Impact assessment – Amendment to the Public Health Agency of Sweden's regulations on self-monitoring programmes for the sale of tobacco products, electronic cigarettes and refill containers

1 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 (LTN), inter alia, to increase the protection of the health of children and young people. In order to achieve this aim, the Public Health Agency of Sweden proposes regulations that specify how self-monitoring programmes for tobacco-free nicotine products should be designed.

We also propose some clarifications on the design of self-monitoring programmes for tobacco products, electronic cigarettes and refill containers. We also propose some editorial changes.

The proposal means that self-monitoring programmes for tobacco-free nicotine products will be subject to regulation equivalent to that applicable to tobacco products, electronic cigarettes and refill containers.

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; the Public Health Agency of Sweden, the county administrative boards and municipalities.

For retailers wishing to sell tobacco-free nicotine products, the regulations may entail certain administrative costs for developing new, or revising existing, self-monitoring programmes. Retailers of tobacco, electronic cigarettes and refill containers may also be affected in a similar way.

The regulations on self-monitoring programmes are proposed to enter into force on 1 January 2024.

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

2.1 The problem

Tobacco-free nicotine products are products that are largely aimed at young people, which, inter alia, is shown in the marketing and seasoning of the products. At the same time, children and young people are particularly sensitive to the addictive properties of nicotine and need to be protected from the products.

The Act (2022:1257) on Tobacco-free Nicotine Products (LTN) aims to limit the harmful effects of the products by rules on, inter alia, age limits and labelling and marketing of the products. One way to realise that goal is to require traders to have self-monitoring programs with procedures that allow them to comply with the Act's requirements.

Section 18 of the LTN states that: retailers of tobacco-free nicotine products shall exercise self-monitoring of sales and handling in general, and ensure that there is an appropriate self-monitoring programme for the activities. However, the provision does not specify how a self-monitoring programme should be designed. In order to make it clearer what a self-monitoring programme for tobacco-free nicotine products should contain and for a more legally certain application of the rules, the Public Health Agency of Sweden proposes that regulations be developed. The proposal means that self-monitoring programmes for tobacco-free nicotine products will be subject to regulation equivalent to that applicable to tobacco products, electronic cigarettes and refill containers.

2.2 Background and proposals

Requirements for self-monitoring exist in several different activities in the retail trade. The manner in which these checks shall be carried out shall be determined by retailers in a self-monitoring programme. Self-monitoring programmes have been required for the sale of tobacco products since 2010 and for electronic cigarettes and refill containers since 2017. The rules have been supplemented by regulations.

Through the LTN, the Public Health Agency of Sweden received several new tasks as the national supervisory authority. In addition, the Ordinance (2022:1263) on Tobacco-free Nicotine Products (FTN) gave the Public Health Agency of Sweden a number of authorisations to issue regulations in this area, including on the design of self-monitoring programmes. The regulations supplement the provisions of the Act.

2.2.1 Self-monitoring

By exercising self-monitoring, traders of tobacco-free nicotine products shall be able to implement and enforce the requirements of the law and the authorities. Self-monitoring includes the organisation, procedures, measures and the like that provide the trader with the conditions for compliance. Self-monitoring is an ongoing process.

2.2.2 Self-monitoring programme

A self-monitoring programme is a practical document that has several functions.

In the self-monitoring programme, the retailer shall establish the procedures necessary for self-monitoring and for ensuring compliance with these procedures. The self-monitoring programme shall be suitable to the activity in question. A clear and updated self-monitoring program makes it easier for the personnel to do the right thing and it helps the retailer to follow up the activities in a structured way, for example, by finding shortcomings that have resulted something being wrong.

The document shall also be a support in the operations so the retailer can ensure that the activities are carried out in accordance with the Act's requirements; the document is a reminder of what applies. It is also an important document for enabling the retailer to demonstrate to the supervisory authority how self-monitoring works and how the requirements are met.

The self-monitoring programme is also a basis for the supervisory authorities in their supervision and dialogue with retailers.

The procedures in a self-monitoring programme shall describe, among other things, how the retailer ensures that the products are properly labelled and that they are not sold or otherwise provided to a person under the age of 18. For this reason, the document shall describe how the retailer ensures that the age verification is carried out during sales and dispensing – including distance and vending machine sales, if the retailer carries out such activities.

A self-monitoring programme shall be attached to a notification of the sale of tobacco-free nicotine products and electronic cigarettes and refill containers, respectively, for an application for authorisation to sell tobacco products.

Draft regulations on the design of self-monitoring programmes

The Public Health Agency of Sweden considers that the self-monitoring programmes for tobacco-free nicotine products should be regulated in the same way as the self-monitoring programmes for tobacco products, electronic cigarettes and refill containers.

