WIJ WILLEM ALEXANDER,
BIJ DE GRATIE GODS,
KONING DER NEDERLANDEN,
PRINS VAN ORANJE-NASSAU,
ENZ. ENZ. ENZ.

Decree of

amending Lists I and IA annexed to the Opium Act [Opiumwet] in connection with the addition of a substance to List I and the addition of a substance group to List IA

[ChainID WGK027900]

At the recommendation of the State Secretary for Health, Welfare and Sport of ..., reference ..., also on behalf of Our Minister of Justice and Security;

Having regard to Articles 3a(2) and 3aa(1) of the Opium Act;

Having heard the Advisory Division of the Council of State (opinion of enter date of opinion of, Council of State, no. enter number of opinion, Council of State);

Having regard to the further report of the State Secretary for Health, Welfare and Sport of enter date of further report, enter reference of further report), also on behalf of Our Minister of Justice and Security;

Have approved and hereby decree the following:

Article I

In List I annexed to the Opium Act, the following is added after the text relating to the substance isotonitazene:

1. in the ‘International Non-proprietary Name (INN)’ column:
   isotonitazepyne;
2. in the ‘other names’ column:
   N-pyrrolidino isotonitazene;
3. in the ‘further description’ column:
   2-[(4-isopropoxyphenyl)methyl]-5-nitro-1-(2-pyrrolidin-1-ylethyl)-*1H*-benzimidazole;

Article II

A substance group is added to List IA annexed to the Opium Act, reading:

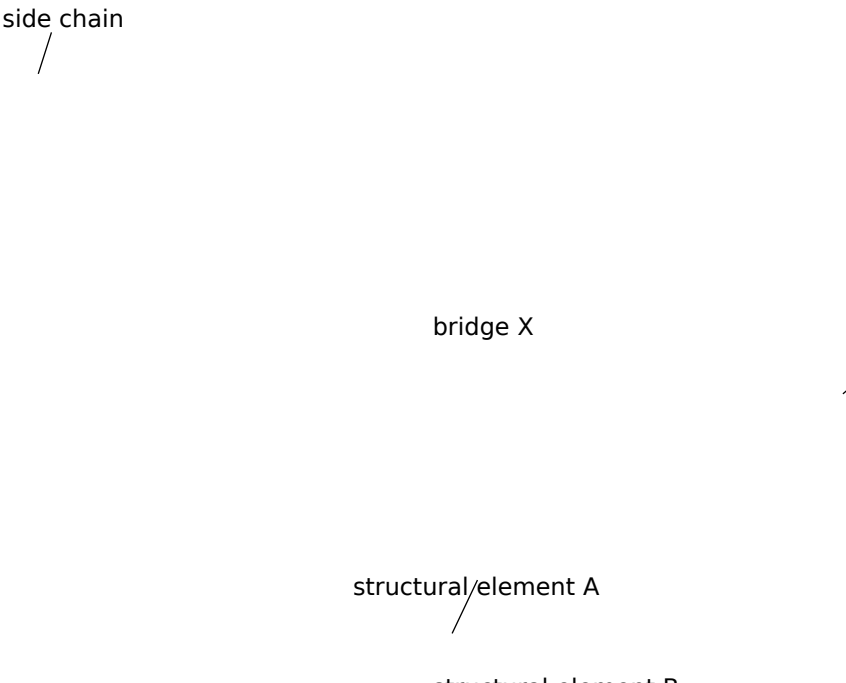
4. Substance group: Benzimidazole opioids (nitazenes)

A benzimidazole opioid (nitazene) is any chemical compound corresponding to the following modular structure:

- a structural element A, which is connected through a bridge X at a defined position;
- to a structural element B;
- and a side chain has a defined position.

Figure 5 shows the modular structure of a nitazene.

Figure 5



Structural element A, bridge X, structural element B and side chain are defined as follows:

4.1 Structural element A
Structural element A comprises a benzimidazole ring system.

This ring system can be substituted at positions R_3 and R_4 with the following atoms or atomic groups: hydrogen, fluorine, chlorine, bromine, iodine, nitro, amino, cyano, isothiocyanate, methyl, trifluoromethyl, methoxy, trifluoromethoxy, acetyl, acetoxy, ethoxycarbonyl, N,N-diethyl carboxamide groups.

4.2 *Bridge*
The bridge may consist of the following atoms or atomic groups which are connected to structural element A under 4.1 and structural element B under 4.3 via the bonding sites:

a) nitrogen, oxygen, sulphur;
b) methylene, methylene oxy, oxymethylene, ethylene or carbonyl group.

