Risk Assessment of Psychoactive Substances: Potentialities and Limitations

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Overview

- Why and how risk assessments on psychoactive substances are carried out
- Examples of WHO, EMCDDA and UK/NL methods
- Scoring systems in the UK/NL
- Main conclusions of assessments in the UK/NL
- Scientific and political limitations of risk assessments

Why do a risk-assessment?

1. To determine if a substance should be controlled under drugs legislation

2. If control is decided, then need to determine control status, i.e. specific schedule and penalties

The elements of risk assessment

- Basic principle of all drugs legislation is to limit the use of harmful substances – it should not be concerned with moral judgements
- Risk assessment is therefore about determining the physical and psychological harms of substances to individuals and to society

Examples of risk assessment: The WHO method

- A list of factors is discussed by ECDD committee (e.g. pharmacology, toxicology, dependence potential). The ECDD makes a recommendation to UN.
- The UN CND makes a decision to control under the 1961 or 1971 Conventions

Examples of risk assessment: The WHO method

The last meeting of ECDD took place a few months ago. Among the substances discussed for possible control under the 1961/1971 Conventions were:

Dextromethorphan
GBL
Ketamine
Khat
Tapentadol
Piperazine derivatives

Examples of risk assessment: EMCDDA

In the EU, a 'Joint Action on new synthetic drugs' was set up in 1997. It was replaced by a Council Decision in 2005, but continued to have three elements:

1. Information collection by Member States
2. Risk assessment of suitable substances
3. Mechanisms for control throughout the EU

Examples of risk assessment: EMCDDA

Guidelines on risk assessment first published in 1999, and updated in 2010.

- Pharmacology
- Health risks
- Social risks
- Organised crime involvement
- Consider relative risks
- Analogy with related substances
- Use a semi-quantitative method
- Evaluate the evidence

http://www.emcdda.europa.eu/html.cfm/index100978EN.html

EMCDDA

Twelve substances assessed since 1997

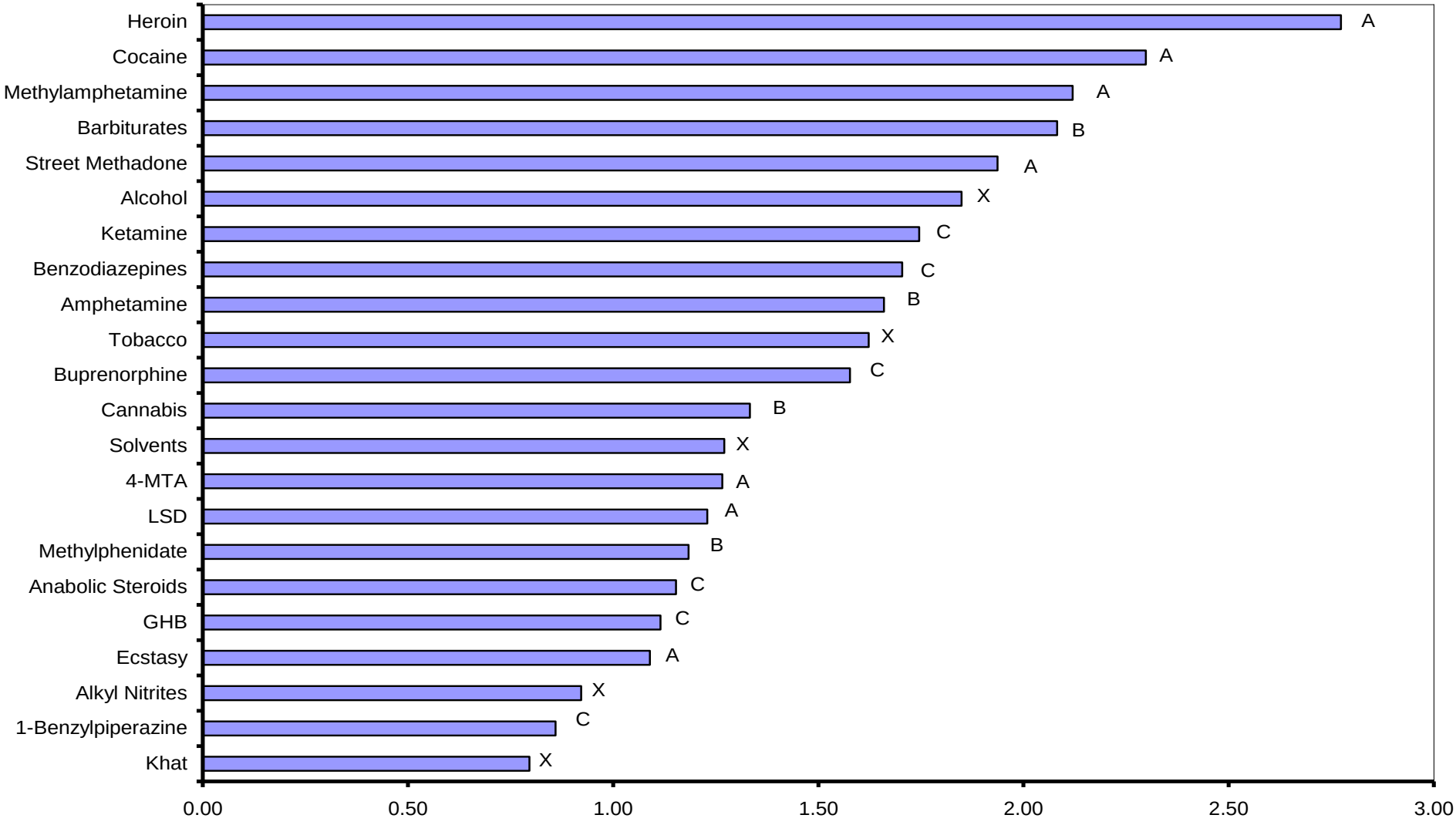
Substance	Risk-assessment report by EMCDDA	Proposed for control in EU	Subsequent Schedule in UN1971
MBDB	1999	No	Not listed
4-MTA	1999	**Yes**	I
GHB	2002	No	IV
Ketamine	2002	No	Not listed
PMMA	2003	**Yes**	Not listed
TMA-2	2004	**Yes**	Not listed
2C-I	2004	**Yes**	Not listed
2C-T-2	2004	**Yes**	Not listed
2C-T-7	2004	**Yes**	Not listed
BZP	2007	**Yes**	Not listed
Mephedrone	2011	**Yes**	Not listed
4-Methylamphetamine	2012	?	Not listed

