

*Advisory Committee*  
*Experiment Closed Cannabis Chain*



*An experiment* with a  
**closed cannabis chain**

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# *An experiment with a* **closed cannabis chain**

Advisory Committee Experiment Closed Cannabis Chain

To:  
the Minister of Justice and Security  
the Minister for Medical Care and Sport  
*The Hague, 20 June 2018*

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# Summary

## The problem

There are currently 573 coffee shops in the Netherlands, in 103 municipalities. These coffee shops exist in their current form thanks to the Dutch tolerance policy. Adults are allowed to buy cannabis for their own use there. They can only do so in coffee shops that comply with national and local regulations. Whereas the sale of cannabis to consumers through coffee shops is tolerated under certain conditions, this does not apply to cannabis production and the supply to the coffee shop. Local administrators have observed for a long time that this design of the current cannabis chain – with a ‘tolerated front door’ and an ‘illegal back door’ of coffee shops – creates problems for public order and safety and risks to public health.

## Ministers ask for advice

The coalition agreement of the current cabinet provides for an experiment with a ‘closed coffee shop chain’. In the context of this experiment, the chain – from the cultivation up to and including the sale to the consumer – is ‘decriminalised’. On behalf of the cabinet, the Ministers of Justice and Security and for Medical Care and Sport asked advice from a committee chaired by Professor Knottnerus. The committee has addressed two main questions: What should a closed chain look like, with decriminalised delivery by quality-controlled cannabis sales outlets participating in the experiment? And secondly: how can the effects of such a closed chain on public health, crime, safety and nuisance be measured and evaluated?

## The committee's approach

The committee had a little over three months to give its opinion on this complex, politically and socially very sensitive issue. During these months, the committee

analysed relevant reports, studied scientific literature and interviewed dozens of experts and people involved in this issue. The committee held round table discussions with mayors, coffee shop owners, producers, regulators, scientists, cannabis users and addiction experts. The committee, consisting of experts in the fields of public health, addiction, surveillance and enforcement, local government, criminology and law, judged and assessed its findings and formulated its advice.

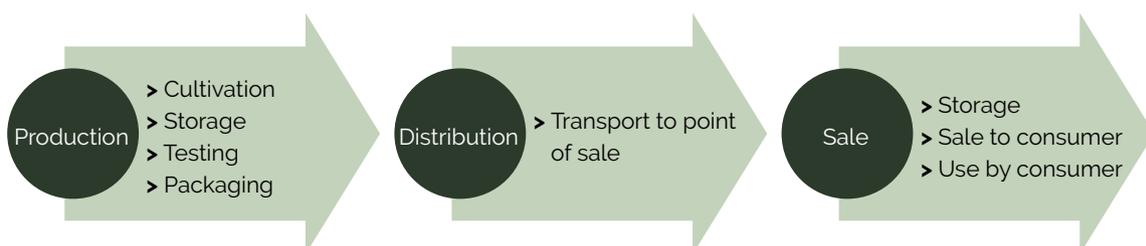
The advisory report successively discusses the two objectives of the experiment: gaining experience with a closed cannabis chain and conducting research into the effects of such a closed chain. The committee concludes with recommendations of a general nature.

## Good example: the medicinal cannabis chain

The Netherlands already has a strong example of a closed cannabis chain: that for medicinal cannabis. Its production, distribution and sale all appear to be connected well. The products meet the highest quality standards (e.g. stability, no undesirable ingredients) and they are not expensive compared to the current market price of cannabis for recreational use. In its proposals for a closed cannabis chain for recreational use, the committee regularly draws on these experiences with medicinal cannabis.

## Intervention: a closed recreational cannabis chain

The first objective of the experiment with a closed cannabis chain is to find a form for the responsible and decriminalised cultivation, transport and sale of quality-controlled cannabis that serves the consumer well. Schematically, this chain looks like this:



### + About the cultivation

During the preparation period, according to the committee, a lot of work will have to be done to deliver a sufficiently varied range of cannabis to the sales outlets that participate in the experiment. During the experiment a limited number of reliable and highly qualified growers must be contracted, who are prepared to meet the set requirements. Over time, it will be possible to examine whether it is desirable and possible to include more growers in the closed cannabis chain in order to serve the market.

### + About the transport

Transport is a vulnerable part of the chain. Distribution from the grower to the seller must be as transparent as possible, so that it can be properly monitored, the risk of errors is minimised and any interference from and 'leaking cannabis' to the criminal world is prevented. The committee therefore advocates limiting the number of transport movements with cannabis as much as possible.

### + About the sale

In its proposals, the committee does not use the term 'coffee shops' but the term 'points of sale', as its recommendations apply to all (conceivable) types of points of sale. To limit the frequency of cannabis transport, the level of the maximum trade stock of a point of sale can be made dependent on the amount of cannabis sold at that point of sale. For this purpose, the turnover per point of sale will have to be made transparent. The committee recommends that the trading stock be at least sufficient for one day. The selling price of cannabis should neither be too high nor too low, but in line with market conditions. As a buffer against excessive margins between cost price and selling prices, a surcharge can be levied to provide a fund for the prevention of cannabis use and addiction.

### + Preventive measures

Regulation can lead to the perception that cannabis is safe and therefore not harmful to people's health, because the government monitors the quality of the product. In addition, in our country cannabis is mainly used in combination with tobacco. This raises the question of how the regulation of the cannabis chain relates to the government's stricter anti-smoking policy. The committee therefore considers it important that the 'intervention' should be accompanied by preventive attention to the health damage that can be caused by both cannabis use and tobacco smoking.

### + Surveillance and enforcement

Surveillance and enforcement in the experiment should be linked as closely as possible to current practice, with a role for the sector itself, for the national supervisors, the municipalities (in the 'local triangle') and finally the Tax and Customs Administration (Fiscal Intelligence and Investigation Service), the police and the prosecutor's office. Within the chain, it is primarily up to all participants to monitor compliance with the rules of the experiment. In addition, external supervisors carry out periodic inspections and intervene where necessary. In the context of the experiment, the committee advocates coordinated surveillance, with good coordination and cooperation between all actors in the field of surveillance and enforcement.

The experiment takes place in the Netherlands, but neighbouring countries may be affected by cross-border effects. That is why during the further preparation of the experiment, consultation with them is important, among other things with a view to possible coordination with surveillance and enforcement.

### Will it be possible to set up a closed cannabis chain?

In order to assess the extent to which the first objective of the experiment – the introduction of a well-functioning closed cannabis chain – has been achieved after four years, the experiment will have to include a thorough process evaluation. Is the chain really closed and are the points of sale in the experiment able to ban illegally produced cannabis? How are the processes within the chain running? Do cannabis users buy from a legal point of sale or do they do so outside the closed chain? What are the user experiences with the cannabis from the closed chain? Will more young buyers come to 'government-approved' outlets, and how will these young people be made aware of the potential damage to their health? Do neighbouring countries notice the effects of the experiment? On the basis of a process analysis, it can be determined afterwards to what extent it has actually been possible to realise a closed cannabis chain and what the main learning and improvement points are.

### What effects can occur?

What effects does a closed cannabis chain have on the use of cannabis, the combination of cannabis with other stimulants, the occurrence of cannabis dependence, cannabis-related acute health effects, driving under the influence of cannabis, crime, safety and nuisance?

To determine the effects of the closed cannabis chain, any changes can best be mapped out in a comparative manner, distinguishing between municipalities where the intervention is and is not applied. The team of researchers (yet to be appointed) could, for example, conduct surveys among users, citizens, coffee shop owners and other stakeholders. The team can also use information that is already routinely recorded, such as visits to hospital emergency departments, complaints from local residents at points of sale, reports and convictions. According to the committee, a well-designed comparative study can provide solid substantiated statements about short-term effects. Health effects that can only be observed in the long term are beyond the scope of an effect measurement that must be completed within four years. Little can be said with any certainty about the consequences for total crime either.

### **When will the experiment be considered a success?**

The committee considers the experiment to have been successful if it has become clear that a closed cannabis chain is feasible and if the measured effects are favourable or do not show any deterioration compared to the current situation. In the committee's view, such an outcome is an unequivocal result that argues in favour of regulating the cannabis chain in the Netherlands. Therefore, according to the committee, the experiment is not only considered successful if it has beneficial effects on health, crime, safety or nuisance. The experiment can also be regarded as successful if it is possible to achieve a successful closed cannabis chain without negative side-effects.

The assignment to the committee refers to a phase-out phase after the experiment, after which the situation 'as it existed before the experiment' must have been restored. When the experiment is successful, the committee finds this next step illogical and risky, and it has practical and ethical concerns about this. It advises the government not to dismantle in case of a favourable result, and to make it clear in advance that it is its aim to implement the closed, regulated cannabis chain on a national level when such a result is achieved.

### **And what if it is not successful?**

If the envisioned closed chain does not turn out to be feasible during the experiment, this leaves a difficult political choice between:

- > Leave the situation as it is at the moment, with the illegal back door and the associated problems continuing.
- > A complete ban on production, sale and use, in which enforceability is a challenge.
- > Full legalisation, whereby 'leakage' from the regulated to criminal circles (and vice versa) no longer exists because there is no longer an illegal circuit.
- > Repeating an experiment under conditions that have been adjusted in such a way that the realisation of a closed chain is more likely.

The experiment may also show that a closed recreational cannabis chain is possible, but that its effects appear unfavourable in one or more respects. In that case, too, a difficult decision has to be made. It is conceivable, for example, that in the short term more nuisance will be recorded or that the use of cannabis will temporarily increase. In the longer term, or in a situation of overall regulation, the picture may look different.

### **The next step: selecting the municipalities**

In the coalition agreement an experiment with six to ten municipalities was planned. At this stage, the committee does not want to anticipate the second phase of its assignment in which it advises on the selection of municipalities. Nor does it want to take on the role of the researchers who are charged with the precise set-up of process evaluation and effect measurement. In the opinion of the committee, this design will dictate the required number of participating municipalities. Nevertheless, the committee has already determined that the value of the experiment depends on a good reflection of the diversity of municipalities in our country, in terms of the number of inhabitants, the number of points of sale, geographical distribution and position close to the national border or not. In order to arrive at a sufficiently representative study and a methodologically sound analysis in which municipalities in the Netherlands can recognize themselves, the committee expects that considerably more than the mentioned six to ten municipalities must participate in the experiment. The exact number will have to be determined in consultation with the research team to be recruited.

# 1 Introduction

## 1.1 The cannabis policy in motion

In the Netherlands, cannabis policy has been under discussion for a long time. For a number of decades, our country has had a policy of tolerance that allows sales by coffee shops and the consumption of cannabis, but not the production and distribution to coffee shops. The purpose of the coffee shops is to provide consumers with a safe environment in which to buy and possibly use cannabis and to reduce their exposure to hard drugs.

It has now become clear that the combination of tolerated sales and non-tolerated cultivation and purchasing of cannabis encourages unsafe situations, in particular regarding the production and distribution of cannabis and its delivery to the coffee shops. In this context, reference is made to the illegal 'back door' of the coffee shop (see figure 1). This situation also complicates the approach to organised crime. In addition, the quality of cannabis cannot be guaranteed, with all the health risks that this entails for the user.

In recent years, various reports and parliamentary debates have drawn attention to a different organisation of the cannabis chain and have discussed future scenarios.<sup>1,2</sup> At the moment, the 'Closed Coffee Shop Chain Act' a private member's bill that was adopted by the Lower House of Parliament, is in the Senate.<sup>a</sup> This is intended to ensure that the entire cannabis chain is organised via a 'tolerance decision'. Relevant international developments have also taken place in recent years. Several countries have now legalised cannabis or are preparing to do so: Uruguay, a few states in the United States and soon Canada, among others.<sup>3,4</sup>

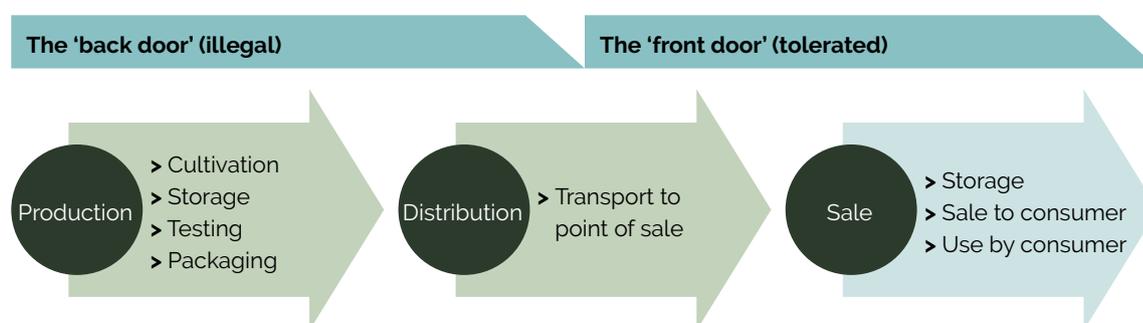


FIGURE 1. THE CURRENT 'CANNABIS CHAIN'

<sup>a</sup> The bill submitted by Ms V. Bergkamp, a member of the Lower House of Parliament, is currently postponed in the Senate, pending the experiment.

## 1.2 The cabinet announces an experiment

In the coalition agreement 'Confidence in the future' (2017), the Rutte-III cabinet announced that an experiment would be conducted in which experience would be gained with the (conditionally) decriminalised cultivation and distribution of cannabis to coffee shops and which would provide insight into the effects of this approach.

*'Legislation and regulations will be introduced to ensure uniform experiments with the tolerated cultivation of cannabis for recreational use. To this end, the government will, if possible, bring forward legislation within six months. These experiments will be<sup>b</sup> carried out in a number of medium-sized or large municipalities (six to ten). The aim of the experiments is to determine whether and how quality-controlled cannabis can be decriminalised and delivered to coffee shops (closed coffee shop chain) and what the effects of this are. The experiments will be evaluated independently, after which the cabinet will consider what needs to be done.'* (from: 'Confidence in the future')

Decriminalisation means that legislation is amended in such a way that cultivation, distribution and sale are no longer punishable under certain conditions. The experiment thus provides important information for the future Dutch cannabis policy.

Cannabis policy is a complex socio-political issue. It must respond to developments in many areas (such as public health, public order, safety, crime prevention and international policy) and to the choices and needs of a large part of the Dutch population. The cannabis policy has to deal with limited knowledge about, for example, health effects and the effectiveness of policy and widely divergent views in society. Given the responsibility that the government assumes in decriminalising and regulating the cannabis chain, a well-organised experiment offers the various parties involved in the cannabis debate the opportunity to make better informed decisions based on facts and lessons learned.

The experiment can also be used to learn from the (often still very early) experiences in other countries. For example, Canada is about to legalize and regulate cannabis production and sales.<sup>4</sup> A number of states in the United States can teach valuable lessons about the consequences of general regulation with relatively much

space for market forces.<sup>3</sup> The international context is also important in view of the large quantities of cannabis that are currently illegally exported from the Netherlands to other countries, and in connection with international laws and regulations.<sup>5,6</sup>

## 1.3 The advisory committee

### 1.3.1 Institution and advice assignment

Based on the coalition agreement, the government set up an independent committee with the task of advising on the design of the experiment.<sup>c</sup> The committee was initially called the 'Experiment closed coffee shop chain' advisory committee. The committee was initially called 'Experiment closed coffee shop chain' advisory committee. However, the committee calls itself the 'Experiment closed cannabis chain' advisory committee because it looks at the entire cannabis chain and not just at the points of sale.

The committee fulfils its advisory role in two phases:

- Phase 1 (March through May 2018): preparing and issuing advice on the design and effect measurement of the experiment and the conditions for participation.
- Phase 2 (June to the end of 2018): preparing and issuing advice on which municipalities will take part in the experiment.

After receiving this first advice, the cabinet intends to draw up a General Administrative Order (AMvB) with conditions for the experiment, after which the experiment can be prepared and carried out.

### 1.3.2 Composition

The committee consists of experts in public health, addiction, surveillance and enforcement, local government, criminology and law. The committee advises independently and the members of the committee participate without instructions or consultation.<sup>d</sup>

In view of the tight timetable within which the committee is to advise, the chairman has requested an employee from the Ministry of Health, Welfare and Sport and an employee from the Ministry of Justice and Security (both with specific expertise on this file) to attend the committee meetings as an observer; they will not take part in the advice given by the committee. In this way, the committee can obtain relevant specific policy information

<sup>b</sup> This is about one experiment (singular).

<sup>c</sup> See the advice assignment in appendix 1.

<sup>d</sup> See appendix 2 for the composition of the committee.

at any time. The chairman agreed with both ministries that these employees would respect the internal nature of the committee deliberations during the advisory process, including discretion when dealing with their own department, and would not make any statements about the content of the deliberations.

## 1.4 A successful or unsuccessful experiment

The committee will call the experiment successful if, after thorough research, it has become clear that a closed cannabis chain is feasible and that the measured effects are favourable or do not show any deterioration compared to the current situation. In the committee's view, such an outcome is an unequivocal result that argues in favour of regulating the cannabis chain in the Netherlands.

However, should the closed chain prove unrealizable, given the conditions of the experiment, a political weighting will have to be made, including at least the following options:

- > Leave the situation as it is at the moment, with the illegal back door and the associated problems continuing.
- > A complete ban on production, sale and use, in which enforceability is a challenge.
- > Full legalisation, whereby 'leakage' of cannabis from the regulated world to criminal circles and vice versa in fact would no longer exist because there is no longer an illegal circuit.
- > Repeating or continuing an experiment under such conditions that the realisation of a closed chain is more likely.