The methylene group may be substituted (R_6) with a methyl, hydroxy, acetonitrile or carbamoyl group.

The nitrogen may be substituted (R_6) with an alkoxycarbonyl group (up to and including C_3).

4.3 Structural element B
Structural element B is a phenyl ring that may be substituted at one or more positions (R_5) with the following atoms or branched or unbranched atomic groups:

a) Hydrogen, fluorine, chlorine, bromine, iodine, hydroxy-, nitro-, amino-, cyano-, alkyl-, trifluoromethyl-, alkoxy-, trifluoromethoxy-, haloalkyl-, haloalkoxy-, 2-ethoxyethoxy-, alkanoyl-, amino-alkyl-, hydroxyalkyl-, thioalkyl-, alkylsulfonyl groups.
   The substituents thus obtained may have an uninterrupted chain of not more than six atoms (excluding hydrogen atoms);
b) substances in which the phenyl ring has been replaced by a benzofuran, a dihydrobenzofuran, a methylenedioxyphenyl or a naphthyl ring system are also covered by the definition.

4.4 Side chain
The side chain comprises an ethanamine group, which is attached to structural element A and which may be substituted (R_1 and R_2) with the following atoms or molecular groups:

a) hydrogen, alkyl, iso-alkyl, or alkenyl groups, with a length of not more than three (3) carbon atoms;
b) Substances in which the nitrogen atom is an integral part of a ring system are also covered by the definition.
   Examples include pyrrolidine, piperidine, morpholine, and 2,4-dimethylazetidine ring.

Article III

This decree enters into force on the day following the date of publication of the Bulletin of Acts and Decrees in which it is published.

I hereby order this decree and its associated explanatory memorandum to be published in the Bulletin of Acts and Decrees.

State Secretary for Health,
Welfare and Sport,

Minister of Justice and Security,

Explanatory memorandum

1. Introduction

This decree adds a substance group to List IA of the Opium Act, namely benzimidazole opioids (hereinafter: nitazenes). This is a class of synthetic opioids that are related to the substance etonitazene.

In addition, this decree adds the substance isotonitazepyne to List I annexed to the Opium Act. This substance falls under the substance group nitazenes and, due to a serious incident, was subject to a risk assessment by the New Drugs Assessment and Monitoring Coordination Point [Coördinatiepunt Assessment en Monitoring nieuwe drugs] in spring 2025 (hereinafter: CAM). In this risk assessment, the CAM recommended adding isotonitazepyne to List I.

These amendments are explained in more detail below. This explanatory memorandum is also on behalf of the Minister of Justice and Security.

2. Reason for and content of the decree

Addition of the nitazene substance group to List IA
With the Act of 29 January 2025 amending the Opium Act with the addition of a third list to counter the production of and trade in new psychoactive substances and several other amendments (Bulletin of Acts and Decrees 2025, 32), a List IA has been added as an appendix to the Opium Act with effect from 1 July 2025. List IA contains a number of substance groups whose chemical structure is derived from more than one psychoactive substance appearing on List I of the Opium Act. These are substances that cause or are intended to cause psychoactive effects similar to those of well-known drugs such as MDMA, THC (psychoactive substance in cannabis) and heroin. This act introduces a generic ban on these groups of substances.

Pursuant to Article 3aa(1) of the Opium Act, substance groups may be added to List IA by general administrative order. A substance group can only be added to List IA if two or more substances forming part of that substance group are or are added to List I of the Opium Act. The CAM is consulted on the necessity of a possible addition of a substance group to List IA.

One group of substances already included in List IA are those derived from 4-aminopiperidine, i.e. fentanyl analogues. These are substances derived from the synthetic opioid fentanyl, which has led to an opioid crisis, particularly in the United States, resulting in many addictions and deaths. Concerns about the emergence in Europe of new synthetic opioids derived from fentanyl have led to the addition of this substance group to List IA.

Meanwhile, nitazene derivatives, substances derived from etonitazene, have also made their appearance in the Netherlands. These synthetic opioids are generally many times more potent than fentanyl and therefore pose a real threat to public health. In the United Kingdom, the use of nitazenes has already led to dozens of deaths. As a result, the United Kingdom has introduced a generic ban on nitazenes.

