

New regulations on snus, snus-like products and chewing tobacco

1. Summary

As of 1 January 2023, the Food Act (2006:804) treats snus-like products as food, just like snus and chewing tobacco. Snus-like products means products that are equivalent to snus in the way they are used. Snus is a tobacco product. Snus-like products are tobacco-free products, with or without nicotine.

The Swedish National Food Agency's proposal is that snus-like products – with the exception of the provisions on additives, flavourings and novel foods – shall be covered by the provisions that currently apply to snus and chewing tobacco under the Swedish National Food Agency's regulations (LIVSFS 2012:6) on snus and chewing tobacco.

The Swedish National Food Agency is also proposing that a list of all ingredients included in the product shall be provided on the packaging of nicotine-free snus-like products, known as a list of ingredients. The reason for this is that tobacco-free nicotine products pursuant to Section 7 of the Act (2022:1257) on tobacco-free nicotine products must have a list of ingredients.¹ Snus-like products containing nicotine are a tobacco-free nicotine product. The Swedish National Food Agency deems there to be no reason for any distinction to be made between snus-like products containing nicotine and those that do not contain nicotine. However, in order to prevent tobacco-free nicotine products from being subject to double regulation, snus-like products containing nicotine are exempted from the requirement for a list of ingredients proposed in the regulations.

Furthermore, the Swedish National Food Agency is proposing that the addition of titanium dioxide (E 171) to snus or chewing tobacco shall no longer be permitted. However, snus-like products are not covered by the proposed provisions on additives and are therefore not subject to this restriction. The Swedish National Food Agency is proposing that the addition of titanium dioxide (E 171) to snus or chewing tobacco shall no longer be permitted because – due to the risks to human health – use of titanium dioxide in food has not been permitted since August 2022. The Swedish National Food Agency finds no reason to make a different assessment for snus or chewing tobacco.

¹ See also Section 11 of the Ordinance (2022:1263) on tobacco-free nicotine products.

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To make things easier for businesses and control authorities, the Swedish National Food Agency is also proposing that provisions relating to snus, snus-like products and chewing tobacco are to be brought together into the same regulations. The fact that new regulations are therefore being introduced does not in itself entail any substantive change for operations currently manufacturing snus and chewing tobacco. However, some linguistic and editorial amendments are being proposed in relation to the current regulations, LIVSFS 2012:6. A new introductory provision is also being proposed, stipulating that snus, snus-like products and chewing tobacco, in addition to the ingredients specifically named in the regulations and with the exception of tobacco and nicotine, may only contain ingredients that do not present a risk to human health.

The draft regulations will replace the current regulations on snus and chewing tobacco, and therefore the regulations LIVSFS 2012:6 are to be repealed when the draft regulations enter into force. The new regulations are to enter into force on 1 January 2024.

To make things easier for operators, certain transitional provisions are also being proposed. To give operators manufacturing snus-like products time to become aware of the provisions and subsequently to notify their operations, the provisions stipulating that manufacturing facilities for snus-like products must be notified to the control authority for registration shall not apply until 1 July 2024. To make things easier for businesses, packaging of snus-like products that does not meet the labelling requirements proposed in the regulations may be made available to consumers until stocks are exhausted, provided that they have been placed on the market or labelled before 1 July 2024. Furthermore, snus or chewing tobacco containing titanium dioxide (E 171) may be made available to consumers on the Swedish market until stocks are exhausted, provided that they have been placed on the market or packaged before 1 July 2024.

2. Background

In Sweden, provisions on snus and chewing tobacco are found in the Act (2018:2088) on tobacco and similar products and the Ordinance (2019:223) on tobacco and similar products, as well as in the Food Act and the Food Ordinance (2006:813). Tobacco products are not food, but certain elements of production involve risks that can be compared to those present in food production. Sweden has therefore deemed it appropriate for snus and chewing tobacco to be subject to the hygiene aspects of the Food Act provisions. In legal terms, this has been done by making the provisions of the Food Act generally applicable to these products as well. Section 3 of the Food Act states that snus and chewing tobacco, for the purposes of the Food Act, are treated as food.

With regard to tobacco-free products intended to be used in the same way as snus, the Swedish National Food Agency deemed such products, in a statement from 2019², not to be food. This assessment of the Swedish National Food Agency applies regardless of whether the product contains nicotine or not. The position is based on the fact that food is generally considered to be substances, ingredients, raw materials, additives and nutrients ingested through the gastrointestinal tract.³ The Swedish National Food Agency's assessment of tobacco-free snus was made on the basis that the product is intended to be

² Ref. No 2019/00929.

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placed under the lip and spit out again and that the main uptake of the product's substances, e.g. nicotine, takes place through the mucous membranes of the mouth. The Swedish National Food Agency is therefore of the view that the intention is not for such products to be ingested. This view is not changed by the fact that users of the products may unintentionally swallow down some substances that go into digestive system.

As of 1 January 2023, snus-like products are also treated as food under the Food Act. In Bill 2021/22:200, Stricter rules for new nicotine products⁴, the Government states the following.

Tobacco-free snus is placed in the mouth and secretes substances that are absorbed by the body through the mucous membranes of the mouth as well as through the gastrointestinal tract. The consequences of contamination or the use of dangerous flavourings or additives may reasonably cause as much harm to the user of these products as to the user of tobacco snus. This applies regardless of whether the product contains nicotine or not. In the Government's view, there is therefore no reason, from a health perspective, to impose lower requirements on these products than on tobacco snus. Consumers should also be entitled to the same information about these products. In addition, as similar products are concerned, there are also some similarities in the manufacturing process and the use of flavourings, etc. There is therefore good reason to make use of the expertise already present at the authorities responsible for food controls of snus and chewing tobacco.