Examples of risk assessment: United Kingdom (2000 – 2003)

- Starting in 2000, the Advisory Council on the Misuse of Drugs (ACMD) carried out risk assessments on 22 substances
- It used a committee of ~ 16 drug experts to assess 9 criteria of harm on a scale of 0 (no harm) to 3 (high harm)
- It was a subjective process and scores were unweighted, i.e. all criteria of harm treated equally

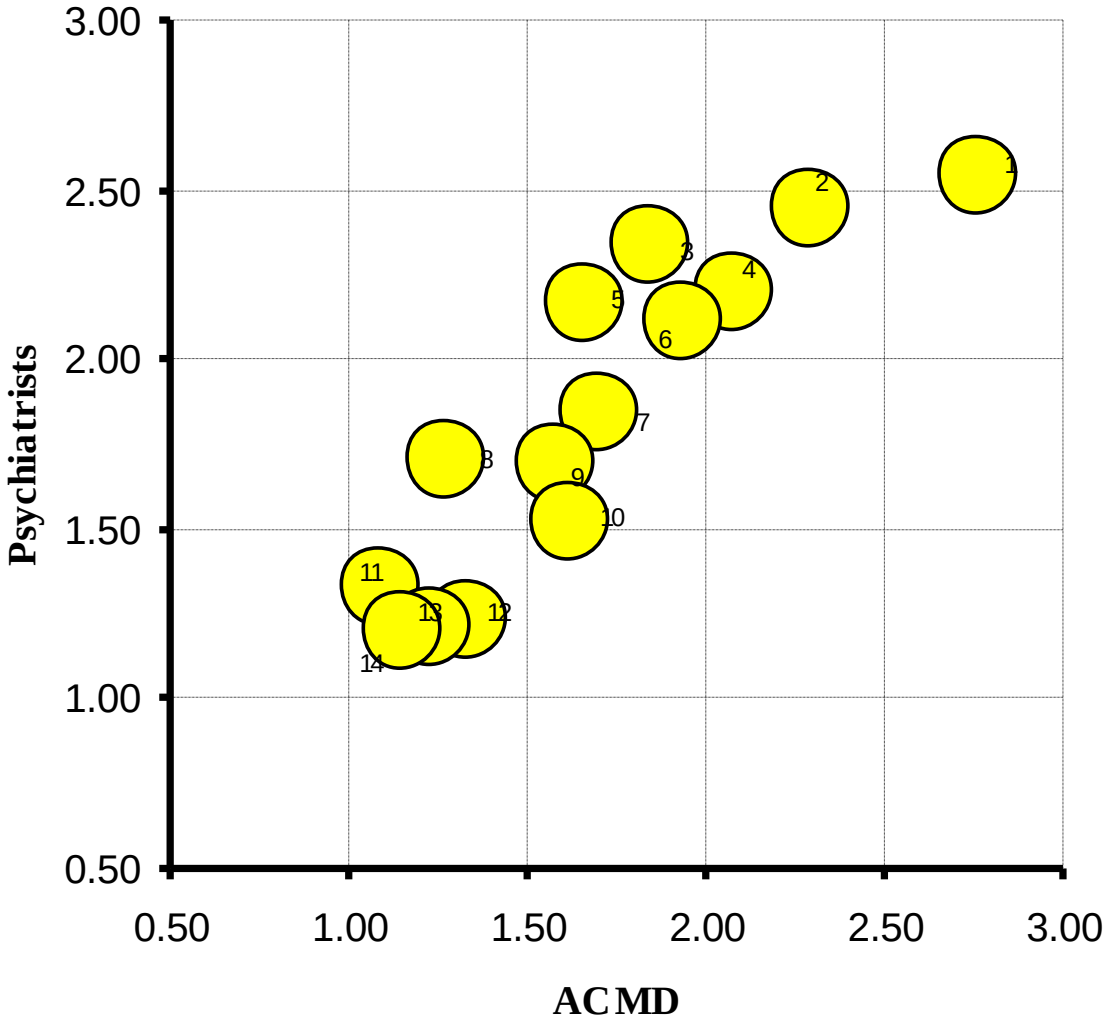
Each parameter scored by ACMD on a scale from 0 (no harm) to 3 (high harm)

Category of harm		Parameter
PHYSICAL HARM	1	Acute
	2	Chronic
	3	i.v. harm
DEPENDENCE	4	Intensity of pleasure
	5	Psychological dependence
	6	Physical dependence
SOCIAL HARMS	7	Intoxication
	8	Other social harms
	9	Healthcare costs



Mean harm scores of twenty-two substances The respective classification (A, B or C) under the Misuse of Drugs Act (X = unclassified) is shown against each bar

Based on: D.J.Nutt, L.A.King, W. Saulsbury, and C. Blakemore, D*eveloping a Rational Scale for Assessing the Risks of Drugs of Potential Misuse,* Lancet, 369, 1047-1053 , 2007



