



European Commission

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Clean drinking water and
safe chemistry
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Impact assessment – notification of draft Order on the import and sale of very toxic and toxic substances and mixtures, etc., on the storage and reporting of the theft of certain substances and mixtures and on prohibiting misleading statements when placing substances and mixtures on the market

1. Background

The draft new Order on the import and sale of very toxic and toxic substances and mixtures, etc., on the storage and reporting of the theft of certain substances and mixtures and prohibiting misleading statements when placing substances and mixtures on the market (hereinafter the Poison Order) is issued in order to pursue and maintain national rules, which have hitherto been contained in the Order on classification, packaging, labelling, sale and storage of substances and mixtures (hereinafter the Classification Order). The Classification Order is repealed in parallel with the entry into force of the Poison Order, expected on 1 January 2023.

The substances and mixtures regulated by Chapter 5 of the Chemicals Act and by the Poison Order are the most deadly and most dangerous to health and the environment that exist.

Combined with Chapter 5 of the Chemicals Act on the sale of toxic substances and mixtures, etc., the Poison Order is primarily intended to ensure that the authorities can obtain an overview of who distributes, manufactures or uses toxic substances and mixtures and about where these substances and mixtures are located. In addition, the Order implements a number of authorisations in the Chemicals Act¹.

Section 2 examines the rules in Chapter 5 of the Chemicals Act. The Requisition System contained in Chapter 5 of the Act is described in Section 3 in connection with the review of the contents of the Poison

¹ Annex 1 contains a parallel list of the individual provisions of the Poison Order and their corresponding legal basis in the Chemicals Act.

Order. Finally, Section 4 carries out an impact assessment of Chapter 5 of the Act and the Poison Order in relation to harmonising regulation in the field of chemicals and in relation to the free movement of goods.

2. The Chemicals Act and the Requisition System for the sale of toxic substances and mixtures, etc., established with it

With the adoption of the First Chemicals Act (originally [lov om kemiske stoffer og produkter](#)) in 1979, the then basic rules on chemical substances and products, namely the Poison Act (Act No 119 of 3 May 1961 on poisonous and health hazardous substances), the Pesticide Act (Act No 118 of 3 May 1961 on funds for the control of plant diseases, weeds and certain pests and on means to regulate plant growth) and Section 7 of the Environmental Protection Act (Act No. 372 of 13 June 1973 on environmental protection) were brought together in a single Act.

Already from its adoption, the Chemicals Act contained provisions in Chapter 5 on the sale, etc., of toxic substances and products. These provisions were largely a continuation of the rules contained in the 1961 Poison Act. Similarly, the Act from the outset required that sales be made only if a special requisition was provided for a specified non-medical purpose. The requisition was to be provided by the police with an endorsement stating that the police allowed provision for the stated purpose.

A major [ændring/revision af kemikalieloven](#) in 1989 established the Requisition System for the sale of toxic substances and mixtures etc. in Chapter 5 of the Act, which remains in force.

The authorisations contained in Chapter 5 of the Act were originally translated into the Classification Order. Reference is made to the examination of the Poison Order below in Section 3, which, as mentioned, essentially continues the implementation of the legal bases in Chapter 5 of the Act in the light of the repeal of the Classification Order.

It is a fundamental principle of Chapter 5 of the Act that it is the seller of very toxic and toxic substances and mixtures who is obliged to ensure that the purchaser is entitled to purchase the substances or mixtures in question. This is underlined by the imposition of objective criminal liability on a seller for breach of Section 24(1) of the Act.

The starting point in Section 24(1), first sentence, of the Act is that the sale of very toxic and toxic substances and mixtures may only be made against requisition. However, Section 24(1), second sentence, excludes the undertakings, institutions and persons listed in Section 25(1) of the Act from the requirement to sell against requisition.

The undertakings, institutions and persons listed in Section 25(1)(1)(a) to (g) of the Act are all already subject to official control to some

extent. There is therefore no need for the additional official controls inherent in the Requisition System for this category of undertakings, institutions and persons, which is why they are exempted.

