

Following the correct TGA Recalls process: Examples

In October 2019 the TGA released a **recalls online form** through the TGA's eBusiness Services (eBS) Portal. Due to the pandemic, the TGA still accepted some email notifications on a case-by-case basis until June 2023. However, the TGA now wish all recall actions and notifications to be submitted via the online form. This technical alert covers information about using the form expected by the TGA under current circumstances.

NOTE: Earlier this year the TGA sought submissions from the public on potential changes to how product recalls are taken in Australia. The outcomes of this consultation are *yet to be published and implemented*. Published submissions are available [here](#). The Government will consider all submissions prior to making decisions to the URPTG. The **online form** will remain in place, however changes to the form may be made in the future. In the interim, existing processes and the online form must be followed.

Sponsors are asked to be aware of the following in regards to the **online form**:

- As of **1 July 2023**, the TGA expect all recall actions to be via the eBS Portal's online recall submission form (unless TGA have given an exception for genuinely urgent circumstances).
- Sponsors who continue to submit actions via email without a sufficient reason will be directed to submit the information via the eBS Portal **within 24 hours**. If this does not occur, the TGA will process this as a 'Recall Not Following the [URPTG](#)', published in the SARA database and notified to state and territory health authorities.
- Some submissions being left incomplete or providing inadequate information are resulting in delays. Mandatory fields are expected to have the correct information included in the field (not terms such as 'see attached document'). All relevant fields should be completed.

E.g., the Problem Description field should plainly and succinctly summarise the problem and the Product Description field should include all relevant identifiers including the product name, ARTG number, any model/batch/lot/code number(s) and expiry date(s) as applicable.

- Key documents for a recall action, *i.e.* draft customer letter, distribution/customer list and the health risk / hazard assessment, must be included with your submission. If any information is not available at the time of submission, please notify recalls@health.gov.au as soon as possible.
- Customer lists: There has been some inadequate attention to detail and some significant variations occurring within the same company *e.g.* suburb information not provided, suburbs and customers incorrectly matched, suburbs and/or customers in the wrong state or territory, irrelevant details such as customer ABN and account numbers. The correct content and format for customer lists are shown on page 22 of the URPTG and must be submitted in MS Xcel format using the attached template.
- In the event of a system issue with the online form, please contact the TBS Helpdesk on 1800 010 624 or by email at ebs@health.gov.au.

Improvement in the quality of submissions will assist TGA assessing and agreeing to market action in a shorter time.

Example documents to assist members:

Examples of the required information for each field of your online submissions, and how this information will eventually be published in the SARA database:

[2023 Example of filling out a TGA Online Recall Submission Form](#) (PDF)

Example of an invented customer list, with a range of guidance information included:

[2023 Example of a Customer List with guidance information](#) (XLXS)

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Other resources:

TGA website: [Submitting recall information](#)

TGA presentation: [New Online Web Form for submitting Recall and Non-Recall actions](#)