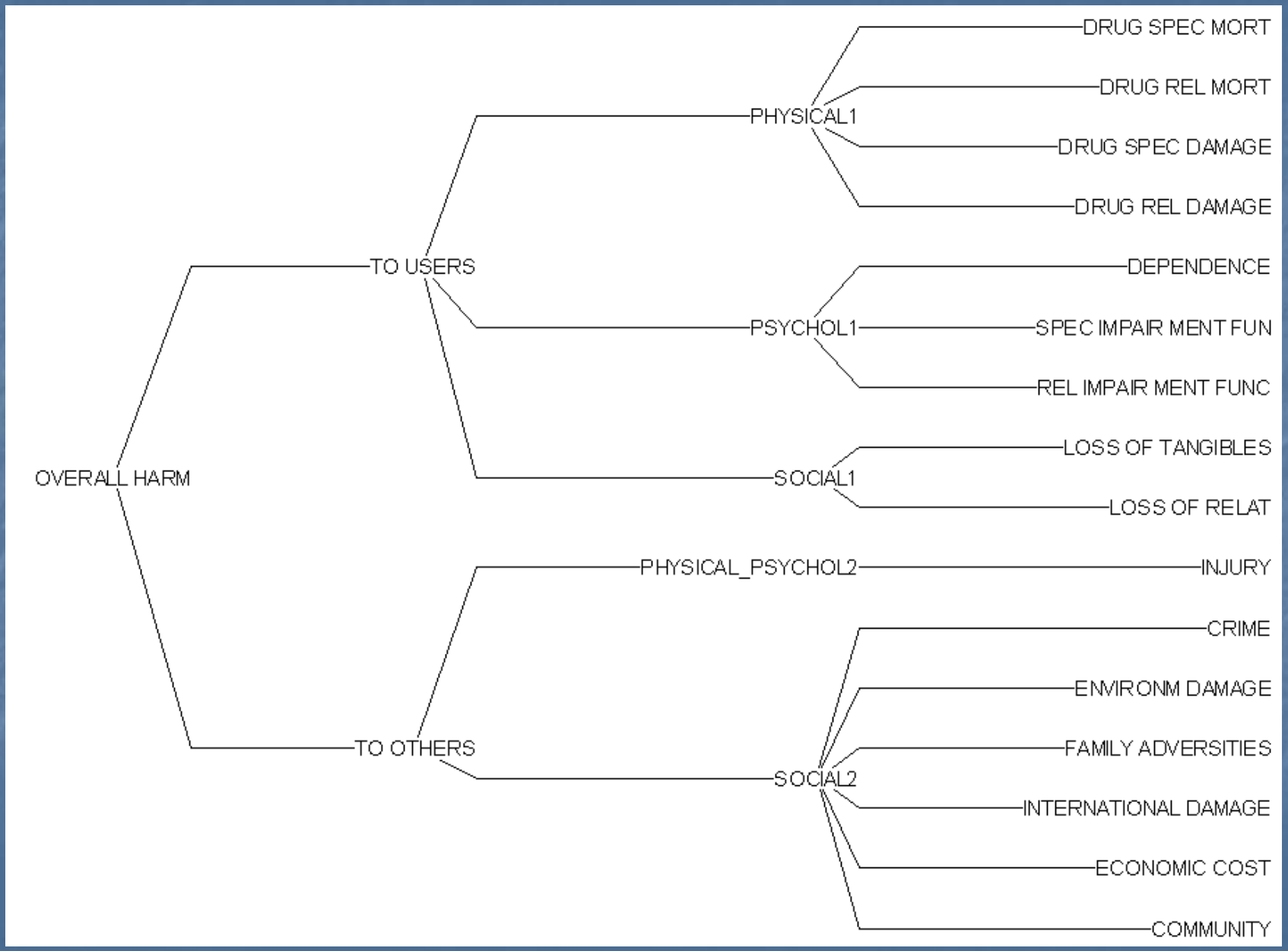
Key: 1 = heroin; 2 = cocaine; 3 = alcohol; 4 = barbiturates; 5 = amphetamine; 6 = methadone; 7 = benzodiazepines; 8 = solvents; 9 = buprenorphine; 10 = tobacco; 11 = ecstasy; 12 = cannabis; 13 = LSD; 14 = steroids.