The self-monitoring programme shall include at the minimum procedures for how the retailer ensures that:

- *the products are notified pursuant to the LTN;*
- *the packaging is labelled in the prescribed manner;*

- *age verification and signage regarding the age requirement is carried out in the prescribed manner;*
- *advertising and marketing comply with the requirements of the Act;*
- *personnel are informed and receive the support they need in order to be able to comply with the Act and associated regulations.*

In particular, on age verifications

Children and young people are a particularly vulnerable group to the harmful effects of nicotine. It is also usually during adolescence that a dependence on nicotine is established. For this reason, it is important that the rules ensuring age verification are observed.

It follows from the LTLP and LTN that the age verification requirements are the same for sales from a physical point of sale as for sales by other means, for example through distance sales or sales from vending machines. An age verification check shall be carried out both at the time of sale and dispensing. For sales from physical outlets, these two operations normally coincide, whereas, for example, in the case of distance selling, they take place at different times.

In its monitoring of municipal decisions concerning tobacco products, the Public Health Agency of Sweden has observed that in some cases there is uncertainty on whether an age verification check should be carried out when dispensing. In order to clarify the law's requirements for age verification checks, we therefore propose that it should be stated in the self-monitoring program how the trader ensures that age verification checks are carried out both when selling and dispensing. We consider that self-monitoring programmes for tobacco-free nicotine products need to be regulated in the same way as self-monitoring programmes for tobacco products, electronic cigarettes and refill containers.

Retail trade to Sweden when the trader has no registered office or permanent establishment for business activities in Sweden

When a trader who has no registered office or permanent establishment for business activities in Sweden sells tobacco products, electronic cigarettes or refill containers to Sweden, it is called cross-border distance sales (Chapter 5, Sections 5 and 15 of the LTLP). In the LTN, this concept does not exist, but there is a regulation relating to sales in the same circumstances ("Retail of tobacco-free nicotine products to Sweden in cases where the trader does not have a registered office or permanent establishment for business activities in Sweden."). We use this formulation for tobacco-free nicotine products.

Editorial changes.

Some amendments have been made to the Act on Tobacco and Similar Products which have repercussions on existing regulations and it is therefore proposed to amend the regulations in accordance with the legislative amendments.

3 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 4 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 LTN;
2. the content and design of a declaration of contents in accordance with Section 7 of the LTN;
3. the way a health warning is to be designed and displayed in accordance with Sections 7 and 10 of the LTN;
4. compliance with the reporting obligation in accordance with Section 14 of the LTN;
5. the information collection system in accordance with Section 15 of the LTN;
6. the notification obligation in accordance with Section 16 of the LTN;
7. the design of self-monitoring programmes in accordance with Section 18 of the LTN; and
8. implementation of control purchases in accordance with Section 37 of the LTN.

Under Section 5 of the Ordinance, the Public Health Agency of Sweden also has the authority to issue regulations on the enforcement of the Act and Ordinance.

3.1 Entry into force and transitional provisions

The Swedish Public Health Agency of Sweden's intention is that the regulations on self-monitoring programmes will come into effect on 1 January 2024.

We do not see any need for transitional provisions.

4 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. Sometimes the authorities leave it to the market operators to take action themselves to achieve the objective.

In other words, the authority to issue regulations does not imply an obligation to do so[1]. If the objective can be achieved in a less intrusive manner, it should not be regulated by regulations. The authorities have to consider both whether the costs

[1] DocRef 1998:43 Starting points for regulatory work by the authorities, p. 21

incurred by the regulations are acceptable and what any other alternative solutions will cost.

We have deemed that regulations are needed to regulate the content of self-monitoring programmes.

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

4.1 General advice

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

The purpose of the provisions on self-monitoring programmes is to protect the health of consumers and to make it easier for retailers to carry out their activities in accordance with the provisions. For this reason, we consider that general advice is too weak a measure to achieve the purpose, and that the provisions should be specified with mandatory requirements. The rules we propose are a minimum level for what a self-monitoring program should contain.

5 Information on those affected by the regulation

5.1 Businesses

5.1.1 Retailers, distributors, dispensers

The proposed regulation concerns retailers who sell tobacco-free nicotine products. For them, the self-monitoring programme is included as part of the notification of sales, but it is also an everyday working tool to ensure that the activities comply with the requirements of the Act.

The regulation also concerns retailers who already sell tobacco products, electronic cigarettes and refill containers. They may need to review their self-monitoring programmes to ensure that their activities comply with the requirements of the Act through the clarifications proposed in the regulations.

Retailers wishing to engage in distance trading may need to agree on new services with subcontractors and dispensing points in order to ensure that the activities comply with the requirements of the Act through the clarifications made in the regulations.