Overall, the Government considers that tobacco-free snus, both with and without nicotine, should be treated as food and thus be subject to food regulation.

Snus-like products means tobacco-free products that are equivalent to snus in the way they are used. Tobacco-free nicotine products as well as tobacco-free nicotine-free products can therefore be snus-like products. The decisive factor for whether or not a product is a snus-like product or not is thus whether the product is used in a way that is equivalent to the use of snus. Snus is usually used by placing the product in the mouth, inside the lip but outside the teeth. The ingredients of the product are mainly absorbed into the mouth, although some of them end up in the gastrointestinal tract. Products used in this way are therefore used in a way that is equivalent to snus.⁵

However, there are some exceptions. Snus-like products are not products that fall under the provisions of:

the Narcotic Drugs (Punishments) Act (1968:64):

the Act (1999:42) Prohibiting Products that are Harmful to Health;

³ Food is defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Article 2 states that food is any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

⁴ Government Bill 2021/22:200 p. 221.

⁵ See Government Bill 2021/22:200 p. 222.

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the Medicinal Products Act (2015:315); or
the Act (2021:600) Laying Down Supplementary Provisions to the EU Medical Devices Regulation.⁶

Snus-like products containing nicotine are also regulated by the Act on Tobacco-free Nicotine Products. The Act contains provisions on product notification, product requirements, sales and marketing of tobacco-free nicotine products. The legislation aims to limit the health risks and nuisance associated with the use of tobacco-free nicotine products. The Act is supplemented by the Ordinance (2022:1263) on tobacco-free nicotine products and future regulations issued by the Public Health Agency.

3. Essence of the proposals

Section 1 Scope

Section 1 of the regulations sets out the scope of the regulations. It is stated that the regulations contain provisions on snus, snus-like products and chewing tobacco intended to be made available to consumers on the Swedish market. This section also indicates that provisions concerning the products covered by the draft regulations can also be found in the Act on Tobacco and Similar Products and the Act on Tobacco-free Nicotine Products.

A similar provision is found in Section 1 of LIVSFS 2012:6. The Swedish National Food Agency is proposing that snus-like products shall be covered by the regulations, and is updating the provision with references to the new laws in this area.

Section 2 Terms and definitions

Section 2 clarifies that the term *food additive* is as defined in Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives and that the terms *flavouring*, *smoke flavouring* and *food with flavouring properties* are as defined in Regulation (EC) No 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC. Furthermore, it is stated that the term *materials and articles intended to come into contact with food* means materials and articles covered by Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

A corresponding provision is found in Section 2 of LIVSFS 2012:6. The Swedish National Food Agency is proposing to add a definition of materials and articles intended to come into contact with food in the provision.

Section 3 Ingredients

Section 3 stipulates that snus, snus-like products and chewing tobacco, in addition to the ingredients specifically named in the regulations and with the exception of tobacco and nicotine, may not contain ingredients that present a risk to human health. This section is new and has no equivalent in the current regulations on snus and chewing tobacco. The

⁶ See Government Bill 2021/22:200 p. 289 et seq.

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purpose of the provision is to establish a kind of framework for the ingredients that snus, snus-like products and chewing tobacco may contain. A comparison can be made with food regulation under EU food law, i.e. Regulation (EC) No 178/2002 of the European Parliament and of the Council⁷, stipulating that food must be safe, i.e. not harmful to health or unfit for human consumption.

Section 4 Additives, including the Annex to the regulations

Section 4 sets out provisions on food additives that may be included in snus and chewing tobacco. Which food additives these are and the conditions for their use are set out in the Annex to the draft regulations. It is also stipulated that food additives shall be used for the functions set out in Regulation (EC) No 1333/2008 and shall comply with the specifications applicable to the food additive in question. A corresponding provision is currently found in Section 3 of LIVSFS 2012:6. The Swedish National Food Agency is only proposing some linguistic and editorial amendments.

As regards the Annex to the regulations, an amendment with respect to the substance titanium dioxide is being proposed. Under the current regulations, titanium dioxide (E 171) may be included in snus and chewing tobacco.⁸ However, the use of titanium dioxide as an additive in food has not been permitted since 7 August 2022.

Titanium dioxide (E 171) is a white colourant that had been authorised as a food additive. However, in 2021 the European Food Safety Authority (EFSA) reassessed this, stating that titanium dioxide was not safe to use as an additive in food. EFSA regularly evaluates EU-authorised food additives to assess whether they are safe to use. The background to the evaluation of titanium dioxide was new data on very small particles in the additive, known as nanoparticles. Following EFSA's assessment, the Commission decided in 2022 that titanium dioxide should no longer be authorised as a food additive.

In view of EFSA's assessment that titanium dioxide is not safe to use as a food additive, the Swedish National Food Agency considers that the substance titanium dioxide should also not be used in snus and chewing tobacco. The Swedish National Food Agency is therefore proposing not to include titanium dioxide in the list of permitted food additives in the Annex to the draft regulations.

