We, WILLEM ALEXANDER,

BY THE GRACE OF GOD,
KING OF THE NETHERLANDS,
PRINCE OF ORANGE-NASSAU,

ETC. ETC. ETC.

Decree of

amending the Public Health Decree because of the introduction of an a licensing obligation and a reporting obligation with regard to the performance of actions with poliovirus

On the recommendation of Our Minister for Health, Welfare and Sport *[date],* reference *[reference]*;

Having regard to Articles 12b(1)(3) and (4), 12c(3) and 12i(1) and (2) of the Public Health Act, Article 11(1) of the Personal Data Processing in Healthcare Supplementary Provisions Act and Article 5(1) of the Pregnancy Termination Act;

Having heard the opinion of the Advisory Section of the Council of State (opinion of *[date]*, No *[number]*);

Having regard to the further report of Our Minister for Health, Welfare and Sport of *[date]*, reference *[reference]*;

Have approved and hereby decree the following:

ARTICLE I

In the Public Health Decree, a chapter is inserted after Chapter V, reading:

Chapter Va. Poliovirus licence and reporting obligation

Article 17a

1. The licensing obligation referred to in Article 12b(1) of the Act will apply to:

a. wild poliovirus type 1, 2 or 3;
b. vaccine-derived poliovirus type 1, 2 or 3;
c. Sabin type 1, 2 or 3;
d. oral polio vaccine 1, 2 or 3;

e. World Health Organization approved novel poliovirus strains, including novel oral polio vaccine strains.

2. The validity period of the licence will be:

a. the period of time remaining, at the time of granting the licence, of a certificate provided to the applicant in connection with the implementation of World Health Organization Resolution WHA71.16;

b. in the absence of such a certificate, 3 years.

3. A person who has previously been granted a licence and who has submitted an application for an extension of the validity period of that licence before the expiry of its validity period or before the situation referred to in Article 12f(1)(a) of the Act occurs may continue to act with the poliovirus in question until a decision has been taken on that application. subject to the authority of Our Minister laid down in Article 12b(5) of the Act.

Article 17b

With regard to the storage, processing, use or otherwise processing of the types of poliovirus referred to in Article 17a(1), the person who performs or intends to perform the actions with them will:

a. be an essential facility; and

b. fulfil the requirements laid down by regulation of Our Minister in connection with the implementation of Resolution WHA71.16 of the World Health Organization.

Article 17c

1. The reporting obligation referred to in Article 12i(1) of the Act applies to the storage, processing, use or otherwise processing of:

a. potentially infections material with wild poliovirus type 1, 2 of 3;

b. potentially infectious material with vaccine-derived poliovirus type 1, 2 or 3;

c. potentially infectious material with Sabin type 1, 2 or 3;

d. potentially infectious material with oral polio vaccine 1, 2 or 3;

e. potentially infectious material with novel poliovirus strains.

2. A notification will be made to the inspectorate by electronic means, prior to commencing the actions referred to in paragraph 1, providing at least the following information:

a. the type and quantity of material;

b. the country of origin and the date on which the material was collected;

c. the nature of the actions and their intended duration.

3. The reporting obligation does not apply to actions by a healthcare provider and related actions, insofar as they are necessary for diagnostics.

4. Further rules on the reporting obligation may be laid down by ministerial order.

ARTICLE II

In subsection II, point 3.1(a), of the Annex to Articles 2 and 3 of the Decree on the disclosure of supervisory and implementation data under the Health and Youth Act, a subsection is added, reading:

v. the results of monitoring and research on the licensing and reporting obligation with regard to poliovirus as referred to in Chapter II, section 6, of the Public Health Act;

ARTICLE III

1. A person who, at the time of entry into force of Article I of this Decree, already performs actions with a type of poliovirus designated in Article 17a(1) of the Public Health Decree may continue the actions in question if:
a. he or she, at the time referred to above, has already reported to the Health and Youth Inspectorate in its capacity as the National Authority for Containment as referred to in Article 36(1)(d) of the Health Act for the purpose of certification in the context of the resolution referred to in that provision; or
b. he or she submits a licence application as referred to in Article 12b(1) of the Public Health Act within 4 weeks of the aforementioned date.
2. The person referred to in paragraph 1 may continue the actions in question until a decision has been taken on the granting of a licence as referred to in Article 12b(1) of the Public Health Act, subject to the authority of Our Minister laid down in paragraph 5 of that article.
3. A person who, at the time of entry into force of Article I of this Decree, already performs actions with material designated in Article 17c(1) of the Public Health Decree will report this to the inspection within 4 weeks following the aforementioned time.

ARTICLE IV

In Article 29(2) of the Decree on the use of citizen service numbers in healthcare, ‘Article 18 of the Decree on care entitlements under the AWBZ’ is replaced by ‘Article 6b of the Public Health Act’.

Article V

In Article 28(1) of the Pregnancy Termination Decree, the words ‘of the Act’ will be inserted after ‘Article 11(6)’ and after ‘Article 11a(6)’.

ARTICLE VI

1. This Decree will come into force at a time specified by Royal Decree, which may differ for the individual articles or parts thereof.
2. If Article V enters into force after 1 January 2025, that Article will expire on 1 January 2025.

I hereby order this Decree, together with its associated explanatory memorandum, to be published in the Bulletin of Acts and Decrees.

The Minister of Health, Welfare and Sport,

EXPLANATORY NOTES

General section

1. Introduction

With this Decree, a licensing obligation is regulated in the Public Health Decree (hereinafter: BPG) for performing actions with certain types of poliovirus, and a reporting obligation is regulated for certain types of potentially infectious material. The basis for introducing this licence and reporting obligation is laid down in Article 12b(1) and Article 12i of the Public Health Act (hereinafter: WPG). These articles derive from the Act of 22 May 2024 amending the Public Health Act due to the introduction of a licensing obligation and a reporting obligation with regard to performing actions with poliovirus and certain other changes.[1] Section 2.1 discusses the licensing obligation in further detail, and Section 2.2 discusses the reporting obligation.

The present Decree also amends the Decree on the disclosure of supervisory and implementation data under the Health and Youth Act. This amendment is explained in more detail in section 2.3.

Finally, the opportunity is taken to rectify an outdated reference in the Decree on the use of citizen service numbers in healthcare and an omission in the Decree on Pregnancy Termination. These amendments are explained in greater detail in the article-by-article section.

2. Main features of this Decree

2.1 Authorisation obligation

Article 12b(1) of the WPG provides for a foundation on the basis of which a licensing obligation can be established by general administrative order for the performance of actions with designated types of poliovirus. The reason for providing for the possibility of establishing a licensing obligation in the WPG is the fact that, on 26 May 2018, the World Health Organization (hereinafter: WHO) enacted resolution WHA71.16[2] on polio eradication (hereinafter: Resolution).[3] This Resolution is part of the WHO's Global Polio Eradication Initiative, a global approach to combating polio in order to achieve a polio-free world. This approach aims to minimise the risks of the release and spread of the virus by destroying poliovirus as much as possible, or to ensure that any facility working with eradicated polioviruses must handle and store poliovirus in accordance with the *WHO Global Action Plan for Poliovirus Containment* (hereinafter: GAP requirements).[4]

2.1.1 Scope of the licensing obligation

The licensing obligation is addressed to ‘everyone’ (Article 12b(1) of the WPG). In practice, the licensing obligation will apply in particular to facilities that carry out operations with poliovirus for the development and production of vaccines or for

---

[1] Bulletin of Acts and Decrees 2024,143.

[2] http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R16-en.pdf

[3] See the explanatory memorandum to the proposal to amend the Public Health Act because of the introduction of a licensing obligation and a reporting obligation with regard to the performance of actions with poliovirus and some other amendments (Parliamentary Papers II 2022/23, 36334, No 3).

[4] These requirements were previously referred to as the *WHO Global Action Plan to minimise poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use.*

monitoring purposes. For the sake of readability of this explanatory note, the term ‘facilities’ will therefore be used below.

This Decree establishes in Article 17a(1) BPG wild poliovirus type 1, 2 and 3 (subsection (a)), vaccine-derived poliovirus type 1, 2 and 3 (subsection (b)), Sabin type 1, 2 and 3 (subsection (c)), oral polio vaccine 1, 2 and 3 (subsection d) and novel poliovirus strains approved by the WHO, including novel oral polio vaccine strains[5] (subsection (e)) designated as the types of poliovirus subject to the licensing obligation. The WHO’s GAP requirements[6] apply to the infectious material of these types of poliovirus.

The licensing obligation prohibits the ‘storage, processing, use or other processing’ of the designated types of poliovirus without a licence. This list of actions in Article 12b(1) of the WPG is in line with the concepts applied by the WHO of ‘handling’ and ‘storing’. This in fact aims to cover the whole range of possible actions. Article 12b(2) of the WPG lists in which case the licensing obligation does not apply. First, this is with regard to actions by a healthcare provider and related actions to the extent that they are necessary for diagnostic purposes (subsection (a)).[7] It follows from the requirement of necessity that the poliovirus must be destroyed after diagnosis, or transferred to a licensed facility. Furthermore, transport is also not subject to a licensing obligation (subsection (b)). Strictly speaking, transport is not covered by the actions listed above, but in order to avoid ambiguities in this regard, this is explicitly provided for in Article 12b(2) of the WPG. The reason for excluding transport is that the laws and regulations on the transport of dangerous substances are sufficient in this respect.[8] Pursuant to Article 12b(2)(c) of the WPG, other actions may be designated by general administrative order for which the licensing obligation also does not apply. This possibility has not been used in the present Decree, as there are currently no specific actions eligible for this. Insight gained may result in there being cause to take advantage of this opportunity at some later point.

2.1.2 Which requirements must be met?

A facility can only be eligible for a licence if it is an ‘essential facility’ and meets the GAP requirements applicable to the specific operations of the facility. ‘Essential facility’ means a facility with a critical national or international role in eradicating the poliovirus, monitoring it or within the scope of readiness, in introducing/reintroducing the poliovirus.[9] The GAP requirements will be aligned with the GAPIV requirements currently applicable. The requirements to be met will be laid down by ministerial order. This will ensure that it is consistent with the differentiation applied by the WHO (temporary or otherwise) with regard to specific containment requirements for different types of poliovirus. By setting the requirements at the level of a ministerial order, the requirements can be adapted dynamically if the WHO amends the GAP requirements. Pursuant to Article 12b(3) of the WPG, the requirements may be laid down in the English language. The

---

[5] Report of the Sixth meeting of the Poliovirus Containment Advisory Group (CAG), 25-27 January 2023.

[6] The current GAPIV requirements entered into force on 1 July 2022. Initially, there was a transitional period during which the previously applicable GAPIII requirements were still applicable. However, according to the report of the 6th the meeting of the Containment Advisory Group (CAG) on 23-25 January 2023, it was decided that as of 1 January 2024, the audits of the National Authorities for Containment should be carried out in accordance with GAPIV requirements.

[7] This includes performing diagnostics.

[8] These are the Transport of Hazardous Substances Act (for land and water transport) and the Aviation Act.

[9] See Resolution (footnote 2), point 2(1).

facilities are accustomed to using the English language, and this can prevent discrepancies or ambiguities from arising from the translation with respect to the authentic version.

The GAPIV requirements aim to minimise the risk of the release of infectious poliovirus from a facility, whether intended or unintentional. To this end, the requirements are subdivided into 14 elements:

1. *Biorisk Management System* – this element requires the establishment, recording, implementation and maintenance of a *Biorisk Management System* that must be appropriate to the nature of the facility and the risk involved in the operations carried out there. These include requirements about the content of the policy and the distribution of roles, tasks and responsibilities.

2. *Risk Assessment and Control* – this element requires the existence of a risk management system that must be established in procedures to identify and manage risks to general safety.

3. *Worker Health Programme* – this element includes requirements for the protection of personnel in order to operate safely in the facility, including by taking preventive and protective measures.

4. *Competence and Training* – this element includes requirements in terms of recruitment, training, competences and availability of staff.