5.2 Public bodies

5.2.1 Municipalities

The self-monitoring programme is an essential part of the notification of the sale of tobacco-free nicotine products. The regulations will thus affect the municipalities in the notification procedure. The regulations will also affect the supervisory activities of municipalities since the self-monitoring programme is also a basis for the supervision of the trade that municipalities shall conduct.

5.2.2 Government agencies

On the state side, the proposed regulations will primarily affect the Public Health Agency of Sweden and the county administrative boards.

5.2.3 Public Health Agency of Sweden

Retailers who have no registered office or permanent establishment for business activities in Sweden must submit their notification of the sale of tobacco-free nicotine products to the Public Health Agency of Sweden. Since the self-monitoring programme is included in the notification of sales, the regulations will affect the way the Public Health Agency of Sweden will handle these traders' notifications and the Public Health Agency of Sweden's supervisory work, since the self-monitoring programme is also a basis for the supervision of the trade that the Public Health Agency of Sweden shall conduct.

The Public Health Agency of Sweden will also be affected by the regulations in its role as responsible body for providing supervisory guidance to the municipalities.

5.2.4 County administrative boards

The County Administrative Board shall monitor the activities of the municipalities and assist the municipalities with information and advice. They will thus be affected by the regulations in this role.

6 Information on the costs and other impacts of the Public Health Agency of Sweden's regulation and an impact comparison of the alternatives to regulation considered

6.1 Economic impact

6.1.1 Retailers

The Public Health Agency of Sweden considers that the draft regulations will not entail any specific costs for retailers (in addition to administrative costs examined in more detail in section 8.2). The consequences for retailers already follow from the requirements of the LTN.

For the retailers that do not have a registered office or permanent establishment for business activities in Sweden, however, the language requirement in the regulation entails a cost for translation of the self-monitoring programme into Swedish or English.

The Public Health Agency of Sweden has clarified in the regulations that it must be clear from the self-monitoring programme how the retailer ensures that age verification checks are carried out both when selling and dispensing. By this clarification, retailers engaged in distance trading can be assumed to have slightly more expensive distribution costs, if a greater workload for age verification is placed on their subcontractors. Agreements concluded with subcontractors may need to be revised and new agreements may need to be drawn up.

In addition, the Public Health Agency of Sweden considers that the regulations will make it easier for retailers and will be a tool for organising the activities and developing procedures for a well-functioning self-monitoring process. A review of decisions submitted by the municipalities to the Public Health Agency of Sweden shows that the single most common reason for refusal when applying for authorisation to sell tobacco products is deficiencies in the self-monitoring programmes.

6.1.2 Municipalities

Municipalities have a responsibility to supervise the trade under the LTN, and the self-monitoring programme is a basis for that supervision. The regulations on self-monitoring programmes can thus facilitate the supervision and also be a basis for dialogue. More areas of supervision may increase the workload and costs of supervision by municipalities – and thus the amount charged for fees. However, these consequences already follow from the LTN and not from the regulations per se.

Municipalities may also need to provide information and other support material on self-monitoring programmes, for example, on their websites. We consider the costs to be limited.

6.1.3 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 deems that the burden on the county administrative boards will be moderate and manageable within their current resources, as they already assist municipalities on self-monitoring programmes for the sale of tobacco, electronic cigarettes and refill containers.

6.1.4 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.

6.2 Environment, gender equality and social impact

6.2.1 Environmental impact

The draft is not expected to have any environmental impact.

6.2.2 Social impact including gender equality and health

The self-monitoring of retailers is to ensure compliance with requirements such as labelling, age verification and marketing. In doing so, self-monitoring programmes help, above all, to increase the protection of children's and young people's health. Since there are a large number of young women using the products, the Public Health Agency of Sweden considers that the proposed regulations, with the aim of ensuring the Act's requirements for labelling, age verification and marketing, can also contribute to increased gender equality.

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

Self-monitoring and self-monitoring programmes for trading tobacco and e-cigarettes do not fall under any harmonised rules of EU law. In addition, self-monitoring programmes for tobacco-free nicotine products are not covered by the harmonised EU rules. Member States are thus free to legislate in the field of tobacco-free nicotine products, provided, inter alia, that the Treaty on the Functioning of the European Union's general rules on the four freedoms are[2] respected. The Public Health Agency of Sweden considers that the proposed regulations are not discriminatory. However, they constitute a certain restriction on the sale of goods. However, this restriction is deemed to be proportionate to what is to be achieved by the regulation, that is to say, to protect human health, in particular the health of children and young people.

The Public Health Agency of Sweden considers these measures to be necessary and proportionate.

Member States are required to notify the Commission of new draft regulations containing requirements on the characteristics of a product, according to *Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services*. The Public Health Agency of Sweden considers that the regulations are technical regulations

[2] Free movement of goods, services, persons, and capital.

that must be notified in accordance with the Directive, since they contain a language requirement that is an indirect requirement in order to comply with the obligation regarding self-monitoring programmes, and self-monitoring programmes are a prerequisite for carrying out the activity.

