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|  |  | Case officer |  | Our case number04320-2022DatePage1 (1) |
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# Impact assessment – The Public Health Agency of Sweden's regulations on tobacco-free nicotine products

# Summary

Tobacco-free nicotine products are now regulated by an Act and an Ordinance. However, some of the rules need to be supplemented in order to achieve the objectives of the Act (2022:1257) on Tobacco-free Nicotine Products, including increased protection for the health of children and young people. To achieve this objective, the Public Health Agency of Sweden proposes regulations specifying the requirements concerning health warnings and declarations of contents, and how the health warnings should be provided in certain marketing aimed at consumers.

To reduce the risk of a deterioration in public health, good knowledge of the products is also required. The Public Health Agency shall therefore collect data to enable:

* an overview of the products being developed and sold to consumers on the market, and supervision of these;
* information to be gathered on suspected harmful effects and the action to be taken against deficient products by manufacturers, importers or distributors;
* monitoring of the impact of nicotine products on public health.

The regulations specify how this data collection will be carried out.

On the public side, our assessment is that the regulations will have a modest impact on the authorities who exercise supervision and provide supervisory guidance in this area, namely the Public Health Agency of Sweden, the Swedish Consumer Agency, the county administrative boards and the municipalities.

On the business side, the regulations mean that manufacturers and importers of tobacco-free nicotine products will incur certain administrative costs for submitting various types of information to the Public Health Agency of Sweden (product notification, reporting of sales volumes and preferences, and notification of deficiencies in the products). For retailers, the regulations mean that they must establish procedures to ensure that the labelling on the products is correct, as they are only allowed to provide products that are correctly labelled to consumers on the market. The costs in this respect are estimated to be modest: For manufacturers and importers because the reporting system is intended to guide the user through the necessary process for retailers, because many of them already sell products (tobacco and/or electronic cigarettes) that have labels that need to be checked.

The regulations on labelling and notification of deficiencies are proposed to enter into force on 2 May 2023; the regulations on product notification and reporting obligations on 1 January 2024.

# Description of the problem and what the Public Health Agency of Sweden wants to achieve

## The problem

The Act on Tobacco-free Nicotine Products entered into force on 1 August 2022. The objective of the Act is to limit the harmful effects of tobacco-free nicotine products. The brains of children and young people are particularly sensitive to the addictive properties of nicotine. The draft regulations, like the Act, aim to increase the protection for public health, especially among children and young people.

Against this background, the Public Health Agency of Sweden deems the issuing of regulations to be justified. Regulations would also clarify the rules in force for the industry. The goal should be for the rules on tobacco-free products to be as similar to the rules on tobacco and electronic cigarettes as the legislation allows. The objective is to make the rules as clear as possible for all those applying them.

## Background and proposals

A tobacco-free nicotine product is a product without tobacco for consumption that contains nicotine, such as tobacco-free nicotine pouches. The new rules in the Act on Tobacco-free Nicotine Products primarily entered into force on 1 August 2022. However, the provisions on product requirements, labelling and associated criminal provisions, and the information collection system will enter into force on 1 January 2023, and the provisions on product notification and reporting obligations on 1 January 2024.

With the new legislation, the Public Health Agency of Sweden will be given a number of new tasks as a national supervisory authority. The Ordinance (2022:1263) on Tobacco-free Nicotine Products (Ordinance) gives the Public Health Agency of Sweden a number of authorisations to lay down regulations in this area. Such regulations supplement the provisions in the Act and Ordinance. The regulations concern product notification, reporting obligations, labelling and notification obligations regarding product deficiencies.

### Product notification

Section 5 of the Act states that manufacturers and importers shall notify the Public Health Agency of Sweden about all tobacco-free nicotine products they intend to supply to consumers on the market. Equivalent requirements can be found for electronic cigarettes and refill containers in the Act (2018:2088) and Ordinance (2019:223) on Tobacco and Similar Products.

In the Act and in the proposed amendment to the Ordinance, certain basic requirements for product notification have been included. The Public Health Agency of Sweden's primary responsibility in this respect is to regulate how the electronic notification is to be designed and submitted.

The format of product notifications for tobacco products and electronic cigarettes is determined by a decision of the European Commission. Given that tobacco-free nicotine products have been deemed equivalent to tobacco and electronic cigarettes from a health perspective, the provisions on product notification for tobacco-free nicotine products are to be formulated in regulations in the same way as for the other products. As the products in question are not harmonised at EU level, it is not possible to use existing systems. For this reason, the Public Health Agency of Sweden considers it necessary for to produce national regulations.