However, in order to facilitate adaptation to the draft regulations for businesses, it is reasonable for them to have a certain amount of time to sell off the products that are already on the market, for example. The proposal is therefore that snus or chewing tobacco containing titanium dioxide (E 171) may be made available to consumers on the Swedish market until stocks are exhausted, provided that they have been placed on the market or packaged before 1 July 2024.

Section 10 of the current regulations, LIVSFS 2012:4, enables the Swedish National Food Agency to examine issues concerning the authorisation of additional food additives and conditions for the use of food additives in snus and chewing tobacco. The Swedish National Food Agency is proposing that this provision be removed. According to the

⁷ Article 14 of Regulation (EC) No 178/2002 of the European Parliament and of the Council.

⁸ See Annex to LIVSFS 2012:6.

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Swedish National Food Agency, requests from operators to use other additives or modified conditions for the use of additives should, in future, be treated as a proposal to amend the regulations. The possibility for operators to point out the need for, or to submit requests for, amendments to the regulations is therefore not being removed. Only the Agency's handling of these requests is being changed and clarified.

The provisions on additives do not cover snus-like products. The Swedish National Food Agency currently lacks sufficient knowledge of the additives contained in the products in question and scientific evidence to regulate the use of additives in snus-like products. This also applies to titanium dioxide (E 171). The Swedish National Food Agency may therefore have reason to revisit this issue.

Section 5 Flavourings

Under Section 5, only flavourings, including smoke flavourings, and foods with flavouring properties that may be used in foods, may be included in snus and chewing tobacco to give or alter its smell or taste. A corresponding provision is found in Section 5 of LIVSFS 2012:6. The Swedish National Food Agency is proposing some linguistic and editorial adjustments to the provision.

The provisions on flavourings do not cover snus-like products. The Swedish National Food Agency currently lacks sufficient knowledge of the flavourings contained in the products in question and scientific evidence to regulate the use of flavourings in snus-like products. The Swedish National Food Agency may therefore have reason to revisit this issue.

Section 6 Novel foods

Section 6 stipulates that only novel foods authorised for use in the EU may be included in snus, snus-like products and chewing tobacco. A corresponding provision is found in Section 6 of LIVSFS 2012:6. The Swedish National Food Agency is proposing some linguistic and editorial adjustments to the provision.

The provisions on novel foods do not cover snus-like products. The Swedish National Food Agency currently lacks sufficient knowledge of what is contained in the products in question and scientific evidence to regulate the use of novel foods in snus-like products. The Swedish National Food Agency may therefore have reason to revisit this issue.

Section 7 Water

Section 7 stipulates that the water used in the production and preparation of snus, snus-like products and chewing tobacco shall comply with the requirements laid down in the Swedish National Food Agency's regulations (LIVSFS 2022:12) on drinking water. A corresponding provision is found in Section 7 of LIVSFS 2012:6.

The Swedish National Food Agency is proposing that snus-like products shall be covered by the provision because it is reasonable for the same requirements to be imposed on the water used in the production and preparation of snus-like products as are imposed on the manufacture and preparation of snus and chewing tobacco. The Swedish National Food

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Agency has also updated the reference to the regulations on drinking water to those that entered into force on 1 January 2023.

Section 8 Contaminants

Contaminants are substances which have an adverse effect on health and which have not been intentionally added to a product but are present in the product as a result of e.g. production and manufacture, or as a result of any environmental pollution. Section 8 specifies the maximum levels for certain substances such as lead, aflatoxins, benzo[a]pyrene and tobacco-specific nitrosamines. A corresponding provision is found in Section 13 of LIVSFS 2012:6.

The Swedish National Food Agency is proposing that snus-like products shall be covered by the provision. However, snus-like products do not contain tobacco and therefore cannot contain tobacco-specific nitrosamines at levels which justify their inclusion in the provision. It is therefore being proposed that this part of the provision apply only to snus and chewing tobacco.

Section 9 Hygiene

Section 9 lists the provisions of Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs that an operator engaged in the manufacture of snus, snus-like products or chewing tobacco must comply with, where necessary, to maintain satisfactory hygiene. A corresponding provision is found in Section 10 of LIVSFS 2012:6.

The Swedish National Food Agency is proposing that the manufacture of snus-like products should be covered by the provision because it is reasonable to impose the same requirements on the manufacture of snus-like products as those imposed on the manufacture of snus and chewing tobacco. Some linguistic and editorial adjustments are also being proposed.

Section 10 Hazard analysis and critical control points

Section 10 of the regulations sets out requirements for operators engaged in the manufacture of snus, snus-like products or chewing tobacco, inter alia, to establish procedures based on the HACCP principles and to ensure that certain documentation is up to date and retained. A corresponding provision is found in Section 11 of LIVSFS 2012:6.

The Swedish National Food Agency is proposing that the manufacture of snus-like products shall be covered by the provision, and in other respects is making certain linguistic and editorial adjustments.

Section 11 Materials and articles in contact with snus, snus-like products and chewing tobacco

Section 11 stipulates that materials and articles that come into contact with snus, snus-like products and chewing tobacco shall meet the requirements for the composition and properties of materials and articles intended to come into contact with food. This means that materials and articles that come into contact with snus, snus-like products and

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chewing tobacco shall, among other things, comply with Regulation (EC) No 1935/2004 and Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food. A corresponding provision is found in Section 14 of LIVSFS 2012:6.

The Swedish National Food Agency is proposing that snus-like products shall be covered by the provision.

