Risk assessment report relating to *paddos* (psilocin and psilocybin)

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1 Executive summary

The Coordination Centre for the Assessment and Monitoring of new drugs (CAM) has carried out a risk assessment on psychotropic mushrooms containing the active substances psilocin and psilocybin.

This drug is not associated with physical or psychological dependency, acute toxicity is largely limited to possible panic and anxiety attacks and, in terms of chronic toxicity, the worst that can happen are flashbacks. Consequently, the use of *paddos* (hallucinogenic mushrooms) does not, on balance, present any risk to the health of the individual.
The product is relatively easy to come by, yet there is little adequate information available to users. The quality of the product is unreliable and the quality awareness of those who sell the product is, for the most part, lacking. On the other hand, we have been pleasantly surprised by findings relating to the scale of use, the vulnerability of the user and the number and seriousness of incidents reported. The risk to public health is therefore judged to be low.
This drug adversely affects the user's reactions (including his or her ability to drive), but there is no danger of it lowering his or her violence threshold. Since usage is usually confined to the home or the open air, there is no inconvenience caused to other people. The risk to public order is therefore judged to be low.
There is no risk in relation to criminal involvement. Only a very small number of individuals on the *smart shop* scene have ties with the *designer drugs* underworld.

In comparison to other drugs for which CAM has carried out risk assessments (MBDB, MTA and GHB), *paddos* score relatively low on the risk scale.

In view of the above, CAM recommends that quality requirements be imposed on the *paddos* product (such as standardisation, purity and labelling) and the trade in *paddos* (such as the provision of reliable information). These measures should help make *paddos* available only in limited supply. The results of the risk assessment do not present any need for a statutory ban on *paddos*.

2 Risk assessment

For each criterion highlighted (numbered) below, the arguments and observations that were raised during the discussion are outlined, and the average of the scores awarded by the risk assessment committee is recorded.

2.1 Risks to the health of the individual

1) The extent of the risk of physical dependency

Use of *paddos* does not cause physical dependency.

1. *none (1.1)*	2. low	3. possible	4. high	5. very high

2) The extent of the risk of psychological dependency

This depends on which definition of psychological dependency you are applying. If this is synonymous with addiction, then there is no risk. There are, however, users who enjoy the experience so much that they want to use *paddos* again – in this sense, you might say there is a slight psychological dependency.

1. *none (1.8)*	2. low	3. possible	4. high	5. very high

3) The extent of the risk of acute toxicity

Incidents regularly occur in which medical help is needed (first aid, admission to hospital). These are mainly due to anxiety and panic attacks. However, the somatic effects (blood pressure, heart rate, etc.) might have been worse. Setting plays a major role here: inexperienced tourists in a country they are not familiar with use all kinds of (soft) drugs over a short period. The occurrence of anxiety and panic attacks may therefore not always be solely attributable to the use of *paddos*.

1. none	2. *low (2.3)*	3. possible	4. high	5. very high

4) The extent of the risk of chronic toxicity

Paddos tend to be taken as an experimental drug. Long-term use is rare. There are examples from other cultures of people taking *paddos* with some regularity throughout their lives without any symptoms of chronic toxicity. There are, however, also users who, after only taking the drug once, have experienced flashbacks for several weeks, even months, after using it. Not enough information is available about mutagenity and teratogenity to be able to draw any conclusion, but there is no logic to suggest that *paddos* might contain these properties. Just like with some other soft drugs, the use of *paddos* may trigger an emotional derailment in emotionally unstable people.

1. none	2. *low*	3. possible	4. high	5. very high

2.2 Risks to public health

5) The degree of risk in relation to the scale and frequency of use and possible increase in use

Paddos are used less than XTC, which, in turn, is used considerably less than cannabis. Across the Netherlands as a whole use is low (only 1.6% of the population has ever used them); it is slightly higher among young people; and the highest figures are recorded among specific groups (pleasure-seekers, foreigners and young truants). In most cases, it is seen as an experimental drug, with people generally stopping after using it a few times. Many users indicate that they do not find it to be a pleasant experience. It makes them unsociable (antisocial) and it has nothing like the empathic effect of XTC, making it unsuitable for use at parties.

1. none	2. *low (2.4)*	3. possible	4. high	5. very high

6) The degree of risk because of the vulnerability of the user

Users tend to belong to a young age group that has yet to reach maturity (and which, incidentally, is also using other substances). The *smart shop* industry indicates that it advises people below the age of 18 not to use the drug. Emotionally unstable people also run a slightly higher risk (see 4).

1. none	2. *low (2.8)*	3. possible	4. high	5. very high

7) The degree of risk due to the lack of adequate information on use

Whilst it is possible to misuse *paddos*, even misuse does not seem to present much of a problem. The degree to which *smart shop* owners or sellers themselves are in possession of adequate information varies from good to zero. In addition, the provision of information sometimes appears to be secondary to the realisation of turnover. This is even more so in tourist shops.

1. none	2. low	3. *possible*	4. high	5. very high

8) The degree of risk in relation to the availability of the product concerned

The sale of *paddos* is not confined to the *smart shops*. *Paddos* can also be purchased from *grow shops*, *head shops* and via the Internet. The number of sales outlets varies dramatically from one region to the next. Amsterdam and the border regions contain a relatively high number of outlets. *Paddos* can therefore be regarded as readily available. The *smart shops* also have quite a stock of *paddos*. It is estimated that the sale of *paddos* makes up around 50% of their turnover.