The Netherlands Poisons and Information Centre [Nederlands Vergiftigingen en Informatie Centrum] (hereinafter: NVIC) has received multiple reports of intoxications

with nitazenes in the Netherlands. A death in March 2025 in the Netherlands has been linked to isotonitazepine, a nitazene, and in the summer of 2024, Dutch police seized a large postal consignment of nitazenes. In Europe, nitazenes are increasingly appearing on the drug market. In March 2025, the Commission on Narcotic Drugs (CND) considered the emergence of these synthetic opioids and decided to place several nitazenes under international control.

These worrying developments have prompted the addition of nitazenes as a substance group to List IA. A number of nitazenes were already on List I and in recent years, several nitazenes have been added to it following an international risk assessment.
In the spring of 2025, the CAM was consulted on the intention to add this group of substances to List IA. The CAM concludes that nitazenes are comparable to fentanyl derivatives and opioids, such as morphine and heroin, in terms of their action and effect. There is a very high potency and high risk of overdose. The CAM reports that the cases reported to the Netherlands Forensic Institute and poisonings or health incidents reported to the NVIC and the Drugs Information and Monitoring System (DIMS) show that nitazenes have reached the Netherlands, where nitazenes in other countries already lead to greater problems. Monitors from the United Nations Office on Drugs and Crime (UNODC) show some 30 countries in which the number of products containing nitazenes found has risen sharply in recent years. The CAM mentions that nitazenes are incorporated into all kinds of products, often without the user's knowledge. Intoxication with nitazene can have a major acute health impact, potentially resulting in death. The CAM concludes that, based on information from other countries, nitazenes constitute a potentially high-risk group of substances that may have serious health consequences.

Based on the precautionary principle, the CAM advises the Ministry of Health, Welfare and Sport to include the nitazenes group of substances on List IA of the Opium Act.

Designation of isotonitazepyne on List I
At the end of 2024 and beginning of 2025, nitazene derivatives, including isotonitazepyne, were found in counterfeit oxycodone tablets in the Netherlands. These counterfeits were linked to several cases of intoxication and isotonitazepyne, including one fatality in the spring of 2025. There has also been a case of severe intoxication with isotonitazepyne following intentional use. This development has prompted the CAM to request a risk assessment of the harmfulness of isotonitazepyne and to advise on the steps to be taken.
In its risk assessment, the CAM concludes that although the current use of isotonitazepyne in the Netherlands appears to be limited, the potential acute health risks are considerable and there are likely to be more risks of dependence. Although the social risks are currently limited, the nature of the substance and signs of criminal distribution warrant vigilance.
The CAM has therefore recommended that, as a precaution and on the basis of analogy of similar opioids, isotonitazepyne be added to List I of the Opium Act. This opinion is followed up with the present decree.

3. Regulation in a European and international context

3.1 International context
The Single Convention on Narcotic Drugs, concluded in New York on 30 March 1961, as amended by the Protocol amending the Single Convention on Narcotic Drugs,[1] concluded in Geneva on 30 March 1972 (hereinafter: the Single Convention), requires parties to the Convention to prohibit the substances listed in Lists I and II thereto. New psychoactive substances (NPS) are regularly added to those lists, which are also added to Lists I or II of the Opium Act in implementation thereof.[2]

The Convention on Psychotropic Substances[3], concluded in Vienna on 21 February 1971, requires Parties to subject the substances listed in the Annexes to this convention to strict rules. New psychoactive substances (NPSs) are regularly added to List II of this convention. These substances are then also added to List I or II of the Opium Act.[4]

However, both Conventions regulate only specific substances. If a substance derived from Etonitazene has been found, as in the case of this amendment decree, it will take a reasonable time before this substance is regulated under one of these conventions and before these measures are carried over to the Opium Act. The regulation of the nitazene group of substances, as set out in this decree, therefore supplements the provisions of the Single Convention and the Convention on Psychotropic Substances. To this end, it is important that substances already listed in List I or II of the Opium Act are exempt from the prohibition in Section 2a of the Opium Act (see Section 2a(2)(j) of the Opium Act). After all, they fall under the prohibitions in Articles 2 and 3 of the Opium Act.

3.2 European context
In the European context, firstly, Article 71(2) of the Schengen Agreement of 19 June 1990 implementing the Schengen Agreement of 14 June 1985 between the governments of the States of the Benelux Economic Union, the Federal Republic of Germany and the French Republic on the gradual abolition of checks at their common borders (hereinafter: the Agreement) is relevant.[5] This provision obliges states to prevent, administratively and criminally, the sale, supply and delivery of narcotic drugs and substances. For the definition of narcotic drug and psychotropic substance, this convention refers to the lists to the Single Convention and the Convention on Psychotropic Substances. In short, the agreement does not regulate a group of substances, as is the case in this decision.