Section 25(1)(2) of the Act concerns undertakings which either manufacture or use very toxic and toxic substances and mixtures. It is a prerequisite for legally being able to sell very toxic and toxic substances and mixtures to this category of undertakings that the undertakings concerned have submitted a notice on this to the Working Environment Authority, see below. This Communication gives the authorities an overview of which undertakings manufacture or use very toxic and toxic substances and mixtures. The authorities thus have the opportunity to check and monitor compliance with health and safety rules, for example. It should be pointed out that the notification does not in itself constitute a restriction on the substances and mixtures concerned. It is only a matter of informing the authorities of the undertakings concerned. See also below in Section 4 for the relationship with the REACH Regulation².

Section 25(1)(3) of the Act concerns sales to undertakings which sell very toxic and toxic substances and mixtures for reselling or to the undertakings referred to in Section 25(1)(1) and (2). The provision is aimed at wholesalers. In order to be able to lawfully sell very toxic and toxic substances and mixtures to wholesalers, the relevant wholesalers must have submitted a notification on this to the Environmental Protection Agency. This communication gives the authorities an overview of which wholesalers sell very toxic and toxic substances and mixtures. This allows the authorities to control and monitor compliance of wholesalers with the Act when reselling very toxic and toxic substances and mixtures. It should again be clarified that the communication does not in itself constitute a restriction on the substances and mixtures concerned. It is only a matter of informing the authorities of the undertakings concerned. See also below in Section 4 for the relationship with the REACH Regulation.

Section 25(1)(4) of the Act concerns sales to retailers other than the wholesalers referred to in Section 25(1)(3). It is a prerequisite for legally being able to sell very toxic and toxic substances and mixtures to such retailers that the retailers concerned have an authorisation from the Environmental Protection Agency. It should be clarified that the authorisation does not in itself constitute a restriction in relation to the substances and mixtures concerned, see also below in Section 4 in

² Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

the relationship with the REACH Regulation. In that regard, it should be noted that, under Section 25(3) of the Act, only pharmacists and retailers who have obtained that authorisation under certain conditions may sell very toxic and toxic substances and mixtures to persons other than the undertakings, institutions and persons listed in Section 25(1). Only the very toxic and toxic substances and mixtures may be sold to the retailer which is covered by the authorisation granted to it, see also Section 3 below. This gives the authorities an overview of the very toxic and toxic substances and mixtures sold by the retailers concerned and to whom these distributors sell the very toxic and toxic substances and mixtures.

As regards the import of very toxic and toxic substances and mixtures, the authorisation provided for in Section 24(4) of the Act is translated into the Poison Order to provide that very toxic and toxic substances and mixtures may be imported only by the undertakings, institutions and persons listed in Section 25(1) of the Act, see also below in Section 3.

The undertakings, institutions and persons listed in Section 25(1)(1) to (4), which are exempt from the requirement to sell against requisition, cover essentially all public and private undertakings which may deal with very toxic and toxic substances and mixtures. It thus follows that the requirement to sell against requisition applies mainly to private individuals. However, for example, teachers who do not teach at higher education institutions will also be subject to the requisition requirement. In addition, undertakings that do not wish to submit a notification may choose to use the Requisition System instead.

Finally, it should be noted that Chapter 8 of the Chemicals Act on self-monitoring, information and investigation obligations applies, where appropriate, to the undertakings, institutions and persons listed in Section 25(1) of the Act.

3. The Poison Order

The Chemicals Act does not contain a proper definition of what is meant by very toxic and toxic substances and mixtures. The reason for this is historical, as the Chemicals Act, as mentioned above, continued, to a certain extent, the rules on the sale of poisons in the then Poison Act of 1961. The Poison Act included positive lists of substances that were considered to be very toxic, toxic or dangerous to health. With Denmark's adherence to the then European Economic Community and thus the need to implement, among other things, the Drugs Directive³, the division and distinction of the Poison Act were no longer appropriate. Thus, at the time of the adoption of the Chemicals Act and the subsequent issue of the Classification Order, it was decided to base

³ Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

the definition of very toxic and toxic substances and mixtures on the classification of substances (and later preparations). This approach has been continued in the Poison Order.