5. *Good Microbiological Practice and Procedure* – this element requires a facility-specific *Biosafety Manual* and adequate implementation and monitoring of the *Good Microbiological Practice and Procedures* by the staff.

6. *Clothing and Personal Protective Equipment* – this element requires the identification, on the basis of a risk analysis, of the clothing and personal protective equipment necessary for carrying out work in the facility.

7. *Security* – this element sets out requirements for the security measures to prevent the loss, theft, misuse or deliberate release of poliovirus from a facility.

8. *Facility Physical Requirements* – this element sets out requirements for the construction of the facility and its layout.

9. *Equipment and Maintenance* – this element contains requirements on maintaining, checking, calibrating, certifying and validating equipment.

10. *Poliovirus Inventory and Information* – this element includes the requirements for the up-to-date maintenance of all poliovirus material present in the facility and its possible transfer to other facilities.

11. *Waste Management, Decontamination, Disinfection and Sterilisation* – this element contains requirements on the treatment of waste and suitable methods of decontamination.

12. *Transport Procedures* – this element sets out the requirements for the transport of poliovirus within the facility and the sending or receiving of material between facilities and the consent for this purpose.

13. *Emergency Response and Contingency Planning* – this element sets out the requirements for preparing for potential incidents and emergencies, including the presence and practice of emergency procedures.

14. *Accident/Incident Investigation* – this element sets out the requirements for the reporting of accidents and incidents and their follow-up and investigation in order to prevent their recurrence.

2.1.3 Licence application

The basic principle is that in order to obtain a licence, an application must be submitted to the Minister of Health, Welfare and Sport (hereinafter: Minister of Health, Welfare and Sport). However, facilities which, at the time of entry into force of this Decree, have a WHO-recognised *(Interim) Certificate of Containment* or for whom the WHO certification process is still ongoing, there is no need to submit a licence application. A licence application will be accepted by operation of law in respect of them. The reason for this is that they are already known. In the WHO's certification process, a role has been assigned to the *National Authority for Containment* (hereinafter: NAC). The Resolution requires each Member State to establish an NAC to act as a certifying authority and to audit the facilities in implementation of the Resolution. The Minister of Health, Welfare and Sport has assigned the task as NAC to the Health and Youth Inspectorate (hereinafter: IGJ).[10] Because of the involvement of the NAC in the WHO certification process, the IGJ is aware of which facilities have been granted a certificate and for which facilities the process is still ongoing. The earlier notification of these facilities to the NAC with a view to obtaining a certificate is automatically regarded as a licence application. This will be further regulated in the ministerial regulation which lays down detailed rules on the submission and processing of a licence application.

For new facilities, if they submit a licence application, this application will also apply as a notification to the NAC with a view to obtaining a certificate. This will be dealt with in the aforementioned ministerial order. With this notification, the WHO certification process can commence. For a description of the certification process, please refer to section 2.3 of the explanatory memorandum to the Act amending the Public Health Act due to the introduction of a licensing obligation and a reporting obligation with regard to performing actions with poliovirus and certain other amendments.[11]

2.1.4 Granting licences

The following applies for the facility that has already gone through the WHO certification process at the time of the introduction of a licensing obligation. If at the facility has been granted a Certificate of Containment, it is eligible for a licence. It follows from awarding the certificate that the facility in question is essential and meets the GAP requirements applicable to it. If at the facility has been granted an Interim Certificate of Containment, a licence is also granted, albeit subject to additional conditions, requirements or restrictions due to the fact that the facility does not yet fully comply with the GAP requirements applicable to it, but has demonstrated that it is likely to comply with them. Article 12c(4) of the WPG provides a basis for this. The validity period of the licence will be equal to the (remaining) validity period of the Certificate of Containment (Interim or otherwise) (Article 17a(2) of the BPG).

---

[10] See the statement to that effect in Government Gazette 2020, 31583, as well as Parliamentary Papers II 2017/18, 25295, No 46 and Parliamentary Papers II 2020/21, 25295, No 1101. This concerns a new task of the IGJ laid down in Article 36(1)(d) of the Health Act.

[11] Parliamentary Papers II 2022/23, 36334, No 3, section 2.3.

For facilities for which the WHO certification process has not yet been completed or has yet to start, a decision on the licence application will only be taken once the certification process has been completed. The decision period is therefore suspended during the certification process. This will be further regulated in the aforementioned ministerial order. If a facility is granted a Certificate of Containment (Interim or otherwise), this will also lead to the granting of the licence (possibly with additional conditions, restrictions or requirements).

However, if a facility is not eligible for a certificate, in principle no licence will be granted. On the basis of the General Administrative Law Act, objections and appeals are available against the rejection of the licence application. Adequate legal protection is thus provided for the facility.[12] If the facility can still demonstrate in objection or appeal that it is an essential facility that meets the GAP requirements applicable to it, this can still lead to the granting of a licence (despite the fact that the facility does not have a certificate recognised by the WHO). It follows from the foregoing that compliance with the GAP requirements are therefore decisive when granting or not granting a licence.

2.1.5 Transitional law

Article 12b(4) of the WPG offers the possibility to make a transitional arrangement for facilities that already perform actions with the relevant type of poliovirus at the time of the introduction of a licensing obligation. This option has been used in the present Decree (Article III(1)). The transitional arrangement provides that facilities remain competent to continue their activities pending a decision on the licence application, if they have previously presented themselves to the IGJ in its capacity as NAC in the context of the WHO certification trajectory or submit a licence application within 4 weeks. As explained above, a ministerial order will provide that a previous notification to the NAC will automatically be regarded as a licence application. In accordance with Article 12b(5) of the WPG, an additional guarantee is provided for in the transitional arrangement. If deemed necessary for the protection of public health, the Minister of Health, Welfare and Sport may, on the advice of the IGJ, order that certain actions or activities be suspended until a decision has been taken on the licence application (Article III(2)).

2.1.6 Renewal of the licence

If, after the expiry of the validity period of the licence, a facility wishes to continue to store, process, use or otherwise process the poliovirus in question, a new licence will have to be applied for.[13] In any event, in the context of that procedure,[14] assess whether the facility still complies with the applicable requirements. Pursuant to Article 12b(4) of the WPG, the present Decree provides that if a licence holder submits an application for renewal of the licence in good time, that is to say before the expiry of the validity period of the licence, the activities may continue until a decision has been taken on that application (Article 17a(3) of the BPG). This is a similar transitional arrangement, as described above. Here too, the Minister of Health, Welfare and Sport has the power to order, on the advice of the IGJ, that certain actions or activities be suspended if this is necessary for the protection of public health.

2.2 Reporting obligation

[12] The WHO certification pathway does not provide adequate legal protection (Parliamentary Papers II 2022/23, 36334, No 3, p. 9).

[13] Moreover, a certificate recognised by the WHO will also have to be renewed after the expiry of its validity period.

[14] This of course does not alter the fact that it can also be assessed in the interim whether a facility still meets the applicable requirements.

Within the framework of the Global Polio Eradication Initiative the NAC annually as part of the Annual Progress Report on Polio Eradication Activities (through the National Certification Committee for Poliomyelitis Eradication) provide the WHO with data on all types of poliovirus used by facilities in the Netherlands. In the light of this, Article 12i(1) of the WPG provides for a foundation on the basis of which a reporting obligation can be established by general administrative order for the performance of actions with designated types of poliovirus. The present Decree (Article 17c(1)) establishes an obligation to notify in respect of actions such as the storage, processing, use or other processing of:

a. Potentially infectious material with wild poliovirus type 1, 2 or 3;
b. potentially infectious material with vaccine-derived poliovirus type 1, 2 or 3;
c. potentially infectious material with Sabin type 1, 2 or 3;
d. potentially infectious material with oral polio vaccine 1, 2 or 3;
e. potentially infectious material with novel poliovirus strains.

The reporting obligation therefore relates to materials other than the licensing obligation. Licensing and reporting obligations therefore do not overlap. However, it is possible that a facility is subject to both the licence and the reporting obligation, namely if that facility works with different types of poliovirus (material).

The reporting obligation concerns materials that may contain certain types of poliovirus, because at the time and place of sampling of the material one or more of the relevant types of poliovirus were in circulation (potentially infectious materials, hereinafter: PIM*)*. PIMs can be present at facilities carrying out work with poliovirus, but also at institutions not conducting specific research on poliovirus. For example, a scientific institution carrying out research with faeces originating from Afghanistan where poliovirus type 1 is still circulating, or a scientific institution carrying out research on sewage from a country where vaccine-derived poliovirus was still found at the time of collection. In order to be able to determine whether a PIM exists as an institution, the WHO has provided tools, such as the PIM Guidance.[15] The WHO has also made it clear per country which samples from which period are potentially infectious and has developed an identification tool.[16]

In 2016, the IGJ carried out an inventory of 860 Dutch facilities/institutions for the presence of poliovirus, including PIMs. The small number (slightly more than 10) of facilities/institutions that had PIMs at that time indicated that they would be destroying the material. Since then, it is not expected that large numbers of PIMs have been brought into the Netherlands. It is estimated that there will be a maximum of around ten facilities/institutions that have PIMs in place. Prior to the entry into force of this Decree, the NAC will bring the reporting obligation to the attention of the previously notified and other new relevant Dutch facilities/institutions.

Moreover, the WHO has also made the current GAPIV requirements applicable to PIMs. However, it is not considered appropriate at this stage to introduce a licensing obligation for dealing with PIMs. A clearer picture of the field must first be obtained before it can be assessed whether a licensing obligation is necessary and proportionate. This insight can be obtained through the reporting obligation.

The notification must be made electronically to the IGJ (NAC), prior to the commencement of the actions (Article 17c(2) of the BPG). If those actions are already carried out at the time of entry into force of this Decree, the notification

[15] Containment Guidance Documents – GPEI (polioeradication.org)

[16] Web annex a country and area-specific poliovirus data, April 2023 update (Containment Guidance Documents – GPEI (polioeradication.org)

must be made within 4 weeks of the date of entry into force of the reporting obligation (Article III(3)). The notification will in any event include information on the type and quantity of material, the country of origin and the date on which the material was collected, as well as the nature of the operations and their intended duration. Further rules may be laid down by ministerial order. In the event of non-compliance with the reporting obligation, an administrative fine may be imposed (Article 12k of the WPG).

2.3. Disclosure of documents

Article 44(1) of the Health Act provides a specific basis for actively disclosing monitoring and implementation data of (among others) the IGJ. In the Decree on the disclosure of supervisory and implementation data under the Health Act and the Youth Act, subsection II of the Annex specifies the information that must be disclosed by the IGJ. Concerning the WPG, this is the following information:

- Point 3.1(a): documented documents of IGJ officials responsible for supervision containing the results of checks and investigations as referred to in Article 44(3)(a) of the Health Act, obtained in the performance of their duties and in which their final opinion is recorded. This excludes, in so far as is relevant here, the results of checks and investigations in response to an enforcement request (sub (ii)) and the results of checks and investigations on which decisions imposing an administrative fine are based[17] (sub (iv)).
- Point 3.1(b): notifications from the IGJ informing the person concerned that surveillance has been intensified, or that such intensification is being extended or terminated.

In relation to facilities that perform work with poliovirus (material), the IGJ performs various activities. First, it carries out work to carry out the task of National Authority for Containment (NAC) as referred to in WHO Resolution WHA71.16 on polio eradication. In addition, it can have an advisory role in the context of the licensing obligation and has a supervisory role with regard to compliance with the requirements of the WPG.

The tasks performed by the IGJ as an NAC are not covered by the disclosure regime of the Decree on the Disclosure of Supervision and Implementation Data under the Health and Youth Act. It follows from the explanatory memorandum to the Decree on the disclosure of supervisory and implementation data under the Health and Youth Act that ‘results of checks and investigations’ are results based on risk supervision in the broad sense and thematic supervision.[18] This means that the results of an audit carried out by the IGJ in its capacity as NAC in the context of the WHO certification process do not have to be actively disclosed on the basis of the Decree on the disclosure of supervisory and implementation data under the Health Act and the Youth Act. It is not deemed desirable to achieve this by amending the Decree on the disclosure of monitoring and implementation data under the Health Act and the Youth Act, because disclosing information about a possible shortcoming at a facility can lead to a risk of the deliberate release of the virus. From a biosecurity point of view, this is obviously not desirable.

