risk Analysis

Release 1 — Release 2

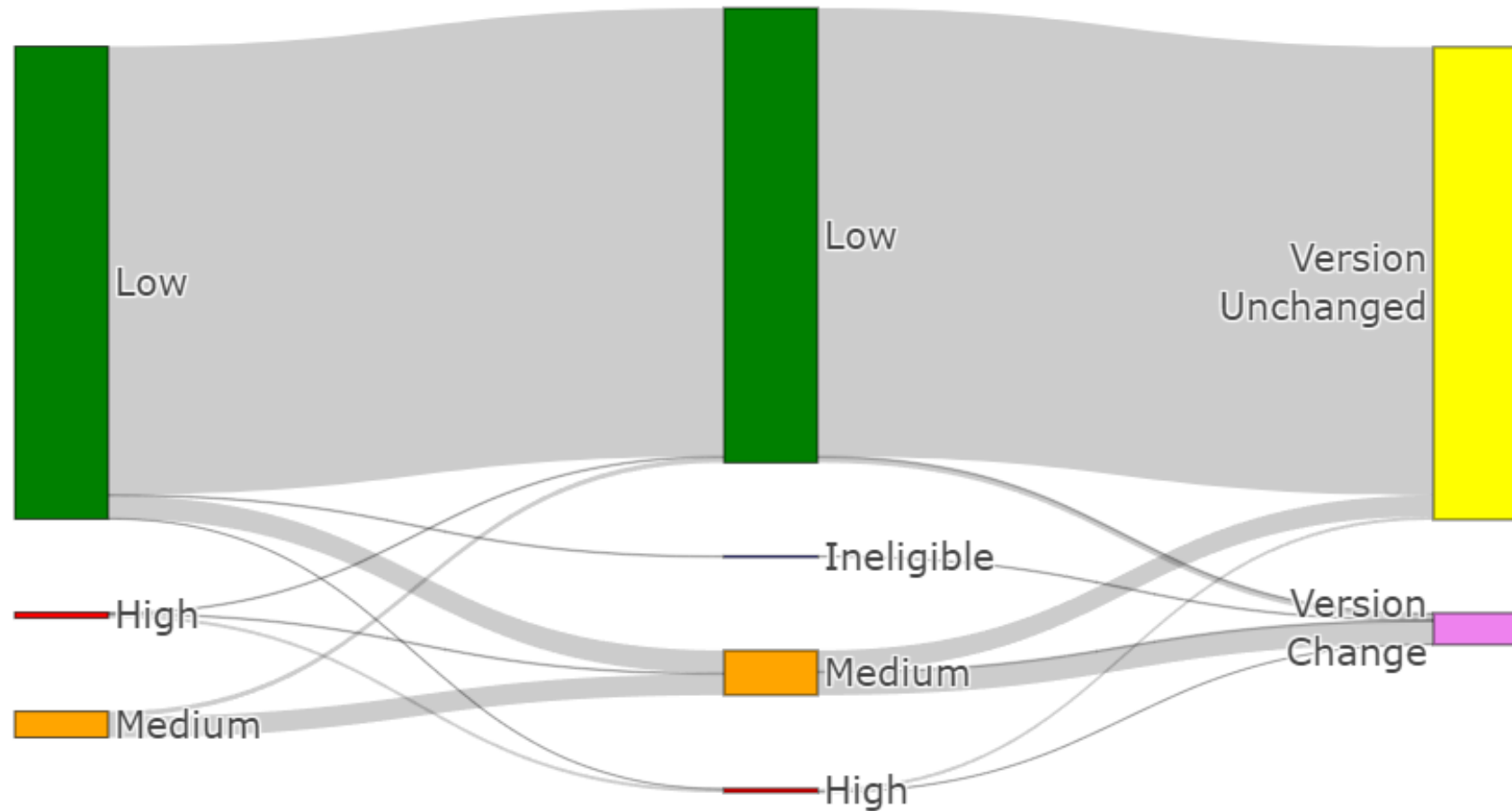Low, Medium, High → Low, Ineligible, Medium, High

Analysis across two releases, effect of version change

Release 1   Release 2   Version change

Sankey Diagram: Change in Risk Analysis

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Analysis over two time points, effect of version change – Discussion

Total number of packages: 892

Sankey Diagram: Change in Risk Analysis

Release 1   Release 2   Version change
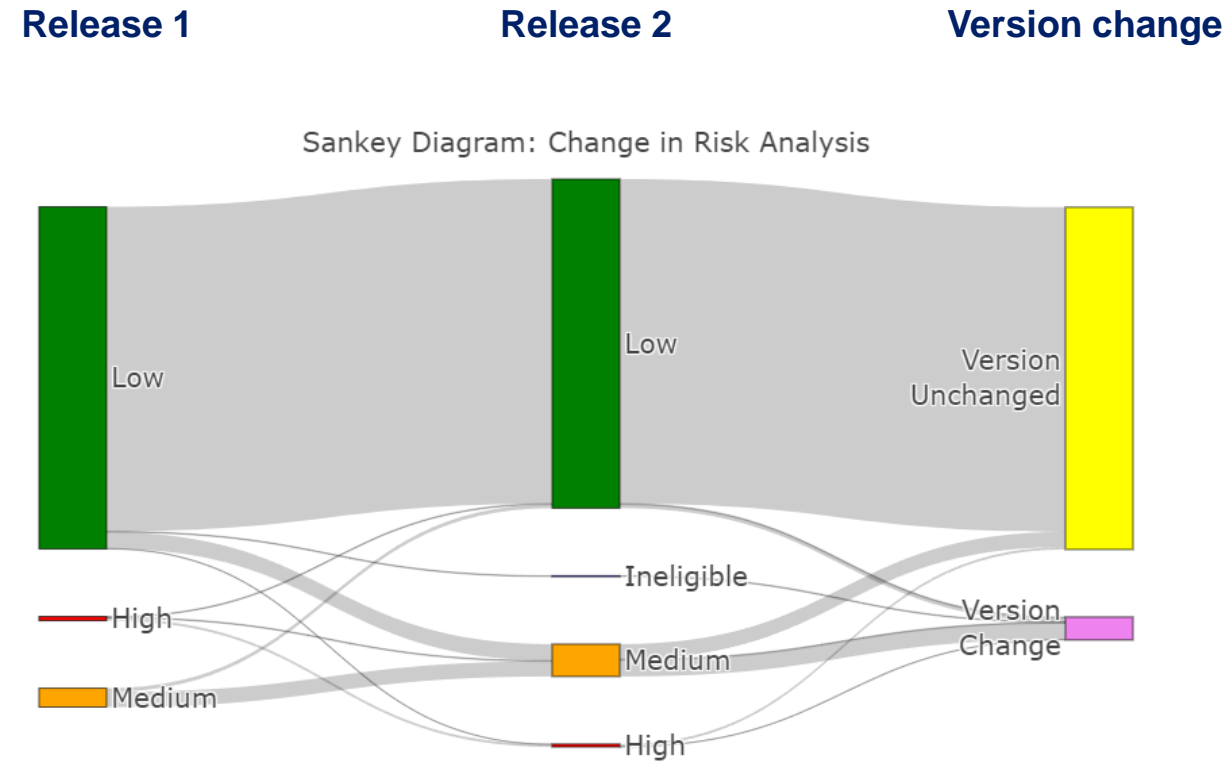
Analysis over two time points, effect of version change – Discussion