However, the Agency considers that the regulations should be limited to regulating the technical solution to be used for product notification. Design details for the notification itself should be determined in the technical solution.

### Declaration of contents and health warning

*Declaration of contents*

Under Section 7 of the Act, packaging for tobacco-free nicotine products must be provided with a declaration of contents. In the draft amendment to the Ordinance, the Government has proposed what a declaration of contents should contain. This largely corresponds to the rules that apply to electronic cigarettes. Through its regulations, the Public Health Agency of Sweden has regulated the language requirements concerning the declaration of contents for electronic cigarettes (Section 6 (HSLF-FS 2018:41)). We propose, in addition to the provision on language requirements, provisions on the design of the declaration of contents, including its location, size and font. The aim is to make it clear to consumers the substances and other ingredients that the product contains. Since the transitional period for adapting to the new labelling requirements may be considered to be relatively short, we propose that stickers may be used to provide the declaration of contents on packaging.

*Health warning*

Section 7 of the Act states that packaging for tobacco-free nicotine products must be provided with a health warning. In the Ordinance, the Government has proposed the following wording for the warning: "This product contains nicotine, which is a highly addictive substance."

However, there are no detailed requirements in the Ordinance for the design of health warnings. In this respect, the situation differs compared to electronic cigarettes and refill containers, where these requirements are laid down in the Ordinance on Tobacco and Similar Products. Since the products in question here also contain nicotine and therefore pose risks to human health, the Public Health Agency of Sweden considers it necessary to regulate the design of the health warning in the same way as for tobacco and similar products. When the rules are equivalent, the rules that actually apply are also clear to the supervisory authorities.

The Public Health Agency of Sweden therefore proposes that regulations be issued regarding the location, size and font of the health warning. Since the transitional period for adapting to the new labelling requirements may be considered to be relatively short we propose that stickers may be used to provide the health warning on packaging.

Unlike tobacco and electronic cigarettes, tobacco-free nicotine products are not subject to marketing bans in commercial advertisements. However, health warnings must be clearly provided in such marketing. The Public Health Agency of Sweden has the authority to issue regulations on how these health warnings should appear in such marketing. As the availability of tobacco-free nicotine products has increased in recent years, there is a risk that nicotine dependence will also increase, not least among young people in the community[[1]](#footnote-1). We therefore deem it justified to issue regulations in this area.

### Reporting obligation

Section 14 of the Act states that manufacturers and importers must report data on sales volumes and preferences of different consumer groups each year to the Public Health Agency of Sweden. Similar provisions can be found for tobacco and electronic cigarettes in the Act on Tobacco and Similar Products. In its draft amendment to the Ordinance, the Government has introduced a provision requiring manufacturers, and where appropriate importers, to provide the data referred to in Section 14 for the previous year by 31 March each year.

The Public Health Agency of Sweden has the authority to lay down how manufacturers and importers are to comply with the reporting obligation. For the Public Health Agency of Sweden to fulfil its task of publishing the data, it is important that the reporting takes place in a consistent manner. It is also of great importance that we can monitor the development of the products on the market.

The data to be reported and the time limit for doing so is already specified in the Act and the Ordinance. What remains, therefore, is to lay down rules on the format in which the reporting obligation is to be fulfilled. We therefore propose regulations to the effect that this should be fulfilled in the same technical solution as that for the product notification.

### Notification obligation

Section 16 of the Act states that a manufacturer, importer or distributor shall take a number of actions when deficient products are detected, and notify the Public Health Agency of this. An identical requirement for electronic cigarettes and refill containers can be found in Chapter 2, Section 11 of the Act on Tobacco and Similar Products. Through its regulations, the Public Health Agency of Sweden has regulated the form to be used for such notifications (Section 8 of the Public Health Agency of Sweden's regulations on electronic cigarettes and refill containers (HSLF-FS 2018:41)). The Public Health Agency of Sweden considers it appropriate that the form for notifying product deficiencies for nicotine products shall be included in the new regulations and that the information is to be provided in the same technical solution as that used for product notification.

# Authority conferred on the Public Health Agency of Sweden

Section 48 of the Act authorises the Government or the authority designated by the Government to issue regulations.