It is also possible that the IGJ issues an opinion to the Minister of Health, Welfare and Sport in the context of a licence application. The IGJ does not do this in its capacity as NAC. Nevertheless, data obtained in the performance of this task are also not covered by the disclosure regime of the Decree on the disclosure of supervisory and implementation data under the Health Act and the Youth Act,

[17] The decision to impose an administrative fine is not (yet) specified in the Decree on the disclosure of supervisory and implementation data under the Health and Youth Acts, and is therefore not actively published.
[18] Bulletin of Acts and Decrees 2019, 9 (p. 28).

since this advisory task does not fall within the scope of risk supervision in the broad sense or thematic supervision. For the same reasons as mentioned above, no reason has been established to bring about the disclosure of these advices by amending the Decree on the disclosure of supervisory and implementation data under the Health Act and the Youth Act.[19]

The results of checks and investigations that the IGJ has obtained in the context of its supervisory task do, in principle, fall under the disclosure regime of the Decree on the Disclosure of Supervision and Implementation Data under the Health and Youth Act. Again, this is undesirable, because disclosing information about a possible shortcoming at a facility can lead to a risk of the deliberate release of the poliovirus. For this reason, an exception has been included in the Decree on the disclosure of supervisory and implementation data under the Health Act and the Youth Act by adding a subsection (v) under 3.1(a) (Article II).

For the aforementioned reasons of biosecurity, no reason has been seen to bring charges under administrative coercion or penalty payments imposed pursuant to Article 12j of the WPG to enforce the requirements applicable to actions with poliovirus within the scope of the disclosure regime of the Decree on the disclosure of supervisory and implementation data under the Health Act and the Youth Act.

3. Relationship with European law and other legislation

The activities in respect of which licensing or reporting obligation is required concern economic activities which constitute a ‘service’ within the meaning of Article 57 of the Treaty on the Functioning of the European Union (hereinafter: TFEU). In the explanatory memorandum to the Act amending the WPG, which provides a basis for establishing a licence or reporting obligation[20], elaborated on the relationship with the requirements stemming from Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market[21] (hereinafter: the Services Directive), as implemented, inter alia, in the Services Act.[22]

Under Article 9(1) of the Services Directive, a licence scheme for service providers within the meaning of Article 4(6) of the Services Directive is permitted – as in the present case – only if the scheme (a) does not have a discriminatory effect, (b) is justified by an overriding reason in the public interest and (c) the objective pursued cannot be achieved by a less restrictive measure. These conditions correspond to those laid down by the Court of Justice of the European Union in its case-law on the justification of restrictions on the free movement of services.[23]

These requirements are fulfilled. The licensing obligation does not have a discriminatory effect, because the system does not distinguish between Dutch facilities or facilities from other Member States of the European Union. The purpose of the licensing obligation is to ensure that only facilities that meet the relevant requirements may carry out work with the designated types of poliovirus.

---

[19] Pursuant to Article 44(3)(e) of the Health Act, advice to administrative bodies on the implementation of designated disclosure regulations may be designated. To date, this possibility has not been used whatsoever.

[20] Parliamentary Papers II 2022/23, 36334, No 3, p.p. 13-15.

[21] OJ L 376, 2006.

[22] In so far as the licensing obligation also affects the free movement of goods, in accordance with the case-law of the Court of Justice, the proposed measure has been examined only in the light of the free movement of services, since the aspect of the free movement of goods is entirely incidental to that of the freedom to provide services and may be linked to it (see, inter alia, Case C-36/02 Omega ECR I-9609, point 26).

[23] CJEU 13 May 2003, C-385/99 (Müller-Fauré), section 68 and CJEU 10 March 2009, C-169/07 (Hartlauer), section 44.

The licensing obligation is therefore necessary to protect public health. This interest has been included in the TFEU as a justification for restricting the free movement of services (Article 62 TFEU read in conjunction with Article 52(1) TFEU) and, under Article 4(8) of the Services Directive, the protection of public health qualifies as an overriding reason in the public interest. As explained in section 2.1 of the explanatory memorandum, the licensing obligation is the only appropriate means of achieving the objective pursued.[24] Only in this way can provision be made for a system that creates a sufficiently high threshold for new facilities, so that only facilities of an essential nature will be allowed to carry out actions with poliovirus. It also provides for a system whereby the compliance of a facility with the applicable requirements is assessed in advance and, if this is no longer the case after licence, the facility may be forced to cease operations as an ultimate remedy.

Furthermore, the limited licence period is in accordance with Article 11(1)(c) of the Services Directive. Due to an overriding reason in the public interest, it is necessary to periodically reassess whether a facility is still eligible for a licence.

Facilities carrying out actions with poliovirus for the manufacture of medicinal products fall within the scope of the European Medicines Directive.[25] This Directive lays down rules on the placing on the market of industrially manufactured medicinal products for human use. This Directive does not preclude the obligation to obtain a licence. The Directive and the licensing obligation pursue different objectives. The aim of the Directive is to protect public health in the use of medicinal products, and to stimulate the internal market for those medicinal products. The purpose of the licensing obligation is also to protect public health, but to prevent the emergence of new polio outbreaks. The latter objective cannot be sufficiently achieved by the rules of the Directive. In so far as the licensing obligation is liable to undermine the objective of the Directive to promote the internal market, it follows from the foregoing considerations that the restriction may be regarded as justified in that regard.

Section 3.2 of the explanatory memorandum to the Act amending the WPG, which provides a basis for the introduction of a licence or reporting obligation, deals with the relationship with the General Regulation. Making a reference to that explanatory memorandum is sufficient in this regard.[26]

Notification

The draft of this Decree is on *[PM]* notified to the European Commission in order to comply with the reporting obligations of Directive 2006/123/EC[27] and Directive (EU) 2015/1535.[28]

4. Impact on regulatory burden

Authorisation obligation

It is currently foreseen that five facilities will go through a licence-granting process. One of these concerns a public authority and therefore does not need to

[24] Parliamentary Papers II 2022/23, 36334, No 3, pp. 3 and 23-24.

[25] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (as amended).

[26] Parliamentary Papers II 2022/23, 36334, No 3, p.p. 15-16.

[27] Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ (EU) 2006, L 376)

[28] 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 (EU)* 2015, L 241).

be involved in the calculation of the regulatory burden. Regulatory burden is calculated on the basis of administrative burden and substantive compliance costs. Administrative burdens are costs incurred in complying with information obligations arising from laws and regulations. This concerns both the fulfilment of obligations and the exercise of rights. Substantive compliance costs are costs that arise from obligations of the government to do or refrain from performing actions or behaviours.

The facilities differ in type of activities and size. The regulatory burden may therefore vary from one facility to another. This section assumes an average regulatory burden, based on the insights obtained from the various facilities.

Administrative burden for the facilities arises from the submission of an application for a Certificate of Participation, a Certificate of Containment and preparing and supporting the audit by the NAC. On average, an administrative burden of 80 hours of preparation time and 153 hours of auditing is foreseen for each facility. Assuming an average hourly rate of EUR 54[29] this amounts to an average of EUR 12 582 per facility.

Substantive compliance costs arise from following up on the findings arising from the audit. Consideration should be given to adjustments (technical or otherwise) to a facility that are necessary to comply with the GAP requirements. It is estimated that a facility will take an average of 305 hours to follow up the findings and the costs for technical adjustments will average around EUR 131 250. For each facility, the average substantive compliance costs are therefore estimated at EUR 147 720.

For each facility, the average total regulatory burden costs are estimated at EUR 160 302. For the four facilities combined, the regulatory burden in 2025 is estimated at EUR 641 208.

The facilities go through this process every 3 years, assuming that the regulatory burden decreases every time because they have met the requirements in the previous 3 years. For subsequent audits, it is expected that the preparation for the audit takes an average of 62 hours, and the audit itself takes 153 hours. For each facility this amounts to EUR 11 610 and for the four facilities together to EUR 46 440. Depending on the results of the audits, the NAC may carry out periodic interim checks.

Reporting obligation

With regard to the reporting obligation as described in Article 12i of the WPG, it is expected that this applies to zero to ten facilities/institutions. They are asked to report if they have reportable material at their disposal, providing certain information. The regulatory burden of this measure is considered to be minimal given the small amount of information requested and the fact that this is a one-off notification.

Regulatory Burden Advisory Council [Adviescollege toetsing regeldruk]

The Advisory Board of Regulatory Pressure Review (ATR) did not select the file for a formal opinion, as it has no significant impact on the regulatory burden.

5. Opinion and consultation

A draft of the present Decree was consulted by means of internet consultation from 27 May to 16 June 2024 (in parallel with a draft of the underlying ministerial

[29] handboek_meting_regeldrukkosten_v_1-1-2018.pdf (kcbr.nl), on the basis of the hourly rate for highly qualified staff.

order). The current facilities and other organisations involved have been made aware of the internet consultation. Three responses were received, two of which are public. The comments received in so far as they relate to this Decree are set out below. The comments relating to the draft ministerial order, which was consulted at the same time, are set out in more detail in the explanatory memorandum to that regulation.

Bilthoven Biologicals B.V. and Poonawalla Science Park B.V. (hereinafter: jointly referred to as Bbio) were given the opportunity to further explain their response orally in response to their request.

Authorisation obligation

Bbio has argued that the licensing obligation goes beyond the WHO certification system, because under the licensing obligation the current GAPIV requirements are declared fully applicable while the WHO applies a differentiation with regard to specific containment requirements for different types of poliovirus. A similar comment was made in the non-public response.

This Decree makes the licensing obligation applicable to the poliovirus strains subject to the GAP requirements. This in itself does not go beyond the WHO certification system. However, respondents rightly pointed out that the WHO applies (temporarily or otherwise) a differentiation with regard to specific containment requirements for different types of poliovirus. The further elaboration of the requirements in the ministerial regulation will ensure that this differentiation will be adhered to, so that no stricter requirements are imposed on facilities in the context of the licensing obligation than by the WHO via GAPIV. In short, facilities that work with the relevant types of poliovirus are therefore subject to the licensing obligation, but do not currently have to comply with the specific containment requirements for those types. This explanatory memorandum has been clarified.

In addition, following Bbio's response, it has been clarified that the GAP requirements apply to: *infectious* material of the mentioned types of poliovirus. Killed material is not covered by the containment requirements of the WHO and therefore not subject to the licensing obligation.

In so far as Bbio argues in the response that elaborating the licensing obligation has a major impact on their production processes and may jeopardise the supply of their vaccines, this fear is based on the assumption that the licence obligation imposes stricter requirements than by the WHO via GAPIV. However, that is not the case, as stated above and confirmed to Bbio at the oral hearing.

Bbio's response has also led to a tightening of the list in Article 17a(1) of the BPG. The list retains the separate mention of Sabin and oral polio vaccine (OPV). Contrary to Bbio's assertions, these types do not completely overlap and the WHO also makes a distinction between these types of poliovirus.

European Law

Bbio argues that the development of the licensing obligation is contrary to European regulations, because facilities in the Netherlands are placed in a more disadvantageous position than facilities located in other Member States. During the oral hearing, Bbio explained that this argument continues on the assumption that the licensing obligation imposes stricter requirements than by the WHO via GAPIV. However, as indicated above, this is not the case and there is therefore no question of a more disadvantageous position of facilities in the Netherlands.

In response to Bbio's other comments on European legislation, the section on European law has been supplemented, in line with what has been included in the explanatory memorandum to the Act. amending the WPG, which provides a basis for establishing a licence or reporting obligation.[30]

Transitional arrangements

In the non-public response, the question was raised as to whether the power of the Minister for Health, Welfare and Sport to order, under the transitional arrangements laid down in Article III, that certain actions or activities be suspended if necessary for the protection of public health has not already been invested with the mayor and/or safety region.