Total number of packages: 892

Packages with the same version: <mark>321</mark>

Sankey Diagram: Change in Risk Analysis

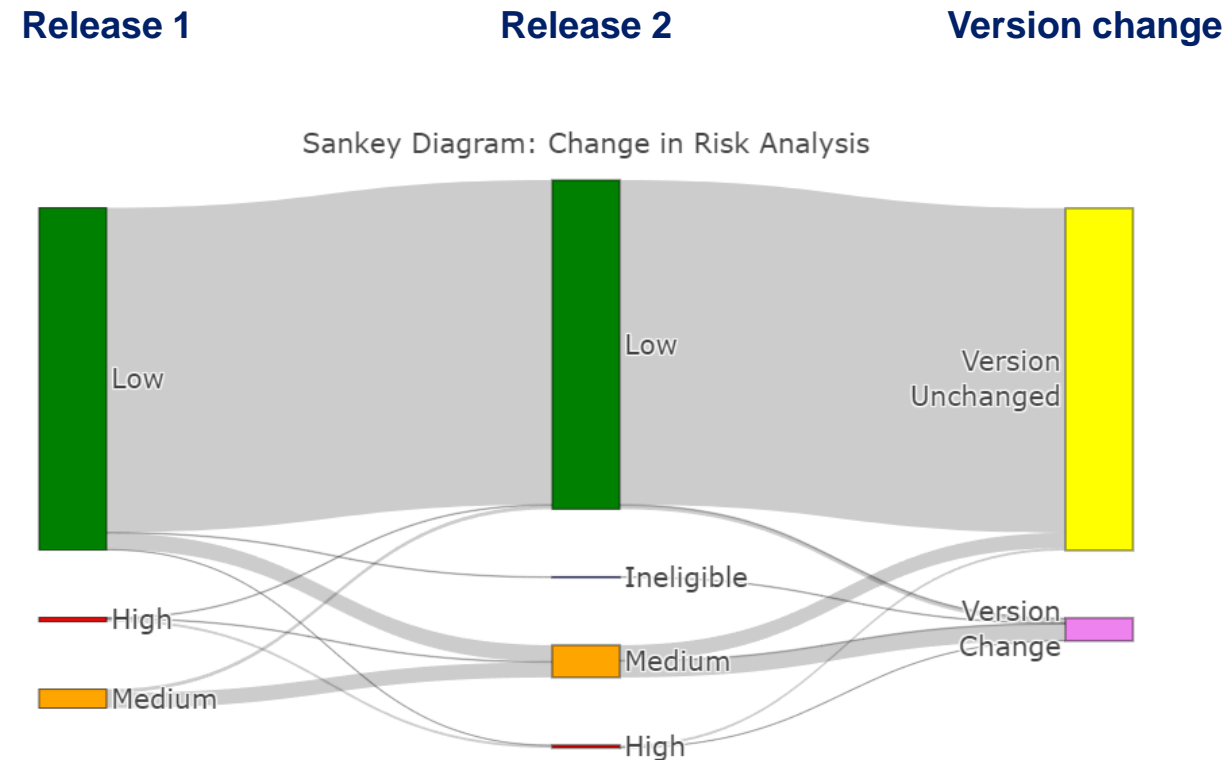Release 1   Release 2   Version change

Analysis over two time points, effect of version change – Discussion

Total number of packages: 892

<u>Packages with the same version: 321</u>

- Risk assessment unchanged: 307 **(95.6%)**

Sankey Diagram: Change in Risk Analysis

Analysis over two time points, effect of version change – Discussion

Total number of packages: 892

Packages with the same version: 321
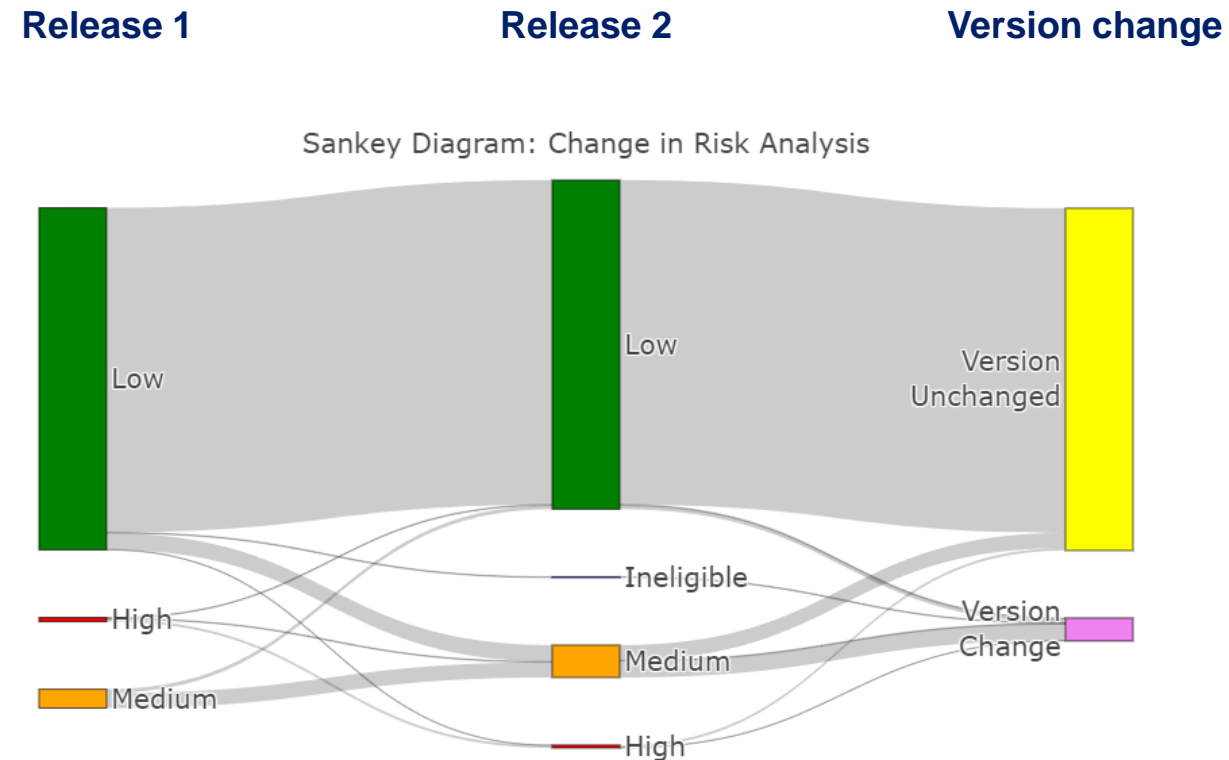
- Risk assessment unchanged: 307 (95.6%)
- Risk assessment changed: 14 **(4.4%)**

Release 1　　　　**Release 2**　　　　**Version change**

Sankey Diagram: Change in Risk Analysis

Analysis over two time points, effect of version change – Discussion

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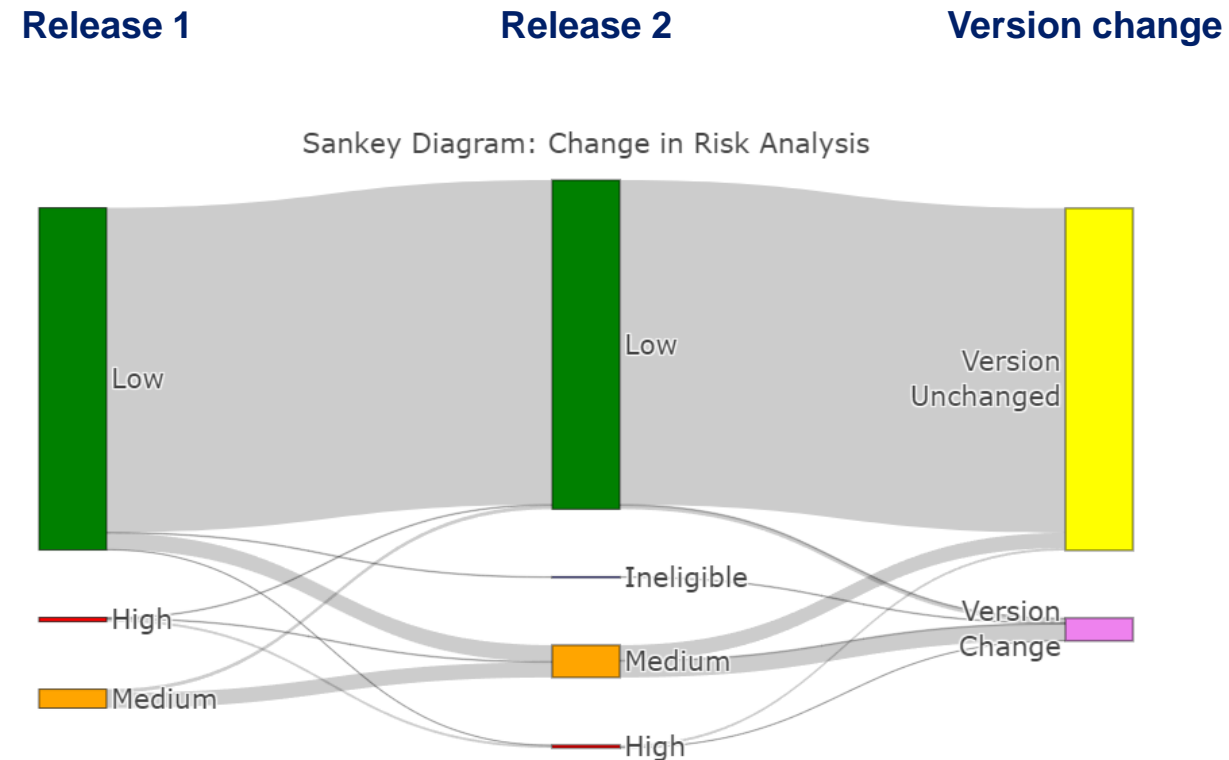- Risk assessment unchanged: 307 (95.6%)
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Packages with new version: 571