It could also be that the experiment shows that a closed cannabis chain is possible, but that its effects appear to be unfavourable in one or more respects, because there is, for example, an increase in cannabis use, or more nuisance. In this case, too, a difficult decision has to be made, in which the following can be added to the aforementioned options: regulation of the cannabis chain, intensifying prevention and enforcement efforts.

It is also conceivable that outcomes on certain effect measures could be unfavourable in the short term, for example with regard to cannabis use or nuisance due to a temporary increase of activities or a higher detection rate due to more systematic measurements or intensified surveillance and enforcement activity. In the longer term, or in a situation of regulation throughout the Netherlands,

the picture may look different. Continued follow-up research into the development of these phenomena may then be considered.

It cannot be expected that changes in rare health effects (such as fatal traffic accidents) or health effects that only manifest themselves after a long time (such as cardiovascular diseases) can be measured during the course of the experiment. Measuring such effects may require long-term and large-scale research. Because of the limited scope and duration of the experiment, it will also only be possible to partially measure the effects on cannabis-related crime, for example, leaving illegal cannabis exports out of the equation. However, the committee does not rule out the possibility that decriminalisation and regulation of the cannabis chain may be followed more widely internationally and will therefore in the long term have an impact on the reduction of total cannabis-related crime.

## 1.5 Reading guide

The advice is structured as follows. Chapter 2 specifies the objective and the questions to be asked, the working method of the committee, the important terms in the advisory report, the dilemmas and the scope of the advisory report. Chapter 3 deals with the intervention: what should the closed chain look like in the experiment, from cultivation to sale to the consumer, including the organisation of surveillance and enforcement, and prevention measures? Chapter 4 deals with the research needed to determine whether the experiment has been successful. This research consists of two parts: a process evaluation of the introduction of the experimental closed cannabis chain and a comparative study of the possible effects of that chain. In the final chapter, the committee formulates a number of additional considerations and recommendations.

## 2 The committee's approach

The government has submitted a series of comprehensive and more detailed questions to the committee (see Appendix 1). In this chapter, the committee discusses the central question and the chosen method of working, important concepts, dilemmas that must be taken into account and the scope of the advisory report.

### 2.1 Goal and question

The goal of the committee's advice is to use this as a basis for a well-considered decision on how the experiment is to be carried out. The central question of the committee is therefore: how can the experiment 'closed cannabis chain' be organised?

This central question has two main elements:

1. How can a closed cannabis chain be organised (from cultivation to sales) in such a way that positive effects are promoted, and negative effects are counteracted?
2. How can the effects of the closed cannabis chain be measured and evaluated, and what methodological requirements must be taken into account?

The dual purpose of the experiment to be carried out is a separate issue:

1. Effectively check whether a properly functioning closed cannabis chain can be achieved;
2. mapping the effects of this on public health, crime, safety and nuisance.

The experiment must be sufficiently valid and generalisable to allow conclusions to be drawn for any future national policy on the recreational cannabis chain.

### 2.2 Working method

The committee has gathered as much information as possible in a period of three months. To this end, it has conducted literature studies, organised discussions with stakeholders and gathered information from individuals and organisations with expertise in the field of cannabis and cannabis policy. The committee subsequently weighed and assessed its findings, and drafted its advice.

#### 2.2.1 Literature research

Much has been written about regulating the cannabis chain; the committee has used this information in its preparation of the advice. For example, the committee studied literature on Dutch policy, international initiatives and experiences, and relevant scientific research.

#### 2.2.2 Issued assignment

The committee asked the Trimbos Institute to carry out further research into the supply of cannabis varieties in coffee shops. The report 'Analysis of the supply of hashish types and weed varieties in the Dutch coffee shops' can be consulted on the website of the Trimbos Institute ([www.trimbos.nl](http://www.trimbos.nl)).<sup>7</sup>

#### 2.2.3 Consultations

The committee has consulted experts and other stakeholders for its judgment. In view of the limited time available to the committee, it has chosen to consult as many people as possible by means of 'round table discussions'. Eight have taken place, focussing on the following themes:

- > Science and research
- > Prevention and addiction
- > Local government
- > Surveillance and enforcement
- > Points of sale
- > The production process
- > The perspective of the consumer
- > Issues regarding use

In addition, the committee held a number of individual interviews. See appendix 3 for a list of the discussion partners

### 2.2.4 Assessment and advice

The committee weighed and assessed the findings from the literature in the light of its own expertise and experience. The committee particularly appreciated the richly and often broadly varied input from experts and experience experts from the various perspectives and judged these as extremely useful. The committee ensured that these contributions could not be linked to individuals but took them into consideration in a broader context for its own analysis, forming its opinion and advising on the intended experiment. It goes without saying that the committee alone is responsible for the content of the presented advice.

## 2.3 Important concepts in this advice

### 2.3.1 The experiment, the intervention and the measures

When talking about the 'experiment', this relates to both the 'closed cannabis chain' intervention and the research design, including the effect measurement. The 'intervention' includes all measures that apply in the context of creating a closed, decriminalised cannabis chain. This mainly relates to measures relating to production, distribution, sales, surveillance and enforcement, and prevention measures.

### 2.3.2 A 'uniform' experiment

The committee defines the term 'uniform' as used in the coalition agreement as: this is an experiment that is to be considered as a whole, for evaluating measures aimed at a closed chain from the cultivation up to and including the sale. However, within the general framework applicable to the experiment, variation and local customisation may be permissible or even desirable to sufficiently align with practice.

### 2.3.3 A 'closed' chain

A 'closed chain' refers to the prevention of 'leakage' of cannabis from the chain into criminal circles and from interference from criminal circles (figure 2). The committee points out that supervising any further trade after sale to the consumer is extremely difficult and intensive. That brings the limit of the closedness of the chain in sight.

### 2.3.4 Cannabis, hemp, marijuana, weed and hash

The cannabis plant has many genotypes and phenotypes, which according to current scientific insights are all varieties of one plant species. Weed (also known as cannabis) is the Dutch name for marijuana, the drug that has been made for centuries by drying the leaves and flowers of the cannabis plant. Hash (or hashish) consists of the (compressed) resin that is produced by glands on the female flowers of the same plant.<sup>9</sup>

When this report talks about cannabis, it does not refer to the agricultural crop (fibre) hemp that is grown for the production of paper and rope and for the seed and oil that can be prepared for the production of paint, soap, lubricants, etc.

### 2.3.5 'Recreational' use: falling outside the medical chain

The coalition agreement talks about recreational use. Strictly speaking, this description is too limited, because it is essentially the use that falls outside the 'medicinal chain' that is regulated and organised separately in the Netherlands and exclusively aimed at the use of medicinal cannabis prescribed by a doctor and only available at the pharmacy.

Thus, this advice is about the cannabis that is bought without a doctor's prescription. This includes the cannabis that is used as 'self-medication' and the cannabis bought by people who are addicted to cannabis.

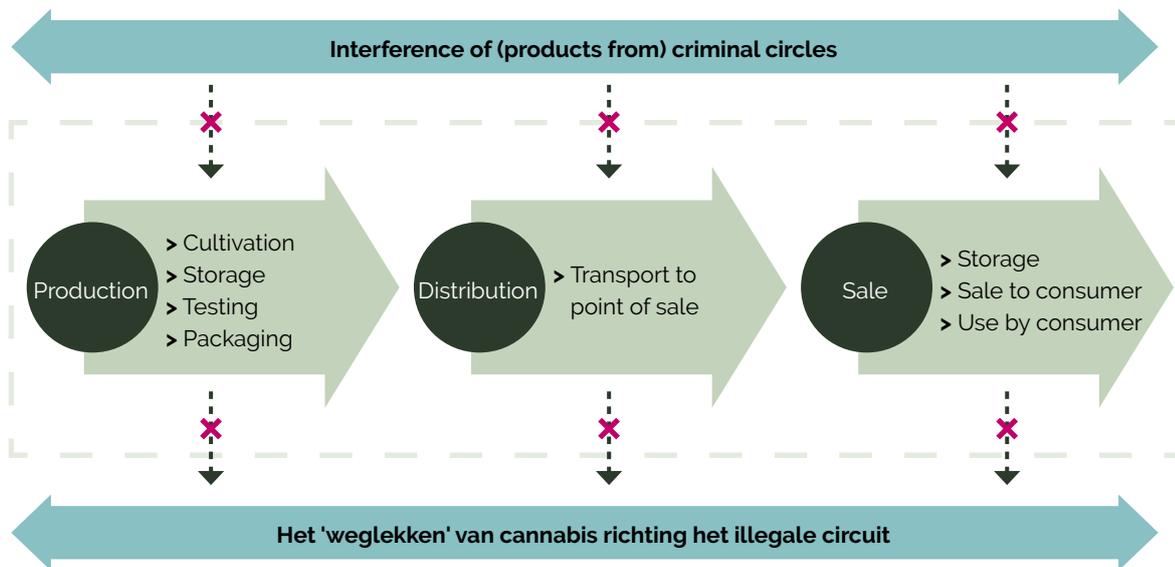


FIGURE 2. THE CLOSED CANNABIS CHAIN

### 2.3.6 The legal concept of 'decriminalised'

The committee advises on the way in which a decriminalised cannabis chain can be realised in the experiment – from cultivation to sales to the consumer. Decriminalisation means that legislation is adjusted in such a way that activities that are necessary in the context of the experimental intervention (such as cultivation) are no longer punishable under certain conditions. Legally, there is a distinction between decriminalisation and legalisation, where an activity is not punishable. The proposed decriminalisation is regulated in the bill 'Uniform experiment closed coffee shop chain'.

## 2.4 Dilemmas

Regulating the cannabis chain involves several dilemmas, whereby a middle way has to be found or choices have to be made. An experiment can be used to see how these dilemmas can be worked out in practice and dealt with.

Some of the dilemmas are:

- > When production by a large number of growers is the goal – with the ultimate goal being a completely free market operation with an unlimited number of qualified growers who meet the requirements to be met – it becomes more difficult to guarantee a truly closed chain and to exercise sufficient control and surveillance. However, if only one grower is chosen for maximum manageability and control, there is

insufficient competition on price, quality and variety of cannabis products; consumers are more likely to continue to prefer products from the illegal market.

- > Regulation contributes to the belief that a properly controlled product is legally available, so that consumers refrain from buying an uncontrolled product on the illegal market. However, regulation can at the same time lead to the perception that cannabis is safe and therefore not harmful to people's health, because the government monitors the characteristics and quality of the product. As a result, the use could – in theory – increase. This may also be the case when ways of use less harmful than smoking are promoted. That is why the committee considers it important that the 'intervention' should be accompanied by preventive attention to the damage to health that can be caused by both cannabis use and smoking.
- > There may be an area of tension between, on the one hand, tightening tobacco control policies and, on the other hand, regulating the production and distribution of cannabis products, which are still mainly used through tobacco smoking in our country. This means that it must be made clear that regulation – in combination with prevention – aims to serve a broad interest.

## 2.5 Scope of the advisory report

With regard to the study design to be developed, the committee limits itself to the key methodological considerations and options. It assumes that an independent study team or consortium will soon be appointed. This team/consortium should work out the study design in more detail and select from the design options and outcome measures that qualify for the experiment. The financial resources available for the experiment will also be important.

The committee does not discuss possible imports of cannabis from abroad, given the obstacles under international law to the production and distribution of cannabis at international and EU level. Nor does it expect these barriers to be removed before the start of the experiment.

Not everyone believes that it is possible to legalise the cannabis chain for recreational use, given the international treaties to which the Netherlands has committed itself. This difference of opinion can be illustrated by research by Van Kempen and Fedorova.<sup>9</sup> In 2014, they concluded that the legalisation, decriminalisation, policy tolerance and/or other regulation of cannabis cultivation for recreational

purposes is not permitted under the UN Conventions on Drugs and EU legislation. In 2016, they concluded that *'in spite of the Single Convention and the Illegal Trade Convention according to the current positive international law, there is room for states to legalise regulated cannabis cultivation and trade for the recreational consumer market'*.<sup>10</sup> This advanced insight came about because in 2016 more emphasis was placed on positive obligations for treaty states, arising from human rights conventions (such as the European Convention on Human Rights) and the right to life, health and privacy laid down therein. According to them, the national government will *'have to be able to demonstrate that a regulated authorisation of cultivation and trade is more effective in achieving human rights than a prohibitive cannabis policy in accordance with the drugs treaties'*.

The committee does not take a position in this discussion. In answering the questions posed in the advice assignment, the commission aligns to the national government's view that a decriminalised cannabis chain is legally possible in the context of the experiment. In addition, the committee notes that experimental research is involved here and that this, as a rule, implies conditions necessary for evaluation that by definition deviate from the general situation, outside an experiment.

# 3 Intervention: a closed cannabis chain

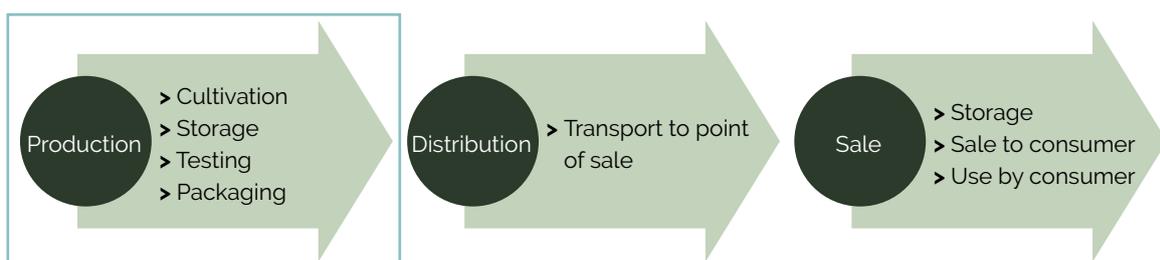
The experiment with a closed cannabis chain will take place in a – still to be determined – number of municipalities throughout the Netherlands. Together, they must properly reflect the diversity of types of municipalities in our country, in terms of number of inhabitants, number of points of sale, geographical spread and location, whether or not located at the national border. The participating municipalities, growers, distributors and points of sale will have to be prepared to comply with the agreements and rules that apply during the experiment and to cooperate in the process evaluation and effect measurement. In this chapter, the committee discusses its recommendations for the design of the intervention for each chain component: production, distribution and sales. It then discusses the need for preventive measures and the tasks facing surveillance.

## 3.1 Production

### 3.1.1 The composition of cannabis

Cannabis contains a wide variety of ingredients, including cannabinoids and terpenes. The plant owes much of its aroma to the terpenes. The cannabinoids can bind to the cannabinoid receptors in the body. The most important cannabinoids, because of their effects on humans, are tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is the most important psychoactive ingredient of cannabis. CBD influences the effects of THC through various – largely unexplained – mechanisms.<sup>8</sup>

Research suggests that CBD is likely to have a beneficial effect on the negative effects of THC on attention and memory. Cannabis with high THC and low CBD levels could increase the risk of (first) psychosis and has an adverse effect on the course of cannabis-related mental illnesses. Some studies also show a correlation between the level of THC content and the risk of the user becoming dependent on cannabis.<sup>11</sup> However, this is not confirmed in other studies.<sup>8</sup> It is also clear that the harmful effects of cannabis depend not only on the concentrations of THC and CBD, but also on the amount of cannabis that a person uses and ultimately ingests. Experienced users who smoke a strong joint – a cigarette that (in the Netherlands) is made up of cigarette paper, a rolled-up piece of cardboard ('tip'), tobacco and weed



or hash – seem to compensate in part for this by inhaling less smoke or putting less cannabis into their joint.<sup>12</sup> The scientific data on the effects and risks of THC and CBD are not unambiguous and have given rise to much debate in recent years.<sup>13</sup>

For the time being, the committee sees insufficient reason in the available data to set requirements in the closed chain for the level of the THC or CBD content or the ratio between them. The – as yet unsubstantiated – possibility that such claims could limit the damage to health by cannabis is currently outweighed by the disadvantage that they could lead consumers to abandon cannabis from the closed chain and turn (back) to the black market.

### 3.1.2 Cultivation requirements

Cannabis can contain contaminants such as pesticides and fungi. The cannabis from coffee shops seems to contain hardly any fungi that are toxic to healthy people.<sup>12</sup> However, a study showed frequent – mostly low – concentrations of pesticides in Dutch cannabis. In 11 out of 25 samples, the amount was higher than prescribed by the Herbal Medicines Directive.<sup>14</sup> Little is known about the harmful effects of this in case of heating (such as smoking cannabis).

The strict quality standards of the European Pharmacopoeia apply to medicinal cannabis.<sup>15</sup> There must be no pollutants or contaminations, such as mould. The cannabis must also have been grown in accordance with the requirements of the quality assurance systems of the food and pharmaceutical industries:

- > Good Agricultural Practice (GAP). The GAP contains regulations on food safety, the environment, nature and working conditions.
- > Good Manufacturing Practice (GMP). The GMP lays down the conditions under which a product is made. If afterwards something turns out to be wrong with the product, it can be determined how it was made, who tested it and which raw materials were used. It also prohibits the use of certain substances in the production process.

Based on the experience in the medicinal chain, the committee expects it to be possible to set similar quality requirements for the product of the closed recreational cannabis chain. The participants in the round table discussion about the production process did not immediately see any obstacles in this respect either. The committee believes that the government, if it also regulates the recreational cannabis chain, accepts a responsibility to limit risks to a minimum.

Local administrators underlined that this was one of the most important aspects of the experiment for them.

