

Compliance Decree e-cigarette: procedure

Here are the instructions for updating e-cigarette products notified to the FPS Public Health in order to comply with the new decree of 7 November 2022 amending the Royal Decree of 28 October 2016 on the manufacture and marketing of electronic cigarettes.

For products currently notified and on the positive list :

- If the modifications are only to comply with the new decree: concerns only the addition of labels and leaflet, a possible change of name (because of several flavours in it), the addition of a Belgian importer if existing.
If the product does not change its name, the information is added to the current notification.
If the product changes its name, a new "product presentation" is added and a "withdrawal date" at the 11/01/2024 is added to the old "product presentation". Old certificates of analysis or attached documents may remain under the old name.
In this case, the changes are not considered substantial and are not subject to a fee.
If the name of the product changes, a withdrawal date of 11/01/2024 is added to the previous Belgian "product presentation" and a new product presentation is added for Belgium. The labels and the leaflet can be added as a single PDF to this new product presentation. You make these changes with a type 7 submission "Correction of clerical/administrative errors in existing product submission".
- If the modifications are more important than to comply with the new decree: concerns any modification other than the addition of labels, leaflet, change of name and addition of a Belgian importer. For example modification of the composition, technical data, ...
In this case, the modifications are considered substantial and are therefore subject to a fee (€165 before 11/07/2023 and €100 from 11/07/2023).

For products currently notified and on the negative list :

- - The issues that led to the negative listing will have to be addressed (missing payment, data compliance) and the adaptations to comply with the new Decree will have to be made.

For non-notified products :

- Standard procedure: payment (165€ before 11/07/2023 and 200€ from 11/07/2023) and data in accordance with the new Decree.