Furthermore, Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking[6] is also relevant. This Framework Decision confirms in Articles 2 and 4 the obligations of the UN Conventions and harmonises, at a minimum level, the maximum sentences for the custodial sentences to be imposed on prohibited

[1] Treaty Series of the Kingdom of the Netherlands 1963, 81 and Treaty Series 1987, 90.
[2] See, for example, the Decree of 11 May 2017, amending Lists I and II annexed to the Opium Act in respect of the addition of the substances α-PVP, acetylfentanyl and 4-FA to List I and the addition of the substance phenazepam to List II (Bulletin of Acts and Decrees 2017, 206).
[3] Treaty Series of the Kingdom of the Netherlands 1989, 129.
[4] See, for example, the Decree of 9 November 2015 amending List I of the Opium Act with the inclusion on that list of substances 25B-NBOMe, JWH-018 AM-2201 and methylon (Bulletin of Acts and Decrees 2015, 429).
[5] Treaty Series of the Kingdom of the Netherlands 1990, 145 and OJ 2000, L 239.
[6] OJ 2004, L 335.

conduct. For this Framework Decree as well, no substance group is regulated, but only specific substances. On the basis of a risk assessment to be carried out by the commission in relation to public health and social risks at Union level, those agents may be included in the definition of 'drug'. However, this Framework Decision allows Member States, without prejudice to the obligations imposed on them under this Framework Decision, to take any national control measures they deem appropriate in relation to new psychoactive substances on their territory (Article 1b of Framework Decision 2004/757/JHA). As explained above, there are grounds for taking additional measures to protect public health.

Since there is no regulation of this substance group in secondary European law, the present regulation must be assessed in light of primary European law. In order to answer the question of whether the present amending decision is compatible with the free movement of goods, it must first be determined whether the regulated products are covered by the free movement of goods. With regard to substances regulated under the Single Convention, the Convention on Psychotropic Substances, Framework Decision 2004/757 or the Convention implementing the Schengen Agreement of 14 June 1985, the Court of Justice of the European Union has ruled that these substances are not covered by the freedoms of movement because they are prohibited in the economic and commercial circuit.[7] Since the substances regulated in this decree do not fall under any of the aforementioned instruments, it cannot be ruled out that these substances do fall under the free movement of goods.

In view of the foregoing, the requirements set out in this decree could be considered a measure having equivalent effect to a quantitative import restriction within the meaning of Article 34 of the Treaty on the Functioning of the European Union (hereinafter: TFEU). Based on Article 36 of the TFEU, Member States are permitted to implement quantitative import limitations or measures having equivalent effect if they meet a number of conditions as laid out in case-law in the Court of Justice of the European Union (hereinafter: CJEU):

- the measure must be justified by overriding reasons relating to the public interest;
- the measure must be suitable for guaranteeing the realisation of the pursued objective;
- the measure may not go beyond what is necessary to achieve the objective;
- the measure must be known and predictable;
- the measure must be applied without discrimination.[8]

Principally, banning the proposed substance groups will protect the interest of public health. The protection of the health and life of humans is explicitly incorporated as a justification in Article 36 TFEU. Importantly, the case law of the CJEU states that Member States should be allowed a wide margin of discretion in protecting public health, as the level of protection may vary from one Member State to another.[9] The group of substances prohibited by this decision includes several substances that are already listed in List I of the Opium Act. This concerns a group of substances, several of which are already covered by international treaties (and the Opium Act) and which, following an

[7] ECJ 16 December 2010, No. C-137/09 (Josemans), recital 42).

[8] ECJ 30 November 1995, No C-55/94 (Gebhard); ECJ 4 July 2000, No. C-424/97 (Haim); ECJ 1 February 2001, No. C-108/96 (Mac Quen et al).

[9] *Vanderborght*, section 71.

intensive risk assessment, have recently been brought under control due to their harmful effects on public health. The measure is therefore appropriate to protect public health. Completely banning the substance groups will make them less available, therefore serving the interest of public health. In view of the precautionary principle, it is justified to ban substances as long as it is unclear whether they are harmful to health. For this purpose, it is important that there are no known legal applications for the substances mentioned. That is the case. In addition, the Opium Act provides for exceptions to the ban, for example, the production of medicinal products and it is possible to apply for an exemption for example, scientific research. Possible legal uses can be designated on the basis of Article 3c of the Opium Act, so that the ban does not apply. In view of this, the measure does not go beyond what is necessary to achieve the objective.