Under Section 16 of the Ordinance, the Public Health Agency of Sweden has the authority to issue regulations on:

 1. product notification in accordance with Section 5 of the Act;

 2. the content and design of a declaration of contents in accordance with Section 7 of the Act;

 3. how a health warning is to be designed and when it must be provided in accordance with Sections 7 and 10 of the Act;

 4. the performance of the reporting obligation in accordance with Section 14 of the Act;

 5. the information collection system in accordance with Section 15 of the Act;

 6. the notification obligation in accordance with Section 16 of the Act;

 7. the design of self-monitoring programmes in accordance with Section 18 of the Act; and

 8. the implementation of control purchases in accordance with Section 37 of the Act.

Under Section 17 of the Ordinance, the Public Health Agency of Sweden also has the authority to issue regulations on the enforcement of the Act and Ordinance.

The regulations that the Public Health Agency needs to draw up depend on which parts the Government chooses to regulate itself. In a proposal amending the Ordinance, the Government has made use of parts of its authorisation regarding product notification, product requirements, labelling and reporting obligations.

## Entry into force and transitional provisions

The regulations need to take into account when the various provisions of the Act and the Ordinance enter into force, as well as the transitional provisions contained in the Act. Given that the draft amending ordinance will not be adopted until the end of November 2022, the Public Health Agency of Sweden will not be able to publish the new regulations until 1 January 2023.

However, it is important that businesses and the authorities are given a reasonable amount of time to become familiar with and adapt to the regulations before they enter into force. For this reason, the Public Health Agency of Sweden has prepared a communication plan covering various information initiatives. With regard to the declaration of contents, health warning and product deficiency notification, we deem 2 May 2023 to be a reasonable date for the entry into force of the regulations. As regards product notification and reporting obligations, we propose the regulations enter into force on 1 January 2024.

# Description of alternative solutions and the impact if no regulation is made

There are different ways to achieve a particular objective. Sometimes this can be done, for example, by an authority issuing regulations, or leaving it to the market operators to take measures themselves to achieve the objective.

The authority to issue regulations does not imply an obligation to do so[[2]](#footnote-2). If the objective can be achieved in a less intrusive manner, regulations should not be used. The authorities must consider both whether the costs arising from the regulations are acceptable and, if alternative solutions are available, what would they cost.

Our assessment is that regulations are needed in all areas covered by this impact assessment, i.e. product notification, labelling (content declaration, health warning and provision of health warning in particular cases), notification of product deficiencies, and reporting of sales volumes and preferences.

The alternative solution primarily available in this case would be general advice. Below we explain why we deem this to be an unsuitable option. We also consider the option of doing nothing.

## General advice

General advice differs from regulations in that it is not binding on authorities or individuals. Instead, general advice constitutes general recommendations on the application of legislation, indicating how one can or should act in a particular respect.

In cases where the objective of the provisions is to protect consumer health, the Public Health Agency of Sweden deems general advice to be too weak a tool to achieve the objective, because there is a risk that the aspects in need of protection will not be taken into account to the same high extent. It is therefore necessary to clarify the provisions with mandatory requirements. This applies, inter alia, to the list of contents of the tobacco-free nicotine products, which we consider must be in Swedish for the purposes of consumer health protection. The same considerations concerning mandatory requirements apply to the notification obligation regarding product deficiencies (Section 16, second paragraph of the Act).

One of the tasks of the Public Health Agency of Sweden is to receive product notifications, notifications of product deficiencies, and reports on sales volumes and preferences. The data will be used to enable:

* an overview of products being developed and sold to consumers on the market and supervision of these;
* information to be gathered on suspected harmful effects and on action to be taken against deficient products by manufacturers, importers or distributors; and
* monitoring of the impact of nicotine products on public health.

On this basis, it is important to ensure that the correct information is provided, that it is submitted in the same way by everyone who is required to notify and report in the system and that it is submitted in a specific format. We deem that this can hardly be achieved in any way other than by a binding and generally applicable regulation. For this reason, our assessment is that specifications concerning product notification, the obligation to notify product deficiencies, and the reporting of sales volumes and preferences cannot be regulated by general advice.