Therefore, in accordance with Section 3(1)(2) of the Poison Order, 'very toxic and toxic substances and mixtures' means substances and mixtures classified under the CLP Regulation as acute toxic Category 1, 2 or 3 (Acute Tox. 1, 2 or 3) or as specific target organ toxic Category 1 (STOT SE 1).

Chapter 3 (Section 15) of the Poison Order provides that Sections 24 to 26 of the Chemicals Act and Chapter 2 of the Poison Order shall apply *mutatis mutandis* to the import and sale of substances and mixtures with serious long-term effects.

Substances and mixtures with serious long-term effects within the meaning of Section 3(1)(2) of the Poison Order are understood to mean substances and mixtures classified under the CLP Regulation as carcinogenic, mutagenic or toxic for reproduction category 1A or 1 B (Carc. 1 A or 1 B, Muta. 1 A or 1 B or Repr. 1 A or 1 B).

Sections 1 and 2 determine the scope of the Poison Order. In particular, Section 1(2), which, together with the definition in Section 3(1)(4) and Section 5 thereof, lays down the scope of the Order in relation to the importation of very toxic substances and mixtures and substances and mixtures with serious long-term effects. In addition, it should be noted that the Order does not apply to pesticides except for a single provision relating to storage, see Section 2(2) of the Order.

Section 4(1) of the Order provides that undertakings covered by Section 25(1)(2) and (3) of the Act must submit a notification digitally on the Danish self-service portal for undertakings, 'virk.dk⁴'. The same entry is used, whether the undertaking is covered by Section 25(1)(2) or (3) of the Act. The notification is automatically distributed to either the Working Environment Authority or the Environmental Protection Agency.

Section 4(2) and (3) sets out the information requirements in the digital communication. Information on several substances or mixtures may be reported in a single notification. The information referred to in Section 4(2)(1) thus constitutes a crossover to the notification, whereas the information in Section 4(2)(2) to (7) is provided at the level of substances or mixtures. The undertaking may at any time of its own motion modify the notification by adding or removing substances or mixtures from the notification. It shall also be indicated if the substances or mixtures are stored in different locations. It is the same

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https://virk.dk/myndigheder/stat/MST/selvbetjening/Meddelelse_om_kemiske_stoffer_og_blandinger_-_Giftmeddelelse/

information that must be reported, whether the undertaking is covered by Section 25(1)(2) or (3) of the Act.

Pursuant to Section 4(5), a notification is valid for three years from the date of the email receipt which is generated and sent when the required information has been provided, see Section 4(4). In the case of the addition of new substances or mixtures under an existing notification, a new email receipt shall be sent for them in accordance with paragraph 4. A reminder is automatically sent to the undertaking when the deadline for a message is about to expire. The undertaking can then choose to simply renew the notification for another three-year period (without having to enter all the information again).

It should be emphasised that the authorities do not carry out any type of case handling or assessment of the reported information before issuing an email receipt. It is also not an authority approval. The only requirement that applies under Section 25(1)(2) and (3) of the Act is that the undertaking gives the notification to the authorities.

Section 6 stipulates that retailers applying for authorisation under Section 25(3) of the Act must indicate the very toxic and toxic substances and mixtures for which authorisation is sought and to whom they are to be sold.

Section 7 of the Order provides for a special scheme for associations whose members use very toxic and toxic substances and mixtures in connection with activities under the auspices of the association. For example, this may be model aircraft associations where the model aircraft are equipped with internal combustion engines that use methanol as fuel. Such associations may also apply for an authorisation under Section 25(3) of the Act, even if the association itself does not act as a retailer. The association is obliged to provide the Environmental Protection Agency with a list of retailers who sell very toxic and toxic substances and mixtures to the members of the association without their own authorisation. The association is also required to keep the list updated. In such a permit, the Environmental Protection Agency may lay down conditions for, inter alia, storage of documentation.

Section 8 lays down provisions on the payment of fees in connection with authorisations in accordance with Sections 6 and 7 of the Order.

In Sections 9 to 12, the system of requisitions referred to in Section 24(1) of the Chemicals Act is implemented. The requisition can be provided by the police or retrieved digitally at www.politi.dk. The requisition must be completed with the required information, must be dated and must be signed by the applicant in person, Section 9(2) and (3).