1. none	2. low	3. *possible*	4. high	5. very high

9) The degree of risk due to the unreliable quality of the product

There do not appear to be any major variations in composition, concentration or dosage. The biological variation of the active ingredient is between 1% and 3.5%. The differences that exist do not appear to lead to major problems. In most cases, there is no standardisation of this natural product. It may also be contaminated with, for example, fungus and mites. There is some risk of confusion with poisonous varieties. In view of the fact that *paddos* are widely available and there have only been a small number of medical incidents, there does not seem to be much wrong with the quality.

1. none	2. *low (2.9)*	3. possible	4. high	5. very high

10) The degree of risk due to the unreliability of the mode of distribution, sales outlets and dealers

A few *smart shop* owners are known to have ties with the *synthetic drugs underworld*. A number of owners are not prepared to disclose the supplier of the *paddos* they sell. The industry as a whole does not feel very strongly about quality awareness, save for a few exceptions. This is certainly true for tourist shops, and such like, where *paddos* are also sold.

1. none	2. low	3. *possible*	4. high	5. very high

11) The degree of risk measured by nature and scale of reports of incidents

Whilst the number of reports has increased (from 5 to 20 per annum), the seriousness of the incidents has not. Medical help has primarily been required to deal with anxiety and panic attacks (see also point 3).

1. none	2. *low (2.5)*	3. possible	4. high	5. very high

2.3 Risks to public order and security

12) The degree of risk in relation to the frequency and seriousness of any inconvenience to other people caused by sale and use

The sales outlets that sell *paddos* do not cause any inconvenience, and usage is usually confined to the home or the open air. Usage involves an *inward* experience for the user. It is only if a panic attack occurs that other people may be accosted or troubled.

1. *none (1.4)*	2. low	3. possible	4. high	5. very high

13) The degree of risk of use leading to a lowering of the user's violence threshold

Users experiencing anxiety and panic attacks may react aggressively if they are addressed (by the proper authorities). However, the number of reactions involving anxiety and panic was lower than expected (see 11).

1. *none (1.7)*	2. low	3. possible	4. high	5. very high

14) The degree of risk of use of the product affecting the user's reactions

Little if any research has been carried out into this but it is logical to expect that this product would affect the user's reactions. Hallucinogenic substances can cause changes in behaviour and perception. This presents a danger in situations where psychomotor skills are needed, especially when driving and operating machinery. *Paddos* may also cause drowsiness.

1. none	2. low	3. possible	4. *high (4.6)*	5. very high

2.4 Risks of criminal involvement

15) The degree of risk of involvement of (organised) crime in production and trade

A few *smart shop* owners are known to have ties with the *synthetic drugs underworld*, and substances covered by the Dutch Opium Act have occasionally been found by the police in several *smart shops* that they have visited. However, no (thorough) research has been conducted into this.

1. *none (1.9)*	2. low	3. possible	4. high	5. very high

16) The degree of risk of involvement of (organised) crime in production of and trade in ingredients

See 15. In this case it is difficult to distinguish between ingredient and end product.

1. *none (1.7)*	2. low	3. possible	4. high	5. very high

2.5 Qualitative and quantitative enumeration of scores

The table below displays the final score for each risk category. The figures reflect the average of the scores awarded for each criterion. The words express the verbal rating allocated to the scores achieved. It is important to note that the scores are an aid for the risk assessment process. For the final verbal rating, primary importance is attached to the (qualitative) arguments raised during the risk assessment. As a basic guideline, a score of 1 to 2 is given a rating of *no risk*, a score of 2 to 3 is a *low risk*, 3 to 4 is a *possible* risk, 4 to 5 a *high risk* and above 5 a *very high risk*.

Risk category	Score	Rating
I. Health of the individual	1.8	no risk
II. Public health/society	2.9	low risk
III. Public order and security	2.5	low risk
IV. Criminal involvement	1.8	no risk
Total score	**9.0**	

3 Conclusions and recommendations

3.1 Conclusions concerning the procedure

The risk assessment for *paddos* containing psilocin and psilocybin is the third one to be carried out according to CAM's established procedure and criteria. A reasonably large amount of information about *paddos* was available. The risk assessment meeting was quick (one meeting lasting 2.5 hours) and largely easy because the procedure and criteria were known. A tape recording was made of this meeting to ensure that all arguments were noted.

3.2 Conclusions concerning *paddos*

This drug is not associated with physical or psychological dependency, acute toxicity is largely limited to possible panic and anxiety attacks and, in terms of chronic toxicity, the worst that can happen are flashbacks. Consequently, the use of *paddos* does not, on balance, present any risk to the health of the individual.
The product is relatively easy to come by, yet there is little adequate information available to users. The quality of the product is unreliable and the quality awareness of those who sell the product is, for the most part, lacking. On the other hand, we have been pleasantly surprised by findings relating to the scale of use, the vulnerability of the user and the number and seriousness of incidents reported. The risk to public health is therefore judged to be low.
This drug adversely affects the user's reactions (including his or her ability to drive), but there is no danger of it lowering his or her violence threshold. Since usage is usually confined to the home or the open air, there is no inconvenience caused to other people. The risk to public order is therefore judged to be low.
There is no risk in relation to criminal involvement. Only a very small number of individuals on the *smart shop* scene have ties with the *designer drugs* underworld.