The Public Health Agency of Sweden also has the authority to specify the design of the list of contents and health warning. In other words, it may specify, for example, the font to be used on labels, the positioning of the label on the packaging, and the surface areas of packaging that are to be covered by the list of contents and the health warning. The objective of the health warning and the declaration of contents is to warn and inform about the products' harm to human health. The label should therefore be clearly visible and prominent on the packaging in terms of its size. In our assessment, this cannot be ensured by general advice, but requires, instead, a binding and generally applicable regulation.

The Public Health Agency of Sweden also has the authority to stipulate that health warnings must feature in commercial advertisements in the case of certain marketing in accordance with Section 10 of the Act. According to said provision, the health warnings are to feature 'clearly'. Our assessment is that regulations are required in order to specify what is meant by this, and thus also to ensure that the objective of the health warning is achieved in marketing.

## The zero option

In this context, the option of doing nothing would entail refraining entirely from specifying the provisions in question and leaving it to manufacturers, importers, distributors and supervisory bodies to decide how to comply with the Act and Ordinance on tobacco-free nicotine products in the areas in question. As described above with regard to general advice, the rules of the Act and the Ordinance are not sufficiently detailed to achieve the objectives of the regulation.

# Information on those affected by the regulation

## Businesses

### Manufacturers and importers

The draft regulations lay down where and how product notifications, notifications of product deficiencies, and reports on sales volumes and preferences are to be made. The regulations also regulate the labelling of the products and how the health warning shall feature in certain marketing. The draft regulations thus affect, in particular, manufacturers and importers of tobacco-free nicotine products.

### Distributors

Retailers will be affected by the regulations as they are not allowed to supply tobacco-free products to consumers on the market unless they are labelled in accordance with the draft regulations. They are also affected by the provision requiring notification in the event of product deficiencies.

Wholesalers, in the capacity of distributors, will be affected by the obligation to notify product deficiencies.

## Public bodies

### Municipalities

The regulations will affect the municipalities, which are responsible for the supervision of tobacco-free nicotine products at physical sales outlets. This means that municipalities need to be familiar with and apply the new regulations during their supervision.

### Government agencies

With regard to government agencies, the draft regulations will have an impact, in particular, on the Public Health Agency of Sweden, the Swedish Consumer Agency and the county administrative boards.

### Public Health Agency of Sweden

The Public Health Agency of Sweden is responsible for providing supervisory guidance to the municipalities and also has some supervisory responsibilities of its own. In these roles, the Public Health Agency of Sweden will be affected by the specified requirements of the regulations.

### Swedish Consumer Agency

The Swedish Consumer Agency is responsible for regulations concerning the marketing of tobacco-free nicotine products. This responsibility involves both its own supervisory activities and supervisory guidance provided to the municipalities. In these roles, the Swedish Consumer Agency will be affected by the specified requirements concerning health warnings and declarations of content.

### County administrative boards

The county administrative boards are responsible for providing information and advice to the municipalities according to the Act on Tobacco and Similar Products. The Act extends the county administrative boards' responsibility for providing information and advice to the municipalities to include tobacco-free nicotine products. As a result, they are also affected by several of the specified requirements of the regulations.

# Information on the costs and other impacts of the Public Health Agency of Sweden's regulation and a comparison of the impacts of the alternatives to regulation considered

## Economic impact

### Manufacturers and importers

On the business side, the regulation will mainly affect manufacturers and importers. However, the assessment of the Public Health Agency of Sweden is that the regulation will not increase costs significantly; see also section 8.

### Retailers and wholesalers

### The assessment of the Public Health Agency of Sweden is that the draft regulations will not entail any separate costs for retailers and wholesalers. Their obligation to check unit packets arises under the Act and is therefore not a consequence of the draft regulations. In their role as distributors, they are affected by the provision requiring notification of product deficiencies. However, the Public Health Agency of Sweden considers that such notifications will, in most cases, be made by manufacturers and importers, not by retailers and wholesalers. The latter will therefore not have to bear the costs of this.

### Municipalities

Municipalities are responsible for exercising supervision over product notification, labelling, reporting obligations, and provision of health warnings in accordance with Section 10 of the Act. The exercise of supervision by municipalities can be expected to become easier in this area too, as the draft provisions are very similar to those for tobacco and electronic cigarettes. The assessment of the Public Health Agency of Sweden is that the impact will be limited and proportionate, as supervision is financed by fees.

### County administrative boards

The county administrative boards are responsible for providing information and advice to the municipalities on the basis of the regulations. The Public Health Agency of Sweden considers that the burden on the county administrative boards will be modest and manageable within the constraints of their current resources, as they already provide guidance to the municipalities for related products with similar requirements.