Indeed, in the context of infectious disease control, the WPG assigns certain powers to the mayor and the chairman of the safety region. It is suspected that the respondent refers to Article 47 of the WPG. This article gives the mayor or the chairman of the security region the power to check a site or building for the presence of an infection if there is a well-founded suspicion of an infection and to take further measures in the event of an infection. An ‘infection’ occurs in the case of the presence of, inter alia, an infectious agent on a site or in a building, which may give rise to a public health risk (Article 1 of the WPG). However, this is always the case in a facility that carries out work with poliovirus (material). Use of the powers provided for in Article 47 of the WPG is therefore not proportionate in that case, since it must be aimed at averting the risk, that is to say, contamination. The competence of the Minister for Health, Welfare and Sport at issue here is one focused on containment, and therefore more adequate authority with regard to facilities carrying out work with infectious poliovirus (material).

Regulatory burden

Bbio has argued that the estimate of the regulatory burden and the financial consequences is significantly too low. Section 4 of the present explanatory memorandum has been amended accordingly.

Other comments

Bbio raises the question whether the lower legislation should not have specified the tasks and powers of the NAC and the training and qualifications of its employees. Apart from the fact that these aspects fall outside the scope of this Decree, the IGJ will comply with the requirements and qualifications attached to them by the WHO when carrying out the tasks as NAC.

In their response, Viroclinics BV and Cerba Research NL asked a question tailored to their facility. This has been answered individually to them.

As a result of the restricted response, the explanatory memorandum has been redrafted on a number of points.

Explanatory notes by article

Article I

A new chapter Va is inserted in the BPG, with three new articles, in connection with the licence and reporting obligation for poliovirus operations.

---

[30] Parliamentary documents II 2022/23, 36334, No 3, p. 3 et seq. and 23 to 26.

Article 17a of the BPG relates to the licensing obligation under Article 12b(1) of the WPG. The first paragraph regulates the types of poliovirus to which the licensing obligation applies. This concerns wild poliovirus type 1, 2 or 3 (subsection (a)), vaccine-derived poliovirus type 1, 2 or 3 (subsection (b)), Sabin type 1, 2 or 3 (subsection (c)), oral polio vaccine 1, 2 or 3 (subsection (d)) and WHO-approved novel poliovirus strains, including novel oral polio vaccine strains (subsection (e)). The WHO's GAP requirements apply to the infectious material of these types of poliovirus.

Article 17a(2) of the BPG regulates the validity period in the event a licence is granted. As explained in the general part, licensing takes place if a facility has a WHO-recognised Certificate of Containment (Interim or otherwise) has been granted. The validity period of the licence will be equal to the validity period of the certificate remaining at the time of issue. If a facility – in accordance with the advice of the NAC for this purpose – is not eligible for a WHO certificate and therefore not for a licence, but the facility in question successfully challenges this through an objection or appeal procedure and is still in possession of a licence, the validity period is 3 years.

Finally, 17a(3) of the BPG stipulates that if a facility submits an application for an extension of the validity period of a granted licence in good time, the relevant actions with the poliovirus may continue pending the decision on that application. An application for renewal will be submitted in due time if it is made before the licence expires. The provision in question does not affect the power of the Minister of Health, Welfare and Sport to intervene if this is necessary for the protection of public health.

Article 17b of the BPG regulates the requirements that a person who carries out operations with a type of poliovirus that is subject to a licence must meet when storing, processing, using or otherwise processing the poliovirus in question. This has been discussed in more detail in section 2.1.2. It must be an 'essential facility' and the GAP requirements must be met. 'Essential facility' means a facility with a critical national or international role in eradicating the poliovirus, monitoring it or within the scope of readiness, in introducing/reintroducing the poliovirus.[31] The GAP requirements will be aligned with the GAPIV requirements currently applicable. These will be established by ministerial order (in English). This will ensure that it is consistent with the differentiation applied by the WHO (temporary or otherwise) with regard to specific containment requirements for different types of poliovirus.

Article 17c of the BPG relates to the obligation to report laid down in Article 12i(1) of the WPG. The first paragraph regulates to which it applies. This is in the case of operations involving potentially infectious material with wild poliovirus type 1, 2 or 3 (subsection (a)), vaccine-derived poliovirus type 1, 2 or 3 (subsection (b)), Sabin type 1, 2 or 3 (subsection (c)), oral polio vaccine 1, 2 or 3 (subsection (d)) or novel poliovirus strains (subsection (e)). This is explained in more detail in section 2.2.

Article 17c(2) of the BPG regulates the time at which a notification must be made, which is prior to the commencement of the actions in question. The report is made to the IGJ and can be made digitally. Such information will include at least information on the type and quantity of material, the country of origin and the date on which the material was collected, as well as the nature of the operations and their intended duration.

[31] See Resolution (footnote 2), point 2(1).

Paragraph 3 provides a basis for further rules to be laid down by ministerial order on the obligation to report, for example on the method of reporting.

Article II

This article amends the Decree on the disclosure of supervisory and implementation data under the Health and Youth Act. This stipulates that the results of the IGJ's control and investigation regarding the licence and reporting obligation do not have to be made public. This is not deemed desirable from a biosecurity point of view, as disclosing information about a possible facility failure could lead to a risk of deliberate release of the virus. This has been discussed in greater detail in section 2.3.

Article III

This article provides for two transitional provisions. The first transitional provision is for facilities already performing operations with the relevant type of poliovirus at the time of the introduction of the licensing obligation. They remain competent to continue their work pending a decision on the licence application, if they have previously presented themselves to the IGJ in its capacity as NAC in the context of the WHO certification pathway or submit a licence application within 4 weeks. However, in accordance with Article 12b(5) of the WPG, an additional guarantee is provided, namely that the Minister of Health, Welfare and Sport may order that certain actions or activities must be suspended if this is necessary to protect public health.

The second transitional provision is for facilities that, at the time of setting up the reporting obligation, are already carrying out operations with the relevant type of poliovirus material. Contrary to the principle that a report must be made prior to the commencement of the actions in question, these facilities must submit a report to the IGJ within 4 weeks after the date of entry into force of the reporting obligation.

Articles IV and V

The opportunity was taken to rectify two omissions. The first concerns an outdated reference in Article 29(2) of the Decree on the use of citizen service numbers in healthcare. With regard to the vaccination programme, that paragraph still refers to Article 18 of the AWBZ Care Claims Decree, which expired some time ago. This Decree corrects that reference (Article IV).

The other omission corrected by this Decree concerns Article 28(1) of the Decree on Pregnancy Termination (Article V). That paragraph refers to Articles 11(6) and 11a(6). Erroneously, the addition ‘of the law’ had been deleted. That is still added, so that it is clear that these are Articles 11 and 11a of the Pregnancy Termination Act. With regard to this amendment, the follow-up procedure of Article 13(2) of the Pregnancy Termination Act must be followed before this amendment can enter into force.

Article VI

This Article provides for the entry into force of the Decree. This occurs by Royal Decree.

There is provision for differentiated entry into force, because the amendment (technical or otherwise) to the Decree on Pregnancy Termination will not enter into force until after the follow-up procedure under Article 13(2) of the Pregnancy Termination Act has been completed. If this results in the amendment entering into force after 1 January 2025, the amendment will enter into force retroactively.

The Minister of Health,
Welfare and Sport,

Regulation of the Minister of Health, Welfare and Sport of ……., reference ……., amending the Regulation on public health because of the introduction of a licensing obligation and a reporting obligation with regard to the performance of actions with poliovirus

The Minister of Health, Welfare and Sport,

Having regard to Articles 12c(5) and 29a(2) of the Public Health Act and Articles 17b and 17c(4) of the Public Health Decree,

Hereby decrees the following:

ARTICLE I

The Public Health Order is amended as follows;

A

Article 1 is amended as follows:
1. The bullets ‘a.’ and ‘b.’ are deleted.
2. In the definition of ‘the law’, ‘the’ is deleted in each case.
3. The following shall be inserted in the alphabetical order:
Decree: Public Health Decree;

B

In Chapter II, the following Article is inserted after Article 5:

Article 5a
1. A notification as referred to in Article 29a(1) of the Act shall contain at least the following information:
a. information about the reporting person;
b. information on the nature of the event, the place and time at which it occurred or was detected and the type of poliovirus;
c. information the measures taken.
2. The notification to the doctor referred to in Article 17 of the Act shall be made to the doctor of the municipal health service of the municipality where the exposure or potential exposure occurred or was detected.
3. The report to the inspection is made via NAC@igj.nl.

C

In Article 8, ‘the Annex’ is replaced by ‘Annex 1’.

D

A chapter is inserted after Chapter II, reading as follows:

Chapter IIA. Poliovirus licence and reporting obligation

Article 14a
1. A licence application as referred to in Article 12b(1) of the Act shall be submitted to the Minister using the application form made available by him or her, accompanied by the documents referred to in that form.

2. An application as referred to in paragraph 1 shall also count as a notification to the inspection in its capacity as the National Authority for Containment as referred to in Article 36(1)(d) of the Health Act for the purpose of certification in the context of the resolution referred to in that provision.
3. Without prejudice to Article 4:15 of the General Administrative Law Act, the period for taking a decision on the application shall be suspended from the day following the notification referred to in paragraph 2 until the day on which a decision on that notification has been taken. The Minister shall then decide on the application as soon as possible, but no later than 6 weeks from the day on which the aforementioned decision on the notification referred to in paragraph 2 has been taken.

Article 14b
1. With regard to the storage, processing, use or other processing of the types of poliovirus referred to in Article 17a(1) of the Decree, the requirements relating to the implementation of World Health Organization Resolution WHA71.16 set out in Annex 2 to this Regulation shall apply.
2. By way of derogation from paragraph 1, the requirements set out in Annex 3 shall not apply to the types of poliovirus listed in that Annex.

Article 14c
A notification as referred to in Article 17c(2) of the Decree shall be made at NAC@igj.nl.

E

The 'Annex under Article 8 of the Public Health Regulation' is replaced by 'Annex 1 ex Article 8 of the Public Health Regulation.

F

Two Annexes are added, worded as follows:

Annex 2 under Article 14b(1) of the Public Health Regulation

The requirements related to the implementation of World Health Organization Resolution WHA71.16 are as follows:

1. Element 1 – Biorisk Management System

1.1 Biorisk Management System

1.1.1 The organization must establish, document, implement and maintain a biorisk management system according to the requirements of this poliovirus biorisk management standard.

1.2 Biorisk Management Policy

1.2.1 The policy clearly states the overall biorisk management objective and a commitment to improving biorisk management performance.
1.2.2 Management demonstrates commitment to the policy concerning the management of facility biorisk (biosafety and biosecurity) including development of the organizational biorisk policies, authorization of resources to meet the requirements of the policies and signing of institutional biorisk policies.
1.2.3 The policy is appropriate to the nature and scale of the risk associated with the facility and associated activities.

1.2.4 The policy commits to:
1. protecting staff, contractors, visitors, the community and the environment from poliovirus materials that are stored or handled within the facility;
2. reducing the risk of the unintentional release of, or exposure to, poliovirus materials to an acceptable level;
3. reducing the risk of the unauthorized intentional release of hazardous biological materials to an acceptable level;
4. complying with all legal requirements applicable to the poliovirus materials that will be handled or possessed and with the requirements of this standard;
5. ensuring that effective biorisk management takes precedence over all non-"health and safety" operational requirements;
6. effectively communicating individual obligations regarding biorisk to all personnel and relevant third parties;
7. continuously improving biorisk management performance;
8. conduct risk assessments and implement the required risk and evidence-based control measures.

1.3 Biorisk Management Review

1.3.1 Management reviews the biorisk management system at planned intervals to ensure its continued suitability, adequacy and effectiveness.
1.3.2 The review includes assessing opportunities for improvement and determining the need for changes to the system, procedures, policies and objectives.
1.3.3 Records are maintained from the management review.