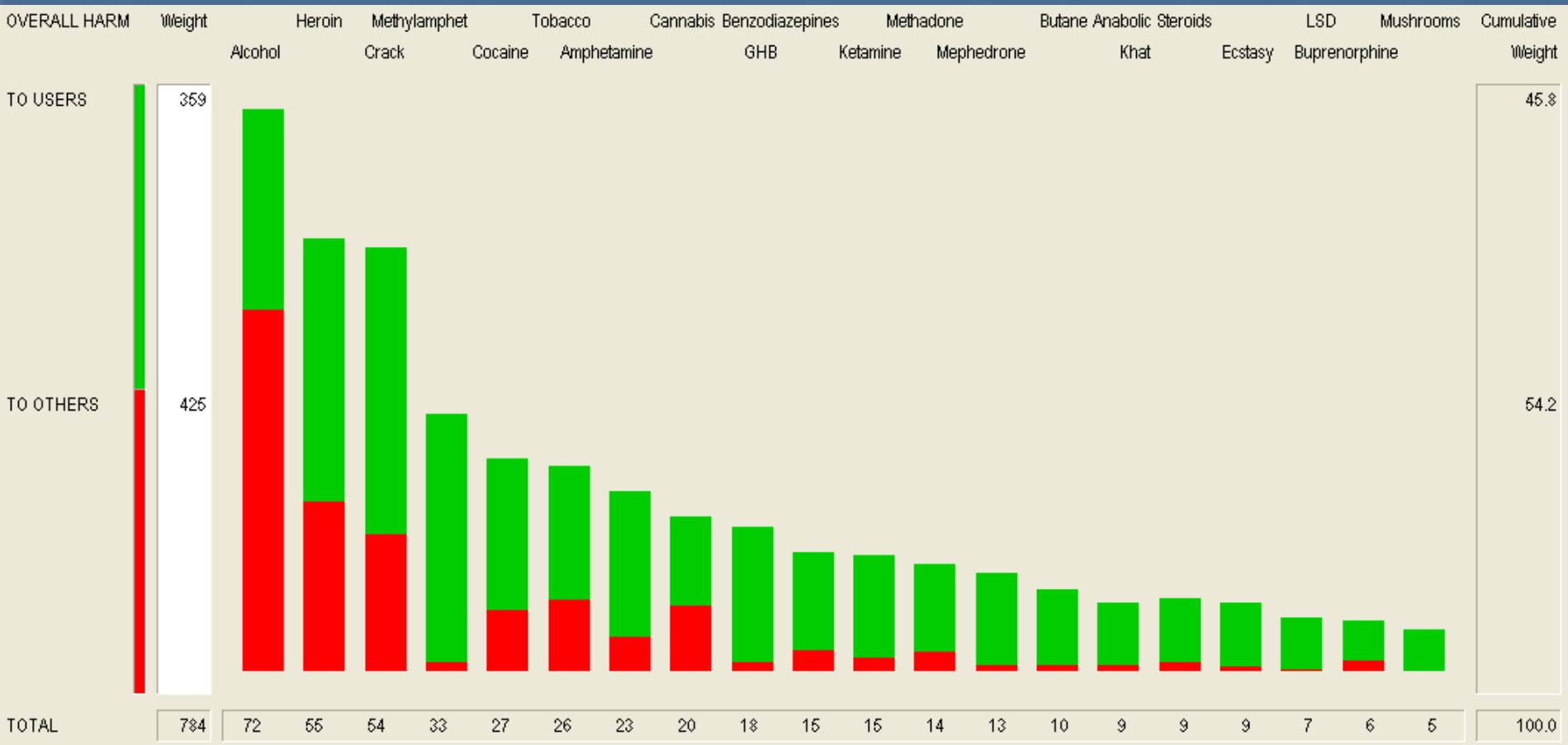
D.J.Nutt, L.A.King, W. Saulsbury, and C. Blakemore, D*eveloping a Rational Scale for Assessing the Risks of Drugs of Potential Misuse,* Lancet, 369, 1047-1053 , 2007

Examples of risk assessment: United Kingdom (2009-2010)

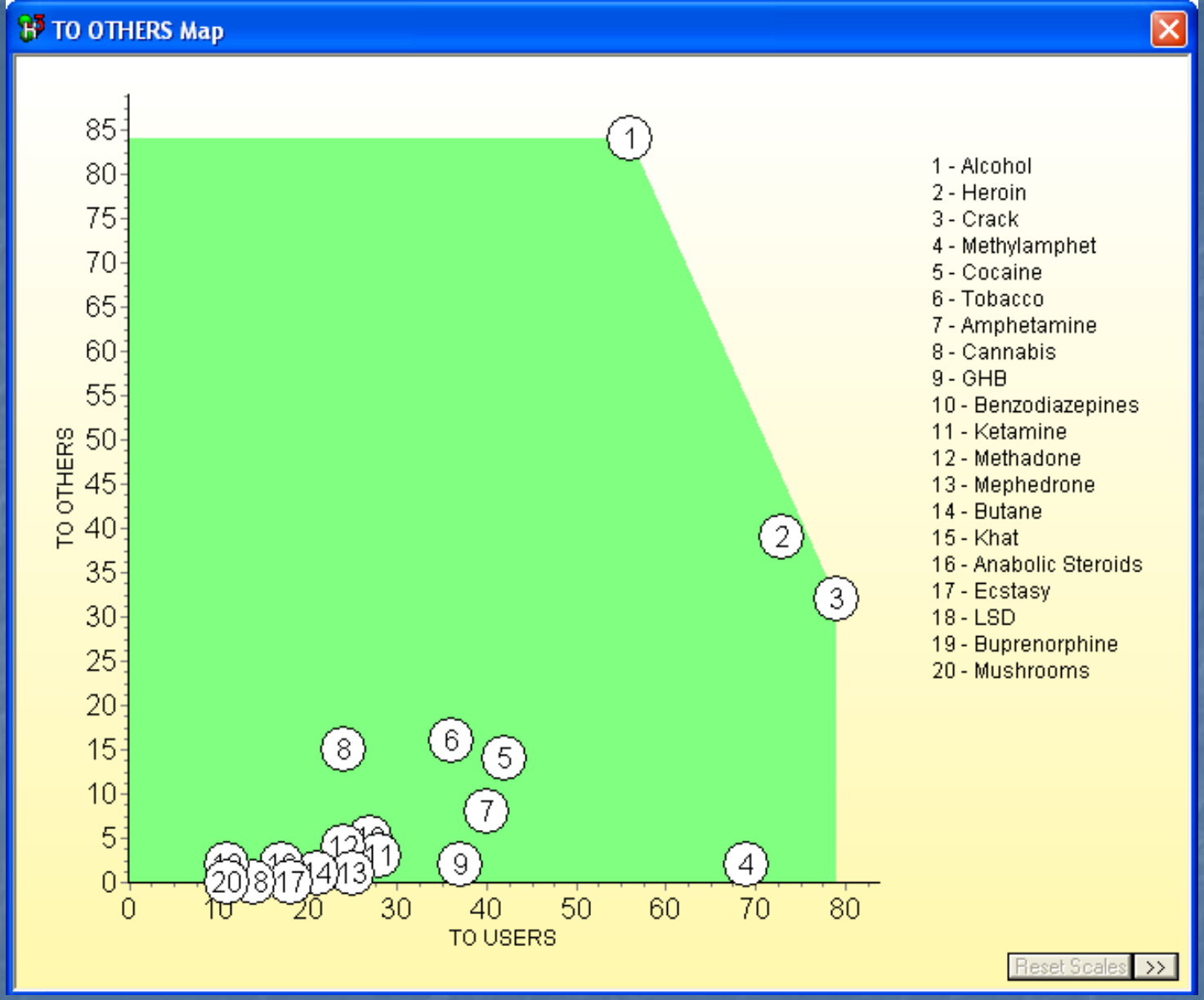
- Using an expert group, Multicriteria Decision Analysis (MCDA) was used to assess the harms of 20 substances
- This used more parameters of harm and included a system for weighting the different elements harm
- But it was still largely a subjective process; many harms cannot be readily quantified