Like the measures described above with regard to Section 25(1)(1) to (4) of the Act on Chemicals, the Requisition System provides the authorities with information on which — mainly private — persons use very toxic or toxic substances and mixtures.

It follows from Section 24(1) of the Chemicals Act that the requisition must be endorsed by the police. Section 10 of the Order lays down additional conditions for police endorsement. In Section 10(2), it is specified that a requisition may not be endorsed by the police if the applicant is under the age of 18, or if the applicant is likely to cause harm to himself or his surroundings, see Section 24(3).

The requisition endorsed by the police shall be provided to the retailer at the time of the sale. A requisition is only valid for a single sale. This also applies even if the sale in question covers only part of the quantity specified in the requisition, see Section 11 of the Order. Section 12 of the Order provides for two specific exceptions to the requirement that the provided requisition must be endorsed by the police.

Sections 13 and 14 of the Order lay down requirements for retailers' storage of requisitions and other documentation.

The provisions on the provision and storage of requisitions and on the storage of other documentation must be seen in the light of the fundamental principle that it is the seller who must ensure that the purchaser is entitled to purchase the substances and mixtures in question. The competent authorities will be able to verify on the basis of the information stored whether an undertaking has sold very toxic and toxic substances and mixtures or substances and mixtures with serious long-term effects in accordance with the legislation.

The rules in Sections 24 to 26 of the Chemicals Act and in Chapter 2 of the Order shall apply *mutatis mutandis* to substances and mixtures with serious long-term effects, see Section 15 of the Order.

Chapter 4 of the Order lays down requirements for the storage of certain substances and mixtures. Sections 16 and 17 lay down requirements for the storage of very toxic and toxic substances and mixtures and substances and mixtures with serious long-term effects, while Section 18 lays down requirements for the storage of a number of specified substances and mixtures which are less harmful to health. Finally, Section 19 lays down requirements for the storage of certain hazardous substances and mixtures.

In Chapter 5 undertakings, institutions, members of an association or other private persons who are in possession of certain specified acute toxic substances and mixtures, are required to submit a notification to the police in the event of reasonable suspicion of the theft of the substances and mixtures in question.

Chapter 6 translates the authorisation in Section 10(4) of the Chemicals Act on the prohibition of misleading marketing, see Section 10(3) of the Act. It should be noted that the prohibition on misleading marketing in Section 21 of the Order applies to *all* substances and mixtures.

Finally, administrative provisions and rules for appeal are laid down in Chapter 7 of the Order, while Chapter 8 contains provisions on penalties and entry into force.

4. Impact assessment in relation to harmonising EU regulation in the field of chemicals and in relation to the free movement of goods

Relationship with the CLP Regulation⁵

The Ministry of the Environment considers that neither Chapter 5 of the Chemicals Act nor the Poison Order, and in particular Chapters 2 and 3 thereof, lay down additional requirements for classification or other categorisation of very toxic and toxic substances and mixtures or substances and mixtures with serious long-term effects than those resulting from the CLP Regulation.

Section 17(1) of the Poison Order provides that very toxic and toxic substances and mixtures and substances and mixtures with serious long-term effects may not be stored in such packaging that may give rise to confusion of the content. It further follows from Section 17(2) that the substances and mixtures in question must be stored in the original packaging or other equivalent packaging which is labelled with the product identifiers of the substance or mixture, additional information, hazard pictograms, signal words, hazard and precautionary statements in accordance with Articles 17(1), 18(2) and (3), 19-22 and 25 of the CLP Regulation. Section 17(4) provides that very toxic and toxic substances and mixtures and substances and mixtures with serious long-term effects shall be stored in the original packaging for persons other than the undertakings, institutions and persons referred to in Section 25(1)(1) to (4) of the Act.

Section 18(2) of the Order provides that substances and mixtures covered by Section 18(1), where the packaging is not fitted with child-proof fastenings, shall be kept at least 1.5 m above floor height by retailers where customers have direct access to the substances and mixtures in question. It further follows from Section 18(3) that the substances and mixtures in question must be stored in the original packaging or other equivalent packaging which is labelled with the product identifiers of the substance or mixture, additional information,

⁵ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

hazard pictograms, signal words, hazard and precautionary statements in accordance with Articles 17(1), 18(2) and (3), 19-22 and 25 of the CLP Regulation.