### Public Health Agency of Sweden

The Public Health Agency of Sweden is responsible for providing supervisory guidance to the municipalities based on the regulations. In this role, the Public Health Agency of Sweden needs to produce guidance material for the municipalities, which can entail certain costs. The Public Health Agency of Sweden also has its own supervisory responsibilities based on the regulations. However, the supervisory responsibility does not stem from the regulations, but is the result of the Act.

### Other government agencies

The Swedish Consumer Agency is responsible for provisions concerning the marketing of tobacco-free nicotine products – including the provision requiring health warnings to feature in marketing in certain advertisements to consumers as specified in the draft regulations. The Swedish Consumer Agency's responsibility involves both its own supervisory activities and supervisory guidance for municipalities. The draft regulations are expected to entail certain costs with respect to guidance material for the municipalities.

## Environment, gender equality and social impact

### Environmental impact

The draft is not expected to have any environmental impact.

### Social impact including gender equality and health

Tobacco-free nicotine products have previously been unregulated. This may have contributed to the fact that a large percentage – 14.6 per cent – of people in the youngest age group 16-29 years of age, use nicotine snus daily or occasionally, the largest proportion being women. [[3]](#footnote-3)

Percentage of people in the youngest age group 16-29 years of age who use nicotine snus daily or occasionally:

* + Total: 14.6%
	+ Women: 17.7%
	+ Men: 11.7%

The assessment of the Public Health Agency of Sweden is that the specification by the means of regulations will contribute to achieving the objectives of Act, namely of limiting health risks and problems associated with the use of nicotine products, especially among children and young people. The regulations can also be expected to contribute to increased gender equality.

# **Assessment of whether the regulation is in line with** or exceeds Sweden's obligations as a Member State of the European Union

The Public Health Agency of Sweden deems that the draft provisions are in line with the requirements and obligations arising from Sweden's obligations as a European Union member. The proposals are being forwarded to the National Board of Trade Sweden in accordance with Section 6 of the Ordinance (1994:2029) on Technical Rules because they constitute technical rules as set out in Section 2 of the same Ordinance. Said Ordinance aligns with Sweden's international obligations under Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services. The rules in the regulations restrict to a certain extent the free movement of goods in order to protect public health (Article 36 TFEU). The restriction of intra-European trade resulting from the rules has been assessed by the Public Health Agency to be proportionate to what is to be achieved, which is to limit the harmful effects of nicotine among children and young people in particular.

# Enterprises

## Description of the number of enterprises affected, the sectors in which the enterprises operate and the size of the enterprises

The preparatory work for the Act indicates that the market for tobacco-free snus is uncertain. As there has been no specific regulation of tobacco-free nicotine products in the past, there has been no obligation to provide information to the authorities. There is also no access to industry statistics with specific industry codes for tobacco-free nicotine products[[4]](#footnote-4). The enterprises affected by the regulations are mainly manufacturers and importers of tobacco-free nicotine products and, to a lesser extent, distributors, including retailers.

According to the Public Health Agency of Sweden's own calculations, the number of manufacturers and importers are 55 in total, of which 33 are based in Sweden (see Table 1 below, which shows how these are distributed according to company size). It is primarily enterprises that manufacture tobacco snus that also manufacture tobacco-free nicotine products.

In assessing the size of the enterprises, the Public Health Agency of Sweden has worked on the basis of the European Commission Recommendation concerning the definition of micro, small and medium-sized enterprises. In addition, we have added the category of sole traders as follows:

* **Large enterprise**: over 250 employees, annual turnover over SEK 525 million.
* **Medium-sized enterprise**: 50-249 employees, annual turnover SEK 100-525 million.
* **Small enterprise**: 10-49 employees, annual turnover SEK 21-105 million.
* **Micro-enterprise**: 1-9 employees, annual turnover SEK 0-21 million.
* **Sole trader**: 0 employees.

The number of traders in Sweden with physical sales outlets for tobacco-free nicotine products can, in the Public Health Agency of Sweden's assessment, be equated with the number of retail licenses for tobacco products plus the number of registered e-cigarette outlets that do not have a tobacco license (approximately 300). The total number of physical sales outlets supplying tobacco-free nicotine products in 2022 should be around 7800. As of 2022, at least 71 traders in Sweden engage in the retail of tobacco-free nicotine products other than at a physical sales outlet, giving a total of 7871 retailers. With respect to distribution by retailer size, the Public Health Agency of Sweden has access to statistics for 2021; see Table 2.