Multicriteria decision analysis: elements of harm





D.J.Nutt, L.A.King and L.D.Phillips, D*rug harms in the UK: a multicriteria decision analysis*, Lancet, 376, 1558-65, 2010

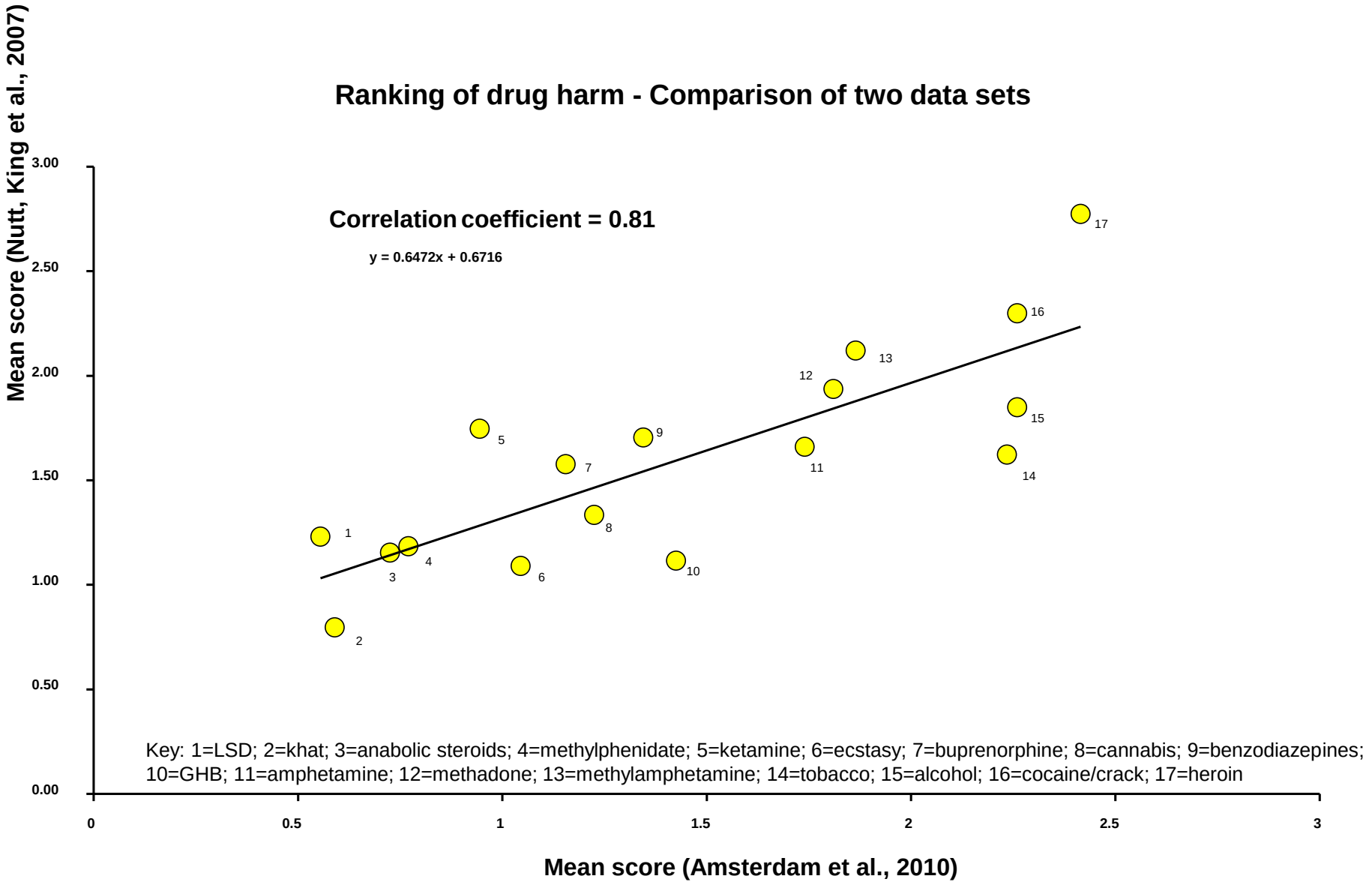


D.J.Nutt, L.A.King and L.D.Phillips, D*rug harms in the UK: a multicriteria decision analysis*, Lancet, 376, 1558-65, 2010

Examples of risk assessment: Netherlands (2008-2010)

- Following the initial UK work published in 2007, the Dutch Government requested the CAM committee to carry out a similar exercise

- This used a different set of criteria of harm, but the results showed a high correlation with the UK study