Sections 12-15 Information on packaging

Section 12 stipulates that certain information such as net quantity, date of manufacture, storage instructions and address shall be provided on packaging of snus, snus-like products and chewing tobacco supplied directly to the consumer. A corresponding provision is found in Section 9 of LIVSFS 2012:6.

The Swedish National Food Agency is proposing that snus-like products shall be covered by the provision, and is making certain linguistic and editorial amendments. The option of the manufacturer, packer or seller to provide a website instead of their address or telephone number in Sweden is also being proposed.

Section 13 stipulates that the designation of the product shall be provided on packaging of snus or chewing tobacco supplied directly to the consumer; in other words *snus* or *chewing tobacco*. A corresponding provision is currently found in Section 9 of LIVSFS 2012:6. With some editorial adjustments, the provision is proposed to be transferred to the new section without changes.

The Swedish National Food Agency is not therefore proposing that the provision should also apply to packaging of snus-like products. This is because snus-like products cover a wide variety of different products that differ from one another. In the Swedish National Food Agency's view, it could therefore be perceived as misleading if the same designation is used for all these products, and the designation may not meet consumers' expectations in terms of being sufficiently descriptive. The Swedish National Food Agency may have reason to revisit this issue.

The draft Section 14 has no equivalent in LIVSFS 2012:6. The provision states that a list of ingredients shall be provided on packages of nicotine-free snus-like products supplied directly to the consumer. The list of ingredients shall indicate all ingredients included in the product, in descending order of weight.

Government Bill 2021/22:200 states that consumers of tobacco-free nicotine products should also be able to easily see what the product they are buying contains. Overall, the Government is of the view that provisions on lists of ingredients equivalent to those that already apply to e-cigarettes and refill containers should also be introduced for tobacco-free nicotine products. The information to be provided in this respect is factual in nature and the provisions do not unnecessarily deprive the trader of the possibility of providing their own text on the packaging. The Government's assessment is also that equivalent requirements for lists of ingredients can be imposed on tobacco-free nicotine products without giving the impression that the products are food.⁹

⁹ Government Bill 2021/22:200 p. 152 et seq.

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In the Swedish National Food Agency's view, the considerations that led to packaging of tobacco-free nicotine products pursuant to Section 7 of the Act (2022:1257) on tobacco-free nicotine products having to be provided with a list of ingredients also apply to other snus-like products, i.e. nicotine-free snus-like products. The Swedish National Food Agency is therefore proposing that a list of ingredients shall be provided on packaging of nicotine-free snus-like products supplied directly to the consumer. The list of ingredients is to contain the information that is to be provided on packaging of tobacco-free nicotine products in accordance with Section 11 of the Ordinance (2022:1263) on tobacco-free nicotine products, namely a list of all ingredients included in the product in descending order of weight.

Section 15 sets out how information on the packaging must be designed with regard to, inter alia, other languages, legibility, visibility and permanence. The provision is found in Section 8 of LIVSFS 2012:6.

The Swedish National Food Agency is proposing that snus-like products shall be covered by the provision, is making certain linguistic and editorial adjustments to the provision, and is clarifying that the labelling information shall normally be in Swedish.

In order to facilitate the adaptation of businesses to the draft regulations, it is reasonable for them to have some time to sell off the products that are already on the market, for example, even though the packaging does not meet the requirements of the draft regulations. For this reason, the Swedish National Food Agency is proposing a transitional rule for packaging of snus-like products. Packages of snus-like products that do not comply with the provisions of Sections 12, 14 and 15 are proposed to be made available to consumers on the Swedish market until stocks are exhausted, provided that they have been placed on the market or labelled before 1 July 2024.

Section 16 Traceability

Section 16 stipulates that snus, snus-like products and chewing tobacco, as well as the ingredients included therein, shall be traceable at all stages of the production, processing and distribution chain. Operators engaged in the manufacture of snus, snus-like products or chewing tobacco shall have systems and procedures in place to identify the actors from which they obtained ingredients intended for or likely to be included in snus, snus-like products or chewing tobacco as well as all actors who have obtained their products, but not consumers. A similar provision is found in Section 12 of LIVSFS 2012:6.

The Swedish National Food Agency is proposing that also the manufacture of snus-like products shall be covered by the provision, and is clarifying what the provision means in practice.

Sections 17-19 Registration

Section 17 stipulates that operators engaged in the manufacture of snus, snus-like products or chewing tobacco shall notify their manufacturing facilities in writing so that they can be registered. Notification shall be made to the authority that is competent under Section 23 of the Food Ordinance to register the facilities. Section 18 sets out the information that a notification for registration must contain, as well as an obligation for

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the operator to provide, at the authority's request, the additional information necessary for handling the notification. Section 19 states that operations at a facility to be notified for registration may commence once the authority has registered the facility. However, operations may commence two weeks after the notification has been received by the authority if the authority still has not yet registered the facility. As of 1 January 2023, corresponding provisions on registration are found in Sections 9a to c of LIVSFS 2012:6.

The Swedish National Food Agency is proposing that snus-like products should be covered by the regulations and, in other respects is only making some editorial changes. Notification for registration is important in order for the control authorities to know that the manufacturing facility exists and thus be able to exercise effective, risk-based control.

One consequence of the proposed provisions on registration and the notification obligation for operators engaged in the manufacture of snus-like products is that decisions imposing fines may be required. Operators who commence operations requiring registrations, without having first notified the facility for registration, shall be subject to a fine in accordance with Section 39c of the Food Ordinance. A fine shall be imposed on anyone who commences operations without having made a notification to the control authority in order to register the facilities for which they are responsible. It is therefore important for operators to have the time and opportunity to become aware of the provisions and then notify operations to the control authority for registration before the operations commence. A transitional period is therefore being proposed between the adoption of the provisions and their application.