Sankey Diagram: Change in Risk Analysis

Release 1   Release 2   Version change

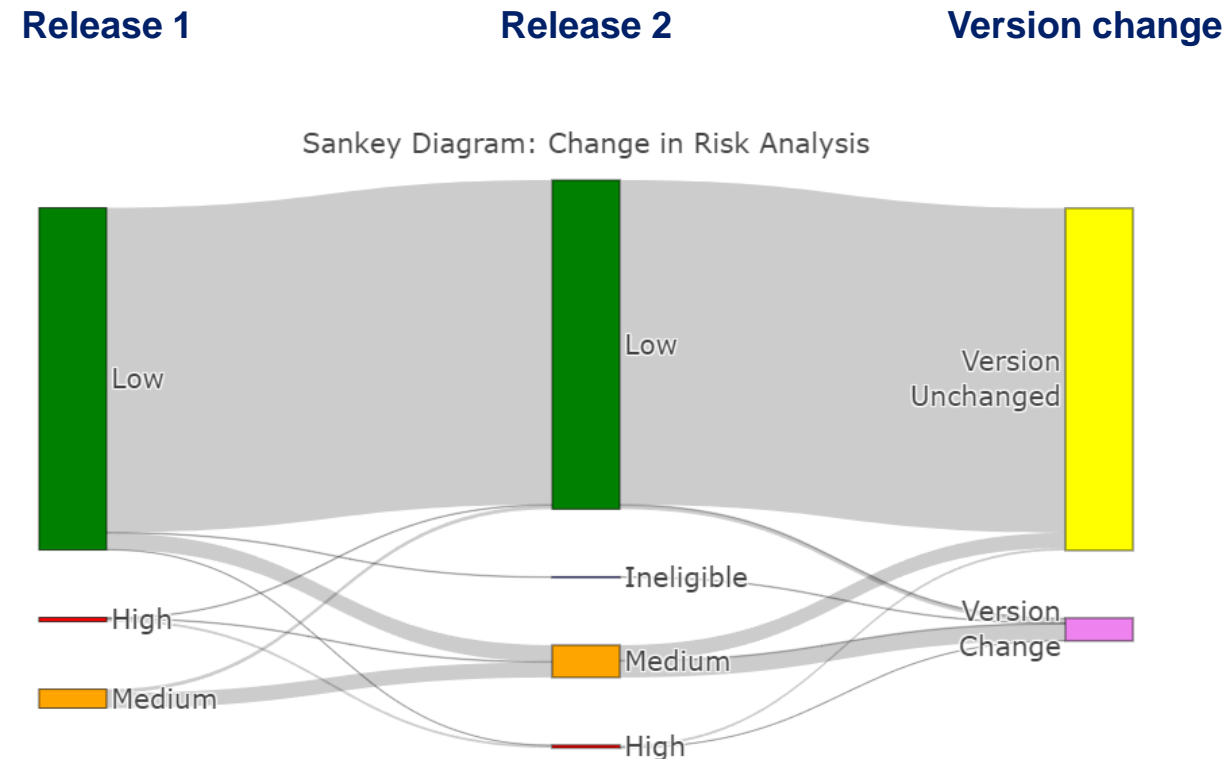# Analysis over two time points, effect of version change – Discussion

Total number of packages: 892

Packages with the same version: 321

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- Risk assessment changed: 14 (4.4%)

Packages with new version: 571

- Risk assessment unchanged: 529 **(92.6%)**

Release 1   Release 2   Version change

Sankey Diagram: Change in Risk Analysis

Low / Low / Version Unchanged / Ineligible / Medium / Version Change / High / High / Medium

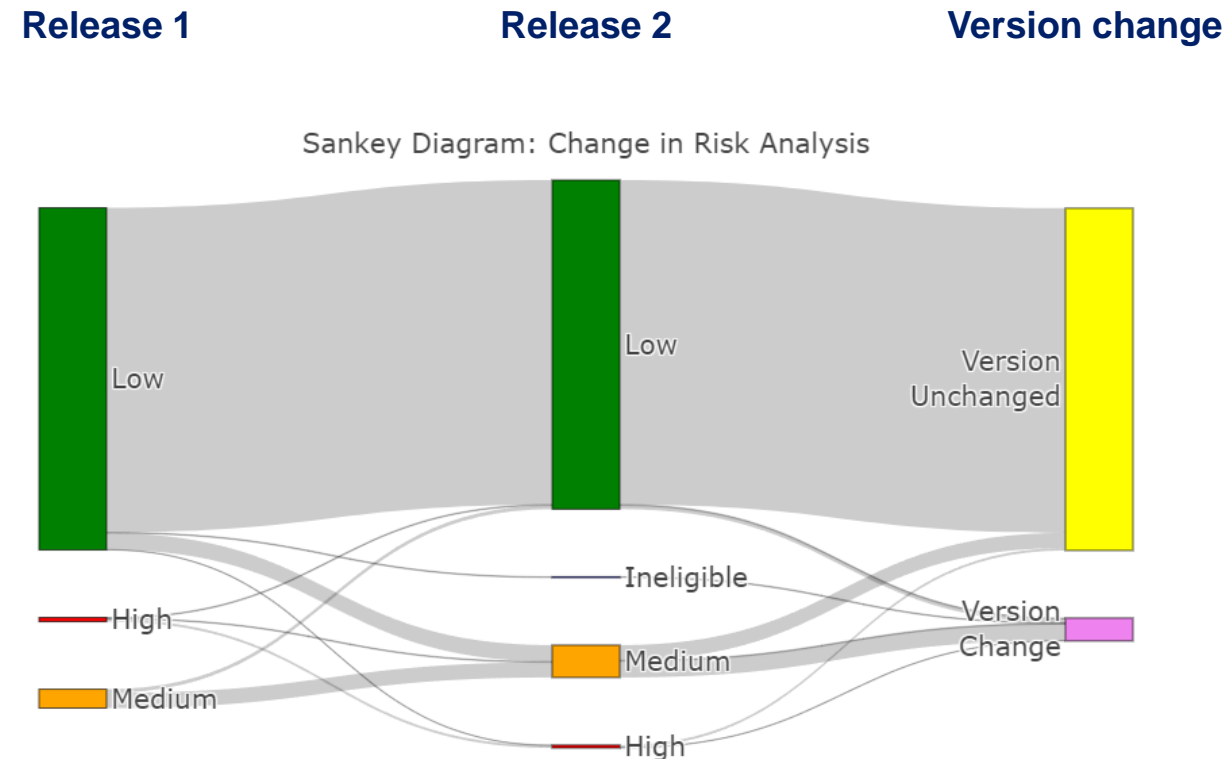# Analysis over two time points, effect of version change – Discussion

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- Risk assessment unchanged: 529 (92.6%)
- Risk assessment changed: 42 **(7.4%)**