The ban is known and predictable. This decision will be published in the Bulletin of Acts and Decrees, thereby making it public. In addition, the prohibited substance group is described in sufficient detail, so that people who work with these substances (and preparations thereof) know which substances are prohibited or for which they must apply for an exemption. Furthermore, communication will take place prior to the entry into force of the ban on the substance group in question. Finally, the proposed bans apply regardless of the nationality of the person performing illicit acts with these substances and regardless of the origin of the substance, meaning that the proposed ban applies without discrimination. Based on the foregoing, the Dutch government deems that this regulation is compliant with the European rules concerning the free movement of goods, insofar as the banned substance groups are covered by them.

3.3 Notification
The draft of this decree was submitted to the European Commission and the other Member States of the European Union on **PM date** pursuant to Article 5(1) of Directive (EU) 2015/1535[10]. This notification was made because Articles II and III of this decree may contain technical requirements within the meaning of Directive (EU) 2015/1535. In response to the notification **PM outcome notification**.

4. Advice received and results presented

4.1 Health Care and Youth Inspectorate (IGJ)
The IGJ has concluded that the draft decree in question does not require any amendments from the perspective of supervision and enforceability. The addition of nitazenes to List IA is expected to lead to an increase in the workload associated with monitoring compliance with the Opium Act. It is expected that there will be a limited increase in the number of applications for an Opium Act waiver for this substance group. An increase in the number of import and export exemptions is also anticipated.

However, attention is drawn to the fulfilment of the advisory task of the IGJ with regard to questions from current and future exemption holders whether a specific substance (with a certain structural formula) falls within the substance group, and whether an adaptation of the permit or exemption is necessary. Further consultations will take place on this issue.

[10] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ 2015, L 241).

4.2 Organisations in the criminal justice system
The organisations in the criminal justice chain involved in the proposed amendment to the Opium Decree, namely the police, the Public Prosecution Service, Judicial Institutions Service (DJI) and Netherlands Forensic Institute (NFI), have expressed their support for the proposed extension of the substance group ban, as this contributes to the fight against drug-related crime. From the point of view of enforceability, these organisations see no objections to the proposed addition of the nitazene group of substances to List IA of the Opium Act.

However, these organisations do take into account incidental costs due to the proposed addition of the nitazenes to List IA of the Opium Act. In addition to an increase in criminal cases that cannot yet be quantified, this concerns, for example, the costs incurred by the Public Prosecution Service for adapting its information provision systems, existing training programmes and Public Prosecution Service guidelines (policy). However, these activities are closely related to adjustments required by the NPS legislation as such, so that the additional incidental costs resulting from the present decision can in all likelihood be absorbed within the existing budgets of these organisations.

The police, Public Prosecution Service, NFI and DJI do not currently expect any additional structural costs, so that no additional financial coverage needs to be found from the Ministry of Justice and Security (for the time being). The effect of the proposed criminalisation of nitazenes on the workload of the aforementioned authorities is difficult to assess in advance. The Ministry of Justice and Security will evaluate the effect of criminalisation on the workload as part of the evaluation of the workload associated with the implementation of the New Psychoactive Substances Act. For this purpose, a period of two years is envisaged, so that a good picture can be obtained of the actual increase in workload.

4.3 Council for the Judiciary
The Council for the Judiciary indicates that the implementation consequences depend on the prosecution policy of the Public Prosecution Service and follows the Public Prosecution Service in this regard. They are therefore also included in the evaluation.

4.4 Online consultation
The draft decision was submitted for online consultation on 1 October 2025 for a period of four weeks. Four comments were received following the online consultation. These entail three responses from citizens who endorse the importance of banning the nitazene group of substances. The fourth response comes from a municipality, which raises a number of questions of an administrative nature. The municipality therefore requests confirmation in this explanatory memorandum that the substance groups listed in List IA fall within the scope of Article 13b of the Opium Act, with a view to ensuring clarity and enforceability. This new group of substances also falls within the scope of Article 13b of the Opium Act, which – in short – provides the mayor with the power to close down businesses in connection with trade.