Some experts believe that certain varieties of cannabis are susceptible to fungi and that it is therefore more difficult, if not impossible, to grow them without pesticides. However, the round table discussion on the production process showed that it is undesirable and unnecessary to use pesticides in cannabis cultivation. The committee also noted that production without the use of plant protection products is possible in the medicinal cannabis chain at a competitive cost price. It therefore advises not to use pesticides in the experiment and, if necessary, to gain more experience with biological pest control. The committee also advises following the medicinal chain with regard to the use of growth-promoting products (GMP allows the use of these products subject to conditions). Among other things, it must not pose a risk to consumers.

In the medicinal chain, 'gamma-irradiation' is used to minimise microbial contamination. During the round table discussions, the committee heard a number of times that many consumers do not want 'irradiated' cannabis. Although scientific studies have found no evidence of risks or of changes in terpenes associated with such irradiation,<sup>16</sup> it cannot be excluded that irradiation of cannabis may make the product less desirable for consumers. The committee therefore recommends that a cautious approach be taken to the irradiation of cannabis for recreational use. It suggests that during the preparatory phase, it should be determined whether the use of gamma radiation in the production for recreational use provides real added value or whether it can be omitted. Clear information must be provided to consumers about this point.

### 3.1.3 Storage

During storage, it is important that safeguards are in place to ensure, firstly, the quality of the product during storage (e.g. for freezing stocks) and, secondly, the security of the storage of the product. The security guarantees are mainly aimed at preventing the 'leaking' of cannabis to, and interference from, criminal circles. The committee advises candidate growers to come forward with proposals for guarantees during the preparation phase and to reach clear agreements on these when appointing growers. Also on this point, the committee advises learning from the experiences of the medicinal chain. In that chain, both the leakage of cannabis and the interference from criminal circles were well prevented, with an acceptable investment for the grower.

An uncertain factor at the start of the experiment is that it is not yet clear exactly how much cannabis is needed. The grower will want to grow enough to meet demand, but not too much as overproduction entails additional costs and security risks for storage. As soon as it is known which municipalities are participating in the experiment, an estimate can be made of the amount of cannabis needed in the experiment. The experiences of and agreements with points of sale can provide a better view and grip on this.

### 3.1.4 Product testing

The committee recommends that in the experiment, in addition to professional quality requirements for cultivation, an independent quality control and analysis of the cannabis should also be carried out. This makes it possible to check whether the product meets the quality requirements and to keep an eye on the THC and CBD content. The independence of this quality control is necessary to avoid conflicts of interest.

In the medicinal chain, very strict margins are used to determine, among other things, THC and CBD levels. This is prompted by the GMP's requirements for products for medicinal use. In the case of non-medical use, the committee does not consider it objectionable to apply slightly less strict margins when determining the THC and CBD content of the various cannabis varieties.

### 3.1.5 Packaging

The committee has taken note of the requirements of the packaging of cannabis products in various states in the US,<sup>3</sup> in Canada<sup>4</sup> and in the medicinal cannabis chain in the Netherlands. Based on these examples, the health risks of cannabis and the requirements of a closed cannabis chain, it recommends that the packaging of cannabis products to be offered should be subject to the requirements set out below.

- > The packaging is child-safe and resealable.
- > The packaging is not attractive to children.
- > The packaging is sealed with an irreplaceable seal.
- > The packaging states:
  - the name of the product;
  - the warning: 'Contains cannabis. Keep out of reach of children';
  - the warning: 'Do not drive a motor vehicle and do not operate heavy machines under the influence of cannabis';
  - the weight, in grams;
  - the universal THC symbol;
  - the THC and CBD content (in %);
  - the unique code of the track and trace system (see 3.5.5)

- The packaging guarantees the shelf life up to the date stated on the packaging.
- > The packaging contains a package leaflet that states:
  - the recommended method of use of the product;
  - the advice not to smoke cannabis, neither pure nor with tobacco;
  - the warning that intoxicating effects may occur with a delay of two hours or more;
  - the warning that cannabis may be harmful, in particular, to mental health;
  - the warning that cannabis is particularly harmful to pregnant women, women who are breastfeeding or intend to become pregnant;
  - the warning that cannabis use can lead to abuse, dependency and addiction;
  - that the product does not contain any pesticides;
  - the other requirements with which the product complies.



FIGURE 3 UNIVERSAL THC SYMBOL ON PACKAGING

### 3.1.6 Requirements for growers

Growers who want to participate in the experiment must comply with the following requirements:

- > As a 'good grower', the grower complies with the requirements for cultivation, product information, storage and distribution to the seller, and delivery.
- > The grower is registered with the Chamber of Commerce.
- > The (candidate) grower makes a proposal on how to cultivate the necessary variation of cannabis and hash varieties.
- > The grower is responsible for ensuring the quality of the cannabis during cultivation and storage.
- > The grower is responsible for safe storage of the cannabis and for a safe working and living environment.<sup>17</sup>
- > The grower keeps transparent records, so that the closed nature of the chain can be properly monitored.
- > To avoid vulnerable transport movements as much as possible, growing, drying and packaging should take place at a single location as much as possible.
- > The grower undertakes to keep the criminal circles completely out of the cannabis chain and to exclusively grow cannabis that becomes available as part of the experiment.

- > Growers meet high reliability requirements, supported by a BIBOB screening of all directors / owners, and have a Certificate of Conduct (VOG) for all their personnel.

The committee recommends that more than one grower participate in the experiment, to prevent a monopoly position and to increase the chance of sufficient variation and continuity. At the same time, the committee recommends not cooperating with a large number of growers in the experiment. This increases the complexity of the experiment and the risk that it will not be possible to keep the chain closed. The committee is therefore thinking of five to ten growers.

The production of some cannabis varieties (e.g. those resembling Moroccan hash) may require specific expertise that is scarce in our country. The committee recommends that growers be given the opportunity to use this expertise, for example from small, experienced growers, if this is necessary to offer a sufficiently varied range of cannabis in the experiment. The condition is that interference from criminal circles is prevented. In this way, benevolent growers could be given the opportunity to leave the illegal sector.

### 3.1.7 Establishing a quality standard for cultivation

The committee recommends using the experiment to arrive at joint guidelines for 'good growth' and standardisation for cannabis production. This concerns, for example, the following aspects:

- > the method of cultivation (including storage and packaging);
- > the conditions under which the product is grown and stored (including temperature);
- > growing from a cutting or seeds.

Differences in measured THC and CBD levels can easily occur. This requires, among other things, standards for the way in which the product is handled, for measuring equipment and measurement methods and for the storage of the product. Here lessons can be learned from the medicinal chain.

The committee believes that growers should work according to a common quality standard from the start of the experiment. This process should develop into a national quality system, supported by sound training and refresher courses for staff.

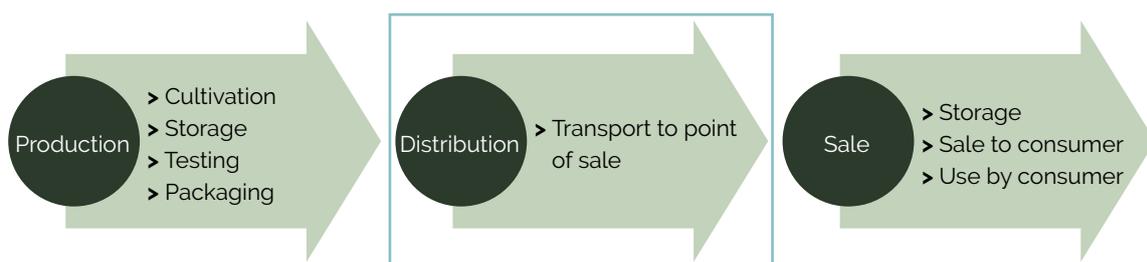
### 3.1.8 The required preparation time

The committee recommends taking into account a preparation time of at least one year for cultivation in the context of the experiment, counting from the moment that the growers are announced, and they can start preparations.

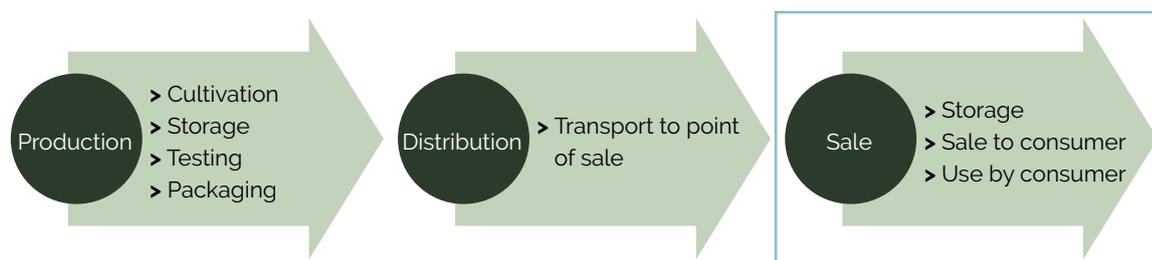
## 3.2 Distribution

The committee advises to ensure that the distribution from the grower to the seller is as transparent as possible, so that it can be properly monitored, the risk of errors is minimised and any 'leaking of cannabis' to criminal circles is prevented. In the medicinal chain, this is controlled nationally via the Office of Medicinal Cannabis (BMC). In the medicinal chain, however, cannabis is also bought by BMC; something that does not happen in the chain of the present experiment. The committee recommends making the grower responsible for the transport (by arranging this by himself or by outsourcing it).

During the preparation phase, candidate growers may be asked to submit proposals on how they wish to organise this and what guarantees they will apply to ensure the safety of transport.



### 3.3 Sale



#### 3.3.1 Storage and maximum trading stock

The moment of transfer between distributor and point of sale is a vulnerable link in the chain. To guarantee the closed nature of the chain, it is important for the seller to register all incoming products, using the previously assigned unique code (see 3.5.5). The security of the storage is discussed in section 3.5 on surveillance and enforcement.

The committee considers it desirable to limit the number of transport movements of cannabis, as this is a vulnerable chain component. This calls for a new look at the size of the maximum trading stock. Currently that is 500 grams per coffee shop. However, the amount of cannabis needed depends on how much is sold. There are major differences between points of sale in this respect. The turnover will have to be made transparent<sup>e</sup> to be able to determine the required economic trading stock. The committee recommends setting the maximum trading stock so that cannabis does not have to be supplied more than once a day, in other words, to allow this stock to be at least sufficient for one day. The committee advises amending the AHOJG-I criteria<sup>f</sup> in this regard for the points of sale that are participating in the experiment.

#### 3.3.2 Variation in the offer

In most cases, the cannabis currently sold in the Netherlands is produced in the Netherlands. In the annual measurement by the Trimbos institute in 2016/17, this weed had an average THC content of 16.9% and was therefore much stronger than the poorly sold imported weed, with an average THC content of 6.9%. Most hash consumed in the Netherlands comes from Morocco. The imported hash had an average THC content of 20.8% in 2016/17. The Dutch hash, which has been available for a few years but still has poor sales, had an average THC content of 35.1% in the same year. Of all cannabis products, only imported hash, as in previous years, had a significant CBD content of 8.4%.<sup>20</sup>

However, the variation in cannabis supply is greater than these average THC and CBD levels suggest. In the samples tested by the Trimbos Institute, the THC content in Dutch weed varied from 2.2 to 25%, in imported hash from 1.9 to 45.8%. The CBD concentration varied from 0.1 to 5.9% in Dutch-grown cannabis, from 0.2 to 13.5% in imported hash. In the cannabis identified as the 'strongest' in the coffee shops examined, the THC content ranged from 10.1 to 27.9%, the CBD content from 0.1 to 0.8%.<sup>20</sup> In addition to these differences in 'strength', consumers also experience different types of 'high' and differences in taste, probably related to different patterns of terpene and cannabinoid concentrations. Based on round-table discussions and analysis of cannabis varieties offered by coffee shops and tested by the Trimbos Institute<sup>7</sup> the committee concludes that a supply of approximately fifteen cannabis varieties and ten hash varieties should be sufficient for a good first start with the closed chain. On the basis of the information it has gathered, the committee also notes that there are trends in cannabis use. Driven by both supply and demand, new variants regularly appear on the market.

The committee believes that the range of cannabis products offered in the closed chain is essential to the

<sup>e</sup> Breuer&Intraval (Bert Bieleman) estimates, with 95% certainty, the total turnover of the 606 Dutch coffee shops in 2013 to be between €875 million and €1.25 billion (written statement from Bert Bieleman, based on a study ordered by WODC<sup>18</sup> and the Ministry of Justice and Security<sup>19</sup>). The differences per coffee shop are expected to be large.

<sup>f</sup> The AHOJG-I criteria bind coffee shops to specific (minimum) rules and prohibit:

- Advertising (to advertise for hash and weed)
- Trading hard drugs
- Causing nuisance
- Allowing young people under the age of 18 in the coffee shop or selling to them
- Selling large quantities (no more than 5 grams at a time) or having them in stock (no more than 500 grams)
- Selling to non-residents (the so-called resident criterion: only sales to people living in the Netherlands are allowed)

success of the experiment. Experienced consumers who prefer one or more specific cannabis varieties could turn (back) to the illegal market if the cannabis offer does not meet their needs. The committee therefore recommends that, during the preparatory phase of the experiment, it should be investigated what range of products is required, using the data from the THC monitor and additional analyses from the Trimbos institute. The preferences and possibilities of the participating growers and points of sale will also have to be taken into account. The committee also proposes that a consumer panel be set up. It believes that such a panel could be of great importance, both during the preparatory phase and during the experiment, in order to be able to respond adequately to the changing needs and wishes of consumers.

### 3.3.3 Method of use

In 2016, the way cannabis is used by Dutch people was investigated with an additional module of the Lifestyle Monitor.<sup>12</sup> Of those who used cannabis in the last year, 66% said they always used it through smoking a joint with tobacco; 24% did so rarely, sometimes or mostly. Other uses, often applied in addition to smoking tobacco joints, were significantly less common:<sup>12</sup>

- > 18% smoked 'pure' cannabis, i.e. without tobacco;
- > 13% used a pipe, chillum or bong;
- > 12% a water pipe;
- > 7% a vaporizer;
- > 1% an e-cigarette;
- > 17% used cannabis in food (including space cake), drinks or in other ways.

This pattern of use – in which 90% of users smoke cannabis – is worrying from a public health perspective. Smoking cannabis is more harmful than inhaling cannabis vapours ('vaping'), mainly because of the effects of the combustion products on the lungs.<sup>8,21</sup> Moreover, by using cannabis with tobacco, the user inhales the smoke from the tobacco, the harmful effects of which – even in relatively small quantities – are now undisputed. A meta-analysis of the internationally available research recently showed that smoking one cigarette per day is already associated with a significantly increased cardiovascular risk. The risk of a heart attack is about 50% higher and the risk of a stroke is 30% higher than for people who do not smoke. The risk increase is 40-50% of the risk increase for those who smoke 20 cigarettes per day.<sup>22</sup> The long-term health damage of one daily joint with cannabis and tobacco is therefore considerable, if only because of the health effects of tobacco smoke. In addition, some effects of smoking cannabis and tobacco, including the addictive effect, may reinforce each other.<sup>23,24</sup>

The committee believes that now that the government has embarked on an experiment for regulating the cannabis chain, it should also take steps to encourage consumers in the Netherlands to switch from smoking cannabis with tobacco to a less harmful method of use, i.e. the inhalation of cannabis vapours by means of an evaporator. It will return to this in section 3.4.

The committee does not recommend offering cannabis in the form of edible products ('edibles') for a combination of reasons: the risk that edibles will lower the threshold for new users; the hazard that children will eat them; the risk of overdose due to the slow effect of the cannabis eaten; and the additional complexity that this would bring in terms of increasing the range of surveillance and enforcement, including the fact that edibles are food products that have to comply with the Commodities Act.<sup>3,4</sup> The committee therefore recommends that, for the time being, the 'space cake' that some coffee shops currently sell should not be made available as part of the experiment.

### 3.3.4 Pricing

The price is an important aspect of the consumer's decision whether or not to buy cannabis in the context of the experiment. The price should therefore not exceed that of the market. The cannabis from the experiment should not be much cheaper either, because that could lead to an increase in use.

When determining the price, the question is which market is being considered: the points of sale/coffee shops or the street trade, where the price in general is (considerably) lower? If the pricing is compared with the price in the illegal sector, this offers room for more competitive pricing. However, it is difficult to accurately determine the price on the illegal market and a 'price war' might be lurking. The committee therefore recommends that the price in the closed cannabis chain be based on the price at the points of sale/coffee shops. In doing so, it expects that the quality and transparency of the product supplied will be appreciated positively by many consumers.

Based on the experiences from the medicinal chain and the high demands placed on cannabis, the committee assumes that it is possible to regulate cultivation and distribution for a market-based price. However, careful pricing of the various cannabis varieties to be offered requires timely preparation, which may also have to take into account differences between local markets.

The sale of cannabis cannot be subject to excise duty and VAT, as it is illegal to sell it within the European Union. The committee recommends examining the option of levying a surcharge to feed a national fund for the prevention of cannabis use, abuse and addiction, including the research required for this purpose. The surcharge in question can form a buffer against excessive margins between cost price and selling price.

### 3.3.5 Points-of-sale variation

The committee considers it desirable for municipalities to be able to adapt the way cannabis is sold to local wishes and needs. The experiment should allow some room for experience to be gained with different types of points of sale. As far as the committee is concerned, however, this room is not unlimited.

Some coffee shops also want to become growers in the experiment. Cannabis Social Clubs also advocates bringing the cultivation and the sale into one hand. The committee takes a different view: it considers that there is a risk of a conflict of interest. In addition, quality may come under pressure when sales interests directly affect production processes. The committee therefore recommends that cultivation and sale be kept separate.