Sankey Diagram: Change in Risk Analysis

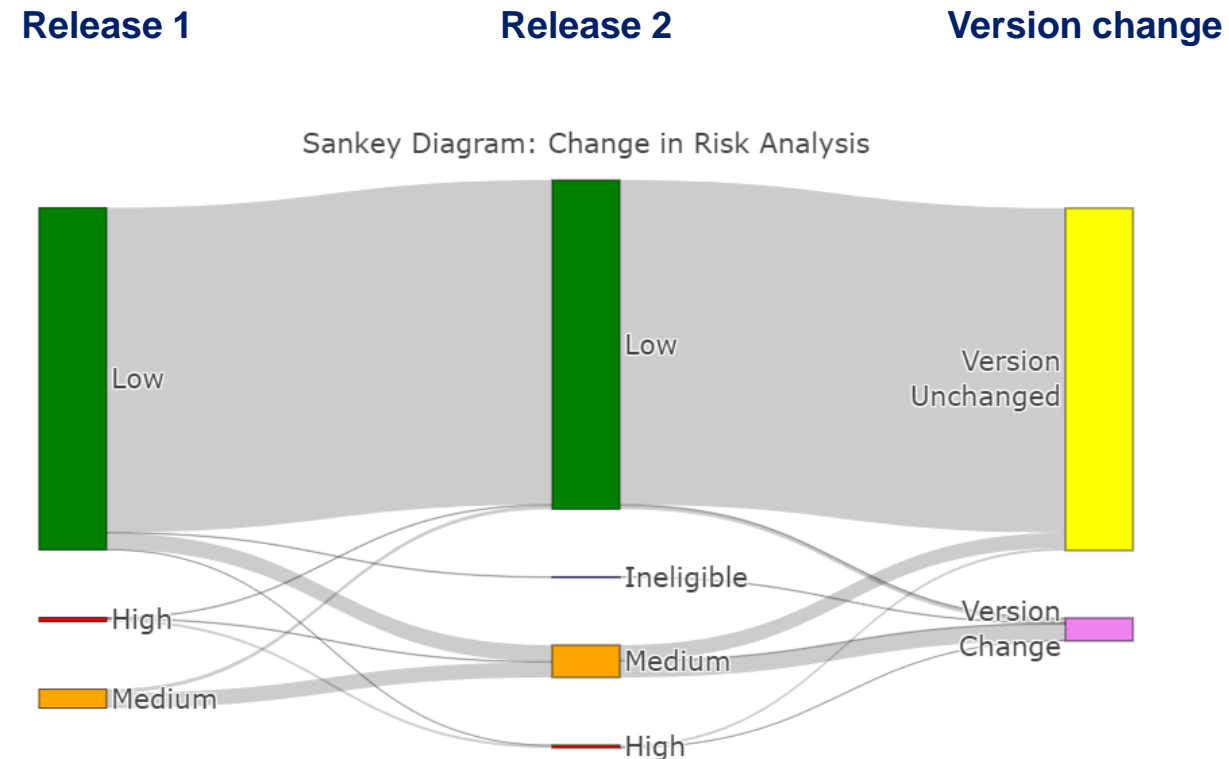# Analysis over two time points, effect of version change – Discussion

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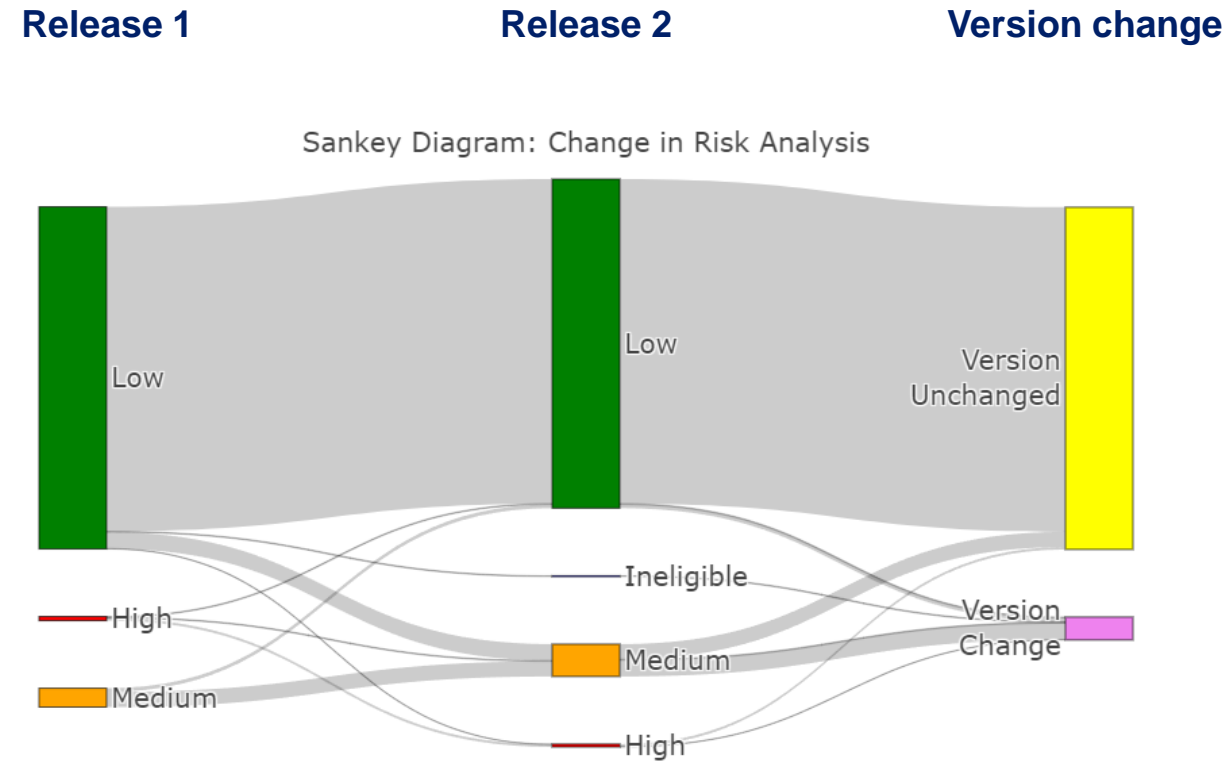- **Risk assessment changed: 14** (4.4%)

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Release 1   **Release 2**   **Version change**

Sankey Diagram: Change in Risk Analysis

What is the impact?

56 (6.3%) packages with changed risk assessments

Sankey Diagram: Change in Risk Analysis

Release 1 — Release 2 — Version change

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Non-impactful changes

53 (94.6%) packages had non-impactful changes

Sankey Diagram: Change in Risk Analysis

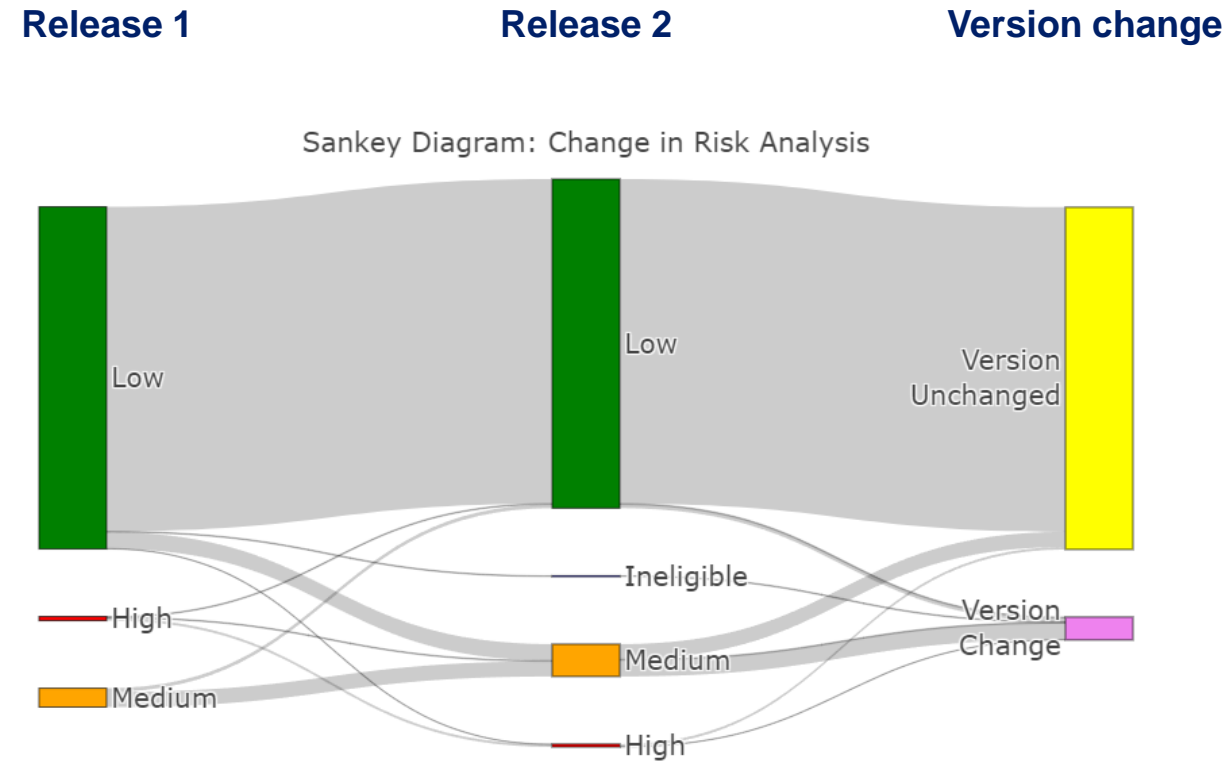# What is the impact?