In addition, the municipality points to the importance of current policy rules for the application of Article 13b of the Opium Act with regard to List IA. The Ministry of Justice and Security (JenV) subsidises the Netherlands Centre for Crime Prevention and Safety (the CCV) to support municipalities in the application of Article 13b of the Opium Act. For this purpose, they organise webinars, for example, and a think tank has been created, in which – among other things – professionals from municipalities participate. In addition, a CCV web dossier is available for the municipalities, including an assessment framework, guidelines and examples of local policy rules.

The CCV will in any case discuss the addition of nitazenes to List IA with the think tank. In addition, the CCV will add current local policy proposals to the web dossier. Finally, the Centre will update the assessment framework and, if necessary, the existing guidelines.

Furthermore, the municipality calls for attention to be paid to information, prevention and early warning with regard to this hazardous substance group. At present, the use of nitazenes is not (yet) common in the Netherlands. Due to the significant health risks posed by these substances, it is essential to be prepared for the possible emergence of nitazenes in our country. This proposal is one of the measures taken by the Netherlands in the context of this preparation. A ban on nitazenes supports the prevention message, as potential users are warned about the risks of these substances. In the run-up to the introduction of this proposed ban, further investments will be made in monitoring, signalling and information materials.

4.5 Preliminary scrutiny

In accordance with Article 3aa(4) of the Opium Act, a draft of this general administrative order was sent to both chambers of the States-General on XX XX 2025 (Parliamentary Documents II 2025/26, xxxx, no. x).

5. Financial impact

The present decision is not expected to have such an impact on the workload of the organisations in the criminal justice chain involved in the proposed amendment to the Opium Decree that it cannot be absorbed within the existing budgets of these organisations.

This decision has consequences for the workload of the IGJ and cooperation partner CIBG (Farmatec). The addition of this substance group is expected to result in a limited increase in the number of applications for an exemption for this substance group, as well as an increase in the number of import and export exemptions. The costs incurred by these organisations as a result of the proposed decision will, on the one hand, be covered by the fees charged for the dispensations. Costs that fall outside of this scope will be included in the annual assignments from the Ministry of Health, Welfare and Sport.

6. Regulatory burden

6.1 Impact on regulatory burden

The substantive compliance costs and the administrative burden together constitute the costs associated with regulatory burden. The government aims to reduce the regulatory burden for citizens, businesses and professionals. The present regulations may have consequences for the regulatory burden on (healthcare) institutions, government laboratories, manufacturers, and wholesalers who will need to apply for an exemption to possess or perform activities involving substances from the nitazene group. In principle, this concerns existing exemption holders who already have an exemption for substances listed in Lists I and II and/or for one or more substance groups listed in List IA of the Opium Act.

If these parties also need an exemption for the substance group nitazenes, they will have to submit an amendment application to the CIBG. To this end, they will need to take a number of steps, starting with familiarising themselves with the relevant regulations and gathering information to determine whether an extension of the existing exemption is necessary. They will then submit an amendment application to the CIBG, requesting an extension of the existing exemption. In most cases, no on-site inspection by the IGJ is

required for the granting of an extension of the exemption. It is expected that this will involve a group of up to 30 existing exemption holders.

Costs structure:

Time x hourly wage
becoming acquainted with legislation and obtaining further information: 2 hours (highly trained personnel) x €54 = €108
Administrative actions (sending change request), registration (administrative staff): 1 hour x €39 = €39
Total cost of regulatory burden for existing holder exemption: €147

Scope Expected number of amendment requests from existing exemption holders: 30 x cost €147= €4,410 occasionally.

The exemption will need to be renewed once every five years. The costs associated with this are structural in nature. However, each year, this concerns only a few applications for renewal of the exemption for which a limited administrative action is required. In view of the limited scope, the impact of these costs on the regulatory burden is considered negligible.

The situation in which a new applicant without an existing opium law exemption would apply for an exemption solely for the nitazene substance group is unlikely and will therefore not be elaborated upon further.

6.2 Advice from the Advisory Board on regulatory burden (hereinafter: ATR)
The ATR has assessed the present proposal and announced that the board has not selected the dossier for formal advice, because it only results in one-off costs for review and adjustment, which are adequately described in the explanatory notes.

7. Entry into force

This decree enters into force on a date to be determined by royal decree. This will deviate from the fixed moments of change and minimum introduction period, as it concerns urgent legislation. In order to prevent health damage, it is necessary to prohibit the harmful nitazenes and isotonitazepyne as soon as possible.

State Secretary for Health,
Welfare and Sport,