Finally, it follows from Section 19(2) that the substances and mixtures covered by Section 19(1) must be stored in the original packaging or other equivalent packaging bearing the product identifiers of the substance or mixture, additional information, hazard pictograms, signal words, hazard and precautionary statements, in accordance with Articles 17(1), 18(2) and (3), 19 to 22 and 25 of the CLP Regulation.

It is the Ministry of the Environment's assessment that the requirements of the above mentioned provisions, which are contained in Chapter 4 of the Poison Order, concern only the storage of the substances and mixtures concerned. It is therefore the Ministry's view that this does not lay down additional labelling or packaging requirements than those resulting from the CLP Regulation.

The prohibition in Chapter 6 of the Poison Order concerns misleading statements in connection with marketing. It is the view of the Ministry of the Environment that such statements are not to be compared with the requirement laid down in Article 48 of the CLP Regulation, according to which any advertising of a substance classified as hazardous must mention the hazard classes or categories concerned.

It is the Ministry's assessment that the remaining chapters of the Poison Order concern matters which are not regulated by the CLP Regulation.

Overall, the Ministry of the Environment therefore considers that both Chapter 5 of the Act and the Poison Order fall outside the harmonised area of the CLP Regulation.

Relationship with the REACH Regulation

Record keeping

Registration will be automatic for the specific very toxic and toxic substances and mixtures and the substances and mixtures with serious long-term effects for which undertakings give notice, see Section 25(1) (2) and (3) of the Act, or for which a permit is sought in accordance with Section 25(1)(4) and (3) of the Act. The sole purpose of this registration of specific very toxic and toxic substances and mixtures and substances and mixtures with serious long-term effects is to provide authorities with an overview of which specific substances and mixtures are manufactured, used or marketed by which undertakings and in what quantities, and where the substances and mixtures concerned are located. Such an overview could, for example, form the basis for emergency response plans, and authorities could also use the information to trace the substances and mixtures concerned through the individual stages of the market in connection with the control or prevention of hazardous abuse.

In practice, such an overview cannot be obtained by any other means than by a mandatory notification. The information on the substances and mixtures concerned is directly linked to the undertaking giving notice or seeking authorisation. Thus, contrary to the obligation to register under Title II of the REACH Regulation, the objective is not to create an independent register which generally contains information on the substances and mixtures concerned in itself for the purposes of their assessment by the authorities, but only to ensure that the authorities can obtain an overview.

Against this background, the Ministry of the Environment considers that the indirect registration of substances and mixtures falls outside the harmonised area of Title II of the REACH Regulation.

Restrictions

Chapter 5 of the Act or the Poison Order does not lay down specific requirements for the manufacture, use, import or sale of the very toxic and toxic substances and mixtures or substances and mixtures with serious long-term effects. This is neither the case for a specific substance nor for a defined group of substances. There is therefore no restriction of any kind on the substances and mixtures concerned in relation to the activities in question.

The Ministry of the Environment therefore considers that both Chapter 5 of the Act and the Poison Order fall outside the harmonised area of Title VIII and Annex XVII of the REACH Regulation.

The public

Neither Chapter 5 of the Chemicals Act nor the Poison Order contains a requirement to publish the information held by the authorities by virtue of the provisions on the granting and application for authorisation.

However, the information held by the authorities will be covered by the general rules on access to documents, as laid down in the Environmental Information Act⁶, the Administration Act⁷ and the Public Accessibility Act⁸, with the possibilities for exemption from access to documents provided for in these legislations.

⁶ Act on public access to environmental information, cf. [lovbekendtgørelse nr. 980 af 16. august 2017](#)

⁷ Administration Act, see [lovbekendtgørelse nr. 433 af 22. april 2014](#), as amended by Section 2 of Act No 503 of 23 May 2018 amending the Act on the Processing of Personal Data by Law Enforcement Authorities, the Act on Mass Media Information Databases and various other Acts

⁸ Act on public access to information in public administration, cf. [lovbekendtgørelse nr. 145 af 24. februar 2020](#)

On this basis, the Ministry of the Environment considers that neither Chapter 5 nor the Poison Order contravenes Articles 118 and 119 of the REACH Regulation. However, it is considered that both Article 118(2) and Article 119 may form part of the authorities' assessment of whether access to the information held by the authorities should be granted in the event that the authorities receive a request for access to the information in question under these legislations.