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- High to Low Risk: **2 (3.6%)** packages

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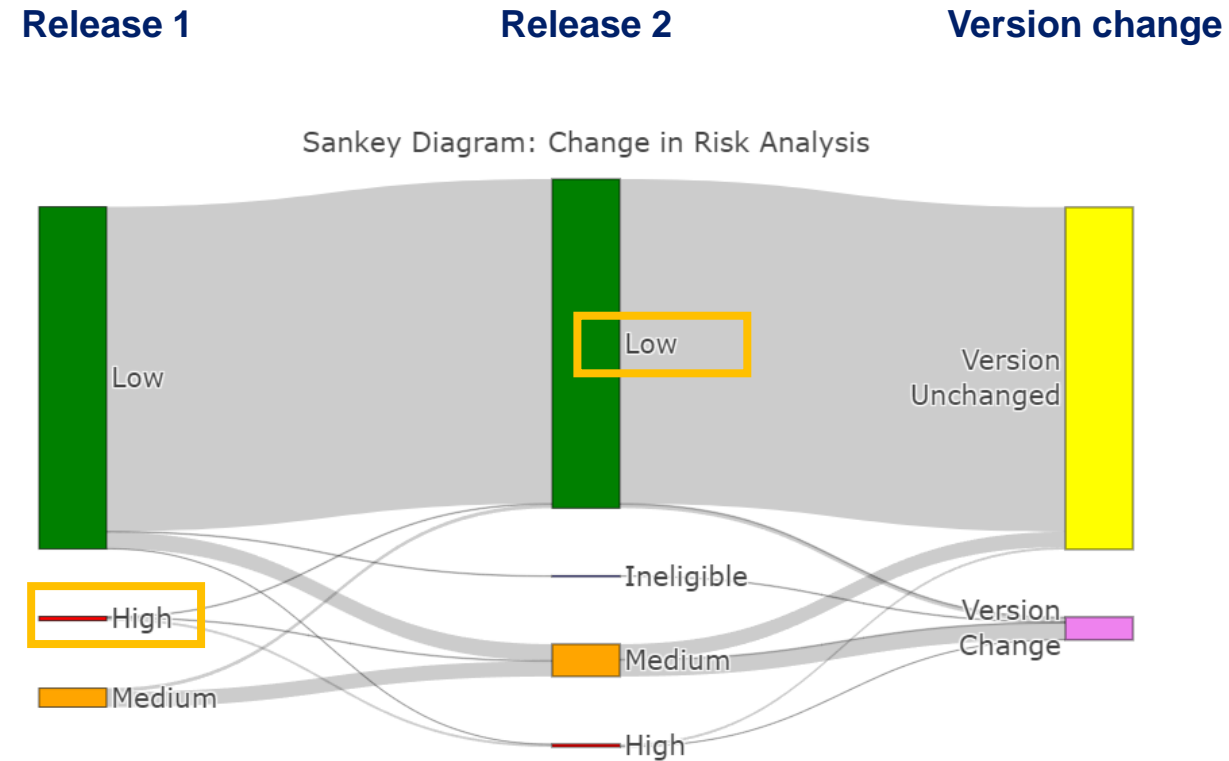
Release 1   Release 2   Version change

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Sankey Diagram: Change in Risk Analysis

Release 1 — Release 2 — Version change

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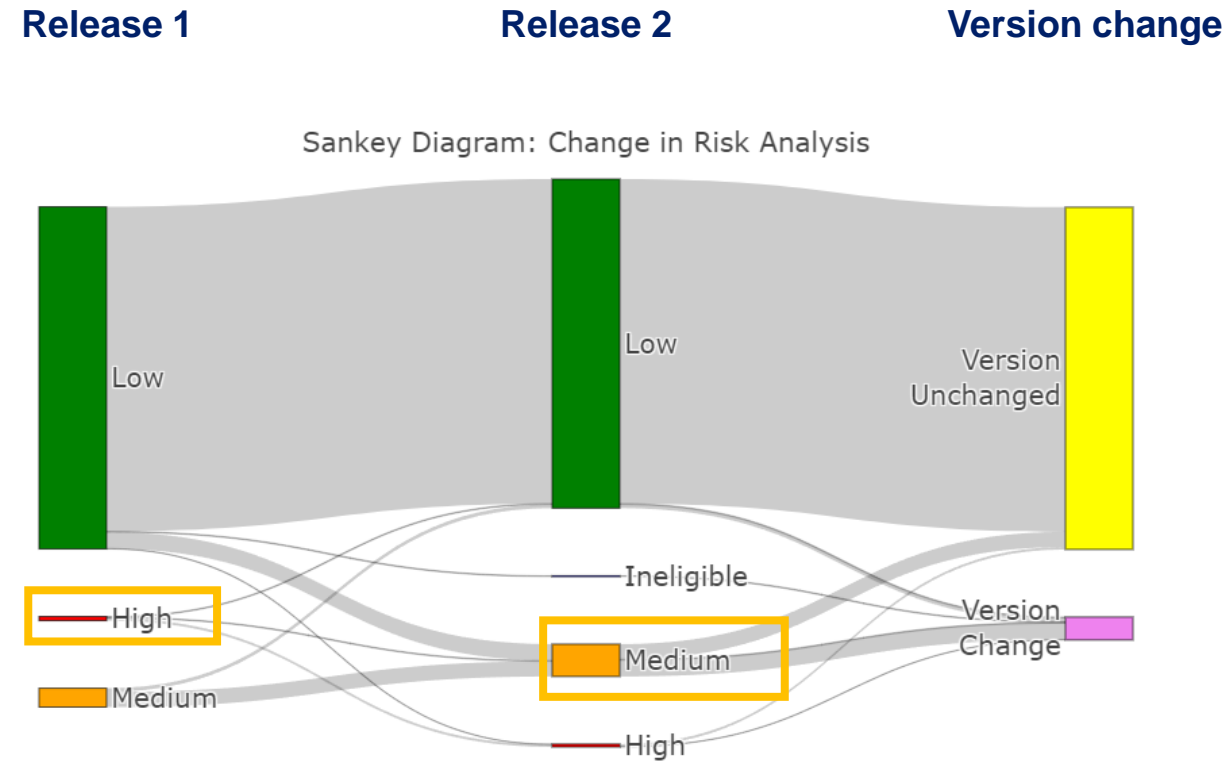- High to Low Risk: 2 (3.6%) packages
- High to Medium Risk: 2 (3.6%) packages
- Medium to Low Risk: **9 (16.1%)** packages