Table 1. Number of manufacturers and importers broken down by company size, 2022.

|  |  |
| --- | --- |
| Company size | Number of enterprises |
| Sole trader | 11 |
| Micro | 12 |
| Small | 2 |
| Medium-sized | 3 |
| Large | 5 |

Source: The Public Health Agency of Sweden's own research.

Table 2. Number of tobacco product retailers broken down by company size, 2021.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| SNI code/Company size | Sole trader | Micro | Small | Medium-sized | Large |
| 47,260 tobacco shops | 431 | 449 | 22 | 0 | 0 |
| 47,111 stores and supermarkets carrying a wide range, mostly food, beverages and tobacco | 48 | 26 | 14 | 28 | 3 |
| 47,112 grocery stores with wide range | 2293 | 1740 | 1297 | 303 | 26 |
| 47,810 stall and market traders with food, beverages and tobacco | 644 | 120 | 15 | 1 | 0 |
| Total(share) | 3416(46 %) | 2335(31%) | 1348(18%) | 333(4%) | 28(0%) |

Source: Enterprises (FDB) by industry SNI2007 and size class. 2008-2021, [Statistics database SCB](https://www.statistikdatabasen.scb.se/pxweb/sv/ssd/START__NV__NV0101/FDBR07N/), extracted 18 August 2022.

## Description of how much time enterprises may need to spend due to the regulation and what the implications are in terms of the enterprises' administrative costs.

The time required by companies and thus the cost of a product notification is difficult to estimate. Based on the new regulation, the Public Health Agency of Sweden will develop a system for product notification that will be user-friendly and efficient. In calculating the administrative costs, we have used the 'Regulations Calculator' tool on the website of the Swedish Agency for Economic and Regional Growth, and assumed that the task of submitting the notification will be carried out by an administrator with an estimated monthly salary of SEK 33,000. The time required for product notification is then estimated at a maximum of approximately 30 minutes, with an approximate administrative cost of SEK 190 per product.

The reporting requirement regarding sales volumes and preferences of different customer groups for tobacco-free nicotine products will be performed in the same system as for product notification. Since the system has not yet been developed, the calculation of the time needed to meet this requirement is difficult to assess. However, we estimate the time needed for reporting to be a maximum of about 15 minutes, with an approximate administrative cost of SEK 95 per product. The cost recurs annually.

The notification obligation in case of detected deficiencies in products will also be performed in the same system, and the time needed is estimated to be 60 minutes, with an administrative cost of SEK 379. However, this type of notification should not be very frequent.

Training may be needed at the companies concerned regarding the electronic system used for notifications, reports and product deficiency notifications. The intention of the Public Health Agency of Sweden is to design the systems so that they guide the user through the required process.

## Description of any other costs the draft regulation may entail for enterprises and the operational changes enterprises may need to adopt as a result of the draft regulation

Due to the tight timeframe for the preparation of the draft regulations, the Public Health Agency of Sweden has not had the opportunity to conduct interviews with the companies concerned regarding the costs of complying with the requirements for the design of the health warning and the declaration of contents.

The Public Health Agency of Sweden has worked on the same assumptions as made in the preparatory work for the Act.

The Government's analysis of the economic impact of the Act shows that lists of ingredients, nicotine content and health warnings are already provided on many tobacco-free nicotine products. It also appears that the cost of changing the product packaging should be relatively small, even for small enterprises, since the producers receive some support from the authorities in terms of design.[[5]](#footnote-5)

The Public Health Agency of Sweden's investigation of the financial impact of the transposition of the Tobacco Products Directive[[6]](#footnote-6) showed, inter alia, regarding to providing a list of contents on snus, that certain manufacturers in the EU adapted their lists of contents to their customers in Sweden. When the product is purchased by the customer, the label is already translated into Swedish and the cost of this is included in the price. For this reason, it is difficult for the importer to distinguish the cost of designing and affixing labels from other stages of the production chain. The companies stated that the obligation to affix the relevant labelling to the products should, as far as possible, be imposed on the manufacturer.