3.3 Placement on the risk scale

The results of this risk assessment and earlier ones involving other substances are presented in the table below. In the evaluation of the first risk assessments carried out, the sounding board group decided to remove the *other risks* category (the Netherlands' image, consequences of measures and applicable legislation relating to comparable products) because the risk assessment committee, whose job it is mainly to perform a technical risk assessment, was straying too far into policy territory by giving an opinion on these aspects. Nevertheless, to make it possible to compare the final scores, the last row contains the scores that the other substances would have achieved had the *other risks* criterion not been included

in the calculations. In that case, a substance can score between 5 and 20 points on the risk scale.

Substance	Health of the individual	Public health	Public order	Crime	Other risks	Total score	Score (comp.)
MBDB	present	present	low	present	present	14.7	11.2
4-MTA	present	present	present	present	high	16.2	11.8
GHB	high	present	low	low	low	13.2	11.0
Paddos	none	low	low	none			9.0

The recommendation after the risk assessment for MBDB was to monitor the situation closely and to perform a new risk assessment after some time. This recommendation has been adopted by the policy. The risk assessment of MTA resulted in the recommendation that measures be taken in relation to production and trade. The Minister has opted for a ban by placing the substance on list I of the Dutch Opium Act, mainly because of the policy-related consideration of not wanting to be out of step with other European countries. The recommendation for GHB was to monitor the situation and perform a new risk assessment the moment it changes clearly. This recommendation has been adopted by the Minister.

Paddos score lower than MBDB, MTA and GHB on both the risk to individual health and the risk to public health, lower than MTA and equal to MBDB and GHB on the risk to public order, and lower than the other three substances on the risk of criminal involvement. Compared with the other substances, *paddos* score particularly low on the risk scale.

3.4 Consequences of measures

The risk assessment committee has summarily discussed the consequences of possible measures. It is aware of the fact that the legal status of *paddos* is still *sub judice*.
The risk assessment committee draws attention to the fact that *paddos* cause few problems across the country in relation to public health, public order and crime. This drug is also hardly known in other European Member States (exception: certain regions of Germany where *paddos* from the Netherlands can sometimes be found). It would therefore be a good idea to give *paddos* a low profile and prevent criminalisation.
In the discussion the point was also raised that the *smart shops* would lose around half of their turnover if a ban were imposed. This could lead them to search for other, possibly more risky products to fill this void. The users too would be affected – if they could no longer buy *paddos* in the *smart shop*, they might well decide to pick their own *paddos* in the wild (high risk of confusion with poisonous varieties) or move on to other, possibly more risky products.

Most of the risks signalled by the committee relate to the variable composition and quality of the products. Poor information and easy availability also play a part.

3.5 Recommendation

In view of the above, CAM recommends that quality requirements be imposed on the *paddos* product (such as standardisation, purity and labelling) and the trade in *paddos* (such as the provision of reliable information). These measures should help make *paddos* available only in limited supply. The results of the risk assessment do not present any need for a statutory ban on *paddos*.

Next steps

CAM offers the risk assessment report, together with the conclusions and recommendation, to the Minister for Health, Welfare and Sports. The policy department advises the Minister on the measures to be taken as a result of the CAM report. An overview of the measures that can be taken is given in Appendix 3.

Appendix 1

Information report on *paddos*

General information

Mushrooms of the Psilocybe ssp. variety and a number of other species (Conocybe, Panaeolus and Inocybe, etc.) contain psilocybin and psilocin as their main active ingredients (both of which are psychoactive alkaloids). Various mushrooms containing psilocybin are found in Europe. Psilocybin is converted in the body into psilocin. These substances act on the serotonin receptors and cause an increase in serotonin in the brain and a temporary reduction in the concentrations of noradrenaline, dopamine and histamine.
Usual dose: 1 gram of dried = 10 grams of fresh mushrooms; this can lead to illusions and hallucinations. LSD, mescaline and psilocybin presumably work according to the same pharmacological principle.

I. Health of the individual

1/2. The extent of the risk of physical and psychological dependency

Physical dependency does not occur with the use of psilocybin.
Psychological dependency is rare, but possible.
As regards the effects of *paddos*, habituation soon occurs. This means that the user has to take a higher dose each time in order to achieve the same effect.
This tolerance wanes if psilocybin is not used for some considerable time.
However, user data leads us to assume that the tolerance factor discourages people from taking the drug again too quickly. Users generally speak of a period of at least 3 weeks before taking more *paddos* so that they can achieve the desired effects.
It is not impossible that pleasant experiences will lead the user to induce this effect again. However, the fact that habituation occurs quickly stands in the way of frequent use.

3. Acute toxicity

The hallucinogenic dose of psilocybin is approx. 6 – 12mg. The lethal dose for humans is estimated to be approximately equal to body weight in fresh mushrooms. Psilocybin is therefore not very toxic (cases with good outcome recorded after ingestion of up to 300 mushrooms). It is true of most products of vegetable origin that acute intoxication is rare. The number of cases involving intoxication caused by products of vegetable origin is relatively small. Consequently, it is not possible to draw general conclusions based on case histories. If

mushroom and plant products gain in popularity, more incidents will probably occur and be reported, despite the relatively low toxicity. The risk of confusion with toxic varieties is a very real one. Confusion between Psilocybe and Cortinarius spp. (which causes kidney failure) is notorious (various cases known).
As yet, there have been no reports of serious incidents in the Netherlands following the ingestion of mushrooms.
Mushrooms offered for sale can be contaminated with LSD, PCP or other substances.
The most common physical symptoms are dilated pupils, loss of balance, parestheses (*pins and needles* all over the body), muscle relaxation, accelerated heartbeat, dry mouth and nausea. Other possible effects are drowsiness, pains in the stomach, vomiting, pseudo-hallucinations, random movements, agitation, fever, chills, eye focusing problems, watery eyes, slowed heartbeat and breathing and a fall in blood pressure.
Psychological symptoms: hallucinogenic compounds can cause long-forgotten memories to resurface and leave a deep impression on users. Adrenergic blockers (such as neuroleptics and propanol) generally act as imperfect antagonists.
Following acute intoxication, users often complain of apathy, extreme tiredness and depressed thoughts. They make a full recovery.