Sankey Diagram: Change in Risk Analysis

Release 1 | Release 2 | Version change

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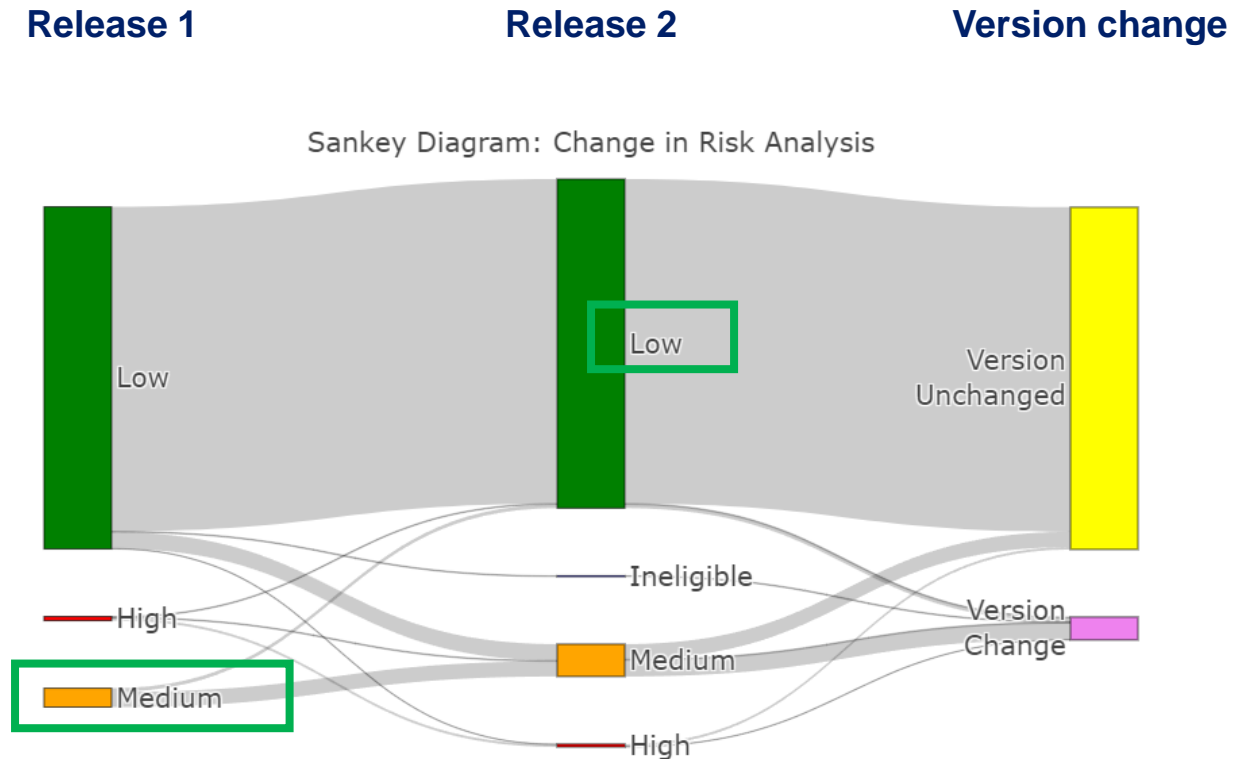- High to Medium Risk: 2 (3.6%) packages
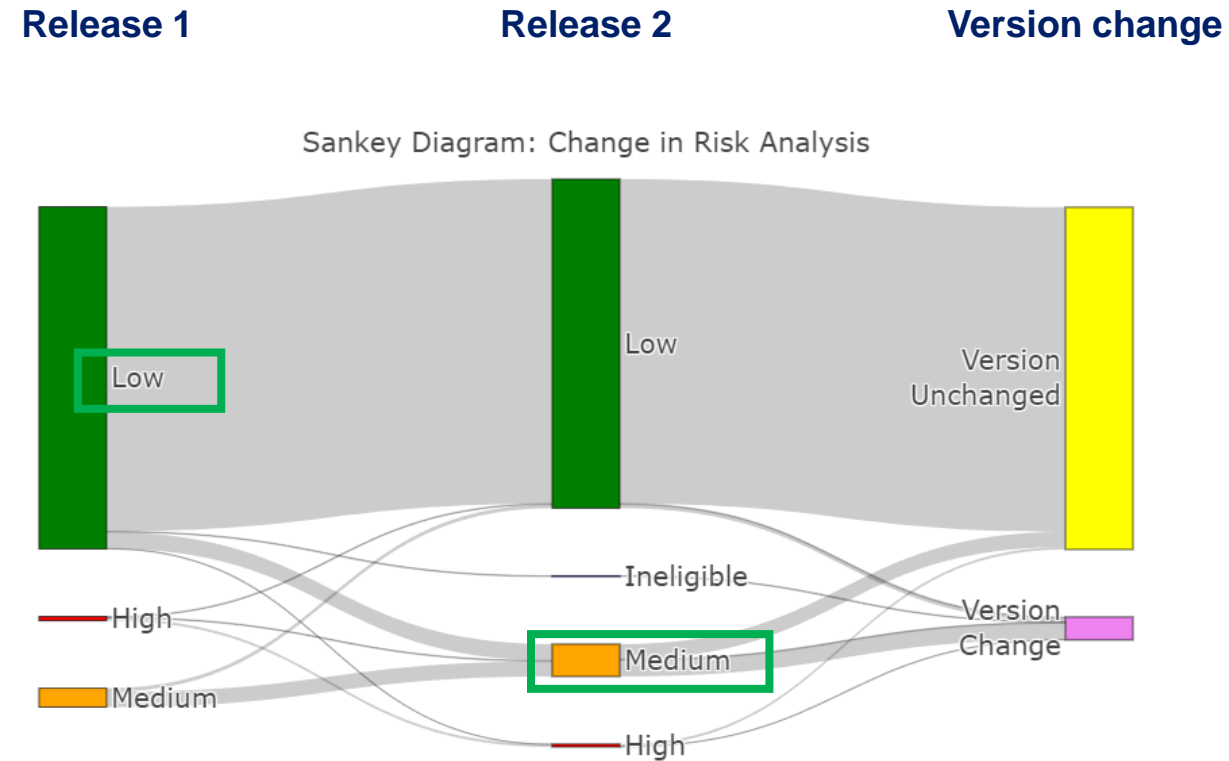- Medium to Low Risk: 9 (16.1%) packages
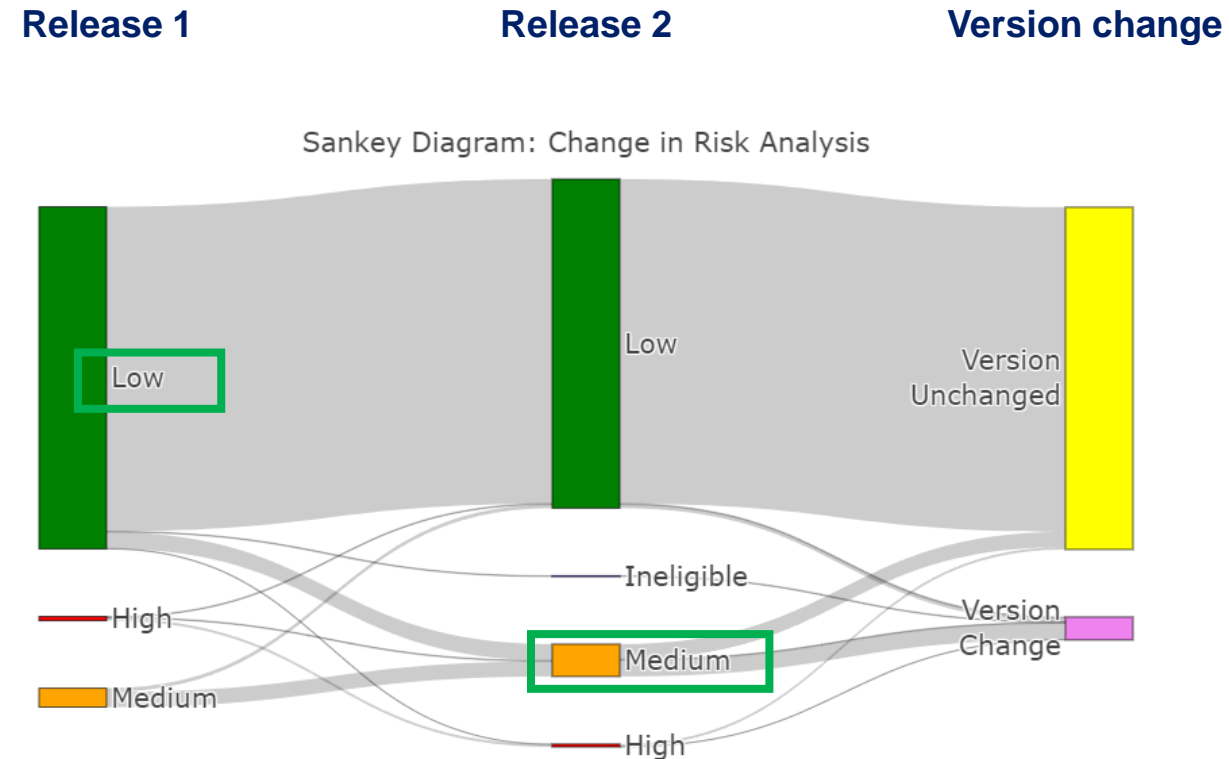- Low to Medium Risk: **40 (71.4%)** packages

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Change in the risk assessment criteria

Sankey Diagram: Change in Risk Analysis

Release 1   Release 2   Version change

What is the impact?

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Change in the risk assessment criteria

- Release 1 Low Risk Criteria: **1,000** downloads p/m

Sankey Diagram: Change in Risk Analysis

Release 1   Release 2   Version change

What is the impact?