Regarding the option to sell cannabis online, the committee advises not to incorporate this possibility into the experiment. It makes it difficult to monitor sales (e.g. age limit). In doing so, it increases the complexity of the experiment, which does not improve the chances of success.

According to experts in addiction care, coffee shops with user space offer the possibility of providing information and identifying problematic use. The committee considers this to be an important advantage, compared to fast street trading and anonymous online sales. It believes that providing information and identifying problematic use should be a task for all types of points of sale participating in the experiment with a closed cannabis chain for recreational use.

### 3.3.6 Participation of all points of sale in a municipality

In principle, all points of sale in a participating municipality should be involved in the experiment with a closed cannabis chain. It is undesirable to simultaneously have multiple enforcement regimes in one municipality. This makes it more difficult to pursue an unambiguous policy and to supervise, thereby increasing the risk that the chain cannot be closed.

For large cities with a very high number of points of sale, the participation of all of those is more complex in terms of manageability and enforceability than for smaller municipalities with few points of sale. The committee will pay extra attention to this point in its second advisory report on the designation of municipalities.

The committee recommends that points of sale in participating municipalities be informed as soon as possible about what participation in the experiment means, including registration and accountability. With the announced AMvB, the central government has drawn up general requirements. In addition, municipalities may impose additional requirements for the experiment, as they already do in the current situation. This may include, for example, the distance to a school, or additional measures to prevent nuisance.

### 3.3.7 Requirements for participating points of sale

All points of sale must comply with the rules of the experiment:

- > Products are purchased exclusively from designated growers.
- > The point of sale does not hold more than the permitted trading stock.
- > Sellers adequately fulfil their responsibilities with regard to product information and prevention.
- > The seller is registered with the Chamber of Commerce.
- > The seller complies with the applicable laws and regulations, including the AHOJG-I criteria.
- > The seller undertakes to keep the illegal circles completely out of the cannabis chain.
- > The seller is responsible for keeping products in such a way that the quality of the product remains constant; the seller must ensure that the products are stored securely and that the safety of the working environment is guaranteed.
- > The seller keeps transparent records, so that the closed nature of the chain can be properly monitored.
- > The seller must comply with the requirements of 'good salesmanship' (see 3.4.1).
- > The seller meets high standards with regard to reliability (see 3.5.6).

In the committee's view, the experiment should allow for differences in the way in which the local government and the local triangle want to implement surveillance and enforcement, given the applicable requirements (see also 3.5.4). This is important in view of local circumstances and preferences. For example, there must be room for

good coordination with local parties in the field of public health, such as the aldermen for public health, municipal health (GGD) and addiction care. And it must be possible to learn from the cross-local variation in the experiment. For example, there is variation in the way in which municipalities apply the requirement that points of sale may only sell to people who live in the Netherlands (the so-called residence criterion), depending, for example, on regional relationships and the requirements of effective nuisance control. The committee believes that this variation should also be represented in the experiment. Where the residence criterion is not maintained in full, this should be expressly justified, according to the committee.

### 3.3.8 Further professionalisation of points of sale

The committee believes it is desirable to work on professional standards for the sector. Point-of-sale representatives say they are in favour of this. There are already some initiatives being suggested, such as the 'Haarlems model' quality mark, which was established in cooperation between the municipality of Haarlem and the coffee shops. In this context, agreements have been made on, among other things, the training of employees. The recommendation of the committee is to develop a national quality mark (including (refresher) training courses and the promotion of employee expertise). In this context, the committee advocates the development of a guideline for 'good salesmanship', as evidenced by the commitment to professional standards and a national and independent verifiable quality system.

## 3.4 Preventive measures

In the Netherlands, numerous activities are already being developed at national and municipal level in the field of the prevention of substance use and its harmful effects. Now that the government is about to take a new step in cannabis policy with the planned experiment, which could possibly lead to an increase in the attraction of cannabis and the associated use of tobacco, the question arises: what additional preventive measures are needed to avoid undesirable effects of the experiment on public health? More specifically, how can we prevent the experiment from increasing the use of cannabis and tobacco by young people?

### 3.4.1 Good salesmanship

Preventing cannabis use by young people is an important element of 'good salesmanship'. The deployment of well-trained and motivated personnel is essential for this. Sales personnel should have basic knowledge of the effects and health risks of cannabis, including the signs and dangers of its abuse and dependence, and of how to use it in the most responsible way possible. In their work, the staff must use this knowledge to advise (potential) clients about a tailor-made way to use cannabis that minimises the risks. In doing so, they should be able to point out written information material that is available at the point of sale. If there are signs of problematic use, they should be able to refer to appropriate information or care: to an online platform (yet to be created) for cannabis users with related online interventions, to a 'drug line' or 'cannabis line', or to local addiction care. Young people under the age of 18 who want to buy cannabis will be told no, and given a clear explanation of why cannabis use at an early age is a bad idea.

### 3.4.2 Effective information

Key points in the provision of information to the permissible customers will have to be:

- > Do not use cannabis with tobacco.
- > Do not smoke cannabis but vaporize it.
- > Do not use cannabis if there is an increased risk of psychiatric problems in the family.
- > Only use cannabis in your spare time and when you feel good.
- > Do not use cannabis during pregnancy.
- > Do not drive under the influence of cannabis.
- > Distinguish facts from fables around self-medication.

The committee believes that this information should be given at the cannabis points of sale throughout the Netherlands, not only in the municipalities participating in the experiment. However, it is quite conceivable that in the municipalities where the closed cannabis chain is introduced, information could be more effective thanks to chain-related measures, the specific requirements for product information, and the fact that only cannabis products with a known THC and CBD content are sold.

### 3.4.3 Communication strategy

The experiment will inevitably be the subject of publicity, even if the government itself does not take the lead. The risk that this will, consciously or unconsciously, suggest that government-controlled cannabis is 'healthy' or 'safe' makes it necessary to develop a well-considered communication strategy. It will have to address the benefits of cannabis, the quality and strength of which is guaranteed, as well as the characteristics of responsible cannabis use. The message must be balanced, respectful and convincing for the main target groups. Such a strategy requires thorough preliminary research into, among other things, the way in which incorrect assumptions among young people and young adults can be adjusted; it also requires tailor-made solutions for different target groups, coordination with alcohol and tobacco policy, well-considered use of different media and proper consultation between national and municipal authorities. Adults present in the vicinity of vulnerable young people with a high risk of problematic cannabis use – parents and teachers, but also employees in, for example, youth care, judicial youth institutions and the care of young people with intellectual disabilities – are an important target group. The committee recommends that, at the same time as the actual preparation of the experiment is commissioned, a (joint) qualified party or parties should be given the task of preparing such a communication strategy.

### 3.4.4 Recommendations for prevention

On the basis of the above, the committee recommends that the ministers add a (further operationalisation of) P(revention) criterion to the AHOJG-I criteria currently in force for coffee shops. The committee also asks them to see to it that an online platform is created which all (potential) cannabis users can turn to for good information and for online help with (the risk of) cannabis addiction. Finally, the committee points out the importance of a good communications strategy to put the experiment in the right light.

## 3.5 Surveillance and enforcement

The committee anticipates that a considerable number of actors will be involved in surveillance and enforcement in the closed recreational cannabis chain (see figure 4). First of all, it discusses a number of general principles and recommendations that it considers important in the design of surveillance and enforcement. It then looks at the surveillance per chain component and at a number of specific aspects.

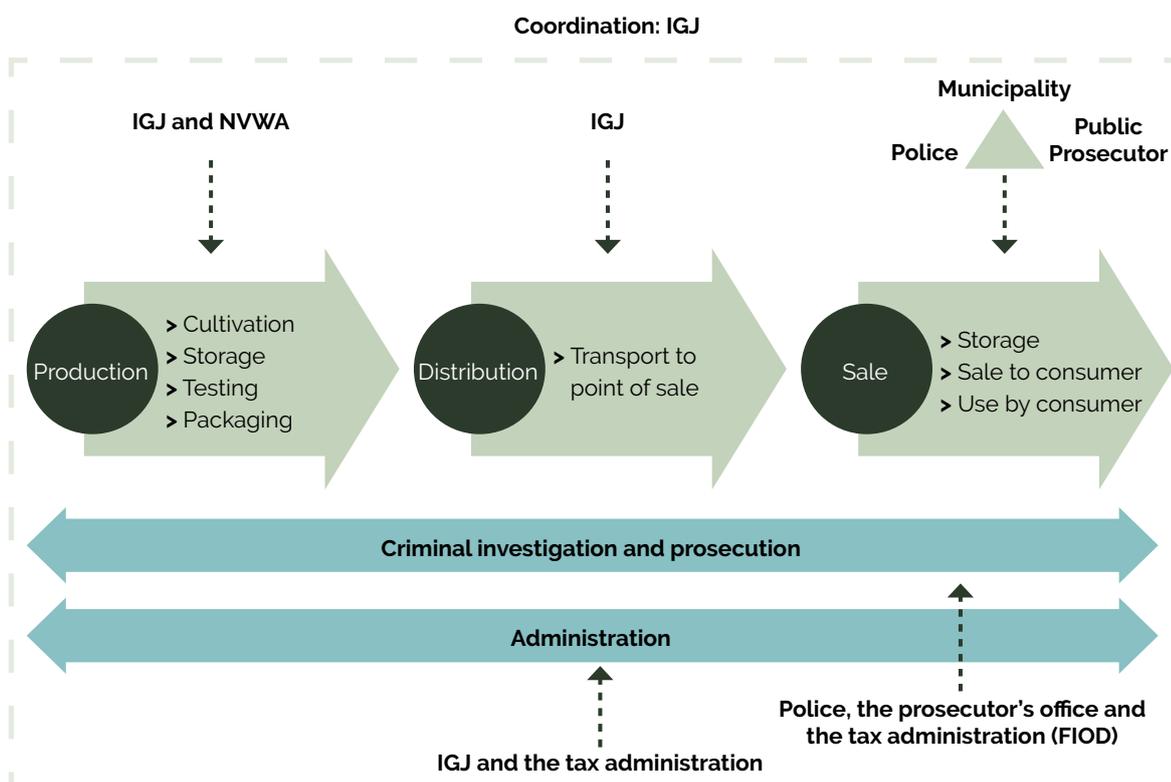


FIGURE 4. SURVEILLANCE AND ENFORCEMENT IN THE CLOSED CANNABIS CHAIN

### 3.5.1 General principles and recommendations

In line with the literature, and on the basis of discussions, the committee has formulated a number of general principles and recommendations which it considers important for the elaboration of the surveillance and enforcement in the context of the experiment:

#### 1. Connect as closely as possible to the current practice of surveillance and enforcement

By adhering as closely as possible to current practice, the experience and expertise of the current surveillance and enforcement authorities are optimally used, and the chances are greatest that surveillance is organized in a way that is workable in practice. This means, among other things, that the responsibility for surveillance and enforcement regarding points of sale (including stock management) and the sale of cannabis lies with local government and that the local triangle has an important role to play in this. New agreements must be made about the surveillance and enforcement of the various chain components.

#### 2. Ensure a clear, transparent enforcement arrangement

Surveillance is as strong as its weakest link. The analysis of the committee and in discussions with actors who play a role in the implementation of surveillance and enforcement<sup>g</sup> shows two potential weaknesses: the links between the various chain components, from production and distribution up to and including sale, and the coordination between the actors responsible for carrying out supervision and enforcement. Clear agreements about who is responsible for what are crucial for a closed chain. The committee recommends establishing a comprehensive enforcement arrangement for the entire chain for all actors responsible for surveillance and enforcement.<sup>h</sup> This involves answers to questions such as: what requirements are imposed on the actors involved? What is the responsibility of the sector itself? What sanctions are in place for (1) administrative surveillance and enforcement and (2) criminal investigation and prosecution? Who is responsible for surveillance and enforcement; who is in the lead,

and when? To stimulate voluntary compliance by the participants as much as possible, it is important that this is clearly communicated before the experiment. This also implements an important core value of good surveillance: transparency.<sup>25</sup>

#### 3. Use a layered division of responsibilities

The sector itself is primarily responsible for taking measures – including proper administration – to ensure a closed, safe chain and the quality of the product. The sector itself makes proposals for the way this is implemented. It is then up to the local government, the national inspection services and the tax authorities to supervise this. Finally, it is up to the judicial authorities to deal with criminal offences.

#### 4. Guarantee national cooperation and coordination

Ensuring a closed cannabis chain will demand a lot from the actors who are responsible for surveillance and enforcement, not only because the surveillance is partly new, but also because of the need to anticipate responses from, and attempts to interfere by, organised crime. The committee recommends that all the actors involved in surveillance and enforcement coordinate their approaches during the experiment at a national level, and in the meantime reflect on the experiment and on the (quality of) surveillance. This in order to optimally learn from the experiment in terms of surveillance and enforcement. The expertise of the National Information and Expertise Centre (LIEC) in tackling organised crime, and of other actors in the area of surveillance and enforcement (e.g. via the Inspection Council), can be used for this purpose. The committee also recommends that one actor be appointed for the coordination of the surveillance within the framework of the experiment. This body supervises the establishment of an enforcement arrangement that is easy to implement in practice, with the associated cooperation agreements. This could be the Healthcare and Youth Inspectorate (IGJ); the Dutch Food and Product Safety Authority (NVWA) can also be an option. In this respect, the committee prefers the IGJ, given its important role in the surveillance of the chain of medicinal cannabis and the surveillance of exemption holders in the context of the Opium Act, such as pharmacists. This experience and expertise are very useful.

#### 5. Set up a hotline

The committee recommends that a hotline be set up during the experiment so that people can report abuses in the sector. This partly because of the concerns that have been expressed about

<sup>g</sup> For optimum readability of the report, the term surveillance is used as a collective term for, among others, the municipality, the police, the Public Prosecutor's Office, the Health Care and Youth Inspectorate, the Dutch Food and Product Safety Authority and the Tax Authorities (VFIOD). Their role is explained in more detail in this section.

<sup>h</sup> For municipalities, it is important to consider this in relation to (supra)regional agreements with other municipalities that may not be participating in the experiment.

possible interference from criminal circles. It is also likely that people will be hesitant to report abuse. Agreements can be made with the actors responsible for surveillance and enforcement about where this reporting hotline is created.

### 3.5.2 Surveillance of production in the experiment

When designing the surveillance of the production, the committee considers it obvious to learn from the experiences in the medicinal chain and the surveillance model developed for this purpose. Following this model means that growers themselves are given an important role in ensuring the safety of the work situation and the surrounding living environment<sup>47</sup>, and supervising compliance with the requirements. Growers themselves must take measures to prevent interference by criminal circles and the 'leaking' of cannabis. The committee recommends making concrete agreements with them about realising a closed chain around the production process. This includes the (private) security of the location, with special attention to the storage and control of the cultivation (for example by counting and labelling the plants, weighing the products at various times and 'sealing' the packaging). A similar approach for the surveillance of the test laboratory would be obvious. Here, too, it is advisable to learn from the conditions set in the medicinal chain.

Cannabis cultivation, drying and packaging should, as far as possible, take place at a single location to minimise vulnerable transport movements. To prevent the risk of 'leaking', it is important that the packaging of cannabis is uniform and contains a standard weight of cannabis (e.g. 5 grams). It is also important that, once the product is ready for transport to the point of sale, the packaging is sealed and cannot be opened without breaking the seal.

In the round-table discussions, some coffee shop owners and cannabis consumers suggested that it might be desirable to use the cannabis from growers who participate in the experiment as well as the cannabis of illegal growers in the initial phase of the experiment. This way, the transition could be gradual and always offer sufficient variation. The committee does not think this is a good idea, because it would not guarantee the closed chain, and interference from the criminal circles could influence the experiment. Moreover, such a situation also makes impact assessment considerably more difficult.

The committee sees an important role for the IGJ in the 'production process' chain component. In the medicinal

chain, the IGJ supervises, among other things, the cultivation location (including storage and the areas in which the cannabis is processed) and compliance with quality requirements (for example with regard to pesticides). The IGJ also monitors the security of the site: how to prevent unauthorised persons from entering, and employees who are not authorised from accessing the product? The IGJ also carries out an inspection visit to potential growers and advises on this before an opium waiver is granted.

The committee also sees a role here for the NVWA. The NVWA is already supervising the application of plant protection products in the cultivation phase. This involves both checking the (correct) application of substances permitted for a crop and monitoring the maximum permitted residue values of the substance applied to the crop. Supervision of the packaging could also be the responsibility of the NVWA. In the case of food packaging, the NVWA is already monitoring innovations in this area.

The committee recommends that the expertise of the BMC be used in the preparation phase, as surveillance of the production process in the recreational chain is new.

### 3.5.3 Surveillance of grower in distribution to point of sale

An important point of attention is the security of the transport. In the current, illegal chain, this is a vulnerable component, with the risk of robbery. Security measures, such as camera surveillance, are important. The committee recommends that the grower should be made responsible for the distribution. The grower must ensure that sufficient safety guarantees are built in and ensure that the agreements are complied with.

In this case too, it is obvious that the IGJ will supervise the requirements imposed on the distribution and the distributor. The IGJ also does this in the medicinal chain, with regard to both the safety of the distribution and the guaranteeing of the quality of the product.

### 3.5.4 Adjusted surveillance of sales to the consumer

It is the responsibility of the points of sale themselves to ensure a safe working and living environment, as well as the safe storage of cannabis. Sellers themselves must take measures to ensure that the chain is closed. Safe storage is of great importance here (with special attention to the doors and the safe, for example, with time delay where the product becomes available in metered quantities as soon as the system indicates that new sales goods are needed).