In summary, the Ministry of the Environment considers that both Chapter 5 of the Act and the Poison Order fall outside the harmonised area of the REACH Regulation.

Relationship with Articles 34 to 36 TFEU

Consequently, the Ministry of the Environment considers that Chapter 5 of the Act and the Poison Order must be assessed solely in accordance with Articles 34 to 36 TFEU.

Article 34 TFEU

The requirement for notification laid down in Section 25(1)(2) and (3) of the Chemicals Act and for authorisation laid down in Section 25(1)(4) of the Act, see Section 25(3), first applies in connection with *sales*.

However, it follows from Section 5, see Section 15 of the Order, that very toxic and toxic substances and mixtures and substances and mixtures may be imported only by the undertakings, institutions and persons listed in Section 25(1) of the Act. Neither the Act nor the Order requires an importer of very toxic and toxic substances and mixtures or substances and mixtures with serious long-term effects to submit a notification.

In that regard, it should be borne in mind that the notification requirement applies only to sales to undertakings which manufacture, use or resell the substances and mixtures concerned. Undertakings which import very toxic and toxic substances and mixtures or substances and mixtures with serious long-term effects for the purposes of reselling to the undertakings listed in Section 25(1)(1) to (4) of the Act are only required, in connection with the sale, to ensure that the undertakings to which they sell are entitled to purchase the substances and mixtures concerned, not in connection with the imports themselves. Similarly, if undertakings import very toxic and toxic substances and mixtures or substances and mixtures with serious long-term effects for their own use in manufacture or application, it is only in the context of the latter activities that the notification requirement applies, not in connection with the imports themselves. The information concerning, inter alia, imports, which must be disclosed pursuant to Section 4(2)(6)(a) to (f) of the Order, must therefore be seen as subsequent information to the authorities about the undertaking's handling of the substances and mixtures concerned and thus also an indication of the company's location in the supply chain.

They should not be seen as a prior condition for importing, for example.

It is therefore the Ministry of the Environment's assessment that the requirement for notification/authorisation is not a prior condition for access to the market. Consequently, it is also the view of the Ministry of the Environment that the requirement does not affect trade between Member States.

It is further the Ministry of the Environment's assessment that the requirement for notification/authorisation is proportionate. First, the requirement applies only to very toxic and toxic substances and mixtures and substances and mixtures with serious long-term effects, as defined in Section 3(2) and (3) of the Poison Order. Secondly, the amount of information required for a notification/authorisation is limited and of such content that it is easily accessible to the undertakings concerned. It is therefore the Ministry of the Environment's assessment that the information required does not go beyond what is necessary to achieve the objective, namely that the authorities can obtain an overview of which undertakings handle very toxic and toxic substances and mixtures and substances and mixtures with serious long-term effects, which substances and mixtures they are and in what quantities, and where the substances and mixtures in question are located and how they are handled (manufactured, mixed, etc., used, imported).

Finally, the Ministry of the Environment considers that the rules in Chapter 5 of the Chemicals Act and the Poison Order do not constitute covert discrimination. The notification/application to be submitted by an undertaking is independent of whether the substances or mixtures concerned are imported or whether they are manufactured in Denmark. This also follows from Section 1(2) of the Order. For example, it is irrelevant for a manufacturing undertaking's obligation to submit the required notification whether the undertaking itself imports the very toxic and toxic substances and mixtures or substances and mixtures with serious long-term effects that it uses, or whether it purchases the substances and mixtures from a Danish undertaking that manufactures the substances and mixtures in question. The same applies to wholesalers which must submit a notification, where it is also irrelevant whether the wholesaler imports the very toxic and toxic substances and mixtures or substances and mixtures with serious long-term effects for reselling, or whether the wholesaler purchases the substances and mixtures in question from a Danish manufacturer.