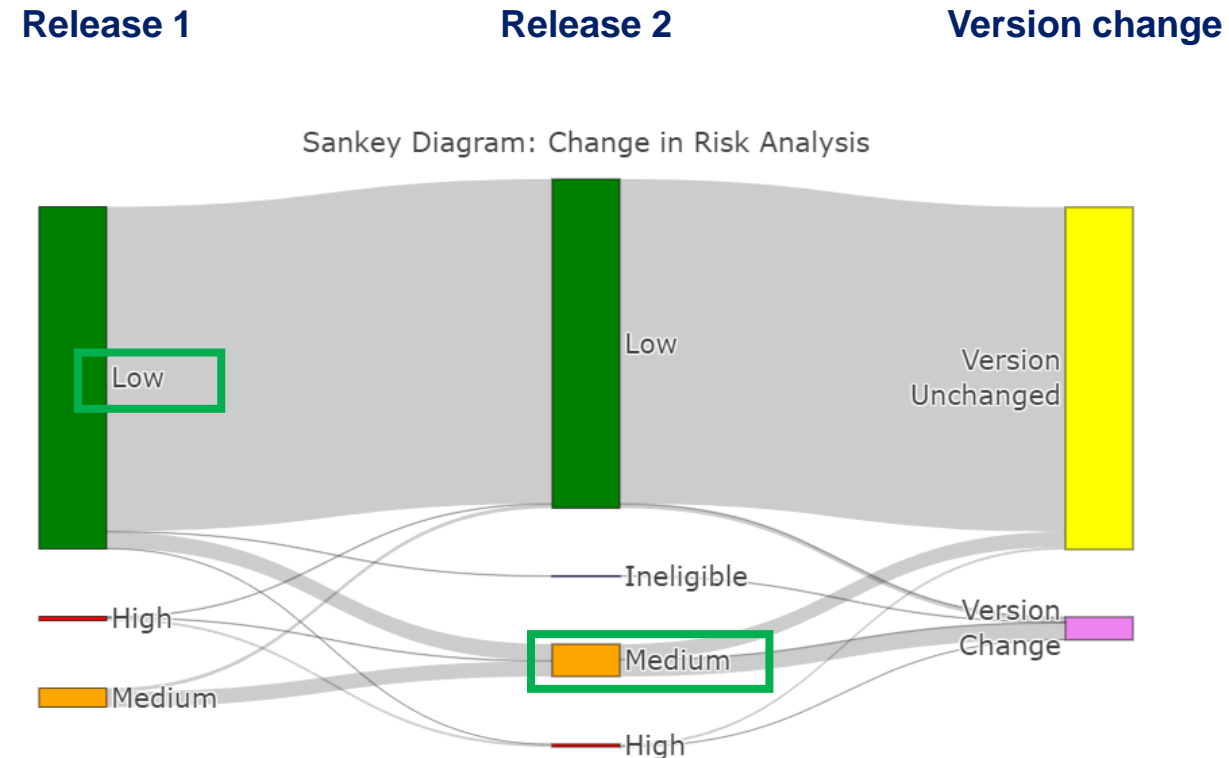**56 (6.3%) packages with changed risk assessments**
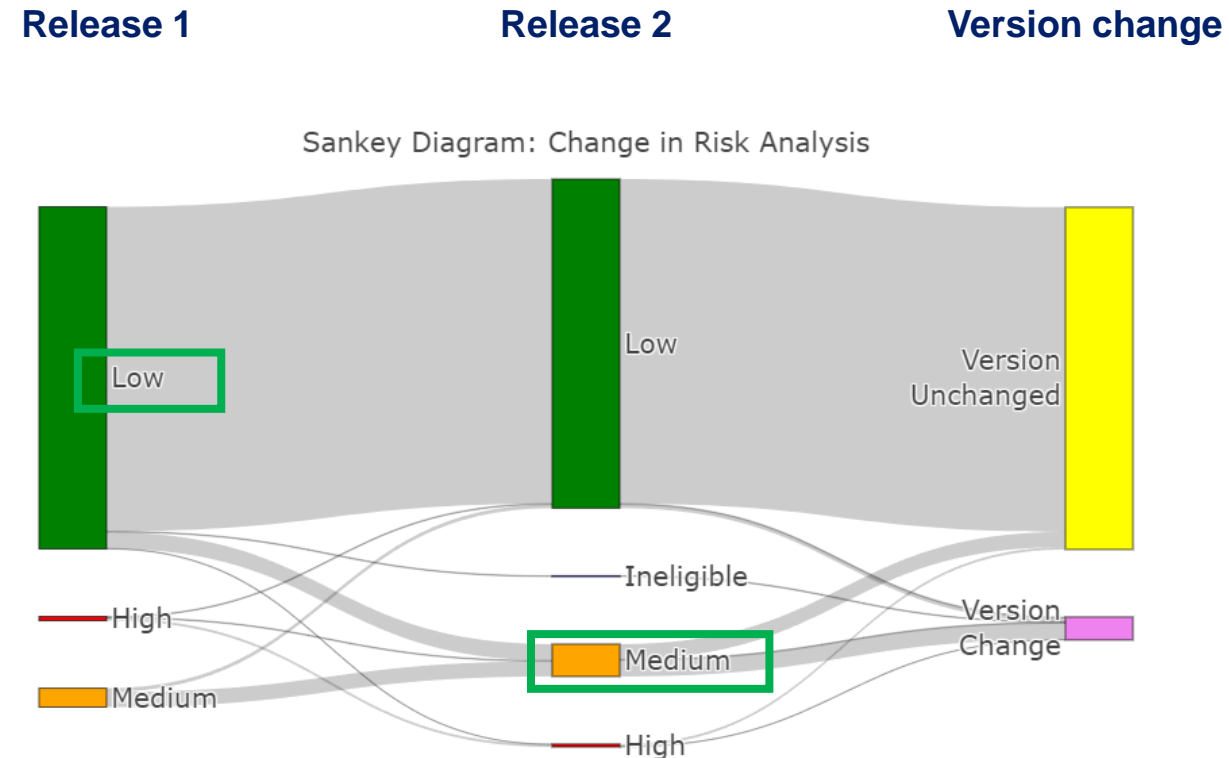
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- Low to Medium Risk: **40 (71.4%)** packages

Change in the risk assessment criteria

- Release 1 Low Risk Criteria: **1,000** downloads p/m
- Release 2 Low Risk Criteria: **50,000** downloads p/m

Sankey Diagram: Change in Risk Analysis

Release 1   Release 2   Version change

What is the impact?

56 (6.3%) packages with changed risk assessments

Impactful changes

Sankey Diagram: Change in Risk Analysis

Release 1   Release 2   Version change

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What is the impact?

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Impactful changes

==**3 (5.3%)**== packages had impactful changes

Sankey Diagram: Change in Risk Analysis

Release 1 — Release 2 — Version change
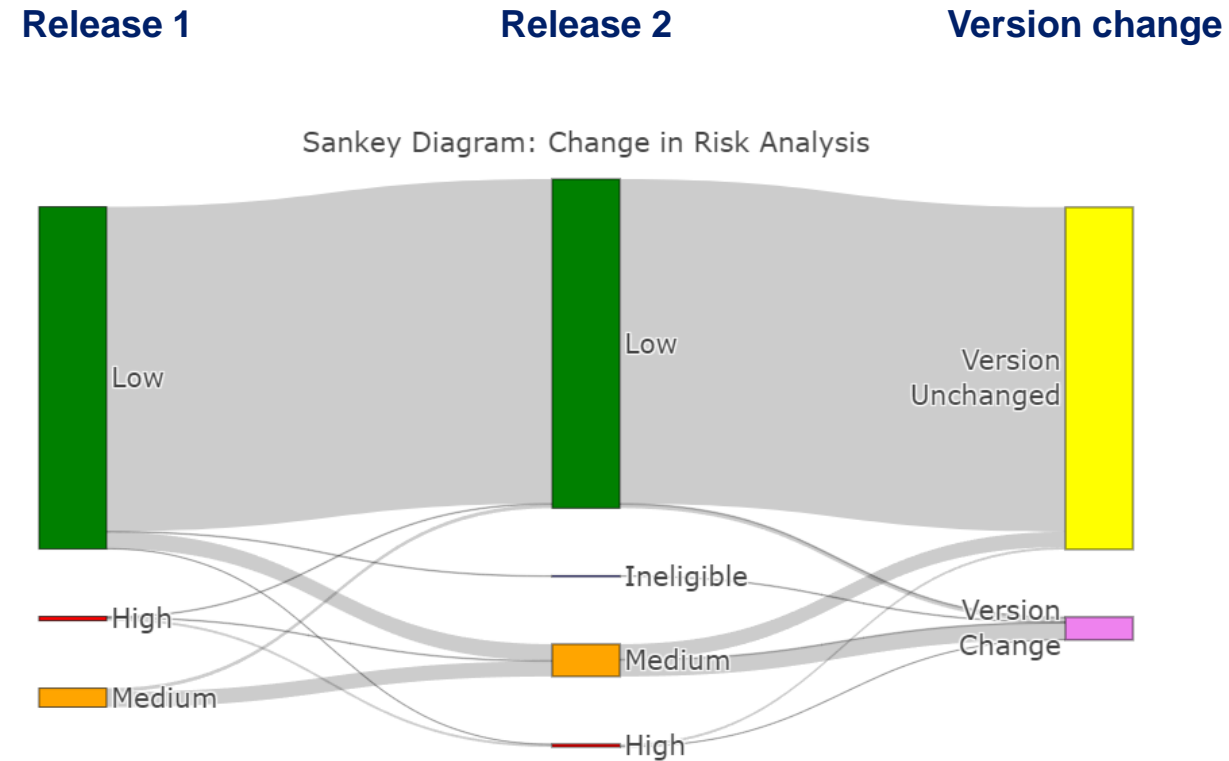
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What is the impact?