In the current situation, the parties from the local triangle (municipality, police and public prosecutor's office) have an important role to play in surveillance and enforcement (administrative and criminal). This is also obvious in the experiment. However, a number of changes are expected in the experiment, for example with regards to the trading stock and the obligation to inform consumers. It is therefore important to consider locally in which areas the current local surveillance needs to be adapted.

Intraval's research shows that physical checks at coffee shops are organised in different ways.<sup>26</sup> For example, it differs depending on who performs the check: only the municipality, or the police or both together. Checks can be announced or unannounced, and the number of inspections varies from municipality to municipality. Joint checks by actors who supervise and enforce can have added value, given the mutually complementary expertise and the various possibilities for enforcement. The committee considers it important that a basic 'Local surveillance and enforcement' protocol should be introduced, which makes it clear on which parts of the experiment the local supervision and enforcement must be unified, and where local customisation remains possible (of course within the uniform framework of the experiment and the enforcement arrangement). This is also important for the scientific evaluation of the experiment.

### 3.5.5 Surveillance of the administration in the chain

Through the entire chain, counting and weighing, in combination with a well-controlled administration, are of great importance to ensure that the chain is closed. Growers, distributors and sellers must keep adequate and transparent records. The committee recommends standardising this working method, so that it is easy to supervise.

The committee recommends the introduction of a track and trace system in which products are provided with a unique code. If each product has such a code, it is possible to monitor where the product has been grown, to whom it has been delivered and how much has been sold. This is also important to prevent, as far as possible, the misuse of packaging from the experiment, making sure that it is not reused to transport illegal cannabis, for example.

The committee recommends exploring the possibilities of developing a web portal where registered, approved points of sale can place their orders with the growers. This can contribute to a well-organized, well-controlled chain.

In the medicinal chain, the IGJ supervises the Opium Act administration (including product registration). The committee considers it desirable that supervision of this is organised centrally as much as possible, to monitor the closed nature of the chain. It suggests that the IGJ, in collaboration with the tax authorities,<sup>i</sup> should be made responsible for the control of the administration throughout the closed cannabis chain for recreational use.

Blockchain technology is being developed (internationally) as a means of recording data and monitoring the closed nature of a chain by excluding data mutation. There are also proposals for the cannabis chain to use this tool, for example in Canada, but also in the Netherlands.<sup>j</sup>

### 3.5.6 BIBOB screening and Certificate of Conduct (VOG)

The committee considers high standards of reliability and a 'clean' sector, free of crime, to be of great importance. All managers/owners of cultivation companies, distributors and points of sale must therefore pass the BIBOB screening with good results.<sup>k</sup> They are also responsible for the integrity of their staff. The committee recommends that all employees provide a Certificate of Conduct (VOG). This procedure is comparable to the screening in the medicinal chain.

It may be easier for new salespeople to pass the screening stage than for salespeople already working in this field. For those who have committed serious offenses, the lack of confidence in this person prohibits a restart in a closed cannabis chain. If illegal behaviour consisted only of dealing with illegal growers which was unavoidable because of the 'backdoor' situation and professionalism has been maintained in the area of sales, the municipality can decide whether participation is possible and under what conditions.

<sup>i</sup> Where necessary by deploying the Fiscal Intelligence and Investigation Service (FIOD).

<sup>j</sup> See <https://hackathon.blockchaingers.org/pss/>, consulted on 31-05-2018.

<sup>k</sup> BIBOB: Bevordering IntegriteitsBeoordelingen door het Openbaar Bestuur (Public Administration (Probity in Decision-making) Act)

### 3.5.7 Sanctions for non-compliance with the conditions of the experiment

Failure to comply with the experimental conditions may result in the application of civil, administrative and/or criminal penalties, depending on the infringement.

As stated earlier, the committee recommends that the sector itself should primarily monitor compliance with the conditions on the basis of guidelines to be developed. In addition, administrative coercion, such as (temporary) closure or a fine could be imposed and/or criminal prosecution could take place. In the enforcement arrangement, the actors responsible for surveillance and enforcement agree on which sanctions are to be applied and when.

In the event of (repeated) non-compliance, a municipality may revoke the permit of a point of sale as part of the experiment and force it to close. If closure is sanctioned, this will be noted by the researchers as an 'end point' and in that sense it will be mentioned in the evaluation of the experiment. A grower's licence could also be revoked.

### 3.5.8 Extra effort

The organisation of the surveillance and enforcement in the experiment requires extra effort from all actors who are or will be responsible for this, partly because of the cooperation at national level. In addition, a number of actors also have new tasks (in particular the IGJ). Various actors expect unrest in the criminal circles, as those players fear for their position. It is important to anticipate this in time; additional enforcement (and protection) may be necessary. It may also be necessary to come down harder on illegal cultivation, as illegal growers may focus more on other (surrounding) municipalities. Municipalities participating in the experiment may also find it desirable to tackle illegal cultivation more severely, now that there is also an available alternative that is not illegal. The committee recommends that the ministries of Health, Welfare and Sport and Justice and Safety consult with the relevant actors about any extra capacity that may be required.

### 3.5.9 International alignment

The experiment will take place in the Netherlands. However, the Netherlands is not isolated and borders on neighbouring countries that could be affected by the cross-border effects of Dutch policy (including the planned experiment).<sup>5</sup> The committee will discuss this in more detail in the final chapter. With regard to surveillance and enforcement, the committee recommends that consultations with the authorities of neighbouring countries be held as soon as possible, discussing any agreements that may be necessary.

## 3.6 Conclusion

The committee expects that it is possible in a closed chain to find a form for the responsible and decriminalized cultivation, transport and sale of a range of cannabis products that meets the needs of the consumer.

Growers who want to participate in the experiment will have to comply with clearly defined requirements for cultivation, storage, packaging, product information, transport and delivery to the seller. They undertake to keep the illegal circles completely out of the cannabis chain and they are demonstrably reliable themselves. The committee recommends that in the experiment, in addition to professional quality requirements for cultivation, an independent quality control and analysis of the cannabis should also be carried out. The independence of this quality control is necessary to avoid conflicts of interest. For the time being, the committee sees no reason to set requirements in the closed chain for the level of the THC or CBD content or the ratio between them.

The points of sale participating in the experiment must also meet strict requirements. They must only purchase cannabis from closed-chain growers, have no more stock in house than the permitted trading stock and store it in such a way that its quality remains constant. Just like the growers, the sellers have been checked for their reliability, have transparent records and are committed to keeping the criminal circles away from the chain. The sellers provide reliable information to their customers, not only about the cannabis but also about help with problematic use. They do not sell to people under the age of 18.

The committee recommends that the ministers add a P(revention) criterion to the AHOJG-I criteria currently in force for coffee shops. The committee also asks them to see to it that an online platform is created which all (potential) cannabis users can turn to for good information and for online help with (the risk of) cannabis addiction. Finally, the committee points out the importance of a good communications strategy to put the experiment in the right light.

The price of the varieties of cannabis that are being offered will have to be carefully determined and will have to be not higher, but also not much lower than in the existing coffee shop market. The committee proposes to raise a surcharge, which can be used to feed a national fund for the prevention of cannabis use and addiction. The surcharge can also be a buffer for excessive margins between cost price and selling price.

Surveillance and enforcement are essential in keeping the cannabis chain effectively closed. The committee recommends a number of basic principles for this:

- > Connect as closely as possible to the current practice of surveillance and enforcement
- > Ensure a clear, transparent enforcement arrangement
- > Use a layered division of responsibilities
- > Guarantee the national cooperation and coordination
- > Set up a hotline

The committee recommends taking into account a preparation time for the closed cannabis of at least one year, calculated from the moment that the growers start their preparations.

## 4 Research: process evaluation and effect study

The experiment outlined by the committee in this advisory report consists of an intervention and a study. The previous chapter dealt with the intervention: setting up a closed cannabis chain. This chapter is about the research that is needed to be able to say at the end of the experiment whether the closed cannabis chain functioned properly and what any – intended and unintended – effects of the intervention have been. To answer the first question, a process evaluation is required. The second question requires an effect study in which the municipalities where the intervention is applied (intervention municipalities) are compared with municipalities where the current policy continues (control municipalities). Appendix 4 discusses the methodological considerations of the committee regarding the possible study design.

### 4.1 The operation of the chain: process evaluation

To determine whether the closed cannabis chain works, a thorough process evaluation is necessary in the municipalities where the chain is introduced. A number of key questions need to be answered:

1. Is the chain really closed? If not, where not and why not?
2. How are the processes within the chain doing?
3. How is the sale of the delivered cannabis going?
4. What are the user experiences with the closed cannabis chain?

The information to be collected about the operation of the chain will not only make it possible to assess the success of the closed cannabis chain at the end of the experiment and to identify learning and improvement points. It is also essential to be able, if necessary during the experiment, to adjust the agreements between the various actors in the chain and the range of cannabis products on offer.

#### 4.1.1 Is the chain truly closed?

A crucial aspect of the experiment is to determine the extent to which the cannabis chain is actually closed. Do the intervention municipalities succeed in eliminating the supply and sale of illegally produced cannabis? Do the participating growers really only supply the points of sale that participate in the experiment? Can the safety of the chain be guaranteed? Does the track and trace system work? And is it possible to exclude criminal interference in cultivation, distribution and sales? The extent to which all these and other aspects of the closed chain are and remain in order during the experiment is a central outcome of the experiment. Data on this subject will be collected and recorded as part of the chain surveillance.

The research team will have to make agreements with the actors responsible for surveillance and enforcement about the way in which they record data on established breaches of the closedness, safety and integrity of the chain, and report to the research team. In addition, the researchers will be able to question the growers, transporters, sellers, administrators and actors responsible for surveillance and enforcement involved in the chain about their experiences in and with the closed chain. This can be done, for example, by means of interviews and focus group sessions in a safe research setting, about which only anonymised data – not traceable to persons – are reported.

#### 4.1.2 How are the processes within the chain doing?

What about the quality and efficiency of the processes of cultivation, storage and supply to the points of sale? What obstacles and points for improvement do the actors involved, including the supervisors, identify? Interviews with, and observation of mutual consultation between, growers and transporters are important sources of information.

### 4.1.3 How does the sale of the delivered cannabis work?

The effectiveness of the new cannabis chain depends not only on its closedness but also on the extent to which cannabis users in the municipalities participating in the closed chain switch from the illegally produced cannabis they previously used to the new cannabis supplied as part of the closed chain. The extent to which this happens can partly be measured by the turnover achieved. Another part of the answer to this question may come from research into consumers' purchasing behaviour. Where did recent users buy their cannabis: from points of sale inside or outside the closed chain, or from home or street dealers, and why did they do so?

#### Turnover

The committee recommends that the intervention municipalities register the cannabis sales made at all points of sale participating in the experiment: both during a period prior to the closure of the chain and subsequently during the entire duration of the experiment. The progress of cannabis sales at the points of sale in the control municipalities is also informative. If opposite trends in sales figures can be observed in intervention and control municipalities, this may indicate that users have started to purchase cannabis from other municipalities. It will therefore be necessary to try to investigate the cannabis turnover also in control municipalities, both before and after closing the cannabis chain, however difficult this may be.

#### Buying behaviour

Research into purchasing behaviour must be carried out before and after the chain is closed in both intervention and control municipalities, in order to make comparisons. This research can make use of the questions posed to a sample of Dutch adults as part of the supplementary module Smoking, Alcohol and Drug Abuse (LSM-A), which is added every two years to the annual Health Survey/Lifestyle Monitor, performed by CBS, RIVM and the Trimbos Institute.<sup>12</sup> The research team could also investigate whether the Grasspoll survey, organised on internet by the Platform Cannabisondernemingen Nederland (platform of Dutch cannabis companies) together with cannabis consumer organisations, could be a useful, independently deployable and valid instrument for this study. Special attention needs to be paid to the purchase of hash: do users in the intervention municipalities switch from imported hash to Dutch hash?

### 4.1.4 What are the user experiences?

The way in which consumers experience the cannabis offered is also important for the experiment. What do

they think about its quality? Do points of sale offer the products they need and how satisfied are they with them? Questions such as these are important for the process evaluation, during and after the experiment and to be able to adjust the supply of cannabis within the framework of the intervention, if necessary. The user experiences are also important to be able to assess to what extent the points of sale in the intervention and control municipalities do what is expected of them in the field of informing about composition, risks and sensible use of cannabis. Do they identify any problematic use and, if so, do they adequately refer their customers?

A survey such as the Grasspoll can be used to investigate the experiences of users with the cannabis on offer, as well as questionnaires and interviews with visitors to points of sale in both intervention and control municipalities. Observation, albeit by 'mystery guests', could be used to get a good view of the operations of the points of sale in the closed chain.

## 4.2 The effects of the chain: effect measurements

In this part of this chapter, the committee will examine what effects could occur due to the closure of the cannabis chain and how these can be measured. Effects are changes that could result from the introduction of the chain and for which it is important to determine whether they have occurred or have not occurred. They can be partly measured by using data that is already collected routinely or in the context of monitoring the closed chain. In part, additional data collection will be needed. The following questions will be addressed in turn:

1. What effects could the intervention have on public health?
2. What are the possible effects on crime, safety and nuisance?
3. How can the effects of the intervention be determined as reliably as possible?

### 4.2.1 What are the health effects that should be identified?

A lower age for the first time use of cannabis, and an increase in cannabis use are important potential side-effects of regulating the cannabis chain. It is conceivable that the supply of cannabis approved by the government will attract new and younger users. It could also lead to an increase in the use by existing users. Therefore, the experiment cannot ignore the health effects of cannabis use. In addition, in the Netherlands cannabis is mainly

smoked in joints that contain tobacco as well as cannabis, and the smoking of one cigarette per day is already associated with apparent health risks (see 3.3.3). The use of other stimulants and drugs – such as alcohol, opiates and psychostimulants – can also be associated with the use of cannabis in various ways and involves health risks.<sup>27</sup>

### **Cannabis use**

Cannabis use is not without risks, although its harmful effects are less pronounced than those of tobacco and alcohol, both from an individual and a population perspective.<sup>28-32</sup> The main risks of cannabis are associated with its use before the age of eighteen. Starting with cannabis use at such a young age is associated with a greater risk of a lower IQ, impairments in cognitive functions, poorer school performance and dropping out of school.<sup>33</sup> It is not known whether, and to what extent, cognitive disorders persist after discontinuation of use.<sup>30,34</sup> The risk of dependence on cannabis (1 in 10 to 11 users on average) is also much higher among people who started using cannabis frequently and intensively at a young age than among those who started using it later. The same applies to the risk of other mental disorders, especially psychoses, although it is not yet clear what proportion of the observed effect is actually caused by the use of cannabis,<sup>35</sup> and what the role is of the THC content of the used cannabis.<sup>36,37</sup>

The relationship between the use of cannabis and the onset of depression is not yet sufficiently certain. Regular users, regardless of age, have an increased risk of chronic bronchitis and reduced lung function. There seems to be no clear link between cannabis use (apart from its combination with tobacco use) and lung cancer.<sup>8,32</sup> Older intensive cannabis users may have an increased risk of heart attack.<sup>31,32</sup> It is not yet clear to what extent this is a consequence of the use of tobacco in combination with cannabis.

### **Research into substance use**

Most of the health effects of cannabis, tobacco and other substances occur in the longer term and cannot be measured within the four years of the experiment. However, the degree of use of these substances can be considered as an important (intermediate) measure of effect in itself, with a certain predictive value for the occurrence of health effects in the longer term.

The use of substances is being investigated in different ways in the Netherlands. Two studies are underway in which students are asked about their health behaviour, including the use of alcohol, tobacco and drugs. The

Youth Lifestyle monitor and the Youth Health Monitor, conducted under the supervision of the RIVM by all the GGD (Municipal Health) departments.<sup>12</sup> In addition to these studies, a study into substance use was conducted for the first time in 2015 among 16- to 18-year-old students at secondary and higher vocational education.<sup>38</sup> Data on the prevalence of substance use among adults are collected annually in the context of the Health Survey/Lifestyle Monitor. The LSM-A also contains questions about, among other things, the frequency and manner of use of cannabis.<sup>12</sup>

In the experiment, these studies will have to be intensified and extended in some respects. For example, additional questions about buying behaviour and user experiences could be added to the existing lists. Reliable information on substance use among schoolchildren, adolescents and adults must be available for all municipalities participating in the experiment. The frequency of the examinations will have to be such that, after a measurement prior to the closure of the cannabis chain, information on substance use will become available at intervals during the experiment. Special attention should be paid to the way cannabis is used, because of the importance of reducing tobacco consumption.

### **Dependency and addiction**

Increased use and use at a younger age can lead to an increasing prevalence of dependency. Cannabis addiction can be accompanied by significant symptoms: high levels of stress, reduced cognitive abilities, absenteeism and high-risk behaviour, such as driving or operating machinery under influence of cannabis.<sup>9</sup> Information on problematic cannabis use in the Netherlands is available because the LSM-A includes the Cannabis Abuse Screening Test (CAST) for those who have used cannabis during this past year.<sup>12</sup> The committee recommends that the LSM-A be administered in the experiment before the chain closes and periodically thereafter, both in intervention and control municipalities.

### **Acute health effects**

In addition to long-term health effects, cannabis use can also lead to acute effects. Sometimes these are serious incidents. In the vast majority of cases, however, these are mild or moderate effects, varying from nausea to – mostly slight – anxiety symptoms. Between 2009 and 2016, the measuring stations of the Drugs Incident Monitor (MDI) of the Trimbos Institute and the Injury Information System (LSI) of VeiligheidNL – with fourteen hospital emergency departments connected to this system – reported a total of more than 6500 acute cannabis-related health incidents

in which cannabis was the only drug used. In addition, there were 1500 reports of incidents in which cannabis was used alongside other drugs.<sup>42</sup> The committee recommends investigating whether, based on data from the MDI and LSI, it is possible to make a reliable estimate of the frequency of cannabis-related health incidents in intervention versus control municipalities.