Based on this, the assessment of the Public Health Agency of Sweden is that neither the costs nor the work associated with the proposed labelling need be particularly high. It can be assumed that the additional costs for amending the voluntary declarations of contents and health warnings will be affected by the surfaces on which the new label will need to be placed.

 Retailers must not supply tobacco-free nicotine products to consumers unless the packaging is properly labelled. This entails a need for this to be checked at some point before the products reach consumers, and for store staff, for example, to set aside time for this task. In this context, it should be mentioned that equivalent requirements are already in place for tobacco products and electronic cigarettes. These tasks may have the consequence that the companies concerned will need to set aside staff to perform them.

## Description of the extent to which the regulation may affect the enterprises' competitive environment

The Public Health Agency of Sweden considers that large and already established companies will find it easier to adapt to the draft regulation compared to small or newly established companies. For example, a larger company can hire an experienced external party to carry out the product notification, which smaller companies are not in the same position to do. In principle, smaller companies, especially start-ups, may face difficulties in establishing themselves on the market.

## Description of how the regulation may impact enterprises in other respects

Because of the labelling requirements, the surface areas on packaging that are available to companies for commercial communication to consumers, for example, will be smaller. The draft regulations specify the size of the contents declaration and health warning. Most tobacco-free nicotine products already have a declaration of contents and a health warning on a voluntary basis (see 8.3 Description of what other costs the proposed regulation entails for enterprises and the operational changes enterprises may need to adopt as a result of the proposed regulation). The regulation will therefore not have a significant impact on companies.

## Description of whether special consideration should be given to small enterprises when drafting the regulations

The objective of the Act is to limit the harmful effects of tobacco-free nicotine products, because nicotine poses a risk to human health. For this reason, the assessment of the Public Health Agency of Sweden is that no special consideration should be given to small companies when designing the rules.

# Assessment as to whether special consideration must be given to the date of entry into force and whether special information initiatives are required

Most of the provisions in the new Act on Tobacco-free Nicotine Products entered into force on 1 August 2022. The labelling provisions will enter into force on 1 January 2023 and the provisions on product notification and reporting obligations on 1 January 2024.

The intention of the Public Health Agency of Sweden is that the parts of the regulations concerning rules that have already entered into force in the Act and Ordinance shall enter into force as soon as possible. However, the draft regulations must first be referred for consultation and also notified to the European Commission. For a period of three months after the notification, the Public Health Agency of Sweden may not decide on the entry into force of the regulations. This means that the regulations will not be in place until 1 January 2023. Our preliminary assessment is that they can be published in spring 2023. The provisions concerning labelling and notification of product deficiencies by the manufacturer, importer or distributor will enter into force on the basis of the dates specified in the Act.

For tobacco-free nicotine products supplied to consumers on the market before 1 January 2024, a product notification shall be made no later than 1 February 2024. The regulations concerning product notification shall therefore enter into force on 1 January 2024. Provisions relating to reporting obligations shall also enter into force on 1 January 2024, according to the date specified in the Act.

Targeted information will be published continuously on the Public Health Agency of Sweden's website during the work.

#  Consultation

The assessment of the Public Health Agency of Sweden is that there is no need for an external reference group, both taking into account the time perspective and that the future regulations are so similar to regulations for related product types. For this reason, we will have no consultation beyond the referral procedure. The new draft regulations and the impact assessment will be referred for consultation to the Swedish Better Regulation Council, the Board of Swedish Industry and Commerce for Better Regulation (NNR), the Swedish Association of Local Authorities and Regions (SKR) and to a selection of relevant authorities, municipalities, companies and other organisations.

# Follow-up and evaluation

The impact of the regulations will be monitored and evaluated on an ongoing basis as they enter into force and are applied. Furthermore, the regulations will be included in the follow-up and evaluation work that is otherwise carried out in accordance with the Public Health Agency of Sweden's plan for such work.

#  Contact persons

**Specify who can be contacted in the event of any questions**

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1. Government bill 2021/22:200 p. 121 et seq. [↑](#footnote-ref-1)
2. DocRef 1998:43 Starting points for regulatory work by the authorities, p. 21 [↑](#footnote-ref-2)
3. Public Health Agency of Sweden, National Public Health Survey – Health on equal terms 2022 [↑](#footnote-ref-3)
4. Government bill 2021/22:200, p.245 [↑](#footnote-ref-4)
5. ibid. p. 251 [↑](#footnote-ref-5)
6. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC. [↑](#footnote-ref-6)