56 (6.3%) packages with changed risk assessments

<u>Impactful changes</u>

3 (5.3%) packages had impactful changes
- Low to High Risk: **1 (1.8%)** package

Release 1   **Release 2**   **Version change**

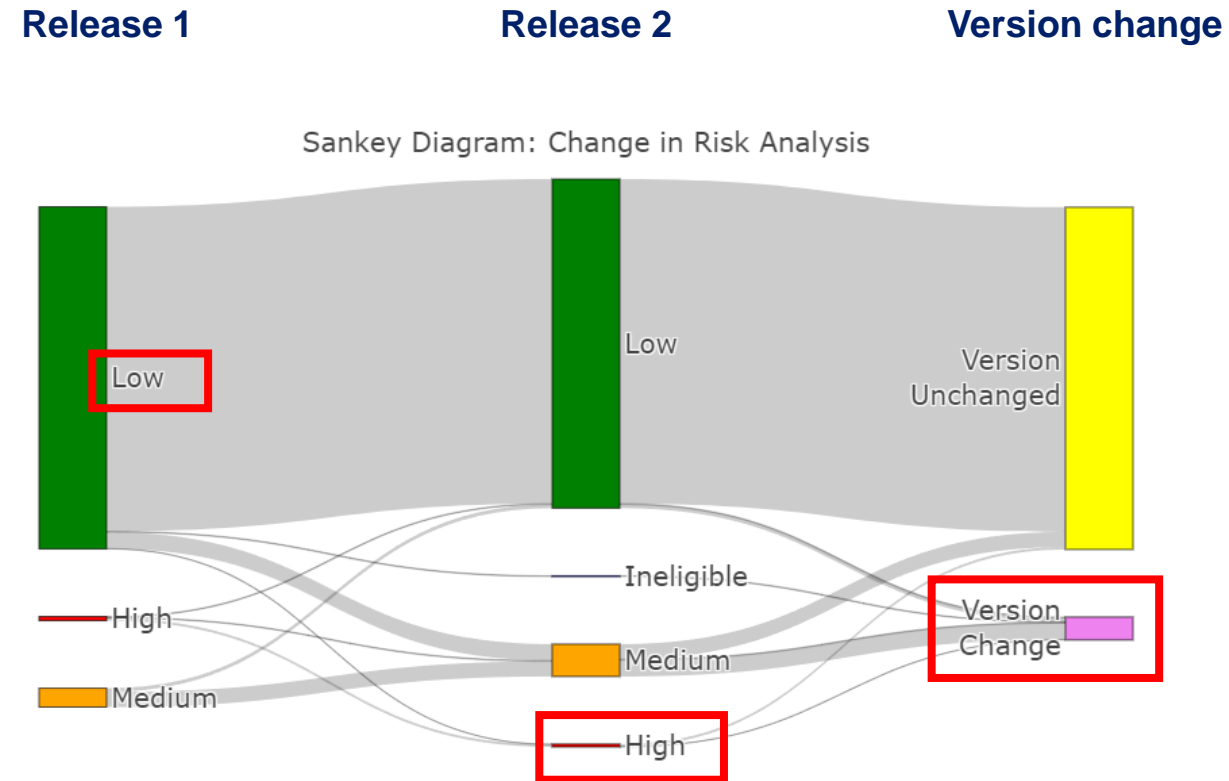Sankey Diagram: Change in Risk Analysis

What is the impact?

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Impactful changes

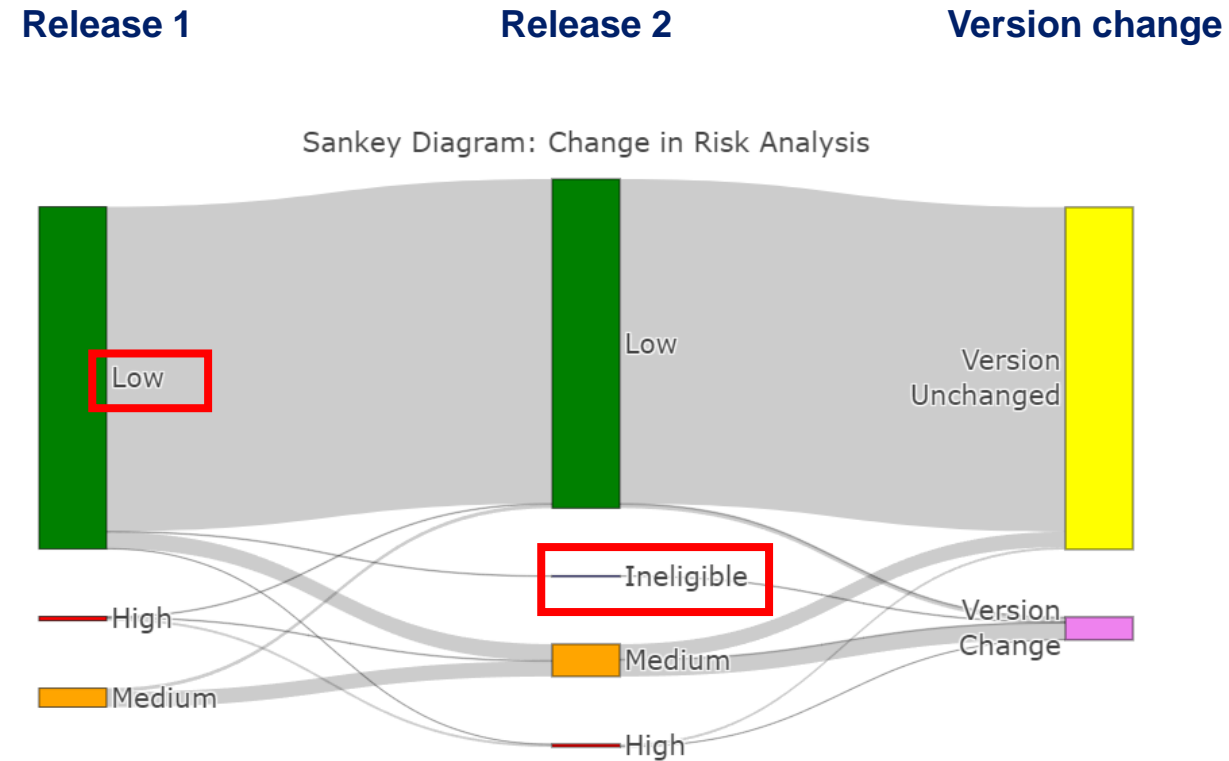3 (5.3%) packages had impactful changes

- Low to High Risk: 1 (1.8%) package
- Low Risk to Ineligible: **2 (3.6%)** packages

Sankey Diagram: Change in Risk Analysis

Release 1   Release 2   Version change

Conclusion

Are the changes in risk assessment impactful?

<mark>**The majority are non-impactful**</mark>

- 56 (6.3%) packages had changed risk assessments

- 53 of these packages had non-impactful risk assessment changes

- Vast majority of changes in risk assessment are changes within low/medium risk

- Small number of reductions in risk assessment

Conclusion

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Handful of impactful changes

- Risk assessment of **1** package increased from Low → High risk

- **2** packages deemed ineligible at Release 2

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As only 3 packages (0.33% of total packages) have impactful changes

- Impact of package version being updated or not is unclear

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Going forward

Periodic Review

Periodically re-evaluate the risk assessment for installed packages

Whichever comes first:

Intervals of ~18 months

When the version of R is upgraded

Bríd Roberts
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Thank you