Section 20 Obligation to provide information

Section 20 stipulates that operators engaged in the manufacture of snus, snus-like products or chewing tobacco shall ensure that the authority has up-to-date information on the registered facilities, including by notifying the authority of significant changes to their operations and of closures of existing facilities. As of 1 January 2023, a corresponding provision is found in Section 9d of LIVSFS 2012:6.

The Swedish National Food Agency is proposing that the manufacture of snus-like products shall be covered by the provision, and in other respects is making some editorial amendments. Effective, risk-based control is only possible if the control authority has up-to-date information on the registered facilities.

Entry into force and transitional provisions

The proposed date of entry into force for the regulations is 1 January 2024. The current regulations on snus and chewing tobacco, LIVSFS 2012:6, will be repealed on the same date. To make things easier for operators, certain transitional provisions are also being proposed.

To give operators manufacturing snus-like products time to become aware of the registration provisions, and then to notify their operations for registration, the Swedish National Food Agency is proposing that the provisions on registration in Sections 17-19 shall not apply until 1 July 2024. Operators who have commenced operations requiring registration before 1 July 2024 will not have any practical opportunity to comply with the requirement in Section 19 after 1 July 2024. So as not to create provisions that some

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operators will have no practical opportunity to comply with, the Swedish National Food Agency is also proposing that the provision in Section 19 should not apply to such operations commenced before 1 July 2024.

To make it easier for operators to adapt to the draft regulations, it is also being proposed that packages of snus-like products that do not comply with the provisions of Sections 12, 14 and 15 may be made available to consumers on the Swedish market until stocks are exhausted, provided that they have been placed on the market or labelled before 1 July 2024. The transitional provision thus allows these operators to use packaging material which is not labelled in accordance with the provisions of the regulations for a limited period of time.

Furthermore, snus or chewing tobacco containing titanium dioxide (E 171) may be made available to consumers on the Swedish market until stocks are exhausted, provided that they have been placed on the market or packaged before 1 July 2024. Operators are thus given a certain amount of time to adapt the products in accordance with the regulations.

4. Alternative solutions for what the Swedish National Food Agency wants to achieve

As of 1 January 2023, the Food Act treats snus-like products as food, just like snus and chewing tobacco. Snus-like products means products that are equivalent to snus in the way they are used. The Swedish National Food Agency is proposing, by virtue of the authorisations conferred on it in the Food Ordinance, that snus-like products shall be covered by those parts of the provisions that currently apply to snus and chewing tobacco, see LIVSFS 2012:6. This includes provisions on ingredients, contaminants, hygiene, labelling on packaging, and traceability. Manufacturing facilities shall also be notified in order to be registered by the competent control authority.

An alternative to these draft regulations would be to leave snus-like products unregulated. However, it is the Swedish National Food Agency's view that there is no reason, from the perspective of protecting human health, to impose lower requirements on snus-like products compared to those imposed on snus. Given the purpose of the Food Act – to ensure a high level of protection for human health and consumer interests – there is no reason to make a distinction for snus-like products and, particularly for snus.

These draft regulations also include provisions requiring a list of ingredients to be provided on the packaging of nicotine-free snus-like products. The alternative would have been not to impose this requirement, as in the case of snus and chewing tobacco. However, a list of ingredients must be provided on the packaging of tobacco-free nicotine products in accordance with Section 7 of the Act on tobacco-free nicotine products.¹⁰ The Swedish National Food Agency does not see any reason to impose lower labelling requirements on the packaging of tobacco-free nicotine-free products than those imposed on the packaging of tobacco-free nicotine products. Thus, all snus-like products are subject to the same requirements.

Another option would have been to extend the proposed requirement for the provision of a list of ingredients on the packaging of snus-like products to also include packaging of

¹⁰ See also Section 11 of the Ordinance (2022:1263) on tobacco-free nicotine products.

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snus and chewing tobacco. The Swedish National Food Agency has no evidence today on which to base the proposal of such a provision. However, the Swedish National Food Agency has noted that a list of ingredients is already provided on many packages of snus. In connection with monitoring and evaluating the proposed regulations, the Swedish National Food Agency may therefore have reason to revisit this issue.

Finally, the Swedish National Food Agency is proposing that the use of the substance titanium dioxide (E 171) in the manufacture of snus or chewing tobacco shall no longer be permitted. The alternative would have been to allow the continued use of titanium dioxide in the manufacture of these products. However, the use of titanium dioxide as an additive in food is no longer allowed in the EU. In the Swedish National Food Agency's view, there is no reason, from the perspective of risks to human health, to make a different assessment for snus and chewing tobacco.

5. Impact if no regulation comes into effect

If the draft regulations are not adopted, the manufacture of snus-like products, which has been deemed to have the same food hygiene risks as snus, will be unregulated. This could pose risks to human health. The continued use of titanium dioxide in the manufacture of snus and chewing tobacco can also pose risks to human health.

Without the draft regulations, there would generally be no requirements for snus-like products as regards ingredients, hygiene and labelling on the packaging. Snus-like products containing nicotine would, however, be covered by certain provisions of the Act on Tobacco-free Nicotine Products and its supplementary ordinances and regulations.