### Driving under the influence of cannabis

Driving under the influence of cannabis has a dose-dependent negative effect on driving ability and is associated with an increased risk of traffic accidents.<sup>8,27,32</sup> The frequency of cannabis-related accidents can be considered in the context of the experiment as a measure of a possible health effect of the intervention and the frequency of driving under the influence of cannabis as a related intermediate effect measure.

Since 1 July 2017, the police have the authority to use a saliva test to select drivers who can then be blood tested to determine whether they are driving under the influence of cannabis. Although the validity of the driving licence assessment based on this saliva and blood test is open to discussion, the number of recorded accidents and cases of driving under the influence of cannabis is an interesting outcome of the experiment.<sup>27</sup>

## 4.2.2 Possible effects on crime, safety and nuisance

### Crime

Closing the cannabis chain will hopefully lead to a reduction in cannabis-related crime. One unanswered question is whether a reduction in cannabis-related crime also goes hand in hand with a reduction in total crime. Crime related to cannabis production and trade could shift to other types of drug crime. Moreover, there are indications that drug-related crime is closely linked to trafficking in human beings and illegal prostitution.<sup>39,40</sup>

In the experiment, it is important to monitor the extent of cannabis-related crime as closely as possible. This can be done on the basis of various indicators recorded by the police and the prosecution: number of cases of manufacture, possession of and trade in soft drugs; numbers of cannabis-related fires; dismantled cannabis nurseries; quantities of tapped electricity; confiscated cannabis.<sup>17,27,41,42</sup> In addition, it should be considered to gather information about street trade and other illegal cannabis sales in both intervention and control municipalities through questionnaires or interviews with municipal officials and local police officers.<sup>42</sup> To determine possible displacement effects, it is advisable to provide

comparable monitoring of indicators and observations of local experts in municipalities that border on the intervention municipalities. In the case of municipalities along the national border, this requires timely consultation with neighbouring countries.

### Safety and nuisance

Coffee shops can cause inconvenience due to traffic and parking problems, odour and noise nuisance and annoying behaviour of coffee shop visitors.<sup>42</sup> The committee considers it important to monitor the developments in the nuisance caused by points of sale in the experiment, also with a view to the process evaluation of the experiment. This can be done, for example, by taking questionnaires about perceived safety risks and nuisance in random samples of local residents or by making observations prior to the closure of the chain and periodically thereafter. Additional information is provided on the frequency of incidents recorded by the police involving 'nuisances in connection with alcohol and drugs'.

The illegal cultivation of cannabis is also accompanied by nuisance and safety risks. Especially if commercial cultivation takes place in homes, there are significant safety risks for local residents. A fire can occur, usually because electrical installations are not installed properly. Houses can collapse, even without fires. Even without such catastrophic events, the welfare and health of local residents can be affected by, for example, water leakage, pollution of drinking water, carbon monoxide, pesticides and mould.<sup>47</sup> Comparing the extent of illegal cultivation in intervention and control municipalities will also provide insight into the possible effects of the intervention on these forms of nuisance and safety risks.

## 4.2.3 Reliable effect measurement through a comparative study

To determine whether or not the introduction of the closed cannabis chain has led to certain changes, a first step is to compare the situation before and after the introduction of the chain. However, such a before-after comparison is not sufficient to conclude that any change is the result of the introduction of the closed chain, unless there are convincing reasons to believe that without the intervention, a stable situation would have been the case. The committee does not see such convincing reasons and thinks that the assumption of a stable situation for the decision-making that will follow after the experiment is too unstable a basis.

If there is to be a serious measurement of the effects of the closed chain, the committee believes that not only the

situations before and after the intervention, but also the changes in municipalities where the intervention is and is not applied, must be compared. Comparing the so-called intervention municipalities (where the closed cannabis chain is realised) with control municipalities (where the current cannabis policy is continued) offers the possibility to distinguish the actual effects of the intervention from changes observed in the control municipalities, which would probably also have occurred in the intervention municipalities if the closed chain had not been introduced there. Thus, participating in the control condition is also an essential form of participation in the experiment.

In this comparative effect study, care must be taken to ensure that the group of intervention municipalities is as comparable as possible to the group of control municipalities. This is necessary because any differences found could otherwise be due to differences in, for example, size or location, as well as to the intervention. To achieve the objective of comparability, the intervention could be applied to a random sample from all the municipalities that apply for the experiment, and the results of this sample could then be compared with those of the other municipalities that apply but are not included in the sample. This, of course, is subject to the condition that a sufficient number of municipalities are available. Such a design is, in essence, a cluster randomized controlled trial: an experiment in which municipalities (to be regarded as 'clusters' of points of sale and residents) that are willing to participate in the experiment, are randomly assigned to the intervention or the control condition. The best way of achieving the desired comparability is to divide the municipalities available for the experiment into categories ('strata') that are homogeneous for a number of relevant characteristics (such as size, number of points of sale, and location) and then, within the strata, to allow chance to determine which municipalities are to be allocated to the intervention and which to the control condition (randomisation). Using statistical analysis afterwards, the effects can be mapped and the remaining uncertainties can be quantified.

Consideration could also be given to opting for a non-randomised (quasi-experimental) comparative design, for example by means of a form of matching. However, if the allocation to the intervention or control group is made not by chance, but, for example, on the basis of self-nomination or a political-administrative decision, there is a greater risk that the groups to be compared will be incomparable and that the results will be distorted.

It may seem strange to municipalities to be classified by chance as an intervention or control group. The committee assumes, however, that the importance of a methodologically optimal approach – instead of a (perhaps no less difficult to accept) classification on political-administrative grounds – is easy to explain. As mentioned above, participation in the control condition is also an essential form of participation in the experiment. The committee also notes that, even in a quasi-experimental design, the participating municipalities will have to be divided into the newly introduced intervention condition and the control condition, respectively. The question then is why it is not better for this distribution to take place at random.

The developments in the municipalities participating in the experiment can be compared during and after the experiment to trends in relevant national statistics and surveys in the areas of evaluation. This comparison is not suitable for establishing the effectiveness of the closed chain because of the limited nature of this data and the risk of selecting the municipalities available for the experiment compared to the unavailable municipalities. However, it can give a general impression of the extent of the selection.

Based on the above, the committee recommends the study team to be selected first of all to investigate whether the effect study can be structured as a stratified cluster randomized trial. It is also possible to examine whether the stepped wedge design variant is possible, with more and more municipalities from the general starting moment, step-by-step, based on randomisation, crossing from the control condition to the intervention condition. However, this is a complex variant.

The final study design will have to be chosen and elaborated by the study team to be appointed after the decision to actually start the experiment.

### 4.3 Representativeness and number of municipalities

As far as the participating municipalities are concerned, the committee's terms of reference (see appendix 1) state that there must be sufficient variation in types of municipalities and geographical spread in order for the effect measurement to be meaningful. The committee endorses this principle. If it is to become clear from the experiment whether an active closed cannabis chain can be introduced in the Netherlands and what the effects

of this would be, the municipalities participating in the experiment must reflect the variation among Dutch municipalities on the characteristics that are essential for the functioning of the chain.

At the same time, the document states – as does the coalition agreement – that the experiment is being carried out in six to ten medium-sized or large municipalities. The committee does not consider this limitation to be consistent with the aforementioned starting point of a meaningful effect measurement. The desirable number of participating municipalities should follow from the requirements that a methodologically sound experiment entails.

According to the committee, the relevant municipality characteristics that must be reflected in the experiment should in any case be: number of inhabitants, number of points of sale, geographical location and located at the border or not. Combining these four characteristics quickly leads to a large number of unique types of municipalities. The committee is expected to require considerably more than six to ten intervention municipalities to achieve the ambition of sufficient variation and a meaningful – whether or not randomized – comparison with a group of control municipalities.

In addition to defining the minimum required number of participating municipalities on the basis of the principle of sufficient representativeness, power analyses can be performed per effect measure (multilevel: municipalities and points of sale) to determine the minimum number of required clusters (municipalities) needed to identify relevant effects with sufficient certainty.

At this first stage of its advisory task, the committee does not express an opinion on the exact number of municipalities in which the experiment should be carried out. The committee believes that the required number of municipalities can only be determined once the study design has been elaborated by the study team to be engaged. It will then become clear how large the number of municipalities must be – with reasonable assumptions about the course, given the control condition, and about the variability of the different outcome variables, and given the characteristics of the chosen study instruments – to be able to make meaningful statements. The power analyses referred to above and the resulting sample size calculations form an essential part of the work required for this.

## 4.4 Ethical, legal and administrative aspects

Although the advisory committee sees fewer rather than more risks for cannabis users in the participating municipalities, it considers it advisable, from the point of view of due care, for the experiment to be independently assessed by the Central Committee on Human study (CCMO). Based on exploratory contact with the CCMO, it has been established that testing can take place once the AMvB on the design of the experiment and the detailed study protocol are available.

It may also be important for the Consumer and Market Authority (ACM) to give an opinion on any changed competitive relationships between participating and non-participating coffee shops in the context of the experiment. The ACM has indicated that the concrete details of the AMvB must be known before it can form an opinion on this. The advisory committee emphasizes that in the context of an experiment there are generally conditions that by definition deviate from the general situation outside the experiment.

As the experiment progresses, political-administrative stability on the cannabis file is a factor of interest. Policy changes that occur before the end of the experiment and which intervene in the closed chain can irreversibly undermine the experiment and its added value.

## 4.5 Conclusion

Has the closed cannabis chain functioned properly and what were the effects of this intervention? These two questions can only be answered as part of the experiment after thorough study: the first question after a process evaluation, the second after comparative study into a series of possible effects.

The process evaluation must provide insight into the degree to which the chain is actually closed, into the course of the processes within the chain, into the sale of the cannabis supplied and into the user experiences with the closed cannabis chain. The comparative study studies the effects of the intervention on the use of cannabis and other stimulants, cannabis dependency, cannabis-related acute health effects, driving under the influence of cannabis, crime, safety and nuisance. The scale and duration of the experiment do not allow long-term health effects and effects on total crime to be investigated. However, it is conceivable to investigate these effects in

any subsequent follow-up measurements. The committee considers the experiment to be successful if it succeeds in realising a well-functioning, closed cannabis chain without negative effects.

## 5 In conclusion

The ministers asked the committee a lot, in a short time. In the preceding chapters, the committee has performed its assigned duties to the best of its ability. In this final chapter, the committee formulates a number of additional considerations and recommendations.

### 5.1 Major interests and a learning government

The interests involved in the intended experiment are considerable, for politics, for the participants in the experiment, and for society. But also, for organised crime, which in a successful experiment has to deal with the consequences of the changed policy and in doing so may lose its role around 'the back door'. The latter category of stakeholders has an interest in framing (as meaningless or not feasible), opposing, disrupting or negatively influencing the experiment from the beginning – possibly via influencing others in the field.

Because the interests are so great, it is essential to keep a close eye on the conditions under which the experiment is carried out. For example, the committee thinks of the requirements to be set for the entire chain with regard to quality, safety and integrity. It also recalls the methodological requirements necessary to achieve reliable and meaningful results. For the same reason, robust and consistent policy-making is important. This requires the government, among other things, to anticipate the possible outcomes of the experiment and the related policy options. A learning government has a long-term focus, offers room for well-considered experimentation and realises that the best route for a complex issue such as cannabis policy cannot always be fully determined after just one experiment.<sup>43</sup> It also requires a policy that is on the one hand binding and trustworthy – certainly in a field in which, as the committee has noted, there is a great deal of mistrust of the government – and on the other hand consistently maintains policy where requirements and agreements made on the ground are not met and where there is criminal activity.

Such a policy requires a comprehensive and integrated approach, without compartmentalisation, with good cooperation between the areas of public health, justice and security. It also requires effective interaction between national and local government.

### 5.2 Appointing an independent study team

In the committee's opinion, an independent study team or consortium should be appointed as soon as possible, with the following tasks:

- substantive and methodological elaboration of the design of the experiment, and
- the substantive preparation, substantive coordination of the implementation, evaluation, and reporting of the experiment.

The independent operation of this team is not only an important condition for a scientifically sound execution of the experiment, but also for effective and credible consultation with the stakeholders involved in the experiment at relevant moments.

The selection of this team/consortium is not the responsibility of the committee. However, it has some recommendations for its composition. Because the experiment is pre-eminently focused on a complex theme at the intersection of policy and study, and encompasses a broad range of substantive and methodical facets, it is recommended to recruit a study team/consortium from government knowledge institutions, universities and possibly also extra-university institutes that complement each other. In doing so, internationally recognised top expertise in our country and, where necessary, foreign centres of excellence can be consulted.

### 5.3 Selection of municipalities

After discussing the present report, the government will make decisions about the design and planning of the experiment. Subsequently, a second advisory report

from the committee is expected on which municipalities will participate. This second report of the committee will have to be prepared in close consultation with the future study team. The second report completes the work of the advisory committee.

The methodological elaboration of the size and composition of the group of participating municipalities in both the intervention and the control conditions (that is necessary in order to answer the study questions), follows from the concrete elaboration of the study design and must be carried out in such a way that the independent study team can take responsibility for it.

## 5.4 Monitoring of the experiment

The committee recommends that an independent monitoring committee be set up. This committee consists of content experts from the most important areas of knowledge for the experiment. This committee supervises the planning, execution and reporting and provides solicited and unsolicited advice to researchers and clients. The committee also advises on the completion, continuation or adjustment of the experiment based on the results of an interim analysis after two years.

Reasons for premature completion may include: prematurely obtaining the answer to the central questions, or the occurrence of important non-correctable problems or adverse side-effects. The possible interim decisions to be taken, and the criteria to be used for them, will have to be anticipated in a protocol to be drawn up for this purpose, also in order to avoid ad hoc influence by stakeholders (whether or not operating legally).

## 5.5 Interdepartmental coordination

During the preparation and implementation of the experiment, the necessary actions must be set in motion and (integral) decisions must be taken by the ministries of Justice and Security, and of Public Health, Wellness and Sports, for example with regard to the appointment of growers. There will also have to be an overview of the entire national field in which the experiment is developing. Where necessary, policy coordination and support will have to take place and information and communication functions will have to be carried out. In view of all these activities and the importance of a single point of contact, the committee suggests that an interdepartmental coordination structure should be set up for this purpose.

## 5.6 International alignment

In the effect measurements of the experiment, any overflow problems in Belgium, Germany and Northern France must also be mapped. Without an understanding of this, the impact assessment is not complete. In addition, the Netherlands is part of the international community and the agreements and established treaties made in that respect.<sup>5</sup> An additional point is that other European countries also have to deal with the search for a good cannabis policy and that international comparative learning can be of mutual help in this respect.

The committee therefore advises the government, in parallel with the further preparations of the experiment, to remain in contact with the governments of the aforementioned countries about the intentions and possible implications of the experiment, relevant effect measurements, and any necessary agreements in the field of surveillance and enforcement. It can also – in cooperation with other countries – develop an international diplomatic strategy aimed at revising international treaties and agreements where necessary and at international comparative learning in a European context.

## 5.7 No phase-out in case of success

In the assignment to the committee it is announced that after the experiment is completed, it will be phased out (see appendix 1). In this phase, the situation must be restored 'as it existed before the experiment' before deciding on future policy. The committee considers such a phasing out, regardless of the results, to be undesirable for a number of reasons. The committee saw its view confirmed in the round table and individual discussions it had organised.

The committee sees the following main reasons why phasing out after the experiment is undesirable:

- In the first place, if the outcome of the experiment is positive, the committee considers it problematic if a closed cannabis chain that has been realised with joint forces must be broken down again after the experiment and the backdoor problems can reoccur to their full extent. The committee finds it illogical and risky if the points of sale in the participating municipalities have to go back to illegal cultivation and delivery, with all the associated risks.
- Secondly, the committee has study-ethical concerns about a scenario in which an experiment is started

with the help of so many, without the commitment in advance that a favourable result will lead to appropriate follow-up steps. Moreover, it cannot be ruled out that some people may subsequently find themselves in an even more vulnerable position than they had previously been in.

- Thirdly, the intended phasing out scenario can undermine the motivation of municipalities and other stakeholders to participate in the experiment.

The committee therefore advises the government to make it clear in advance that it is committed to implementing the closed, regulated cannabis chain nationwide in the event of a positive outcome. This clarity beforehand would underline the government's commitment to a closed cannabis chain with a long-term impact.

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# Appendix 1

## Questions and answers

***At the start, the ministers gave the committee a document entitled 'Advisory questions to the Independent Committee on the closed coffee shop chain experiment in the Netherlands'. This appendix contains the full text of this document. The questions asked by ministers are accompanied in italics by references to the (sub)sections of this advisory report in which the committee answers the questions.***

### INTRODUCTION

The Minister of Justice and Security and the Minister for Healthcare and Sport are implementing the pledge made in the coalition agreement to introduce legislation that allows uniform experiments aimed at determining whether and how quality-controlled cannabis can be supplied to coffee shops and what the effects of this would be. The government will explore the impact of the experiment to establish a controlled supply of cannabis to coffee shops in terms of improving public health and safety, and of reducing crime and antisocial behaviour.