4. Chronic toxicity

Research has been carried out, but so far chronic toxicity has not been proven.
Not enough information is available about mutagenity and teratogenity to be able to draw any conclusion. There are no records of irreversible organ failure caused by psilocybin.

Long-term effects cannot be ruled out because of the cross-tolerance with LSD. For example, a user may experience flashbacks, sometimes months after only taking the drug once (reliving parts of a previous trip). There are even rare cases recorded of persistent psychiatric symptoms (panic attacks). However, long-term effects are more likely to affect people with an underlying psychiatric complaint.

Public health/society

5. Scale and frequency of use/increase in use (inter)nationally

Hallucinogenic mushrooms have been used for centuries in various countries in ritual and spiritual settings. Recent decades have seen a noticeable trend in Western society towards use of these mushrooms for recreational purposes.
In the Netherlands, these mushrooms have been gaining in popularity since 1997. They are used increasingly by young people for recreational purposes. The emergence of *smart shops*

and the presence of *smart stalls* at clubs and discos might be having a major effect on the degree and frequency of use of mushroom products. It is likely that large-scale use of these drugs will lead to an increase in the number of medical incidents. Increased use of wood chippings on paths in, for example, parks, might lead to a greater distribution of the mushrooms that are found in the countryside (including Psilocybe cyanescens).

For most young people and young adults, use of the drug continues to be occasional, experimental and recreational. Many users stop after taking it once or just a few times. Research shows that *paddos* have become popular in a relatively short time compared with other drugs. Among school pupils aged 12 and older, 4.3% have used a *paddo* at one time or other. In absolute numbers, this means that there are estimated to be between 39,000 and 43,000 pupils that have actually taken a *paddo*. A quick study has revealed that 10% of young people and young adults (aged 15-24) have dabbled in mushrooms. Half of all those that have ever used *paddos* have only used them once or twice.

The impression is that the supply is growing. According to the latest estimates, there are currently around 100 sales outlets in the Netherlands.

6. Degree of vulnerability of user/age/experience/knowledge/circumstances

Incidents of intoxication are usually the result of a person mistaking a poisonous mushroom for a non-poisonous one. In spite of their knowledge, even experts can make fatal mistakes. The intensity of the effect depends on the dose. It is young people between the ages of 15 and 19 in particular who experiment with *paddos* (boys > girls).
Individuals who are highly unstable or who suffer from depressive thoughts or psychiatric disturbances are more likely to experience psychological complications and medical incidents. No psychoses have been described as a result of consuming psilocybin-containing mushrooms. Although the toxicity resulting from the use of psilocybin-containing mushrooms is low, behavioural change is a possibility. Suicidal behaviour may occur during a *bad trip.* There are no known case histories relating to suicidal behaviour following the consumption of psilocybin-containing mushrooms. It is assumed that the toxicity of psilocybin is more serious in children than in adults.
If psilocybin-containing mushrooms are used at the same time as other drugs, such as alcohol and marijuana, synergism (the mixing of sensory perceptions) may occur.

The vast majority of people who have had experiences with *paddos* have also had (earlier) experiences with cannabis or XTC.

Doses from approx. 6 to 12 mg psilocybin can result in illusions and hallucinations. These may occur several times per minute and are usually of a visual nature: e.g. the user sees moving coloured patterns. These images may be experienced as pleasant, but also as frightening. There have also been descriptions of disinhibition, fits of laughter and euphoria, but also of unrest, anxiety, panic and depressive thoughts. The user is easily approachable between hallucinations, and it is possible to interrupt the hallucinations verbally, although it is never possible to predict whether the user will react in a positive or negative mood. This is connected with his/her individual sensitivity.

7. Degree of availability of adequate user information*
presence and quality of information leaflet/misleading information/appearance of product

Mushrooms (and plant products) contain a range of different pharmacologically and toxicologically active ingredients. There is little pharmacological and toxicological literature about the known ingredients. Furthermore, this literature varies in terms of content, quality and accessibility.
As a result of this, it is often difficult to make a clear judgement about the harmfulness of these substances. In addition, natural products are often wrongly considered to be wholesome and harmless. Moreover, the 'harmlessness' of the product is often something that is claimed by both users and sellers.

It may be an advantage for the product to be sold in *smart shops*, if this reduces the risk of confusion with toxic varieties (Psilocybe, in particular, is notoriously confused with the highly nephrotoxic Cortinarius spp.).

It seems that mushrooms are by far the most popular product sold in *smart shops*. However, research clearly shows that not all *smart shops* provide users with precise information. The knowledge of those selling the product in the *smart shops* also appears to vary greatly. In particular, the information provided in *grow shops* and *head shops* is far below standard.

As a rule, the information leaflets provide no information about the maximum shelf life and do not describe the nature of the possible, unwanted effects ("side effects"), so inexperienced users will have no knowledge of them. The proportion of active substances (psilocybin/psilocin) contained in the mushrooms is not mentioned. Owing to the variation in the active substance content, users are unable to determine what dose of the active substance they are taking when they consume a certain quantity of mushrooms.