Without the proposed regulations, manufacturing facilities for snus-like products would not have to be notified in order to be registered by the competent control authority, which would in itself make official controls more difficult.

6. Who would be affected by the regulation?

The regulations will affect operators engaged in the manufacture of snus, snus-like products or chewing tobacco. However, for operators engaged in the manufacture of snus and chewing tobacco, there will be no major changes compared to what already applies under the current regulations.

The regulations will also affect the control authorities, i.e. municipalities, and the Swedish National Food Agency which, pursuant to Section 29 of the Food Ordinance, coordinates the activities of other control authorities and provides support, advice and guidance on such activities. To some extent, the regulations also affect the county administrative boards which, pursuant to Section 28 of the Food Ordinance, coordinate the activities of the municipalities in the county and provide them with support, advice and guidance.

7. The authorisations on which the Swedish National Food Agency's decision-making power is based

The Swedish National Food Agency's has power to make these decisions by virtue of the authorisations granted in Sections 5-7, 30 and 31 of the Food Ordinance.

8. Information on the costs and other impacts of the regulation and an impact comparison of the considered regulatory alternatives

For operators engaged in the manufacture of snus-like products, the obligation to notify manufacturing facilities to the competent control authority will entail a certain administrative burden and certain costs. However, the notification only needs to be done once. The notification fee for a food facility is usually between approximately SEK 1,000-3,000; also see section 12 below. It is reasonable to assume that the notification fee for a facility at which snus-like products are manufactured will be at a similar level. It is also a one-off cost. Operators currently engaged in the manufacture of snus or chewing tobacco are already obligated to notify.

The fact that the municipal control authorities are to register manufacturing facilities for snus-like products will also entail some administration and some costs for the authorities. However, the total number of facilities across the country as a whole is expected to be small, about 20. The control authorities will also be able to cover the costs of handling such notifications by means of a registration fee.

The regulations will also affect the Swedish National Food Agency, and to a certain extent the county administrative boards with respect to their responsibility for the coordination and guidance of control authorities. The Swedish National Food Agency has been allocated some additional funds in 2022 and 2023 which are intended to cover the Agency's initial costs for carrying out information initiatives, supporting control authorities and developing regulations.¹¹ The costs incurred by the county administrative boards as a result of the proposals are difficult to estimate, but are considered to be insignificant.

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

The draft regulations constitute national rules that go beyond Sweden's obligations arising from EU legislation. For example, the requirements imposed on tobacco products in the Tobacco Products Directive¹² are the requirements that have been deemed necessary to maintain a high level of protection of public health in the European Union. These requirements do not apply to tobacco-free nicotine products as these products are not subject to any specific rules at EU level.

The draft regulations will be notified to the National Board of Trade in accordance with the Ordinance (1994:2029) on technical rules, since the regulations constitute technical rules. The draft regulations will therefore be notified to the European Commission and other Member States before they are adopted. Notification to the European Commission entails a period in which the regulations may not be adopted of normally three months,

¹¹ Government Bill 2021/22:200 p. 240.

¹² Directive 2014/40/EU of the European Parliament and of the Council 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.

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but the period may be extended by a further three months if the Commission or a Member State has comments.

However, the draft regulations do not need to be notified under the Ordinance (2009:1078) on services in the internal market as they do not impose any requirements on service activities.

10. Assessment as to whether special consideration needs be given regarding the date of entry into force and whether special information efforts are required

The proposed date of entry into force for the regulations is 1 January 2024. The Swedish National Food Agency's current regulations on snus and chewing tobacco, LIVSFS 2012:6, will be repealed on the same date. As mentioned above, the draft regulations must be notified to the European Commission and other Member States before they can be adopted. Notification to the European Commission entails a period in which the regulations may not be adopted of normally three months, but the period may be extended by a further three months if the Commission or a Member State has comments. The date of entry into force may therefore need to be postponed.

Some transitional provisions are being proposed to make it easier for businesses to adapt to the regulations. To give operators engaged in the manufacture of snus-like products time to become aware of the provisions and then notify their operations, the provisions on registration in Sections 17-19 shall not apply until 1 July 2024. The provision in Section 19 shall then not apply to operations commenced before 1 July 2024.

Packages of snus-like products that do not comply with the provisions of Sections 12, 14 and 15 are proposed to be made available to consumers on the Swedish market until stocks are exhausted, provided that they have been placed on the market or labelled before 1 July 2024. The transitional provision allows these businesses to use packaging material which is not labelled in accordance with the provisions of the regulations for a limited period of time.

Furthermore, it is proposed that snus or chewing tobacco containing titanium dioxide (E 171) may be made available to consumers on the Swedish market until stocks are exhausted, provided that they have been placed on the market or packaged before 1 July 2024. Businesses are thus given a certain amount of time to adapt the products in accordance with the regulations.

Information campaigns will be run in connection with the adoption of the regulations and information will be provided to companies, trade associations and control authorities through the Swedish National Food Agency's official channels, news mailings and information on the Agency's website.

The fact that information initiatives are being carried out before any aspects of the new regulations apply is particularly important given that operators who do not notify their manufacturing facilities for registration may face a fine. A fine shall be imposed on anyone who commences operations without having made a notification to the control authority in order to register the facilities for which they are responsible.

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11. Number of companies affected, the sectors in which they operate, and their sizes

According to 2021 data in reporting by the control authorities to the Swedish National Food Agency, there were 18 manufacturers of snus and chewing tobacco in the country in 2021.