#### **The current situation:**

There are 573 coffee shops in the Netherlands, distributed over the 103 municipalities which allow them. These coffee shops exist in their current form as a consequence of Dutch policy on tolerating certain practices that are officially banned. Under this policy, as long as coffee shops observe the criteria set out in the Public Prosecution Service's Opium Act Instructions and any additional requirements set by the local authorities, the sale of cannabis to consumers through coffee shops is tolerated. But the cultivation of and trade in cannabis are not tolerated.

Local authorities in particular have indicated that the current system under which coffee shops operate – the sale of cannabis is tolerated, but not its procurement – creates problems for public order, safety and health, and makes it difficult to fight crime that undermines society.

As current legislation does not permit cannabis to be cultivated for the purposes of such an experiment, an amendment to the Opium Act is required. To this end, the government will be drafting a bill and an order in council. The bill will in any case include a detailed description of the aim, duration and scope of the experiment, and will form the basis for supplementary rules set out in an order in council. The order in council will specify the parameters within which the experiment will be conducted, including the requirements for the cultivation of cannabis and its sale in coffee shops. The aim is to submit the bill to the House of Representatives before the summer recess.

The experiment will be conducted in six to ten medium-sized or large municipalities. There should be sufficient variation in the type and geographical spread of the municipalities to ensure the impact assessment is meaningful.<sup>1</sup>

The experiment consists of different phases, starting with the establishment of the independent advisory committee on the experiment with a controlled supply of cannabis to coffee shops. The committee, consisting of scientists and experts, will advise on the design and implementation of the experiment, the conditions under which it will take place and the selection of participants. This advice will be drawn on when drafting the order in council. The committee will also advise on which municipalities may be eligible to participate in the experiment.

<sup>1</sup> Participating coffee shops will in any case be subject to the following requirements:

- no advertising other than a brief notice on the premises in question;
- no hard drugs in stock or for sale;
- no public nuisance, such as lots of parked cars, noise annoyance, litter or customers hanging around in front of or near the premises;
- no sale or admission to minors (there is a minimum age of 18 years);
- no sale of large amounts in a single transaction, i.e. not more than appropriate for personal use (5 grams).

The **preparatory phase** will then follow, once the bill and the order in council based on it come into force. In this phase, one or more cannabis cultivators and municipalities will be designated and given the opportunity to prepare for participation in the experiment. At the same time, a research team or research consortium will be set up, overseen by an independent supervisory committee.

The **experimental phase** will then follow, in which the experiment will be carried out. During this phase, cannabis can, as part of the experiment, be produced and supplied to coffee shops located in participating municipalities and sold there. The draft bill specifies that the experimental phase will last four years.

Once the experimental phase ends, the experiment will be phased out over a period of several months, i.e. we will revert to the situation as it existed before the experiment began. We envisage that six months will be needed for this process.

The experiment will be independently evaluated by the research team or research consortium.

The exact remit of the advisory committee on the experiment with a controlled supply of cannabis to coffee shops is set out in this document.

## REMIT OF THE ADVISORY COMMITTEE ON THE EXPERIMENT WITH A CONTROLLED SUPPLY OF CANNABIS TO COFFEE SHOPS

The advisory committee on the experiment with a controlled supply of cannabis to coffee shops has been asked to advise on the design of the experiment.

This will take place in two phases. Phase I concerns advice on the design of the experiment, in particular where it concerns the cultivation of cannabis, the selection criteria for municipalities participating in the experiment, the participation of coffee shops, preventive measures, monitoring and enforcing compliance with the rules of the experiment, and measuring the effects. Phase II concerns selecting the municipalities that will participate in the experiment.

### Phase I:

The committee has been asked to submit its advisory report no later than 31 May 2018. The ministers will then finalise the experiment's design. Municipalities can then indicate whether they would like to participate.

### Phase II:

The committee has been asked to nominate in writing, in autumn 2018, between six and ten municipalities to participate in the project. In this document we set out a number of questions to be addressed in the advisory report, under different headings. The committee is also free to advise on issues not addressed in these questions.

## SELECTION OF MUNICIPALITIES

### *Selection of participating municipalities*

The experiment will be conducted in six to ten medium-sized or large municipalities. There should be sufficient variation in the type and geographical spread of the municipalities. The coalition agreement refers to uniform experiments, with the aim of determining whether and how quality-controlled cannabis can be supplied to coffee shops and what the effects of this would be. One consequence is that only individual municipalities are eligible to participate. There will therefore be no regional experiments involving more than one municipality. Another consequence is that the design of the experiment must be comparable in each municipality. It has also been decided that all coffee shops in a participating municipality must take part in the experiment.

It is expected that more municipalities than the number envisaged by the government (six to ten) will want to participate in the experiment. More than ten municipalities have already registered interest with the Ministry of Justice and the Association of Netherlands Municipalities (VNG). The order in council will specify the selection criteria for designating municipalities. The selection procedure must in any case be initiated by a request from the mayor. The Minister of Justice and Security is ultimately responsible for designating municipalities.

### *Local coffee shop policy*

Coffee shops can only exist with the cooperation of the municipality in which they are located. There are currently coffee shops in 103 municipalities. Local coffee shop policy is the responsibility of the mayor. Under section 13b of the Opium Act, the mayor can draft administrative rules on the conditions under which administrative enforcement action can be taken. In other words, a coffee shop will not be closed by the mayor as long as it respects local coffee shop policy. Each municipality has different rules on the establishment and running of coffee shops. In some municipalities, coffee shop owners are given a permit allowing them to operate under certain conditions. In others, a hospitality business operating licence is required. There are also wide variations in the number of coffee shops permitted within a municipality: while the four largest municipalities account for almost half of all coffee shops, other municipalities only have one. Accordingly, the recommended parameters for the experiment will affect each participating municipality differently.

Since 2013, the residence criterion has been part of the framework set out in the Public Prosecution Service's Opium Act Instructions, under which the sale of cannabis is tolerated. A number of municipalities have also added this criterion to local administrative coffee shop policy and actively ensure that no 'coffee shop tourists' (non-residents) are admitted to coffee shops. These are generally border municipalities which have in the past experienced a great deal of nuisance from large numbers of coffee shop tourists. Many municipalities do not actively enforce the residence criterion. This is because they do not experience any problems with coffee shop tourists as few tourists visit their area, or because they anticipate a sharp increase in the nuisance associated with illegal street dealing if they were to do so. It is up to the mayor to decide to what extent administrative instruments should be used, and to make agreements with the chief public prosecutor and the local chief of police on how enforcement capacity will be deployed in this regard. The residence criterion may be set aside for the purposes of this experiment, except in border municipalities.

## QUESTIONS

- 1. Which selection criteria would the committee recommend for the group of municipalities participating in the experiment? Please focus in particular on geographical distribution and variety between municipalities.**

*Municipalities that are willing to participate in the experiment should be prepared to comply with the agreements and rules that apply during the experiment (see 3.3 and 3.5) and to cooperate in the process evaluation and effect measurement (see 4.1 and 4.2). The size and composition of the group of participating municipalities will follow from the concrete elaboration of the study design by the study team (see 4.3 en 5.3).*

- 2. What should be the minimum preconditions for participating municipalities?**

*See ad 1.*

## PARTICIPATING COFFEE SHOPS

### *Taking supply out of the hands of criminals*

Coffee shops exist in their current form as a consequence of the Dutch policy on tolerating certain practices that are officially banned. Under this policy, as long as coffee shops observe the criteria set out in the Public Prosecution Service's Opium Act Instructions and any additional requirements set by the local authorities, the sale of cannabis to consumers through coffee shops is tolerated. The cultivation of and trade in cannabis is not, however, tolerated. There is an inherent tension in the fact that the trade in and cultivation of cannabis are prohibited, and that the sale of cannabis in coffee shops is prohibited but tolerated. As part of the experiment, coffee shops will be able to buy controlled cannabis from one or more cultivators. This will take the supply of cannabis to coffee shops out of the hands of criminals.

As explained above, the details of coffee shop policy are determined locally. Each municipality has its own rules on the establishment and running of coffee shops. Some municipalities stipulate that anyone wishing to establish a coffee shop must demonstrate that they are above reproach. Others screen coffee shop proprietors by conducting an investigation under the Public Administration (Probity Screening) Act.

### *Existing toleration criteria apply*

Cannabis cultivated as part of the experiment will be supplied to coffee shops in participating municipalities. The existing toleration criteria will continue to apply. This means that participating coffee shops will in any case be subject to the following requirements: no advertising other than a brief notice on the premises in question; no hard drugs in stock or for sale; no public nuisance, such as lots of parked cars, noise annoyance, litter or customers hanging around in front of or near the premises; no sale or admission to minors (minimum age of 18 years); no sale of large amounts in a single transaction, i.e. not more than appropriate for personal use (5 grams).

Existing coffee shop policy also specifies the maximum quantities that coffee shops can stock. This is decided in local tripartite consultations (between the mayor, police and Public Prosecution Service) on tolerated coffee shops. In principle, no action is taken provided the amount held in stock is under this maximum. Under current policy, stock must in any case not exceed 500g. As part of the experiment, the current maximum quantity may be departed from, within a certain margin.

The coalition agreement clearly emphasises supply to coffee shops, meaning that only existing, or new, coffee shops can sell cannabis. Sale through other outlets or online is not permitted.

## QUESTIONS

### **1. What should be the minimum preconditions for participating coffee shops?**

*The points of sale participating in the experiment must comply with the rules that apply during the experiment (see 3.3) and with additional requirements imposed by the municipalities in which they are located .*

### **2. What does the committee advise regarding the price of cannabis?**

*See 3.3.4.*

### **3. What are the implications of increasing the maximum amount that can be held in stock? What margin would the committee advise for the increase in the maximum stock?**

*See 3.3.1.*

## CANNABIS CULTIVATION

Coffee shops in the participating municipalities need to be provided with quality-controlled cannabis. There must also be enough cannabis, available in various types, to represent the range of products typically available. Possible indicators of quality and variety include the use of pesticides and the content and relative levels of THC and CBD. To this end, the bill on the uniform experiment with a controlled supply of cannabis to coffee shops provides for one or more cultivators to be designated. A contract award procedure will need to be followed, resulting in one or more cultivators being appointed to provide a reliable, high-quality product for exclusive use in the uniform experiment.

It is also important to ensure that the cannabis is properly packaged. The packaging should clearly state the composition of the product and how it should be used, and warn the user of possible risks. This will ensure that users are optimally informed.

Strict, additional conditions will apply to the storage, transport and packaging of the cannabis. As a special product that must not, under any circumstances, be allowed to end up in the hands of criminals, it must be cultivated, stored and transported securely and packed under controlled conditions.

## QUESTIONS

- 1. What does the committee advise in terms of the *types* of cannabis (including hashish) that will need to be cultivated?**

**What does the committee advise in terms of *quality*? Bear in mind that sufficient variety of cannabis needs to be available in the interests of a representative experiment. What would the committee advise in this respect?**

**What requirements can or must be set with regard to the possible use of pesticides, plant protection products and growth-enhancing products?**

*See 3.1 and 3.3.2.*

- 2. What criteria must the cultivator(s) meet?**

*See 3.1.6.*

- 3. What criteria must the cultivation sites meet?**

*See 3.1.6.*

- 4. What criteria must be met by the packaging for the cultivated cannabis, and the user information and warnings it bears (e.g. on a sticker/label)?**

*See 3.1.5.*

- 5. What would the committee advise in respect of security risks?**

*See 3.5.2.*

## PREVENTION

The main emphasis of Dutch policy on drugs is on discouraging their use. Throughout this experiment, and as part of it, information will be provided in participating and non-participating municipalities alike on the risks of cannabis use. Information campaigns will be introduced nationally as well as in coffee shops in participating municipalities. Coffee shop customers must be actively informed of the risks of cannabis use. This is because the government does not want the experiment to have the effect of normalising cannabis use and thus attracting new users. Customers must also be informed how they can reduce the health risks. We therefore ask the committee for advice on adequate public information and prevention.

## QUESTIONS

- 1. Which obligations relating to product and user information and prevention can be imposed on participating coffee shops – in addition to the existing requirements – without compromising the effectiveness of the experiment (i.e. ensuring that it accurately reflects how coffee shops usually operate)?**

*See 3.4.1 and 3.4.2.*

- 2. Does the government need to take extra preventive measures – in addition to existing interventions – to discourage the use of cannabis, both in general and by teenagers and young adults in particular, without compromising the effectiveness of the experiment (i.e. ensuring that it accurately reflects how coffee shops usually operate)?**

*See 3.4.4.*

- 3. Does the committee have any other recommendations with regard to preventing quality-controlled cannabis having an attraction for people who do not currently use it (young people in particular)?**

*See 3.4.3.*

- 4. Does the committee believe that coffee shops have a duty of care in the sense of flagging problematic cannabis use?**

*See 3.4.1.*

## MONITORING AND ENFORCEMENT

Under current policy, the sale of cannabis to consumers through coffee shops is tolerated as long as coffee shops observe the criteria set out in the Public Prosecution Service's Opium Act Instructions and any additional requirements set by the local authorities. Municipalities monitor this on the basis of general municipal bye-laws, under which some of them grant hospitality business operating licences or temporary exemption orders to coffee shops. In addition, the Tax and Customs Administration monitors bookkeeping.

The prohibition of the acts listed under section 3 (B) and (C) of the Opium Act will be lifted for the duration of the experiment, in so far as they are performed as part of the experiment. Monitoring is needed to establish to what extent coffee shops comply with the rules of the experiment. This requires closer supervision than is exercised by municipalities and the police under the current system.

To guarantee the closed nature of the coffee shop supply chain, and to prevent cannabis ending up in the hands of criminals, clear insight into and/or close monitoring of the following areas is needed:

- > the cultivation of the cannabis;
- > the packaging and transportation of the cannabis;
- > the sale of the cannabis in coffee shops;
- > record-keeping.

However monitoring is organised, the police will continue to be responsible for investigating crimes, and the Public Prosecution Service for prosecuting offenders. If the rules of the experiment are not respected, the lifting of the prohibition of certain acts will no longer apply. Consequently, they will revert to being offences under the Opium Act, and it will be possible to deploy the enforcement instruments specified in the same Act to enforce compliance or punish contraventions.

In addition to being alert to the risk of cannabis ending up in the hands of criminals, the quality of the cultivated cannabis must also be controlled. A system needs to be developed to guarantee the quality of the cannabis.

## QUESTIONS

- 1. How can the controlled supply of cannabis to coffee shops best be organised (based on the existing enforcement arrangements)? Please focus in particular on the allocation of responsibility and the closed nature of the coffee shop supply chain.**

*See 3.5.*

- 2. What requirements should be set for records to be kept by participants in the supply chain?**

*See 3.5.5.*

- 3. What are the consequences for participants should they commit an offence?**

*See 3.5.7.*

- 4. What form should the monitoring of and checks on the cultivation, storage, packaging, records and distribution of cannabis take, and how can quality be assured?**

*See 3.5.*

- 5. How can cultivated cannabis be secured to minimise the risk of it falling into criminal hands (taking costs/investments for the cultivator into account)?**

*For the security during production see 3.1.3 and 3.5.2, and at the point of sale 3.5.4.*

## IMPACT ASSESSMENT

The coalition agreement states that the aim of the experiments is to determine whether and how quality-controlled cannabis can be supplied to coffee shops and what the effects of this would be. The government wishes in any case to explore the impact that the controlled supply of cannabis to coffee shops has on public health, crime, safety and/or antisocial behaviour.