8. Degree of product availability

Psilocybe, Panaeolus, Conocybe spp., Psilocybe semilanceata and Psilocybe cubensis are often sold in *smart shops*. In addition to dried and fresh mushrooms, growing kits are also available.

Paddos are widely sold in *smart shops* as a highly effective substance amid a large range of expensive, primarily New Age, placebo/*fake* products. They are also supplied in tourist shops where products such as cannabis/coke pipes, T-shirts and badges, etc. are sold. As a result of this method of supply, the distribution of *paddos* is great. Young foreigners, in particular, are exposed to them. Amsterdam is experiencing a boom in this commercial trade.

Many people from Amsterdam have taken *paddos* at one time or other. However, the consumption of *paddos* among users from Amsterdam seems to have passed its peak and, according to some, it is even on the decline again.
Young, foreign tourists, who flock to the Red Light District in the summer months and traipse from one coffee shop to another, have also discovered the *smart shops*. They make up a new consumer group, which is boosting the *smart industry* in the city centre. In the Red Light District especially, the number of *smart shops* has increased considerably, and the industry is focusing more and more on the tourists.

9. Reliability of product quality*
production method/purity/toxicity of by-products/place of production

There are no product controls. Not all the substances contained in any mushroom (or plant product) are known. Harmful components, whether added or not, may be found that affect the organs. Increasing amounts of herb blends and processed products contribute to the lack of clarity. The biotransformation method has already been seen on the Internet. When tryptamine is added to the substrate, the psilocybin content increases and the psilocybin content decreases. Biotransformation in the mushroom is the only way of raising the alkaloid content.

The current situation lacks a system of integral quality monitoring, control and supervision in the chain from production up to supply to the end user. Furthermore, it is not clear whether the instructions for use, if supplied, are sufficiently based on fact. Owing to the variation in the active substance content, users are unable to determine what dose of the active substance they are taking when they consume a certain quantity of mushrooms.

Variation in the active substance is smaller in cultivated mushrooms than in those that occur naturally. Psilocybin is stable at room temperature and it is preserved in dried mushrooms.

When mushrooms are dried at temperatures above 50°C, psilocybin is broken down into non-active products.

10. Reliability of the mode of distribution, sales outlets and dealers

There is no product control. These products are primarily sold in *smart shops*. In some cases, *smart shop* owners have been involved in *criminal* activities in the past.

It seems that, on a limited scale, there are connections between sales outlets, (wholesale) trade and producers on the one hand, and criminals and key figures in organised crime (relating to synthetic drugs) on the other.

The fact that this industry is organised nationally and sets itself standards regarding *ethics* and product quality is an argument in favour of the *smart shop* phenomenon. This is demonstrated by the fact that the industry has asked mushroom growers to grow these *paddos* for them.

11. Nature and scale of reports of incidents
Emergency wards/first aid posts/National Poisons Control Centre (NVIC)

The number of cases recorded relating to intoxication as a result of taking mushrooms is relatively small (see pp. 27/28, table 4.4 of this report). Only two cases of fatal intoxication with Psilocybe spp. are reported. According to the author, neither of these cases were the result of psilocybin intoxication. In 1982, there were a total of 31 reports of clinical intervention due to psilocin intoxication throughout the whole of America.

As yet, there have been no reports of serious incidents in the Netherlands following the ingestion of mushrooms. According to the National Poisons Control Centre (NVIC), until some time ago, they were only asked for information regarding mushroom intoxication occasionally (approximately 2 to 3 times a month). However, recently the number of requests for information has increased. In the period from 9 June 1997 to 13 August 1997, the NVIC provided information 17 times. The information was for the benefit of users of hallucinogenic mushrooms, whose ages varied between 15 and 39 (average age 20), for whom medical help had been required due to severe, acute effects on their health. These effects mainly consisted of panic attacks, severe restlessness and motor agitation, anxiety, hallucinations, confusion and visual disturbances.
The number of emergency calls has been increasing for a few years now. It has been observed that the use of *paddos* leads to severe panic attacks and/or states of disintegration. When the Central Ambulance Service receives reports relating to *paddos* it is generally necessary to take the person concerned to the emergency ward of one of the various city

hospitals. This indicates how serious the panic attack is. As far as we know, none of these side effects has resulted in fatal complications.
It has been observed that emergency situations arising through the use of *paddos* often involve foreigners. The number of incidents is relatively small compared with those relating to cannabis (Netherlands/ethnic: 13, foreign: 24, of which involving transport to first aid post/hospital: 23; in 1997). After being taken to hospital, 7 people were admitted in connection with XTC/*paddos* and placed under observation for between 24 and 48 hours. All were discharged once they had recovered. Not a single patient has died as a result of these emergency situations following the consumption of recreational drugs.

Public order and security

12. Frequency and seriousness of inconvenience to other people caused by sale and use

These products are primarily sold in *smart shops*.
A quick scan has been carried out by the National Criminal Intelligence Service (CRI), with the help of information available from the regional police forces. The working group sent a questionnaire to the municipalities belonging to the inter-authority Security and Drug Addiction Treatment Taskforce containing, amongst other things, questions about crime and inconvenience. Inconvenience as a result of the sale or use of these substances was not observed. *Paddos* are still not seen as a party drug. The majority of users prefer to experience *paddos* either in the open air or at home. Many partygoers do not consider hallucinogenic substances suitable to be taken in night-clubs. They are still only rarely used in a dose recommended by the *smart shops*.

13. Does the substance lead to the user's violence threshold being lowered?

A *bad trip* can lead to feelings of anxiety and panic.