In that regard, it should be borne in mind that the notification requirement applies only to the manufacture, use or resale — and not to imports. It is therefore important to keep in mind in what capacity the undertakings in question are acting. A manufacturing or wholesaler which, as an importer, purchases very toxic and toxic substances and mixtures or substances and mixtures with serious long-term effects

from a supplier abroad, is not obliged to notify, nor is the foreign exporter obliged to ensure that the undertaking, as an importer, is entitled to purchase the substances and mixtures in question.

Overall, the Ministry of the Environment considers that neither Chapter 5 of the Act nor the Poison Order constitutes a quantitative restriction on imports or a measure having equivalent effect, contrary to Article 34 TFEU.

Article 35 TFEU

It follows from Section 8(1), first sentence, of the Chemicals Act that the Act does not apply to substances and mixtures exported, unless the Minister decides otherwise. Section 8(2), first sentence, of the Act provides that the Act does not apply to substances and mixtures manufactured abroad and which are only passed through the country as transit goods.

Pursuant to Section 8(1), first sentence, of the Act, Section 2(4) of the Poison Order provides that the Order does not apply to substances and mixtures exported. By way of derogation, a number of provisions are set out in the Poison Order which relate to storage. The storage requirements laid down in those provisions shall apply *mutatis mutandis* to storage for export purposes.

Section 8(2), first sentence, shall apply *mutatis mutandis* to regulations issued pursuant to the Act.

It is on that basis that the Ministry of the Environment considers that neither Chapter 5 of the Act nor the Poison Order constitutes a quantitative restriction on exports or a measure having equivalent effect within the meaning of Article 35 TFEU.

Annex 1

Provision in Order	Legal basis in the Chemicals Act	Comments
Section 1(1)	Does not require a legal basis (defines the scope).	
Section 1(2)	Section 24(4), second sentence	
Section 2(1)–(3)	Does not require a legal basis (delimitation of scope).	
Section 2(4)	Section 8(1)	
Section 2(5)–(7)	Does not require a legal basis (delimitation of scope).	Re Section 2(1)(5): Substances and mixtures in transit are regulated by Section 9 of the Chemicals Act.
Section 3(1) and (4)	Does not require a legal basis (defines definitions).	
Section 3(2) and (3)	Section 3(3)	
Section 4(1)	Section 55(1) and (2)	
Section 4(2.3) and (5)	Section 25(2)	
Section 4(4)	Section 56(1)	
§ 5	Section 24(4)	
§ 6	Section 25(3)	
Section 7(1) and (3)	§ 6	
Section 7(2)	Section 24(5), second sentence	
Section 8(1)–(3)	Section 25(4)	
Section 9(1)–(3)	Section 24(5), first sentence	
Section 10(1) and (2)	Section 24(5), first sentence	It follows from Section 24(2) of the Chemicals Act that a requisition must be endorsed by the police.
Section 11(1) and (2)	Section 24(5), first sentence	
Section 12(1) and (2)	Section 24(5), first sentence	
Section 13(1)–(4)	Section 26 ⁹ *)	
Section 14(1)–(4)	Section 26 *)	

Provision in Order	Legal basis in the Chemicals Act	Comments
Section 15	Section 27(2) *) (2)	
Section 16(1) and (3)-(5)	Section 23(1), *) first sentence	
Section 16(2)	Section 23(2) *)	
Section 17(1)-(4)	Section 23(1), *) first sentence	
Section 18(1)-(4)	Section 23(1), *) first sentence	
Section 19(1) and (2)	Section 23(1), *) first sentence	
Section 20(1)-(4)	Section 42a	
Section 21	Section 10(4)	
Section 22(1)	Section 45(1)	
Section 22(2)	Section 47, last indent	
Section 23(1)-(4)	Section 47, last indent	
Section 24	Section 45(1)	
Section 25(1) and (2)	Section 59(4)	Section 25(1) and (2) must be seen in conjunction with Section 59(1)(1), (3) and (4) of the Chemicals Act.
Section 25(3) and (4)	Section 59(5)	
Section 25(5)	Does not require legal basis	
Section 26(1) and (2)	Does not require legal basis	

^{9b)} Covered by Section 25(3) of the Order, see Section 59(5) of the Chemicals Act.