## QUESTIONS

- 1. What does the committee believe are the minimum prerequisites for conducting an impact assessment regarding public health, crime, safety and/or antisocial behaviour? Please take particular account of the scale of the experiment, feasibility and the importance of having a baseline measurement and control municipalities. It is important that the committee gives clear advice about what can and cannot be measured.**

*See 4.2.*

# Appendix 2

## Composition of the committee

- > Mr André Knottnerus, Professor of General Practice, University of Maastricht, *chairperson*
- > Mr Tom Blom, Professor Criminal (Process) Law, University of Amsterdam
- > Mr Wim van den Brink, Emeritus Professor Addiction care, Academic Medical Centre, University of Amsterdam
- > Mr Jan Mans, former mayor
- > Mrs Dike van de Mheen, Professor of Care Transformations, Tilburg University, Tranzo, School of Social and Behavioural Sciences
- > Mr Jaap Seidell, Professor of Nutrition and Health, Free University, Amsterdam
- > Mr Albert van Wijk, Former Attorney General Public Prosecutor's Office, chairman of the Board of Directors at the IJsselland hospital, Capelle aan den IJssel
- > Mrs Karin van Wingerde, Professor of Criminology, Erasmus School of Law, Erasmus University Rotterdam
- > Mrs Sanne van Eerden, *secretary*
- > Mr Nico de Neeling, *secretary*

### **Audience:**

- > Mrs Wendy Opperman, Ministry of Justice and Security
- > Mr Dave Kumpe, Ministry of Health, Welfare and Sport

### **Editorial support:**

- > Mrs Mieke de Waal

# Appendix 3

## Persons consulted

- > Mrs M. van Asselt, Dutch Safety Board
- > Mr H. Baerveldt, Patients Group of Medicinal Cannabis Users
- > Mr T. Bart, Jellinek
- > Mr D. Bergman, Association Lifting Cannabis Ban
- > Mr W. Best, Healthcare and Youth Inspectorate
- > Mr B. Bieleman, Intraval
- > Mrs L. Boekholt, The Cannabis Supplier
- > Mr L. Bolsius, municipality of Amersfoort
- > Mr P. Booms, the Belgian Embassy
- > Mrs M. Boudreau, Controlled Substances Directorate, Canada
- > Mr D. Breeuwer, CannaWijzer
- > Mrs B. Brohl, B J Brohl Strategies, LLC, Colorado
- > Mr W. Bruining, Coffeeshop Mellow Yellow
- > Mr M. Daniel, Chief Constable
- > Mr P. Depla, municipality of Breda
- > Mr P. van Doesburg, municipality of Hof van Twente
- > Mrs R. Donders, municipality of Roermond
- > Mr W. van de Donk, King's commissioner in North Brabant
- > Mr R. van Dorp, Environmental and Transport Inspectorate
- > Mr C. Dorpmans, Novadic Kentron
- > Mr R. Dufour, Drug Policy Foundation
- > Mr A. Dunn, platform of the Dutch flax and hemp sector
- > Mr H. Dupont, Mondriaan Addiction Care, Maastricht University
- > Mr A. Ederveen, municipality of Valkenswaard
- > Mr W. van Egmond, Het Dilemma Foundation
- > Mr J. Erkelens, Bedrocan
- > Mr T. Erkelens, Bedrocan
- > Mr V. Everhardt, municipality of Utrecht
- > Mr C. Fijnaut, Tilburg University
- > Mr M. Geuzinge, Association of Dutch Municipalities
- > Mr F. Goossens, Trimbos Institute
- > Mrs N. Groot Bruinerink, Bureau Medicinal Cannabis
- > Mr M. Groot Nibbelink, Association of Dutch Municipalities
- > Mr J. Hamming, municipality of Zaanstad
- > Mr A. Hazekamp, researcher
- > Mr R. Hebben, Cannabis Connect
- > Mr J. Helms, Federation of Cannabis Retailers
- > Mr V. Hendriks, Tilburg University
- > Mr L. Heuts, Scientific study and Documentation Centre
- > Mr S. Hoorens, RAND Europe
- > Mr C. Hoornaert, the Belgian Embassy
- > Mr T. Horn, municipality of Haarlemmermeer
- > Mrs R. Janssen, Rijksinstituut voor Volksgezondheid en Milieu (National Institute for Public Health and the Environment)
- > Mr K. Keuch, Het Zwarte Gat (national network of client councils for addiction care)
- > Mr P. de Koning, municipality of Genneep
- > Mr D. Korf, University of Amsterdam
- > Mrs M. van Laar, Trimbos institute
- > Mrs L. Lankes, Association of Coffee Shop Owners Eindhoven
- > Mr L. Lichtendahl, Leli Holland
- > Mr A. de Loor, Drug Consultancy Bureau
- > Mrs N. Maalsté, Cannabis Connect
- > Mr A. Marcouch, municipality of Arnhem
- > Mr D. Martín Olivera Couto, Secretaría Nacional de Drogas, Presidencia de la República Uruguay
- > Mr B. Meijer, municipality of Westland
- > Mr J. Meijers, Stichting JoinUs
- > Mr J. Nauta, municipality of Leiden
- > Mr H. Nelen, University of Maastricht
- > Mr P. Oskam, municipality of Capelle aan den IJssel
- > Mr P. den Oudsten, municipality of Groningen
- > Mr M. Out, municipality of Assen
- > Mr S. Paul, Dutch Food Safety Authority
- > Mrs A. Penn, municipality of Maastricht
- > Mr E. Poot, University of Wageningen
- > Mr R. Rademaker, Bedrocan
- > Mrs L. Rastovac, Meteor Systems
- > Mr T. Rau, Legal Cannabis Coalition
- > Mrs N. Reigwein, Coffeeshop The Point, The Hague
- > Mr P. dos Reis, Greenlabs
- > Mrs R. Ricci, Cannabis Social Club Tree of Life Amsterdam
- > Mr M. Rodríguez Araújo, Instituto de Regulación y Control del Cannabis, Uruguay

- > Mr T. Roes, De Correspondent
- > Mrs C. Sandvos, Bureau Medicinal Cannabis
- > Mr H. Schafrat, Platform Cannabis Companies  
Netherlands
- > Mr S. Scheer, municipality of Rotterdam
- > Mr F. Schenk, municipality of Bunnik
- > Mr A. Scholten, municipality of Venlo
- > Mr T. Schouten, municipality of Oldenzaal
- > Mr D. Schrijer, municipality of Zwijndrecht
- > Mr J. Smilde, Public Prosecutor's Office
- > Mr P. Smit, municipality of Oldambt
- > Mr M. van de Velde, Bureau Medicinal Cannabis
- > Mr P. Verhoeve, municipality of Oudewater
- > Mr C. Visser, municipality of Katwijk
- > Mr B. Vollenberg, Epicurus Foundation
- > Mr P. Vossenbergh, Association for Addiction Medicine  
Netherlands
- > Mr R. van de Waart, CanCan
- > Mr B. Welten, Dutch Safety Board
- > Mr T. Weterings, municipality of Tilburg
- > Mrs A. van Zeeland, Moedige Moeders

# Appendix 4

## Methodological considerations regarding the study design

### Introduction

In this appendix, the committee discusses methodological considerations that it finds important in evaluating the feasibility of the chain and its effects. The options for the study design (design options) are also discussed.

The committee makes two general remarks beforehand.

- The experiment to be initiated is not a laboratory test in which all conditions can be artificially imposed and maintained at a constant level. The experiment must be in line with social and administrative reality, obviously within the framework of the uniformity required for the introduction of the closed chain and an adequate national evaluation thereof. This means that, given the generally applicable framework, there must be room for customisation that is necessary on the basis of local knowledge, expertise, experience and responsibilities. Without the possibility of such customisation, not only are important learning moments missed, but it can also lead to less local support to accept the results of the experiment as a guiding principle. That aspect will have to be included in the experiment.
- The final study design and its implications for the number of participating municipalities, for example, will have to be further elaborated by the designated study team after the decision to actually start the experiment has been taken. This issue is discussed in more detail in chapter 4.

### Process evaluation

In order to determine whether and to what extent the first main objective of the experiment – the realisation of a closed cannabis chain – has been achieved, the experiment will have to include a thorough process evaluation. The following main questions will have to be answered for the municipalities in which the chain is being introduced:

1. Is the chain really closed? If not, where not and why not?
2. How are the processes within the chain doing?
3. How is the sale of the delivered cannabis going?
4. What are the user experiences with the closed cannabis chain?

The information to be collected about the operation of the chain will not only make it possible to assess the success of the closed cannabis chain at the end of the experiment and to identify learning and improvement points. It is also essential to be able, if necessary during the experiment, to adjust the agreements between the various actors in the chain and the range of cannabis products on offer.

For this process evaluation, the functioning of the 'closed chain' intervention will be carefully mapped and monitored from its introduction. It is important not only to use quantitative data but also qualitative study methods, in order to learn from the experiences gained during the experiment by participating growers, sellers, users, administrators, and actors responsible for surveillance and enforcement. This can be done, for example, by means of interviews and focus group sessions in a safe study setting, with anonymised data that cannot be traced back to persons. Observation, for example by mystery guests, can also be used to obtain a clear picture of the performance of the points of sale in the closed chain.

## Effect study

The second main objective of the experiment – to evaluate the effects of the intervention on cannabis use, public health, crime, safety and nuisance – cannot be achieved by a process evaluation alone. In addition to the process evaluation, this requires an effect study. This section discusses – in broad outline – several relevant design options.

### Before-after comparison

A basic condition for any effect study is a 'baseline measurement': an assessment of the state of affairs in the areas just mentioned before the start of the intervention. For this purpose, the situation in the period prior to the experiment should be mapped out. Follow-up measurements must be carried out, consisting of monitoring developments in the experiment and a final measurement of the situation at the time of completion. The difference between the baseline measurement and the follow-up measurements provides insight into the changes that have occurred in the various areas since the start of the intervention. In this context, this is referred to as a 'before-after comparison'.

An important pitfall of limiting to a before-after comparison is that changes can also occur in the aforementioned areas without intervention. It would mislead politics and society if such changes were then – wrongly – attributed to the intervention. A before-after comparison is therefore only suitable if there are convincing reasons in advance to assume that the areas in question would remain stable in the coming years if the closed chain were not introduced. Partly because of the dynamics in these areas and the possible impact of the roll-out of the experiment itself, the committee does not see these convincing reasons. It considers that the assumption of a stable situation for the decision-making that will follow the experiment is too unstable a basis.

### Comparison between intervention and control conditions

#### General remarks

The pitfall just mentioned can be avoided by comparing the changes between the baseline measurement and the follow-up measurements in the situation with intervention (the intervention condition) with the changes between the baseline measurement and the follow-up measurements in the situation without intervention (the control condition). The difference between these two changes then represents the right 'contrast' for the experiment. In other words, any trend differences between both conditions provide insight into the effects of the intervention.

The intervention condition includes all activities that are considered important in the context of the implementation of the closed cannabis chain in the 'intervention municipalities', including local customisation within the framework of the national agreements made for the closed chain. The control condition includes all activities that take place in 'control municipalities' in which the closed chain is not implemented and the current policy is continued. This therefore concerns the usual policy in municipalities and the development that it experiences during the period in which the experiment takes place. Comparing the intervention and control municipalities offers the possibility to distinguish the actual effects of the intervention from changes (observed in the control municipalities) that would probably also have occurred in the intervention municipalities if the closed chain had not been introduced there.

In order to be able to determine the effects of the intervention – in terms of the contrast between the intervention and control conditions – as well as possible, every effort must be made to avoid sources of distortion (confounding and bias) or to minimise their effects. An important risk of distortion in this experiment is 'selection bias' as a result of (political-administrative) designation of the intervention municipalities on the basis of self-nomination and the selection of control municipalities from the group that does not register for the intervention. For example, it is conceivable that municipalities that are willing to participate will already have more effective policy than other municipalities, and would therefore also score more favourably on the effect measures without an experimental approach. But it can also happen that a good performance of intervention municipalities does not become clearly visible if they have an unfavourable starting position as a result of extra-large local problems. Based purely on registration data, it may even appear that such municipalities are doing worse. A study in which such distortions can have a strong influence therefore does not at all offer society any clarity.

This should also be borne in mind when comparing the developments in the municipalities participating in the experiment with trends in relevant national statistics and surveys in the areas of evaluation. This comparison is not suitable for determining the effectiveness of the closed chain, not only because of the limited amount of data but also, and above all, because of the risk of selection of the municipalities available for the experiment compared to the other municipalities. However, it can give a rough impression of the extent of such selection.

In order to minimise the risk of selection biases, maximum efforts should be made to ensure that the starting position of intervention and control municipalities is comparable.

### Quasi-experimental design

Comparability can be pursued by means of a quasi-experimental design<sup>m</sup> in which municipalities participating in the intervention apply and are subsequently designated, and in addition – after matching with pre-existing characteristics, possibly using propensity score methods – a group of municipalities that are as comparable as possible is selected from the other municipalities. The external validity is often named as a strength of a quasi-experimental approach, of course provided that the internal validity is adequate. As far as internal validity is concerned, however, in the case of administrative designation of intervention municipalities on the basis of self-nomination, the previously discussed risk of selection bias based on, for example, motivation or local policy experience must be seriously taken into account. Such selection bias can be avoided by applying the intervention to a random sample from all the municipalities that register for the experiment and then comparing the results of this sample with those not included in the sample. This, of course, is subject to the condition that a sufficient number of municipalities register. Such a design is, in essence, a cluster randomized controlled trial.

### Cluster randomized controlled trial

Random assignment to an intervention or control group offers the best possible guarantee that differences found in an experiment are the result of the intervention and not of any pre-existing differences, in this case for instance in terms of the motivation, size or location of municipalities. For this experiment the design of the pragmatic cluster randomized trial (CRT) can be considered. In it, the municipalities available for the experiment ('clusters' of points of sale and inhabitants) are randomly assigned to the intervention or control conditions. The term pragmatic means: as representative of and generalisable as possible for the practice to which the results of the experiment should relate. This has implications for, for example, the representativeness of the group of participating municipalities, the alignment with the currently available repertoire of cannabis products and the scope for local customised governance and enforcement.

The probability of comparability between the groups of municipalities can be further increased by first dividing municipalities into categories ('strata') that are homogeneous for a number of relevant characteristics such as number of inhabitants, number of points of sale, national distribution, and whether or not they are located in a border region. Then, within the strata, chance can be allowed to determine which municipalities are to be assigned to the intervention condition and which to the control condition (randomisation). Randomisation can also be applied with the aid of 'minimisation', whereby the relevant characteristics are balanced as far as possible between the groups to be compared.

Randomisation must take place at the level of municipalities because the intervention is also used at the level of the municipalities. Furthermore, randomisation at the point-of-sale level would, due to the limited distance between them, present a very high risk of 'contamination', i.e. users could very easily switch from 'intervention points of sale' to 'control points of sale' and vice versa. This would seriously distort the contrast between the two comparison conditions. This would also require the establishment of two surveillance and enforcement regimes within one municipality (suitable for the closed and unclosed chain respectively), which could cause implementation and legitimacy problems. Where relevant, additional multilevel analysis may be carried out at the point-of-sale level.

### Stepped wedge design

One problem could be that municipalities that are available for the experiment and that are assigned to the control condition have difficulty waiting for the experiment to end and in the meantime will try to create their own closed chain. This can reduce the desired contrast within the experiment. To counter this, the CRT sub-variant cluster stepped wedge design could be a solution.<sup>n</sup> This design means that from the general starting moment onwards, more and more municipalities are gradually entering the intervention condition on the basis of randomisation. An additional advantage of this approach is that the closed chain intervention is not rolled out for all intervention municipalities at the same time, and that municipalities that join later learn from the earlier intervention municipalities. However, this subvariant is complex, requires an extra meticulous follow-up registration, and during the experiment leads to a decreasing number of control municipalities and an

<sup>m</sup> Tugwell P, Knottnerus JA, McGowan J, Tricco A. Big-5 Quasi-Experimental designs. *J Clin Epidemiol.* 2017 Sep;89:1-3. doi: 10.1016/j.jclinepi.2017.09.010

<sup>n</sup> Hemming K, Haines TP, Chilton PJ, Girling AJ, Lilford RJ. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ.* 2015 Feb 6;350:h391. doi: 10.1136/bmj.h391

increasingly shorter intervention follow-up for intervention municipalities that have joined at a later stage.

### Effect analysis

With the help of existing or newly developed measuring instruments, systematic measurements will have to be made with regard to the effect measures that are central to the experiment. In addition, data that are already routinely collected can be used (see also chapter 4). These measurements should be carried out in both the intervention and the control situation. In some cases, this can be done randomly, also to limit the Hawthorne effect.

By comparing the measured outcomes in the intervention and control conditions, statements can be made about the effects of the closed chain intervention. Statistical analysis makes it possible to quantify remaining uncertainty and to correct for remaining non-comparability with respect to key characteristics, as far as they are measured. Correction for this will be more difficult – and sometimes impossible – the smaller the number of participating municipalities. Strong selection bias due to essential non-comparability of municipalities in advance cannot be corrected.

The relevant effect measures will be measured partly at the municipal level, partly at the point of sale/coffee shop level and at the level of users (of course anonymised). The power depends on the unit of analysis and the frequency of the effect. For example, it will be greater when it comes to effects on buyers than when it comes to the amount of nuisance in a municipality.

In the analysis, variables that are an expression of local customisation, such as whether or not the *i* criterion is strictly enforced, can be included as effect modifiers, provided there are sufficient participating municipalities.

## Conclusions

To assess the extent to which the first main objective of the experiment – the realisation of a closed cannabis chain – has been achieved, the experiment must include a thorough process evaluation. On this basis, it can be established whether and to what extent it has actually been possible to achieve a closed cannabis chain and what important learning and improvement points can be identified.

With regard to the second main objective, the effect measurement, the most appropriate method is to compare the intervention condition with the control condition. In

that case, the intervention condition includes all activities that are considered important in municipalities in the context of the implementation of the closed cannabis chain. The control condition includes all activities that take place within the framework of the usual policy in municipalities and the development that this policy experiences during the period in which the experiment takes place. Participating in the control condition is also an essential form of participation in the experiment. By comparing the measured results in the intervention and control conditions, it is possible, supported by statistical analysis, to make statements about the effects of the closed chain intervention.

The committee recommends that the study team first examines whether the impact study can be organised as a stratified cluster randomized trial: an experiment in which municipalities (to be considered as 'clusters' of points of sale and residents) that are willing to participate in the experiment, can be divided into strata in which they can be appointed at random to the intervention or the control condition. In addition, it is also possible to examine whether the stepped wedge design variant is an option, with increasing numbers of municipalities admitted from the control condition to the intervention condition step by step, from the general starting moment, based on randomisation. However, this is a complex variant.

Consideration could also be given to opting for a non-randomised (quasi-experimental) comparative design, for example by means of a form of matching. However, if the allocation to the intervention or control group is made not by chance, but, for example, on the basis of self-nomination or a political-administrative decision, there is a greater risk that the groups to be compared will be incomparable and that the results will be distorted.

If municipalities cooperate, a randomised design is, in the committee's opinion, feasible. However, it may seem strange to available municipalities to be classified by chance in the intervention or control group. The committee assumes, however, that the importance of a methodologically optimal approach – instead of a (perhaps no less difficult to accept) classification on political-administrative grounds – is easy to explain. As mentioned above, participation in the control condition is also an essential form of participation in the experiment. The Committee also notes that even in a quasi-experimental design, the participating municipalities will have to be divided into the newly introduced intervention and control conditions respectively. The question is why it would not be better for this division to take place at random.

The final study design will have to be further elaborated by the designated study team after the decision to actually start the experiment has been taken. Given the concrete design and the operationalised impact measures, this will have to determine the number of required participating municipalities per comparison condition, taking into account the necessary variation between municipalities.





Colophon

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