14. Does the substance affect the user's reactions (ability to drive, operate machinery)?

The effects start after approximately 30 minutes and usually last for less than 3 – 4 hours (6 – 12 mg). The effects can sometimes last longer (up to around 12 hours, depending on the dose).
Changes in behaviour usually occur when under the influence of hallucinogenic substances. This can lead to dangerous situations, for example, it may affect the user's ability to drive and operate machinery.
Psilocybin and psilocin affect the neurotransmitter serotonin. The effects can be compared with those of LSD. Hallucinations of space and time travel are particularly vivid. The effects

are shorter than those associated with LSD, between 2 and 4 hours. The effects on perception make it clear that it is hazardous to carry out psychomotor activities in general and driving in particular. Someone who perceives the crash barrier as a writhing snake cannot be regarded as a safe driver.
Psychologically, (considerable) changes may occur in the perception of space and time, as well as changes in mood. Higher doses cause emotional disturbances and, usually, visual hallucinations. Acoustic hallucinations occur much less frequently.
Euphoria and drowsiness may also occur.

Criminal involvement

15. Is (organised) crime involved in production and trade?

Criminal involvement in the production of and trade in eco-drugs and *smart* products has been established to a limited extent but it does not seem that this has reached a critical level at this point (1997).
In the case of the *Kerkdriel* growers there was, and is, nothing to prove the presence of criminal groups wanting to grow *paddos* commercially (or have them grown) on a large scale. The growers in question were amateurs who, at their own expense and risk, transformed a struggling mushroom farm into a profit-making company.
At the National Office of the Public Prosecution Service little is known about the criminal aspects of *paddo* use and trade.
Enquiries have been made at two district public prosecutor's offices (Amsterdam and Den Bosch) about the criminal aspects of *paddos.* Both offices provided the same information – there are no firm indications that there is any criminal involvement. However, there is also no reason to assume that this is not the case. In the Den Bosch district, the 'gap' created by the growers from Kerkdriel was soon filled by others. There is a lot of money to be made from growing and trading in mushrooms.
The public prosecutor's office in Amsterdam reports that there is no concrete evidence of criminal involvement. There are, however, so many questions surrounding the supply of *paddos* that a decision has now been made to carry out an investigation, led by the manager of the Red Light District, into criminal involvement.

16. Is (organised) crime involved in production and trade of ingredients?

No details found. See also 14.

Points for discussion – consequences of measures

Extent of risk of international political problems relating to import or export

Hallucinogenic mushrooms, which were dried and ground, were produced on a large scale in the Netherlands (1998). The ground *paddos* were then put in little bags, which were then sealed by sewing. After this they were transported to Germany (Cologne), where they were sold through a distribution chain under the guise of “scented cushions”.

Applicable legislation relating to comparable products

Every substance that is available in *smart shops* always falls under the general provisions of the Dutch Commodities Act.
Psilocybin and psilocin are the active substances in *paddos* and are on list I of the Dutch Opium Act.
The Netherlands Supreme Court has judged that fresh mushrooms do not fall under the Dutch Opium Act while mushrooms that have been processed in any way do. According to the Supreme Court, growing mushrooms may be deemed a punishable act of preparation (18-11-1997, Netherlands Law Journal (NJ) 1998, 213). In the proceedings on the substance of this case, the Den Bosch court has judged that, under certain circumstances, growing mushrooms is an act of preparation in accordance with Article 10a of the Dutch Opium Act. In this case, the circumstances were that, after growing the mushrooms, the grower processed them (active drying process). The court finds that, through processing, mushrooms become a preparation as defined by the Dutch Opium Act.
This court has also judged that psilocin and psilocybin do not constitute a danger to public health, but that it is not at liberty to rule that psilocin and psilocybin are wrongly included in list I of the Dutch Opium Act. This is a matter for the legislator.
The provisional result of the decision by the Supreme Court and the ruling of the Den Bosch court is that *any processed* mushroom falls under list I of the Dutch Opium Act.
The definitive status of mushrooms is still being considered by the courts.

Negative consequences of a ban for legal economic and industrial sectors

The sale of *paddos* accounts for a large proportion of the turnover of *smart shops*. A few mushroom growers have also switched over to *paddo* growing.

Appendix 2

1 Composition of risk assessment committee

Ministry of Health, Welfare and Sports (VWS): Mental Welfare, Drug Addiction Treatment and Social Service department (GVM): dep. chairman	Mr A. Cramer
Ministry of Health, Welfare and Sports (VWS): Medicines department (GMV)	Mr W.K. Scholten
Health Care Inspectorate (IGZ)	Mr R.J.J.Ch. Lousberg
Inspectorate for Health Protection, Commodities and Veterinary Affairs	Mr B. Kustner[1]
Trimbos institute/Focal Point	Ms M. van Laar
Trimbos institute/Drug Information and Monitoring System (DIMS)	Ms I.P. Spruit
Ministry of Justice	Ms N. van der Arend
Ministry of Justice/Research and Documentation Centre (WODC)	Not present
Public Prosecutions Department (OM)/Synthetic Drugs Unit (USD)	Mr J.J.T.M. Pieters
National Criminal Intelligence Service (CRI)/USD	Mr A. Elissen
Economic Investigation Service (ECD)	Not present
Forensic Laboratory (GL)	Mr H. Huizer
National Poisons Control Centre (NVIC)	Ms I. de Vries
Leiden University Medical Centre: Lab. for Toxicology	Prof. F.A. de Wolff
Municipal Medical & Health Service (GG&GD) Amsterdam	Mr R. ter Haar
University of Amsterdam: faculty of law and criminology	Mr T. Nabben
Coordination Centre for the Assessment and Monitoring of new drugs (CAM): coordinator/secretary	Ms C.A. Rutgers

2 Procedures for risk assessment

There are three procedures, which differ only in terms of their speed:

A. A very fast procedure (fast assessment) for situations in which there is an acute risk to public health (e.g. atropine). This procedure must be completed within 24 hours.
B. A reasonably fast procedure (moderate assessment) for situations in which the risk to public health is not acute, but where there is nevertheless a risk in the short term. A reasonable period for this procedure would be 12 days.
C. A procedure on request for which there is no strict time limit (preventive assessment). This procedure may take a few months.

