

WP 8, deliverable 8.2 | Release 1.0, 28/07/2025

GAPP-PRO D8.2

Update of the EUROGTP II Interactive Assessment Tool

Date of submission	28/7/2025
Work Package	WP8
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Dissemination level	Public



**Co-funded by
the European Union**

GAPP-PRO, Piloting GAPP model approach for assessing and authorizing novel substances of human origin preparation PROcess, is a project co-funded by the Health Programme of the European Union.

Grant Agreement 101128035 – EU4H-2022-JA-07, February 2024 – June 2027. Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HADEA. Neither the European Union nor the granting authority can be held responsible for them.

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Abbreviations

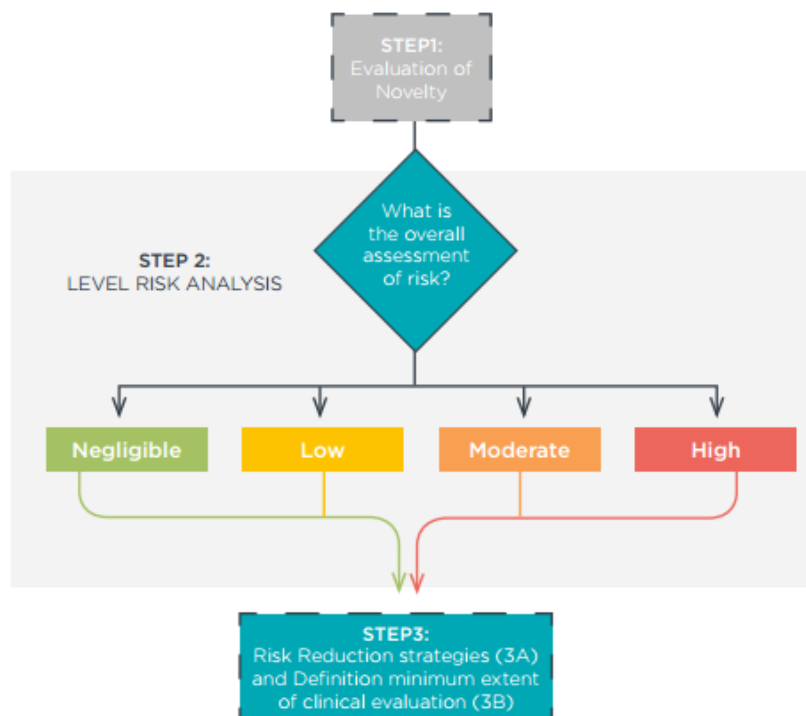
CSS	Cascading Style Sheets
GUI	Graphical user interface
HTML	Hyper Text Markup Language
IAT	Interactive Assessment Tool
SoHO	Substance of Human Origin
TCTP	Tissue and Cellular Therapy/Product

1. The EuroGTP II Interactive Assessment Tool

The EuroGTP II Interactive Assessment Tool – Other Substances of Human Origin is a simple web page, available at <https://tool.goodtissuepractices.site/staging/indexS.html>, on which a set of specific steps collect several inputs from users, through multiple sections and subsections.

When all inputs have been provided it computes them, applies the algorithm defined by EuroGTP II, and displays the calculated results.

It executes the assessment procedure defined by the EuroGTP II Guide (Step 1, 2 and 3), as depicted below:

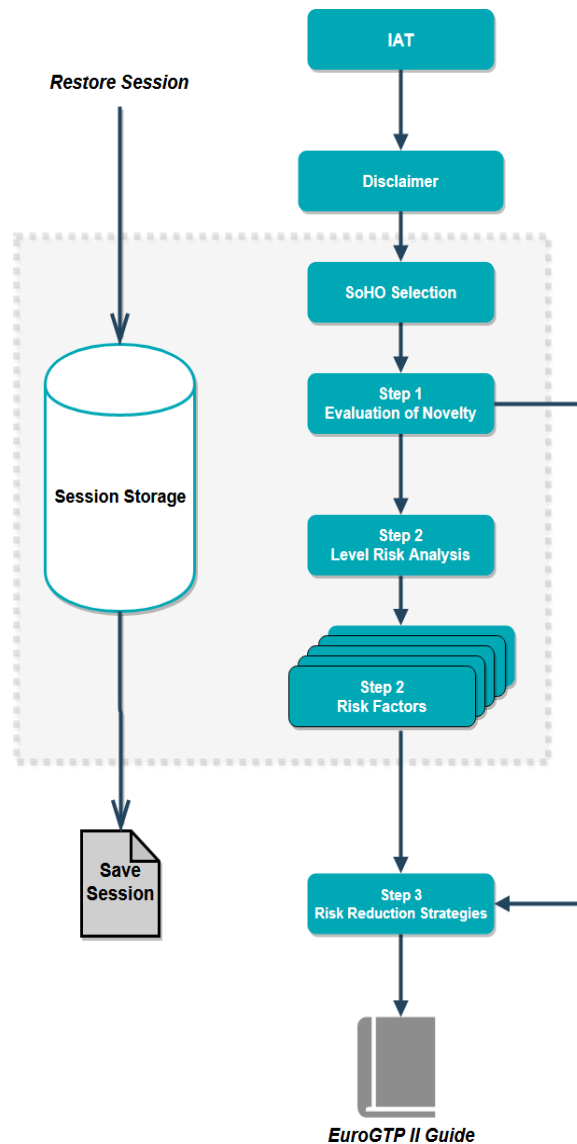




Using the IAT, and after the user has agreed to the presented disclaimer, the Substance of Human Origin (SoHO) must be defined. The tool includes human milk, blood components for topical use or injection and intestinal microbiota. Based on type of SoHO and the information provided on step 1, the tool determines if this SoHO/therapy/process introduces novelty, and if so, the tool moves to step 2. Otherwise, the assessment is terminated as no novelty has been identified.

On step 2 individual risk factors are analyzed and user shall introduce details for each applicable risk consequences. The set of risks factors and risk consequences presented is based on the SoHO initially defined by the user.

Once all information has been collected, the IAT presents a report, which includes all data introduced in the risk assessment. This report presents also the summary of “extent of studies proposed according the level of risk” and the links for the “risk reduction strategies” and the “clinical evaluation” proposed in the *EuroGTP II/Other Substances of Human Origin Specific Chapter*.



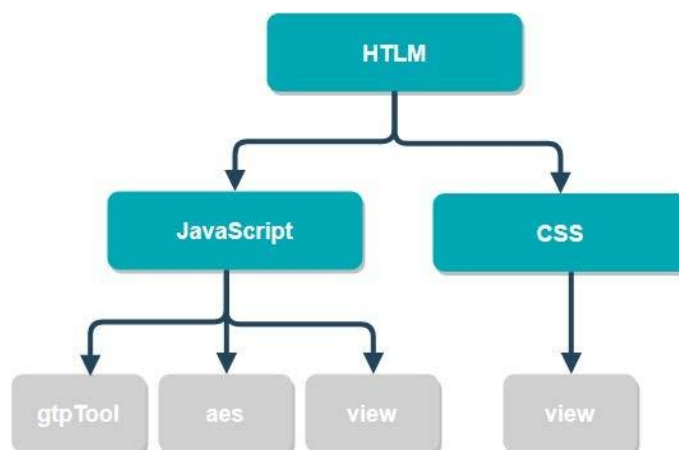
The process here described is extensively detailed on the *EuroGTP II/Other Substances of Human Origin Specific Chapter*, and additional details can be found on that document.

The data submitted in IAT is temporarily stored on the browser’s session storage, which will be lost as soon as the browser is closed. The user has the option to save this assessment by downloading the session file (.gtptool extension). Thus, users can restore the session on the IAT home page.

The current version of the tool has been developed using the following technologies:

- HTML – simple HTML pages using forms (textboxes, radio buttons, checkboxes) to collect the inputs from the user.
- JavaScript – used to trigger (dynamic pages, input validation, data storage) specific behaviors of the tool, and to apply the defined algorithm.
- HTML5 Storage – HTML5's sessionStorage is used to store the user inputs along the session (no cookies used).
- CSS – for style/presentation of the pages.

As the tool relies on technologies that were recently introduced, a modern browser must be used in order to have a properly functional behavior.



The tool itself is composed by the following software modules:

- HTML – several files define the IAT GUIs containing the forms where the user inputs data, and where the results will be presented.
- JavaScript
 - gtpTool – it contains all the relevant logic components of the EuroGTP IAT. Here implemented is the IAT algorithm, the navigation handling, the dynamic content logic, the session handling, among other features.
 - aes – cryptographic library developed by Google (CryptoJS v3.1.2). It is used to encrypt the saved session file using a static key contained on gtpTool.
 - view – helper methods for visual elements of the IAT.
- CSS view – defines the appearance.