1.4 Objectives, Targets and Programme

1.4.1 Objectives and targets for effective biorisk management throughout the organization are established, implemented and maintained.
1.4.2 Management must establish the biorisk controls and enact documented procedures for monitoring the effectiveness of those controls to reduce or eliminate the risks identified in the risk assessment process.

1.5 Roles, Responsibilities and Authorities

1.5.1 Top management takes ultimate responsibility for the organization's biorisk management system.
1.5.2 Top management ensures that roles, responsibilities and authority related to biorisk management are defined, documented and communicated to those who manage, perform and verify work associated with the control of polioviruses.
1.5.3 Top management demonstrates its commitment by ensuring the availability of resources to establish, implement, maintain and improve the biorisk management system.
1.5.4 A senior manager is designated operational responsibility to oversee the biorisk management of the facility. An alternate is assigned should the senior manager be unable to fulfil their oversight role.
1.5.5. The designated senior manager is responsible for:
1. providing appropriate resources to ensure the adequate provision of personnel, facilities and other resources deemed necessary for the safe and secure operation of the facility;

2. reporting to top management on the performance of the biorisk management system and any need for improvement;
3. ensuring adoption and promotion of the biorisk management system throughout the organization;
4. instituting review, audit and reporting measures to provide assurance that the requirements of this standard are being implemented and maintained effectively.

1.5.6 A biorisk management committee is constituted to act as an independent review group for biorisk issues associated with the poliovirus facility.

1.5.7 The biorisk management committee reports to the designated senior manager and:
1. has documented function and scope;
2. includes representatives from a cross section of expertise, appropriate to the nature, scale, safety and security concerns of the activities undertaken;
3. ensures issues addressed are formally recorded and actions are allocated, tracked and closed out effectively;
4. is chaired by a senior individual with experience in biorisk management;
5. meets at a defined and appropriate frequency, and when otherwise required.

1.5.8 One or more competent individuals are designated to provide advice and guidance on biorisk management issues.

1.5.9 The role of the biorisk management advisor is independent of the functions of those responsible for implementing the programme of work.

1.5.10 The biorisk management advisor:
1. reports directly to the designated senior manager;
2. advises the biorisk management committee;
3. has delegated authority to stop work in the event that it is considered necessary to do so.

1.5.11 One or more individuals responsible for the scientific programme within the facility are designated with responsibilities relevant to biorisk management.

1.5.12 The scientific manager is responsible for:
1. ensuring all work is conducted according to established policies described in this standard;
2. supervising workers, including ensuring only trained, competent and authorized personnel can enter and work in the facility;
3. planning and conducting work activities, and ensuring adequate staffing levels, time, space and equipment are available;
4. ensuring required authorizations for work are in place;
5. ensuring facility biosafety and biosecurity risk assessments have been performed, reviewed and approved, and the required control measures are in place;
6. ensuring all at-risk personnel have been informed of risk assessments and/or provisions for any recommended precautionary medical practices (e.g., vaccinations or serum collections).

1.5.13 One or more individuals responsible for occupational health within the facility are designated with responsibilities relevant to biorisk management.

1.5.14 The organization must establish an occupational health programme commensurate with the facility's activities and risks.

1.5.15 One or more facility managers are designated with responsibilities relevant to the facilities and equipment requirements established in this poliovirus biorisk management standard.

1.5.16 A security manager is designated with responsibilities conforming to the security requirements established in this poliovirus biorisk management standard.

1.5.17 One or more individuals responsible for emergency response within the facility are designated with responsibilities relevant to biorisk management.

1.5.18 In laboratories where animals are kept, an animal-care manager is designated with animal- related responsibilities conforming to the requirements established in this poliovirus biorisk management standard.

1.6 Contractors and Suppliers

1.6.1 Purchases (including services) must conform to specified requirements. Controls on purchases (including services) are applied depending on the potential impact to the biorisk involved.

1.6.2 Suppliers are evaluated and selected based on their ability to provide products/services that meet the requirements of this poliovirus biorisk management standard.

1.6.3 Criteria for selection, evaluation and re-evaluation of suppliers are established.

1.6.4 Records are maintained of evaluation results and any necessary actions arising from the evaluation.

1.7 Records, Documents and Data Control

1.7.1 Records, documents and data are established, controlled and maintained to provide evidence of conformity to the requirements of this poliovirus biorisk management standard.

1.7.2 Records, documents and data are handled in such a way that they remain legible, readily identifiable and retrievable.
Documented records are maintained in paper or electronic form for a minimum of six years from their original containment certification audit and are available for review during subsequent containment certification audits.
If not already in place, the collection and retention of records, documents and data must start immediately.

1.8 Analysis of Data

1.8.1 The suitability of the biorisk management system is assessed by identifying, collecting, and analysing appropriate data. This analysis is used to evaluate where continual improvement of the system can be made.

1.9 Programme of Work

1.9.1 The programme of work for the facility is defined, documented and reviewed.

1.9.2 Work that requires prior approval is defined by established criteria.
Any change to the poliovirus programme of work or processes that affect biorisk are required to be reported to the NAC to maintain certification, as outlined in the Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment (GAP-CCS).

1.10 Change Management

1.10.1 All changes associated with the design, operation and maintenance of the facility are subject to a defined and documented change management process.

1.11 Consultation and Communication

1.11.1 Relevant biorisk information related to an organization's activities is communicated to and received from personnel and other relevant parties.
1.11.2 Involvement of personnel in communication and consultation arrangements is documented.
1.11.3 Personnel have access to adequate and up-to-date information about the biorisks and the mitigation measures in place to control those risks.

1.12 Legal Requirements

1.12.1 The organization ensures that all relevant legal requirements are identified and fulfilled within the biorisk management system. Legal requirements include national/federal, regional/state, provincial, city and local regulations with which the organization must comply. If this standard differs from regulations or legislation, facilities must satisfy the more rigorous requirement.

1.13 Preventive Action

1.13.1 Action is taken to identify and eliminate the causes of potential nonconformities to prevent their occurrence.
1.13.2 Preventive actions must be commensurate to the effects of the potential nonconformities.

1.14 Inspection and Audit

1.14.1 An inspection and audit programme that is appropriate to the risk associated with the facility is conducted in accordance with the guidance provided in the GAP-CCS.
1.14.2 Internal inspections and audits are conducted at planned intervals to determine if the biorisk management system conforms to the documented plans and the requirements of this Biorisk Management Standard and if it is effectively implemented and maintained.
An external audit programme is conducted regularly by the relevant national authorities to determine if the biorisk management system conforms to the requirements of this standard and is functioning properly and to ensure necessary corrective actions are taken and verified without undue delay.
1.14.3 Management responsible for the area being inspected/audited ensures that any corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.
1.14.4 Follow-up activities include verification of the actions taken and reporting of the verification results to top management.

1.15 Control of Nonconformities

1.15.1 Situations that do not conform to the requirements of the site-specific biorisk management policy are identified and controlled to prevent undesirable consequences.

1.15.2 Records of the nature of the nonconformity and any subsequent corrective action taken are maintained.

1.16 Corrective Action

1.16.1 To prevent the recurrence of any nonconformities, action is taken to develop a procedure that enables elimination of their causes using the requirements of this poliovirus biorisk management standard.

1.16.2 Corrective actions are in proportion to the effects of the nonconformities encountered. For containment certification audits, they are prioritized by the classification of the nonconformity as major (category 1) or minor (category 2), as described in the GAP-CCS.

1.17 Continual Improvement

1.17.1 The organization continually improves the effectiveness of the biorisk management system through:
1. the policy;
2. its objectives;
3. the internal audit programme;
4. audit results;
5. the analysis of available data;
6. risk assessments;
7. corrective and preventive actions;
8. management review.

2. Element 2 – Risk Assessment and Control

2.1. General Risks

2.1.1 A formal process is in place to identify and manage risk that may compromise general safety.

2.2 Process, Methodologies and Procedures

2.2.1 The organization ensures that a risk assessment system is established, implemented and maintained.

2.2.2 The performance of the risk management system is reported to the designated senior manager for review. This review is used as a basis for improvement.

2.2.3 Relevant personnel within the organization identify those operations and activities associated with risks, including possible biological risk and where control measures are to be applied.

2.2.4 Activities associated with possible biological risk, including maintenance, are carried out under conditions specified by the risk management system.

2.3 Assessment Timing and Scope

2.3.1 The approach to risk assessment is defined according to its scope, nature and timing to ensure it is proactive rather than reactive.

2.4 Roles and Responsibilities for Risk Assessment

2.4.1 Resource requirements are identified, and adequate resources are allocated, including assigning competent personnel to perform risk assessments and evaluation activities, such as internal review of risk control measures in place.

2.5 Hazard Identification

2.5.1 The hazards associated with proposed work are identified and documented.

2.6 Risk Evaluation and Control

2.6.1 Suitable methodologies for assessing and recording risks are identified, implemented and maintained. Risk assessment methodology and outcomes are documented.

2.7 Implementing Risk Control Measures

2.7.1 Suitable methodologies for assigning actions that result from risk assessments are identified, implemented and maintained, including timelines, responsible persons and associated reporting and approval mechanisms.

2.8 Monitoring Effectiveness

2.8.1 Risk controls are monitored for effectiveness and revised when needed.

3. Element 3 – Worker Health Programme

3.1 Worker Health Programme

3.1.1 The organization ensures that the risk to worker health, and that of other personnel whose health could be directly harmed by exposure to poliovirus materials, is managed effectively, including through preventive and protective measures.

3.1.2 The requirements of the health surveillance programme are determined by a defined health hazard identification and risk assessment process that involves all relevant personnel.

3.2 Vaccination of Personnel

3.2.1 Personnel, contractors, and visitors must demonstrate established immunity to poliovirus through evidence of poliovirus antibodies before entering the containment perimeter. The need for subsequent vaccination and antibody titre testing is determined based on risk assessment and is consistent with national occupational health guidelines.

3.2.2 A vaccination policy is defined and implemented.

3.2.3 Access to laboratories or work is restricted for individuals until they comply with the vaccination policy.

3.3 Medical Emergencies

3.3.1 A system is established to effectively manage medical emergencies, including but not limited to identifying potentially infected workers and providing

immediate medical care to exposed, ill or injured workers. This system is in alignment with the legal framework for reporting public health events involving polioviruses set forth in Annex 2 of the International Health Regulations 2005.

4. Element 4 – Competence and Training

4.1 Recruitment

4.1.1 Qualifications, experience, and reliability to observe appropriate codes of practice and aptitudes related to biorisk are considered as part of the recruitment process.

4.2 Training

4.2.1 Requirements and procedures for biorisk-related training of personnel are identified, established and maintained.

4.3 Competence

4.3.1 Personnel who have responsibilities and/or perform tasks within the poliovirus facility that may impact biorisk management are competent to execute those responsibilities and tasks. No personnel are exempt from demonstrating competence, irrespective of rank, experience or background.

4.3.2 Competence levels are judged on appropriate education, training, experience together with a demonstrated ability to correctly perform their assigned responsibilities in a safe and secure manner.

4.3.3 Personnel who conduct activities within the facility are under close supervision until they have demonstrated competency.

4.3.4 The organization must define required levels of competency in accordance with this standard and with any existing legal regulations. The designated manager is responsible for ensuring only competent personnel access the facility (see Element 1.5.12).

4.3.5 Records are maintained that show staff members have attained and demonstrated those levels of competency.

4.4 Human Factors

4.4.1 The organization establishes and maintains a programme to address risk associated with human behaviour, including the management of how personnel interact with each other, the facility and its equipment.

4.5 Continuity and Succession Planning

4.5.1 Adequate backup and contingency measures are in place to address the need for continuity and succession planning.

4.6 Exclusion and Reinstatement

4.6.1 Measures are put in place for the removal and exclusion of personnel (both temporary and, if appropriate, permanent) from the facility, where deemed necessary through risk assessment.

4.6.2 Measures are put in place and documented for re-evaluation of temporarily excluded personnel when deemed appropriate through risk assessment.