Member States shall also notify the European Commission of new requirements, or changes to existing requirements, relating to service activities, according to *Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market*. The Public Health Agency of Sweden considers that the proposed regulation is of such a nature that it must be notified under the Services Directive because it contains requirements for service activities.

8. Enterprises

8.1 How many enterprises are affected, which sectors do they operate in and how large are they

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 2023 should be around 7,800. In 2022, at least 71 retailers in Sweden engaged in the retail trade of tobacco-free nicotine products other than at a physical point of sale, giving a total of 7,871 retailers. With respect to distribution by retailer size, the Public Health Agency of Sweden has access to statistics for 2022; see Table 1.

Table 1. Number of tobacco product retailers broken down by company size, 2022.

SNI code/Company size	Sole trader	Micro	Small	Medium-sized	Large
47,260 tobacco shops	429	430	25	0	0
47,111 stores and supermarkets carrying a wide range, mostly food, beverages and tobacco	68	22	15	28	3
47,112 grocery stores with wide range	2,293	1,707	1,303	314	29
47,810 stall and market traders with food, beverages and tobacco	640	142	9	1	0
Total (share)	3,430 (46%)	2,301 (31%)	1,352 (18%)	343 (5%)	32 (0 %)

Source: Enterprises (FDB) by industry SNI2007 and size class. 2008-2022, Statistics database SCB, extracted on 2 May 2023.

8.2 Description of how much time the enterprises may need to adjust to the regulation and what the implications are in terms of the enterprises' administrative costs

The government estimates that the cost of a notification of the sale of tobacco-free nicotine products, including self-monitoring programmes, corresponds to approximately one working day (govt. bill 2021/22:200 p. 254). The Public Health Agency of Sweden concludes that the cost of the self-monitoring programme is the largest cost item in such a estimate, since the notification itself is usually made in a form format (which can be assumed to take an hour). With an administrative cost of SEK 379 per hour, the cost of developing a self-monitoring programme could then be estimated at SEK 2,653 (7 x SEK 379).

For retailers who already trade in tobacco products, electronic cigarettes and refill containers or tobacco-free nicotine products, and who need to revise their own self-monitoring programmes after the clarifications in the regulations, the Public Health Agency of Sweden estimates the work required to be three hours. With an administrative cost of SEK 379 per hour, the cost could then be calculated at SEK 1,137 (3 x 379 SEK).

The self-monitoring programme is a living document that needs to be adapted and updated in line with legal developments and other circumstances affecting the business. However, the administrative burden of this is deemed to be moderate and to be around a couple of hours per year. The annual cost can thus be estimated at SEK 758 (2 x SEK 379).

There are a number of factors that can reduce costs according to the above calculations, such as the fact that the retailer has already developed procedures in a self-monitoring programme for the sale of tobacco or electronic cigarettes and refill containers. Or that the retailer is supported by a trade organisation that assists its members in developing models for self-monitoring programmes.

8.3 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

The regulation means that traders need to create procedures in their day-to-day operations in terms of control of labelling, age requirements and marketing etc. They also need to train their personnel and familiarise the personnel with the self-monitoring programme. This may entail some costs. However, the cost of this is considered moderate, especially if the trader has already developed procedures in a self-monitoring programme for the sale of tobacco or electronic cigarettes and refill containers.

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

The proposed regulations will facilitate and serve as a tool for retailers to organise their activities and develop procedures for a functioning self-monitoring process, whether it a is one-man company or a large grocery retail chain. The regulations will thus not adversely affect the conditions of competition, regardless of company size.

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

Without a self-monitoring programme that meets the requirements of the regulations, the trader may be prohibited from selling tobacco-free nicotine products. The regulations, in many cases, can be assumed to be the starting point for such an examination.

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

A self-monitoring programme shall be appropriate for the activities for which it has been developed. This means that it should be adapted to, for example, the size of the business. Usually, a more detailed self-monitoring programme is needed for a larger business (for example, with more employees and more products) than for a small one. However, the examination of whether the self-monitoring programme is appropriate for the activities for which it has been developed is part of the audit and supervisory activities and does not justify different rules for smaller companies.

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

The Act on Tobacco-free Nicotine Products – including the provision on self-monitoring programmes – entered into force on 1 August 2022.

The Public Health Agency of Sweden's intention is that the regulations 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. Based on this, the Public Health Agency of Sweden's intention is that the regulations will apply with effect from 1 January 2024.

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

10. Consultation

The Public Health Agency of Sweden has considered that there is no need for an external reference group, as the upcoming regulations are very similar to those for closely related product types. For this reason, we will have no consultation beyond the comments 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.

11. 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.

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