[1] Represented by Ms W. Kleinjan

The steps are the same in all three procedures:

1. Notification of a (supposed) new drug or the application for a risk assessment is received by the network's coordination centre. Notification from other Member States may be received via Europol or the Focal Point (Trimbos).
2. The coordination centre reports to the executive committee on whether a procedure is being initiated. If so, the coordination centre collects information on the new drug via its network. This is used as a basis for drawing up the information report. The report is sent to all or selected committee members. (4 days)
3. The members use this information as a basis for carrying out an individual risk assessment using the score form with the specified criteria. If the procedure allows, the outcome is discussed jointly. (2 days)
4. The completed risk assessment forms are collected and evaluated by the coordination centre. On the basis of this assessment the coordination centre draws up a risk assessment report containing conclusions and recommendations. (4 days)
5. If possible, this report is submitted to the members for comments and to the executive committee for approval. (2 days)
6. The risk assessment report is submitted to the Minister of Health, Welfare and Sports (VWS) via the Senior Inspector for Pharmacy and Medical Technology (FMT) of the Health Care Inspectorate.
7. The procedure is evaluated (optional).

3 Risk assessment criteria

I. Health of the individual:

1. Degree of risk of physical dependency
2. Degree of risk of psychological dependency
3. Degree of risk of acute toxicity (leaving aside the effect intended by the user)

frequency and seriousness of complaints/use of other substances/doses and variations thereof/usual method used to take substance/frequency of use/effects that the consumer is unable to perceive but nevertheless influence behaviour.

4. Degree of risk of chronic toxicity (see 3)

II. Public health:

5. Degree of risk in relation to scale and frequency of (increase in) use on a national/international level
6. Degree of risk because of vulnerability of user

age/experience/knowledge/circumstances

7. Degree of risk due to absence of adequate user information

presence and quality of information leaflet/misleading information/appearance of product

8. Degree of risk in relation to availability of product

9. Degree of risk due to unreliable quality of product

production method/purity/toxicity of by-products/place of production

10. Degree of risk due to unreliable mode of distribution, sales outlets and dealers
11. Degree of risk measured by the nature and scale of reports of incidents

emergency wards/first aid stations/National Poisons Control Centre (NVIC)

III. Public order and security

12. Degree of risk in relation to inconvenience (frequency and seriousness) to other people caused by sale and use
13. Degree of risk in relation to the fact that the substance lowers the user's violence threshold
14. Degree of risk resulting from the user's reactions being affected (ability to drive, operate machinery)

IV. Criminal involvement:

15. Degree of risk in relation to possible involvement of (organised) crime in production and trade
16. Degree of risk in relation to possible involvement of (organised) crime in production of and trade in ingredients

4 Risk assessment score table (Degree of risk in relation to…)

Name of person completing table: Name of substance:

I. HEALTH OF THE INDIVIDUAL	1	2	3	4	5	Score
(1) Physical dependency	none	low	present	high	very high	
(2) Psychological dependency	none	low	present	high	very high	
(3) Acute toxicity	none	low	present	high	very high	
(4) Chronic toxicity	none	low	present	high	very high	
II. PUBLIC HEALTH	1	2	3	4	5	
(5) Scale and frequency of use	none	low	present	high	very high	
(6) Vulnerability of user	none	low	present	high	very high	
(7) Absence of user information	none	low	present	high	very high	
(8) Availability of product	none	low	present	high	very high	
(9) Unreliability of product quality	none	low	present	high	very high	
(10) Unreliability of mode of distribution	none	low	present	high	very high	
(11) Nature and scale of incidents/reports	none	low	present	high	very high	
III. PUBLIC ORDER	1	2	3	4	5	
(12) Frequency and seriousness of inconvenience for other citizens	none	low	present	high	very high	
(13) Lowering of violence threshold	none	low	present	high	very high	
(14) Influencing of reactions	none	low	present	high	very high	
IV. CRIMINAL INVOLVEMENT	1	2	3	4	5	
(15) Criminal involvement in end product	none	low	present	high	very high	
(16) Criminal involvement in ingredients	none	low	present	high	very high	

Appendix 3

Possible measures for controlling risk

Globally speaking, there are five categories of possible measures:

1. no action,
2. monitoring,
3. prevention,
4. targeted measures relating to production and trade
5. ban (national/international).

In the area of monitoring and prevention, a number of existing instruments can be used (e.g. Drug Information and Monitoring System (DIMS), information programmes).
Any measures taken and any bans imposed need to have a basis in law. Four pieces of legislation can be considered: the Opium Act, the Medicines Act, the Commodities Act and the Penal Code.

Commodities Act

The Commodities Act stipulates that it is prohibited to attribute preventive or curative effects to a product that is marketed (article 19). It also stipulates that action can be taken if public health is endangered by a defective product (article 18). Finally, it provides for the possibility of setting standards, by means of an Order in Council, for the quantity of a certain substance that may be present in a product (article 4).