5. Element 5 – Good Microbiological Practice and Procedure

5.1 Biosafety Manual

5.1.1 The biosafety manual contains site-specific information for promoting a safe, secure workplace and reducing the probability of a release of poliovirus containing material and is based on risk assessments focused on hazards associated with poliovirus/poliovirus containing materials.

5.1.2 All personnel in the facility where poliovirus materials are used or stored or who may encounter poliovirus materials during the course of their job duties must read and adhere to the biosafety Manual.

5.2. Good Microbiological Practice and Procedure

5.2.1. All personnel handling poliovirus materials must be competent in good microbiological practices and procedures. All manipulations of poliovirus infectious materials are performed within primary containment as described in Element 8.3.4.

5.2.2. Appropriate resources (including time and equipment) are available to ensure good microbiological practices are adhered to effectively.

6. Element 6 – Clothing and Personal Protective Equipment (PPE)

6.1 Clothing and Personal Protective Equipment (PPE)

6.1.1 PPE needs are identified through project-specific risk assessment.

6.1.2 Suitable PPE is specified, made available, used and maintained appropriately within the facility.

7. Element 7 – Security

7.1 Physical Security

7.1.1 A risk assessment process for identifying physical security needs is in place in accordance with Element 2. Controls are implemented and maintained for the physical security of cultures, specimens, samples, animals and potentially contaminated materials or waste, determined as part of the risk assessment process.

7.2 Information Security

7.2.1 A policy and procedures are in place to identify sensitive information.

7.2.2 A review and approval process is used to control access to sensitive information.

7.3 Personnel Control

7.3.1 A personnel reliability policy is defined and implemented.

7.3.2 The organization ensures that personnel access to facilities or work is controlled, according to the policy.

7.4 Personal Security

7.4.1 A policy is in place to provide personal security awareness training, where appropriate. Documented security drills and exercises are conducted and prepare personnel to learn from any deficiencies.

7.5 Contractors, Visitors and Suppliers

7.5.1 The organization ensures that suppliers, contractors, visitors and subcontractors adhere to the requirements of the management systems and do not compromise the facility's biorisk management system.

8. Element 8 – Facility Physical Requirements

8.1 Planning, Design and Verification

8.1.1 A formal planning, design and redesign process is adopted for the facility, based on an assessment of risk associated with the materials to be used and activities undertaken.

8.1.2 The design process identifies and incorporates all relevant legislative requirements, recognized standards, considers guidelines from the WHO Laboratory Biosafety Manual Fourth Edition and associated monographs, industry good practices and facility-specific risk assessments.

8.1.3 The design process identifies and facilitates consultation with all relevant parties associated with the facility and its operation.

8.1.4 All design features, construction techniques, materials and equipment selected are documented in line with the needs of the design specifications.

8.1.5 New construction and physical facility modifications, including refurbishing and retrofitting, are carried out according to an approved plan.

8.2 Commissioning and Decommissioning

8.2.1 A formal process exists for the initial commissioning of facilities and the final decommissioning of facilities.

8.3 Infrastructure and Operational Management

8.3.1 Facilities, equipment and processes are safely and securely designed and operated. With respect to biorisk management, the poliovirus facility incorporates features that are guided by biosafety and biosecurity risk assessments for the loss of poliovirus from containment.

8.3.2 Poliovirus facilities are either poliovirus dedicated or non-dedicated laboratories. Non-dedicated facilities must demonstrate effective segregation and decontamination procedures between work with poliovirus and other pathogens to prevent cross-contamination.

8.3.3 Existing facilities must provide a containment perimeter sealable for fumigation and with sealed penetrations to prevent uncontrolled outward airflow irrespective of the choice of primary containment. New facilities and those undergoing retrofitting or refurbishing must ensure the sealable containment perimeter, irrespective of the choice of primary containment.

8.3.4 The use of devices that are validated to maintain primary containment are required for all procedures using live poliovirus unless otherwise specified (Element 8.3.16).

8.3.5 Controlled entry into the containment perimeter is through a double-door personnel airlock. Features include alarms, interlocking doors or an equivalent system to ensure that more than one door cannot be opened at a time and associated operating procedures to ensure the building systems function effectively at all times. Anterooms, material airlocks, and personnel airlocks for entry are considered to be within the containment perimeter, must be sealable for fumigation and meet all requirements of spaces within the containment perimeter.

8.3.6 All containment facilities where live poliovirus is stored, handled, treated and disposed of must be marked with biohazard signs. Signs are posted in prominent locations at the entry to the working area where poliovirus is being stored, handled, treated and/or disposed of and that only authorized personnel are permitted to enter. An emergency contact phone number must be displayed at all times and kept up to date.

8.3.7 Handwashing sinks operated by a hands-free mechanism with running water and soap are provided within and near the exit of the containment perimeter.

8.3.8 Controlled exit from the containment perimeter includes appropriate steps and procedures to prevent exposure to contaminated PPE or personnel. Procedures for exiting the containment perimeter and the requirement for an exit shower must be determined by a facility-specific risk assessment.

8.3.9 All exits are clearly marked. Emergency exit doors from the containment perimeter are alarmed.

8.3.10 The controlled air system maintains directional airflow via a dedicated ventilation system with ductwork sealable for fumigation. HEPA filtration of exhaust, backflow protection on supply, and monitors/alarms to ensure directional airflow can be readily validated. For facilities working with small quantities (volume and concentration) of poliovirus alternative mitigation measures may serve as a substitute for HEPA filtration of exhaust as determined by a risk assessment approved by the NAC.

8.3.11 The decontamination of all effluent (including emergency shower water, eyewash, handwash, unsterilized autoclave condensate) from within the containment perimeter is achieved through a validated inactivation procedure. Backflow prevention is implemented on all liquid services/utilities passing across the poliovirus containment boundary and measures to prevent release through traps, sinks and emergency shower drains. Non-dedicated effluent treatment systems must include appropriate mitigations for cross-contamination risk as determined by a risk assessment approved by the NAC.

8.3.12 The decontamination of materials exiting the containment perimeter is achieved through a validated sterilization/decontamination procedure or otherwise meets the standards for transport described in Element 12.

8.3.13 Kill-tank rooms or equivalent must meet all construction, sealing, and HVAC requirements of the primary containment space and are required to have an anteroom/personnel airlock for controlled entry as described in Element 8.3.5.

8.3.14 Storage of poliovirus must be performed under appropriate containment conditions as outlined in Sub-element 10.5.

8.3.15 Manufacturing processes and transfer of intermediates must be carried out in closed systems that have been leak tested and validated.

8.3.16 A poliovirus animal facility will incorporate features according to risk assessments and will meet all poliovirus containment criteria as described in this biorisk management standard, including:
1 complying with containment criteria for animal facilities, consistent with all other controls outlined in this document;
2. specially training and supervising personnel responsible for safe handling of poliovirus infected animals, including inoculating, harvesting, sampling, performing animal necropsies, and for any other manipulations so as to prevent personal injury and exposure;
3. requiring the use of devices (e.g., BSCs, flexible film isolators, or local exhaust ventilation) that are validated to maintain primary containment for all animal manipulations with live poliovirus. Specific manipulations that cannot be performed within primary containment without increasing the risk to the lab worker may be performed outside of primary containment devices as determined by a risk assessment with enhanced mitigation procedures approved by the NAC;
4. handling infected animals as poliovirus infectious materials and housing them in primary containment, separate from uninfected animals;
5. ensuring provisions are in place to manage animal associated waste according to this standard;
6. maintaining barriers to prevent infected animals from escaping and from introducing poliovirus to unexposed animals;
7. maintaining accurate records and accounting for all infected animals and their final disposition;
8. meeting international criteria and country-specific requirements for laboratory animal care;
9. using security procedures specific for facilities housing animals involved in biomedical research.

9. Element 9 – Equipment and Maintenance

9.1 Maintenance, Control, Calibration, Certification and Validation

9.1.1 Documented procedures are established and executed to ensure equipment and physical components of the facility that may influence biorisk are maintained, controlled, calibrated, validated, and certified in a manner consistent with the requirements of the biorisk management system and this standard.

9.1.2 Due to their criticality in maintaining containment, biological safety cabinets (BSCs) and other primary containment devices will be certified on a regular schedule in accordance with relevant national standards. If the primary containment device has no relevant standard against which it can be certified, it must be tested at regular intervals to ensure primary containment is maintained based on use and appropriate risk assessment of non-conformity. The results of these tests must be documented.

10. Element 10 – Poliovirus Inventory and Information

10.1 Inventory

10.1.1 An accurate and up-to-date poliovirus materials inventory is established and maintained.

10.2 Information and Records

10.2.1 Records related to the poliovirus materials inventory are current, complete, and stored securely with adequate backup provisions.

10.3 Transfer of Poliovirus Materials

10.3.1 Transfer of poliovirus materials between laboratories within the facility or into and out of the facility are recorded and controlled. Material containing live poliovirus to be removed from the containment perimeter adheres to the requirements outlined in Element 12.

10.4 Monitoring and Control

10.4.1 The inventory is reviewed at predetermined intervals and at a level based on risk so that materials can be accounted for in an appropriate manner.
10.4.2 Measures are put in place to minimize the quantities of poliovirus materials in the inventory.

10.5 Storage Procedures

10.5.1. Areas used for the storage of poliovirus materials are secured against entry by non- authorized personnel as outlined in Element 7.
10.5.2 For secondary (back-up) storage locations where poliovirus material such as stocks or equivalent are not normally used, the NAC may approve storage in leak-proof containment containers within a dedicated freezer that is subject to labelling requirements, security and access restrictions appropriate for the storage of poliovirus materials, as determined by facility risk assessment.
10.5.3 Storage of poliovirus must be performed under appropriate containment conditions as determined by a risk assessment approved by the NAC. Any derogations applied for and accepted by the NAC will be reflected on the certificate scope and associated certificates and will be regularly reassessed.
10.5.4 Movement of stock to and from storage locations outside the containment perimeter must be in line with the requirements outlined in Element 12.
10.5.5 The poliovirus material storage area must be equipped with a back-up emergency power source and with recording and alarm systems to monitor freezers.

11. Element 11 – Waste Management, Decontamination, Disinfection and Sterilization

11.1 Management of Biological Waste

11.1.1 The organization establishes and maintains an appropriate waste management policy for poliovirus materials.
No viable poliovirus will be released from the facility unless it adheres to the requirements outlined in Element 12. Potential routes whereby viable poliovirus could unintentionally exit the facility are identified and adequate prevention measures put in place through risk assessment.
11.1.2. All contaminated or potentially contaminated waste (including those that may result from an emergency) has been identified and documented. All waste is managed according to the waste management policy.

11.2 Inactivation of Poliovirus Contaminated Materials and Decontamination of Facilities

11.2.1 Procedures are established and maintained to ensure appropriate disinfection and decontamination methods are chosen and implemented effectively.

11.2.2 Procedures are established, validated and maintained for the effective poliovirus decontamination of the facility and equipment.

11.2.3 Procedures are established to manage waste generated by emergencies, accidents and other incidents.

11.2.4 Procedures are established and maintained to ensure the complete inactivation of poliovirus from all materials and liquid/ solid waste streams leaving the containment perimeter using validated methods excluding those materials packaged according to Element 12. The procedures cover normal conditions as well as response to failure of the decontamination procedure or equipment.

11.3 Poliovirus Material Inactivation for Conducting Work Outside the Poliovirus Containment Perimeter

11.3.1 Procedures are established, validated in-house and maintained to ensure appropriate inactivation methods are chosen and implemented effectively for poliovirus material that is to be inactivated for future use.
Each individual conducting a poliovirus material inactivation procedure must verify the inactivation procedure was successful the first time they conduct the procedure.

11.3.2 The results of any inactivation for conducting work outside the poliovirus containment perimeter are recorded, including documentation of
1. the material owner;
2. date of inactivation;
3. material description/identity and destination;
4. inactivation method used and how it was validated;
5. contact information of the individual conducting the inactivation or the owner of the material;
6. any other relevant information.