As far as snus-like products are concerned, the Government states in Bill 2021/22:200 that data on the market for tobacco-free snus is subject to uncertainty. As there has been no specific regulation of tobacco-free nicotine products in the past, there has been no obligation to submit any information to the authorities. With regard to industry statistics, the Government notes that there are no specific industry codes for tobacco-free nicotine products. In surveys of tobacco habits, it is not possible to determine which figures referring to snus relate to tobacco-containing and tobacco-free snus. The Government states that an estimated 15-18 million cans of tobacco-free snus are expected to be sold to Swedish consumers.¹³

The above circumstances make it difficult to estimate the size of the market for snus-like products and also to estimate the number of companies that may be affected by the draft regulations.

Based on a limited study of a number of online stores, SOU 2021:22 estimated there to be 17 manufacturers of tobacco-free nicotine products (nicotine pouches), 12 of which were deemed to be small enterprises.¹⁴ The Swedish National Food Agency carried out a similar review of a number of online stores. However, the Agency's review focused on nicotine-free snus-like products. The Swedish National Food Agency found eight companies manufacturing nicotine-free snus-like products in Sweden. Two of these companies were multinational corporations, and a further two of the eight were subsidiaries of those multinationals. Six of the eight companies also manufactured snus alongside nicotine-free snus-like products. One company produced only tobacco-free snus-like products, both with and without nicotine. Finally, there was one company that, along with nicotine-free snus-like products, manufactured food supplements.

The two corporations manufacturing nicotine-free snus-like products have to be regarded as very large enterprises. In the previous financial year, the two subsidiaries turned over approximately SEK 600 million and SEK 110 million respectively, and should therefore be regarded as large enterprises. The other companies turned over between SEK 34 million and SEK 1 million in the previous financial year, and should therefore be regarded as small or micro-enterprises.¹⁵

If these companies are added to those that the investigator in SOU 2021:22 found as manufacturers of tobacco-free nicotine products, this would mean that there are about 25 companies manufacturing snus-like products in Sweden (17+8). However, given that most companies that manufacture nicotine-free snus-like products in Sweden, also manufacture snus and/or tobacco-free nicotine products, the Swedish National Food

¹³ Government Bill 2021/22:200 p. 245. See also Swedish Government Official Report SOU 2021:22 p. 393.

¹⁴ SOU 2021:22 p. 400.

¹⁵ Cf. definitions in Article 2 of the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises.

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Agency assumes that the majority of the eight companies identified by the Agency are among the 17 companies identified by the investigator in SOU 2021:22. The Swedish National Food Agency is therefore of the view that the draft regulations will primarily affect about 20 companies that manufacture products and have not previously been subject to Agency regulations. The majority of these companies operate in the tobacco sector. However, there are some companies that appear to operate only in the health food sector.

12. How much time companies will need to spend on the regulation and the impact it will have on their administrative costs

Operators currently engaged in the manufacture of snus-like products, unlike manufacturers of snus or chewing tobacco, are under no obligation to notify their facilities for registration. However, the draft regulations are to impose such an obligation on these operators. The proposed registration requirement will thus entail a certain increase in administrative burden and time expenditure for operators manufacturing snus-like products at manufacturing facilities that were not previously registered.

Facilities requiring notification shall be notified to the competent control authority of the municipality where the operations are carried out. The municipalities themselves set the registration fee. However, the fee tends to be between SEK 1,000 and 3,000. As mentioned previously, most companies manufacturing snus-like products are also engaged in the manufacture of snus or food supplements. However, if the manufacture of snus-like products takes place in the same facilities as are used for the manufacture of tobacco snus or food supplements, the facility does not need to be notified again.

The Swedish National Food Agency estimates that notification for registration will not take much time. It should be a relatively simple notification procedure for the operator. Therefore, for operators who are required to notify their facilities for registration, the notification procedure should not impose any appreciable administrative burden. What's more, the notification only needs to be done once.

Controls of operators engaged in the manufacture of snus-like products are expected to be similar to the controls now being carried out on operators who manufacture snus and chewing tobacco. The Swedish National Food Agency does not consider that the control itself will entail any appreciable time expenditure for companies or any administrative costs.

In view of the above, the Swedish National Food Agency considers that the draft regulations will only bring about a marginal increase in the administrative burden on operators engaged in the manufacture of snus-like products. The same applies to the time that operators will have to allocate to administrative tasks as a result of the draft regulations. However, depending on the packaging and the products themselves, some time will need to be dedicated in order to bring the manufacture, packaging materials and content of the products in line with the provisions of the regulations. Such time expenditure will vary depending on the product and the operator, and the time required is therefore very difficult to estimate.

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13. Additional costs that are incurred by companies due to the proposed regulation and operational changes that the companies may have to make as a result of the proposed regulation

Registration and inspection of the facility

In accordance with Section 11 of the Ordinance (2021:176) on fees for official controls on foodstuffs and certain agricultural products, anyone who notifies an operation to a competent authority for registration shall pay a fee for the authority's examination of the notification. The municipalities themselves set the registration fee. However, the fee tends to be between SEK 1,000 and 3,000.