Medicines Act

According to the European Court of Justice, the Medicines Act (WOG) applies to all pharmaceutically active substances (see ruling of 16 April 1991 concerning the definition of a drug). However, it is always up to the national courts to give a final ruling on each specific substance. The other criteria from the WOG (pharmaceutical form, presentation as a drug and the making of medical claims) also play a role here. Another factor may be whether the substance is (or has been) present on the Dutch market as a registered drug. Most recreational drugs are used to influence the functioning of the brain, but are sold in pharmaceutical form (pills, powder, capsules), albeit without any medical claim being made. The WOG stipulates that a licence is required to prepare and trade in drugs and that a drug may only be marketed if it has been registered by the Medicines Evaluation Board. The WOG mainly targets the legal production of and trade in drugs and the registration of drugs. ‘Legal’ registration of recreational drugs under the WOG is impossible due to the absence of a medical indication.

In May 1999, a special working group (IGZ/OM, ‘Opsporing overtredingen WOG’ [‘Detecting violations of the WOG’], 19 May 1999) concluded that, in its current form, the WOG is not particularly well-suited to tackling the abuse of drugs (such as recreational drugs or doping), due to the low level of the penalties imposed. A proposal has been made with the aim of resolving this problem (increasing the punishment for violations of certain articles in the Act through incorporation into the Economic Offences Act). The bill will be debated in the Council of Ministers in the spring of 2000.

Opium Act

Incorporation into the Opium Act would mean a total ban on import/export, production, trade and possession. As far as penalties are concerned, the Opium Act distinguishes between list I substances (unacceptable risk to public health) and list II substances (acceptable risk). No distinction (in terms of level of risk) is made between the various substances on list I.
One particular limitation is that only list I can be amended at national level (list II can only be amended if the UN Convention on Psychotropic Substances is amended). This means that new substances can only be placed on list I (with the highest penalties).
The Opium Act allows (adequate) action to be taken against all acts involving recreational drugs. It is possible for persons or institutions to apply for an Opium Act permit from the Minister of Health. However, these permits may only be issued for certain purposes (drug production and trade, research and education).

Penal Code

Art. 174 of the Penal Code provides for the possibility of taking action in the event that harmful products are deliberately sold (i.e. the seller knows that they are harmful) and their harmful nature is deliberately concealed. Proving that this has occurred, however, remains a problem.

Appendix 4

Chronological description of risk assessment procedure for *paddos*

On **27 September 1999** the Mental Welfare, Drug Addiction Treatment and Social Service Policy Department (GVM) of the Ministry of Health, Welfare and Sports submitted a request for a risk assessment procedure to be initiated for *paddos*.

On **1 October 1999** the executive committee of the Coordination Centre for the Assessment and Monitoring of new drugs (CAM) decided that a risk assessment procedure would be set up for *paddos*.

On **1 October 1999** CAM made a request for information via the sounding board group members, and on **24 November 1999** the information report (containing the collected, analysed and summarised information) was sent to all members of the risk assessment committee with a request for them to carry out an individual risk assessment.

On **9 December 1999** the risk assessment committee met to carry out the joint risk assessment.

On 10 January 2000 the draft report was sent to the members of the risk assessment committee for comments.

On 8 February CAM presented the final report to the executive board and on 23 February it was approved.

The procedure took **5 months** in total.

Appendix 5

1 Terms

Crime: If the law is consciously violated and this is a person's usual method of acquiring income.

Euphoria: Heightened feeling of well-being and unfounded optimism.

Empathy: The ability to sympathise with the feelings of others.

Habituation: Acquired tolerance.

Organised crime: In groups, networks or other associations. The use of violence to defend positions etc. must be present.

Risk assessment: A (scientific) evaluation of the likelihood of known or potential adverse consequences (both quantitative and qualitative) arising in relation to (public) health, public order and society.

Risk: An estimate of the likelihood that, and extent to which, an adverse consequence will arise in relation to (public) health, public order or society.

Hallucination: Sensory perception without the associated sensory input.

Illusion: Incorrect interpretation of sensory input.

Mutagenic: Promoting or bringing about mutations (in the DNA).

Inconvenience: An undesirable social situation caused, for example, by drug-related crime, aggression and (street) violence, aberrant behaviour and public order disturbances.

Teratogenic: Promoting or bringing about malformation (in the unborn foetus).

Tolerance: Low sensitivity to the pharmacological effect of a substance.

Addiction: Dependency expressed in the form of withdrawal symptoms in the event of abstinence. Physical: e.g. shivering, trembling, redness of the face and neck, disturbances in ability to feel. Psychological: e.g. restlessness, agitation, anxiety, depression, hallucinations.

2 Abbreviations

CAM	Coordination Centre for the Assessment and Monitoring of new drugs
2-CB	4-bromo-2, 5-dimethoxyphenethylamine (Nexus)
CNS	Central nervous system
DIMS	Drug Information and Monitoring System
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
GABA	Gamma-aminobutyric acid (a neurotransmitter)
GBL	Gamma-butyrolactone
GHB	Gamma-hydroxybutyrate
LSD	Lysergic acid diethylamide
MBDB	1-(1,3-benzodioxol-5-yl)-2-(methylamino)butane
MDMA	3,4-methylenedioxy-N-methylamphetamine (=XTC)
MTA	4-methylthioamphetamine
UN	United Nations
VLOS	*Smart shops* trade association
WOG	Medicines Act