11.4 Decontamination of Equipment Prior to Servicing or Removal

11.4.1 Procedures are established, validated and maintained to ensure equipment, tools and other similar items are appropriately decontaminated before they are serviced in the lab or removed from the poliovirus containment perimeter. If equipment cannot be decontaminated for servicing, equipment must be serviced within the containment perimeter under the same containment requirements and protective measures as when the equipment is used in operation.

11.4.2 Equipment, tools, or other treated items cannot be serviced or removed from biocontainment until the validation tests demonstrate there is no live poliovirus present. The results of any equipment decontamination are recorded, including documentation of
1. the equipment owner;
2. date of decontamination;
3. equipment description/identity and destination;
4. decontamination method used and how it was validated;
5. contact information of the individual conducting the decontamination;

6. any other relevant information.

12. Element 12 – Transport Procedures

12.1 Transport Procedures

12.1.1 Procedures for the safe and secure transport of cultures, specimens, samples and contaminated and potentially contaminated materials, both inside and outside the facility containment perimeter, are established by risk assessment and maintained in accordance with national and international legal requirements for the transport of dangerous goods.

12.2 Transfer Approval

12.2.1 Transfer of poliovirus materials to another containment facility is executed under controlled conditions according to national regulations and international agreements after authorization by the receiving PEF. The relevant NPCCs are notified of any transfer of poliovirus collections to be included in the poliovirus survey and inventory activities; relevant NACs are notified of any poliovirus material transfer that could change the scope of facility certification.

13. Element 13 – Emergency Response and Contingency Planning

13.1 Emergency Scenarios

13.1.1 All credible and foreseeable emergency scenarios that may impact the organization's handling of biorisks must be identified.

13.2 Emergency Response Planning

13.2.1 Plans and procedures are established and maintained to:
1. identify and assess risk for incidents and emergency scenarios involving poliovirus and other hazardous materials;
2. prevent their occurrence to the degree possible;
3. respond to emergency situations;
4. report any exposure or breach of containment involving poliovirus materials to the relevant national authorities;
5. limit the likelihood of illness or other damage that may be associated with the emergency situation.

13.2.2 Emergency planning covers all aspects of biorisk and includes general safety, security and medical issues. The organization must demonstrate that there are linkages between the response and contingency plans addressing containment breaches in place at the facility level, as verified by the NAC.

13.3. Emergency Plans

13.3.1 Biorisks are considered when preparing and implementing emergency plans. A system in accordance with national and international legislation is in place to effectively manage incidents that are determined by the organization to be significant poliovirus exposures, including:
1. implementing measures to prevent exposure of unimmunized individuals, including exposure to stool and associated waste;

2. educating individuals under investigation, their family and close contacts on the risk of poliovirus infection to the community, the procedures for diagnosis and the precautionary measures required to prevent possible transmission;
3. initiating procedures to determine whether exposed individuals are infected, by collecting and testing nose, throat and stool specimens daily for a minimum of seven days post-exposure;
4. communicating with relevant national, regional and local officials;
5. disinfecting areas potentially contaminated by infected individuals within the facility.

13.3.2 Control measures in place are demonstrated as being reasonable and proportionate to the scale and nature of the emergency.

13.3.3 Emergency plans are effectively communicated to all personnel and relevant third parties and tested with the goal of making everyone aware of their roles and responsibilities.

13.4 Emergency Exercises and Simulations

13.4.1 Structured and realistic emergency exercises and simulations, including security drills, are conducted at regular intervals, based on risk, to test the emergency plans, prepare personnel and learn from any good practices or deficiencies identified.

13.5 Contingency Plans

13.5.1 In the event of an emergency, adequate contingency measures are in place to ensure the safety and security of continued operations.

14. Element 14 – Accident/Incident Investigation

14.1 Accident/Incident Investigation

14.1.1 Documented procedures are established and maintained to define, record, report, analyse and learn from accidents and incidents involving poliovirus materials.

Annex 3 under Article 14b(2) of the Public Health Regulation

1. By way of derogation from Article 14b(1) of the Regulation on public health, the requirements referred to in point 2 shall not apply to the types of poliovirus referred to in point 3.

2. Requirements not applicable to the types of poliovirus referred to in point 3:
a. Element 3: 3.2.1;
b. Element 5: 5.2.1, second sentence;
c. Element 8;
d. Element 10: 10.3.1, second sentence, and 10.5.4;
e. Element 11: 11.2.4, 11.3 and 11.4.

3. The types of poliovirus referred to in point 1:
a. Sabin types 1 and 3;
b. oral polio vaccine 1 and 3;

c. the following World Health Organization approved novel poliovirus strains, including novel oral polio vaccine strains:
- nOPV1 candidate 1 (aka nOPV1-c1, or S2/cre5/S15domV/rec1/hifi3/S1P1);
- nOPV2 candidate 1 (aka nOPV2-c1, or S2/cre5/S15domV/rec1/hifi3/S2P1);
- nOPV3 candidate 1 (aka nOPV3-c1, or S2/cre5/S15domV/rec1/hifi3/S3P1);
- nOPV1 candidate 2 (aka nOPV1-c2, or S2/cre6/S15domV/CpG30/rec1/hifi3/S1P1);
- nOPV2 candidate 2 (aka nOPV2-c2, or S2/S15domV/CpG40);
- nOPV3 candidate 2 (aka nOPV3-c2, or S2/cre6/S15domV/CpG30/rec1/hifi3/S3P1);
- nOPV2 candidate 3 (aka nOPV2-c3 or S2/cre6/S15domV/CpG40/rec1/hifi3);
- S19S1;
- S19S2;
- S19S3;
- S19S1_N18S;
- S19S2_N18S;
- S19S3_N18S;
- S19Mah;
- S19MEF1;
- S19Skt;
- S19Mah_N18S;
- S19MEF1_N18S;
- S19Skt_N18S.

ARTICLE II

A notification already made at the time of entry into force of this Regulation to the Health and Youth Inspectorate in its capacity as National Authority for Containment as referred to in Article 36(1)(d) of the Health Act for the purpose of certification under the resolution referred to in that provision shall be regarded as a submitted application as referred to in Article 14a(1) of the Regulation on Public Health.

ARTICLE III

This Regulation enters into force at the time when the Decree of #### amending the Decree on public health because of the introduction of a licensing obligation and a reporting obligation with regard to the performance of actions with poliovirus (Bulletin of Acts and Decrees ####, ##) enters into force.

This Regulation and the explanatory notes shall be published in the Government Gazette.

The Minister of Health,
Welfare and Sport,

Explanatory notes

General section

1. Introduction

With this Regulation, the Regulation on Public Health (hereinafter: RPG) included further rules due to the introduction of a licensing obligation and two reporting obligations in relation to the performance of actions with poliovirus. This concerns the licensing obligation referred to in Article 12b(1) of the Public Health Act (hereinafter: WPG), which applies to the provisions of Article 17a(1) of the Decree on public health (hereinafter: BPG) mentioned types of poliovirus. This is discussed in more detail in section 2.1.

With regard to the two reporting obligations, this first concerns the reporting obligation referred to in Article 12i(1) of the WPG, which applies to the types of poliovirus material referred to in Article 17c(1) of the BPG. In addition, this concerns the reporting obligation referred to in Article 29a(1) of the WPG, which applies in the event of (potential) exposure to the types of poliovirus referred to in Article 17a(1) of the BPG (types of poliovirus subject to a licensing obligation). These reporting obligations are discussed in more detail in sections 2.2 and 2.3.

2. Outline of this Regulation

2.1 Authorisation obligation

Article 17a of the BPG specifies which types of poliovirus are subject to the licensing obligation of Article 12b(1) of the WPG. Pursuant to Article 12c(5) of the WPG, rules must be laid down by ministerial order on the submission and processing of a licence application. This is implemented by the present scheme (Articles 14a and 14b of the RPG). A licence application must be submitted to the Minister for Health, Welfare and Sport (hereinafter: Minister of Health, Welfare and Sport). An application form must be made available and the documents referred to in that form must be submitted when the application form is submitted. An application submitted also serves as a notification to the Health and Youth Care Inspectorate (hereinafter: IGJ) in its capacity as the National Authority for Containment (hereinafter: NAC) with a view to obtaining a certificate from the World Health Organization (hereinafter: WHO). With this notification, the WHO certification process can commence.[32] As long as that certification process is ongoing, the time limit for deciding on the licence application shall be suspended. A decision on the application shall only follow after a decision has been taken in the context of the certification process. If a facility is granted a Certificate of Containment (Interim or otherwise), this will also lead to the granting of the licence (possibly with additional conditions, restrictions or requirements). If such a certificate is refused, the application will in principle be rejected. The decision on the application will be taken as soon as possible, but no later than 6 weeks from the day on which a decision has been taken in the context of the certification process.

The present scheme provides for a transitional provision according to which facilities that already have a WHO-recognised certificate at the time of the entry into force of the scheme or for which the certification process is still ongoing do not have to submit a licence application. Because of the involvement of the NAC in the WHO certification process, the IGJ is aware of which facilities have been granted a certificate and for which facilities the process is still ongoing. The earlier notification of these facilities to the NAC with a view to obtaining a certificate from the WHO is automatically regarded as a licence application.

[32] For a description of the certification process, please refer to section 2.3 of the explanatory memorandum to the bill amending the Public Health Act because of the introduction of a licensing obligation and a reporting obligation with regard to the performance of actions with poliovirus and some other amendments (Parliamentary Papers II 2022/23, 36334, No 3).

To be eligible for a licence, a facility must be an 'essential facility' and meet the GAP requirements. This follows from Article 17b of the BPG. The GAP requirements are determined by the present regulation (Article 14b(1) and Annex 2 to the RPG). This is in line with the current version of the current GAPIV requirements. Pursuant to Article 12b(3) of the WPG, the requirements are laid down in the English language. The facilities are accustomed to using the English language, and this can prevent discrepancies or ambiguities from arising from the translation with respect to the authentic version.
However, with regard to certain types of poliovirus, the WHO applies (temporarily or not) a differentiation with regard to some specific containment requirements. Article 14b(2) and Annex 3 of the RPB make provision for this by excluding a number of specific requirements for certain types of poliovirus. This ensures that no more stringent requirements are imposed on facilities in the context of the licensing obligation than the WHO does via GAPIV.

Detailed explanation of Annex 2

The GAPIV requirements aim to minimise the risk of the release of infectious poliovirus from a facility, whether intended or unintentional. To this end, the requirements are subdivided into 14 elements:

15. *Biorisk Management System* – this element requires the establishment, recording, implementation and maintenance of a *Biorisk Management System* that must be appropriate to the nature of the facility and the risk involved in the operations carried out there. These include requirements about the content of the policy and the distribution of roles, tasks and responsibilities.

16. *Risk Assessment and Control* – this element requires the existence of a risk management system that must be established in procedures to identify and manage risks to general safety.

17. *Worker Health Programme* – this element includes requirements for the protection of personnel in order to operate safely in the facility, including by taking preventive and protective measures.

18. *Competence and Training* – this element includes requirements in terms of recruitment, training, competences and availability of staff.

19. *Good Microbiological Practice and Procedure* – this element requires a facility-specific *Biosafety Manual* and adequate implementation and monitoring of the *Good Microbiological Practice and Procedures* by the staff.

20. *Clothing and Personal Protective Equipment* – this element requires the identification, on the basis of a risk analysis, of the clothing and personal protective equipment necessary for carrying out work in the facility.

21. *Security* – this element sets out requirements for the security measures to prevent the loss, theft, misuse or deliberate release of poliovirus from a facility.

22. *Facility Physical Requirements* – this element sets out requirements for the construction of the facility and its layout.

23. *Equipment and Maintenance* – this element contains requirements on maintaining, checking, calibrating, certifying and validating equipment.

24. *Poliovirus Inventory and Information* – this element includes the requirements for the up-to-date maintenance of all poliovirus material present in the facility and its possible transfer to other facilities.