In addition, for operators carrying out operations requiring registration at a facility that has not previously been registered with the control authority, there is an additional cost for the official inspection of the facility; see Sections 8 and 9 of the Ordinance on fees for official controls of foodstuffs and certain agricultural products. For small manufacturing facilities, the annual control fee is estimated to be approximately SEK 3,000-5,000. For larger manufacturing facilities, the control fee is estimated to be approximately SEK 15,000-20,000. In addition, an operator may also have to pay additional fees, e.g. where a control authority is required to carry out follow-up inspections as a result of detected discrepancies.¹⁶

Information on packaging

For snus-like products, the draft regulations contain certain requirements as regards information on the packaging. Many manufacturers of snus-like products already label their packaging with the information that the Swedish National Food Agency is now proposing should be provided on the packaging. For operators whose packaging of snus-like products does not currently comply with the labelling requirements proposed in the regulations, the proposed labelling rules may entail some increased costs. This will vary depending on the product and the operator, and the cost is therefore very difficult to estimate. However, the transitional provision allows these businesses to use packaging materials which are not labelled in accordance with the provisions of the regulations for a limited period of time.

When it comes to snus and chewing tobacco, the labelling information on packaging pursuant to Section 8 of LIVSFS 2016:6 must be in a language that can be easily understood by consumers. However, in the regulations now proposed by the Swedish National Food Agency, this information must be in Swedish. Another language may be used if the language differs from Swedish only insignificantly. Given that the aforementioned labelling information on the packaging of snus is currently in Swedish in the vast majority of cases, the Swedish National Food Agency does not consider that this amendment will have a significant impact on the manufacturers of snus. In the case of chewing tobacco, the Swedish National Food Agency does not have sufficient evidence to assess the impact, if any, of the said amendment on manufacturers of chewing tobacco.

Other costs

For snus-like products that have not previously been covered by the regulations, the draft regulations also contain certain requirements as regards, for example, ingredients,

¹⁶ Government Bill 2021/22:200 p. 250.

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hygiene, the establishment of procedures based on the HACCP principles and traceability. If the business does not already meet these requirements, the business will need to be adapted to the requirements of the regulations. It is difficult to say how high these adjustment costs may be. This will vary depending on the business, and the cost is therefore very difficult to estimate.

14. The extent to which the regulation may affect competitive conditions for the companies

Under the draft regulations, manufacturing facilities of snus-like products are to be subject to certain hygiene and traceability provisions. Many of the companies currently manufacturing snus-like products do so in facilities that meet the proposed requirements. The proposed rules should therefore lead to a more equal level of competition compared to today.

It is also proposed that certain mandatory particulars are to be provided on packaging of snus-like products. The majority of snus-like products currently on the market are already labelled with most of the information that is proposed to be mandatory. In this regard too, the proposed rules should therefore lead to a more equal level of competition compared to today.

The assessment of the Swedish National Food Agency is also that the proposed registration obligation for operators manufacturing snus-like products will result in more equal competitive conditions between operators, as all operators will be subject to control by a control authority. Greater equality of control also promotes fair competition between companies.

15. Other respects in which the regulation may affect the companies

The Swedish National Food Agency deems that the regulation will not affect companies in any other respects.

16. Description of whether special consideration needs to be taken of small enterprises when drafting the regulations

Smaller enterprises generally have less capacity to cope with administrative burdens. These companies can therefore be expected to be more negatively affected than other companies by the proposed regulations on, for example, registration. However, as mentioned above in section 12, the Swedish National Food Agency is of the opinion that the proposed regulations will only result in a marginal increase in the administrative burden on the companies. In view of this, and given that the purpose of the proposed regulations is to ensure a high level of protection for human health and consumer interests, the Swedish National Food Agency does not see any need for special consideration to be given to small enterprises when drafting the regulations.

17. Impact on municipalities or regions

Pursuant to Sections 23 and 25 of the Food Ordinance, the municipalities are the authorities competent to exercise official control over and register facilities manufacturing snus, snus-like products and chewing tobacco. The proposed registration requirement for facilities manufacturing snus-like products will thus entail a certain

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increase in administrative burden and time expenditure for municipalities that need to register such facilities. However, as mentioned above, it is estimated that only a few manufacturing facilities are not already registered. Today, it is mainly operators manufacturing snus who also manufacture snus-like products. However, there are a few businesses, an estimated 10-20, specialising in only snus-like products. As these operations are currently unregulated, the Swedish Food Agency does not have more precise information on the number of operations that currently exist.

If the proposed regulations are adopted, the municipal control authorities will be given responsibility for control over an activity and product category that is new for them, namely the manufacture of snus-like products. The control authorities are therefore likely to incur some additional costs due to e.g. training on the nature of snus-like products and planning controls of these activities. Municipalities may also have to make certain decisions on fines because – once the registration requirement has entered into force – a fine shall be imposed on an operator who commences an operation requiring registration without having notified it for registration. However, the overall assessment of the Swedish National Food Agency is that the proposed regulations will only have a marginal impact on municipalities.

Within the county, the county administrative boards coordinate the activities of the municipalities and provide them with support, advice and guidance. The Swedish National Food Agency does not consider the county administrative boards to be affected by the regulations to any appreciable extent.

18. Environment and gender equality

The Swedish National Food Agency considers the proposed regulations to have no impact on the environment or gender equality.

19. Follow-up and evaluation of the regulations

In the coming years, the Swedish National Food Agency intends to follow up on how the regulations are being applied in order to evaluate whether the proposed requirement for a list of ingredients on packaging for snus-like products without nicotine should also apply to packaging of snus and chewing tobacco and whether the regulations need to be adjusted in any other respects.

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