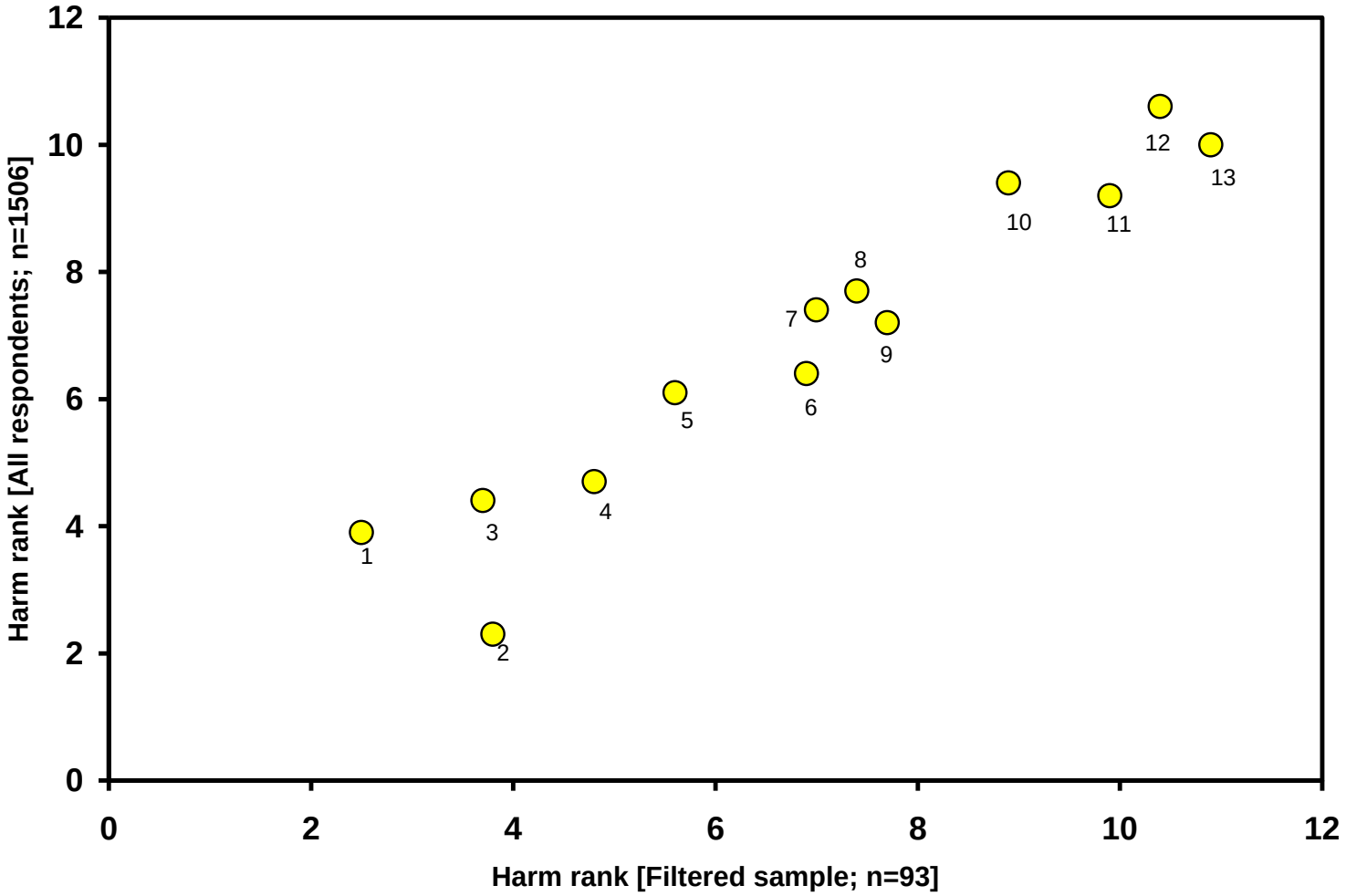


Based on: J. van Amsterdam, A. Opperhuizen, M. Koeter and W. van den Brink, *Ranking the Harm of Alcohol, Tobacco and Illicit Drugs for the Individual and the Population*, *Eur. Addict. Res.*,16:202–207, 2010

What do UK drug users think of relative harms?

- Online survey of (1506 respondents) in 2010 asked about mephedrone use, availability etc.
- We also asked the users to rank the harmfulness of mephedrone and 12 other substances

The ranking of overall harm of thirteen substances by respondents to an online survey



Key: 1 = alcohol; 2 = heroin; 3 = tobacco; 4 = cocaine; 5 = amphetamines; 6 = GHB; 7 = benzodiazepines; 8 = mephedrone; 9 = ketamine; 10 = MDMA; 11 = LSD; 12 = cannabis; 13 = magic mushrooms

R.L.Carhart-Harris, L.A.King and D.J.Nutt, *A web-based survey on mephedrone* Drug and Alcohol Dependence, 118(1), 2011

Other estimates of drug harm from online surveys of drug users

1. C.J. Morgan et al. (2010) *Harms associated with psychoactive substances: findings of the UK National drug survey.* J. Psychopharmacology 24: 147-153

2. C.J. Morgan et al. (2012) *Harms and benefits associated with psychoactive drugs: findings of an international survey*. J. Psychopharmacology - in press)

Both studies came to a similar conclusion to the earlier work

Risk assessment – summary findings

- Despite their largely subjective nature, and despite different approaches to determining harm, there is wide agreement about the relative harms of well-known substances…

Risk assessment – summary findings

- All surveys show that the most harmful substances include Heroin, cocaine, tobacco and alcohol
- All surveys show that the least harmful substances include MDMA, khat, 'magic mushrooms' and LSD

Risk assessment – summary findings

- There is no correlation between harm and current classifications of substances in the UK Misuse of Drugs Act or the Schedules of the US Controlled Substances Act

Risk assessment – limitations

- New psychoactive substances cannot be risk-assessed using the methods described. There is often no information in the literature on their pharmacology, toxicology, potential for dependence etc.
- Proposals to recalibrate the UK classification of MDMA were rejected by politicians
- Legislation often ignores evidence, but is guided instead by moral principles. Thus the preamble to the UN 1961 Convention refers to the "evil of drug addiction"

Risk-assessment - Conclusions

- A valuable tool for determining the legal status of well-known substances
- Not suitable for new substances
- Hence, new substances are not suitable for inclusion in normal drug legislation
- Other methods of regulation are needed for new substances