25. *Waste Management*, *Decontamination*, *Disinfection and Sterilisation* – this element contains requirements on the treatment of waste and appropriate methods of decontamination.

26. *Transport Procedures* – this element sets out the requirements for the transport of poliovirus within the facility and the sending or receiving of material between facilities and the consent for this purpose.

27. *Emergency Response and Contingency Planning* – this element sets out the requirements for preparing for potential incidents and emergencies, including the presence and practice of emergency procedures.

28. *Accident/Incident Investigation* – this element sets out the requirements for the reporting of accidents and incidents and their follow-up and investigation in order to prevent their recurrence.

The relevant requirements are explained in more detail in GAPIV ('guidance relating to the requirements').

A number of requirements require further clarification.

- Requirement 1.12.1: this requirement obliges the facility to take into account all laws and regulations relevant to the Biorisk Management System. If the IGJ finds that a facility does not have a complete picture of the relevant laws and regulations, it will point this out to the facility. However, the role of the IGJ – both in its capacity as NAC and as supervisor of compliance with the requirements of the WPG and underlying regulations – does not extend to ensuring that the facility actually complies with other laws and regulations that fall outside its domain.

- Requirements 1.14.1 and 1.14.2: to the extent that these requirements are also addressed to the national authorities, the Facility will be subject to the requirement to cooperate with the said inspection and audit of the NAC.

- Requirement 3.2: this requirement does not include a full vaccination obligation for the entire staff of a facility. The objective is for a facility to have policies in place that determine, on the basis of a risk analysis, for which premises in the facility or for which activities it is necessary that staff have been vaccinated.[33] This applies, for example, to the containment perimeter, as this is where the risk of contamination is greatest.

- Requirement 4.3.4: the reference in this requirement to Element 1.4.12 (Roles, Responsibilities and Authorities) is incorrect, which has been adapted in the Annex to a reference to 1.5.12.

- Requirements 8.3.10, 8.3.11, 8.3.16, 10.5.2, 10.5.3 and 13.2.2: the possible approval or assessment by the NAC is conducted in the context of the audit by the IGJ (NAC).

- Requirement 12.1.1: the same applies here as was considered for requirement 1.12.1.

- Requirement 13.2.1: point 4 requires any exposure or breach of containment involving poliovirus material to be reported to the relevant national authorities. This requirement

[33] Whether personnel are employed who demonstrably have protective antibodies.

goes beyond the obligation to report laid down in Article 29a(1) of the WPG, because not every breach of containment must have involved (potential) exposure. The relevant national authority is the IGJ (NAC).

- Requirement 13.3.1: diagnostic procedures to determine whether a person is infected may only be carried out on the basis of that person's consent or, failing that, on the basis of an explicit legal basis (for example, Article 31(3) of the WPG). To the extent that this requirement refers to national and international legislation, the same shall apply as contemplated in requirement 1.12.1.

Detailed explanation of Annex 3

The requirements set out in point 2 of this Annex will not apply to the types of poliovirus set out in point 3 of this Annex. This is in line with the differentiation that the WHO currently applies with regard to some specific containment requirements. These are Sabin type 1 and 3, oral polio vaccine 1 and 3 and the WHO Poliovirus Containment Advisory Group (CAG) approved novel poliovirus strains, including novel oral polio vaccine strains.

- Requirements 3.2.1, 10.5.4, 11.2.4, 11.3 and 11.4: for the mentioned types of poliovirus, it is not required that the operations take place in the containment perimeter.

- Requirements 5.2.1 and 10.3.1: for the reason given above, the second sentence does not apply- The first sentence applies.

- Element 8: all the requirements of element 8 do not apply to the mentioned types of poliovirus. However, for facilities that keep animals, a number of similar requirements via other elements do apply (e.g. requirement 7.1 regarding a risk assessment process).

2.2. Reporting obligation under Article 12i of the WPG

Article 12i(1) of the WPG provides that a general administrative regulation may stipulate that anyone who performs certain actions with designated types of poliovirus must report this to the Minister of Health, Welfare and Sport. Article 17c(1) of the BPG stipulates that this reporting obligation applies to transactions with:

a. potentially infectious material with wild poliovirus type 1, 2 or 3;
b. potentially infectious material with vaccine-derived poliovirus type 1, 2 or 3;
c. potentially infectious material with Sabin type 1, 2 or 3;
d. potentially infectious material with oral polio vaccine 1, 2 or 3;
e. potentially infectious material with novel poliovirus strains.

Article 17c(2) of the BPG stipulates that the notification must be made electronically. In the present regulation, this is further specified in Article 14c, namely that the notification must be made at NAC@igj.nl. The notification must be made prior to the commencement of the actions in question and with the provision of the information referred to in Article 17c(2) of the BPG.

2.3. Reporting obligation under Article 29a(1) of the WPG

Article 29a(1) of the WPG regulates a reporting obligation, in addition to the reporting obligations already laid down in Chapter V, Section 2, of the WPG. This concerns a reporting obligation in the event of (potential) exposure to a poliovirus that is subject to the licensing obligation of Article 12b(1) of the WPG. This may involve a (potential) exposure to a specific person (such as an employee of a facility[34]), but also to an exposure in a general sense (for example because the virus

[34] If this person reports to a doctor, the reporting obligation of Article 22(1) of the WPG may also apply in the event of a infection (suspected or otherwise). For the sake of completeness, it should be pointed out that there is no exposure within the meaning of the reporting obligation under Article 29a(1) of the WPG in the event that a person is vaccinated with a polio vaccine.

has leaked into the sewer or through the air). In that case, a notification must be made without delay to the IGJ and the infectious disease control doctor of the municipal health service (hereinafter: GGD) of the municipality where the (potential) exposure took place or was detected (Article 5a(2) of the RPG). Following the notification, the IGJ can make an assessment of the seriousness and the danger to any data subjects and/or public health in general and, if necessary, tighten up supervision and/or take enforcement measures against the facility. Pursuant to Article 29a(2) of the WPG, rules must be laid down by ministerial order regarding this reporting obligation, including the information to be provided in the event of a report. This is implemented by the present Regulation. It follows from Article 5a(1) of the RPG that, first of all, information about the reporting person must be provided, including contact details. In addition, information must be provided on the nature of the event, the place and the time at which it took place or was found to have taken place. Of course, it is also important to mention to which type of poliovirus (potential) exposure has occurred. Finally, details of the measures taken must be given.

3. Relationship with European law and other legislation

The activities subject to a licence or reporting obligation are economic activities which constitute a 'service' within the meaning of Article 57 of the Treaty on the Functioning of the European Union. In the explanatory memorandum to the Act amending the WPG, which provides a basis for the introduction of a licence or reporting obligation, the relationship with European law was discussed in more detail. The relationship with the General Data Protection Regulation and other regulations was also discussed. Making a reference to that explanatory memorandum is sufficient in this regard.[35]

Notification
The draft of this regulation is on *[PM]* notified to the European Commission in order to comply with the reporting obligations of Directive 2006/123/EC[36] and Directive (EU) 2015/1535.[37]

4. Impact on regulatory burden

The present regulation only specifies a number of aspects of the licensing obligation and reporting obligations. The consequences for the regulatory burden due to that licensing obligation or reporting obligations have already been explained in the explanatory memorandum to the Decree of #### amending the Decree on public health because of the introduction of a licensing obligation and a reporting obligation with regard to the performance of actions with poliovirus (Bulletin of Acts and Decrees ####, ##). The scheme in question does not have any additional impact on the regulatory burden.

The Advisory Board of Regulatory Pressure Review (ATR) did not select the file for a formal opinion, as it has no significant impact on the regulatory burden.

5. Opinion and consultation

A draft of the present regulation was consulted via internet consultation from 27 May to 16 June 2024 (simultaneously with a draft of the above general administrative regulation). The current facilities and other organisations involved have been made aware of the internet consultation. Of the responses received, two responses – one of which is not public – relate to the present scheme.

Bilthoven Biologicals B.V. and Poonawalla Science Park B.V. (hereinafter: jointly referred to as Bbio) were given the opportunity to further explain their response orally in response to their request.

Authorisation obligation

[35] Parliamentary Papers II 2022/23, 36334, No 3, p.p. 13-16.
[36] Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ (EU) 2006, L 376)
[37] 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 (EU)* 2015, L 241).

Bbio has argued that the licensing obligation goes beyond the WHO certification system, because under the licensing obligation the current GAPIV requirements are declared fully applicable while the WHO applies a differentiation with regard to specific containment requirements for different types of poliovirus. A similar comment was made in the non-public response.

The licensing obligation applies to the poliovirus strains subject to the GAP requirements. This in itself does not go beyond the WHO certification system. However, respondents rightly pointed out that the WHO applies (temporarily or otherwise) a differentiation with regard to specific containment requirements for different types of poliovirus. The further elaboration of the requirements in the present Regulation is part of this differentiation. In the context of the licensing obligation for facilities, therefore, no stricter requirements are set than by the WHO via GAPIV. In short, facilities that work with the relevant types of poliovirus are therefore subject to the licensing obligation, but do not currently have to comply with the specific containment requirements for those types. This explanatory memorandum has been clarified.

In so far as Bbio argues in the response that elaborating the licensing obligation has a major impact on their production processes and may jeopardise the supply of their vaccines, this fear is based on the assumption that the licence obligation imposes stricter requirements than by the WHO via GAPIV. This also applies to what Bbio has argued that the effect of the licensing obligation is contrary to European legislation, because facilities in the Netherlands are placed in a more disadvantageous position than facilities located in other Member States. However, as indicated above, the licensing obligation does not impose stricter requirements, as was also confirmed to Bbio during the oral hearing.

Finally, Bbio noted that the detailed requirements set out in Annex 2 differ from GAPIV. Annex 2 is attached to the current version of the current GAPIV requirements. Some typos and other imperfections have been corrected.

Other comments

The non-public response has led to a clarification in the explanatory memorandum to the obligation to report under Article 29a of the WPG.

In addition to the internet consultation, a response has been received from GGD Rotterdam-Rijnmond. This response led to an amendment of Article 5a of the RPG and the related explanatory memorandum.

Explanatory notes by article

Article I

A

This subsection amends Article 1 by adding a definition of ‘decision’ and making a technical amendment to the definition of ‘law’.

B

This subsection adds an Article 5a. The first paragraph of this article lists the information that must in any case be provided in a notification as referred to in Article 29a(1) of the WPG. This concerns the notification in the event of a (potential) exposure of poliovirus that is subject to a licensing obligation. The second paragraph stipulates that the notification to the infectious disease control doctor must be made to the doctor of the municipal health service of the municipality where the (potential) exposure has taken place or has been detected. The third paragraph determines how the notification is to be made to the IGJ, namely at the email address indicated.

C and E.

On the basis of these elements, the Annex referred to in Article 8 of the RPG is now referred to as Annex 1.

D

This subsection adds a Chapter IIa to the RPG, in which the licensing obligation of Article 12b of the WPG and the reporting obligation of Article 12i of the WPG are further elaborated. Article 14a of the RPG lays down rules on the submission of the licence application and the processing thereof. Article 14b sets out the requirements to be met in order to obtain and maintain a licence. This is explained in greater detail in section 2.1. Article 14c of the RPG sets out how a notification is to be made. This is explained in greater detail in section 2.2.

F

Subsection F adds two new annexes to the RPG. Annex 2 sets out the requirements that a facility must meet in order to obtain and maintain a licence. These are in line with the current GAPIV requirements. Certain requirements are explained in more detail in section 2.1. Annex 3 sets out a number of specific requirements for certain types of poliovirus. This is in line with the differentiation currently applied by the WHO with regard to specific containment requirements for different types of poliovirus. This is also explained in more detail in section 2.1.

Article II

This Article provides for a transitional provision under which facilities that already have a WHO-recognised certificate at the time of the entry into force of the scheme or for which the certification process is still ongoing are not required to submit an a licence application.

Article III

This Regulation enters into force at the same time as the related amendments to the BPG.

The Minister of Health,
Welfare and Sport,