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22 November 2010

Dear Claire,

Former Bayer CropScience, Hauxton: Risk Assessment of Contaminants Not Previously Identified; Grid Cells G12, G13, G14, G17 and H17 (CNPI letter No. 6)

Further characterisation sampling and analysis have identified one contaminant not previously identified (CNPIs) requiring further assessment and derivation of Remedial Targets. This CNPI was notified to South Cambridgeshire District Council by Harrow Estates (25.10.2010).

The grid square in which the CNPI has been identified, and the treatment beds in which the materials have been placed, are summarised in Table 1. The CNPI will be added to the contaminants of concern verification list for both the respective grid cell in which the CNPI was identified and the corresponding treatment beds. The grid squares are shown on the enclosed Site Survey Reference Grid plan.

Table 1 – CNPIs Requiring Further Assessment and Derivation of Remedial Targets

Contaminant	Grid squares	Treatment beds
Nicotine	G12	TB118, TB119

The compounds presented in Table 2 are CNPIs that have been risk assessed previously and for which Remedial Targets have already been derived. The CNPIs will be added to the list of verification sampling priority contaminants for the relevant grid cell and corresponding treatment beds.

Table 2 – CNPIs Risk Assessed in previous CNPI reports

Contaminant	Grid squares	Treatment beds
Dichloromethylphenol	H7, H10, H13, I9, I10, I11, I15, J10, J11, J12, K10, K12, K13, L11, L12, G12	TB6, TB17-18, TB23, TB30-31, TB46-47, TB50-51, TB53, TB59-60, TB63, TB67, TB69, TB70a, TB70b, TB71, TB73, TB77-80, TB83-88, TB91-102, TB104-106, TB108-109, TB111-114, TB118-119
1-methylnaphthalene CAS 90-12-0	K10, I12, I13, G13	TB6, TB69, TB71, TB73, TB78, TB80, TB91-92, TB102, TB104. TB108-109, TB111, TB113, TB118

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Seven further compounds were identified, however these were encountered and assessed during the site investigation and were deemed not to be priority contaminants.

Toxicological assessments and human health and controlled waters risk assessments have been carried out for the new CNPI and, where sufficient toxicological, physical and chemical data is available, preliminary Remedial Targets have been derived. The preliminary Remedial Targets will be provided to Vertase, who currently intend to use these for the CNPI.

The CNPI Remedial Targets and required laboratory limits of detection (LODs) are summarised in Table 3. As for the previously identified contaminants of concern, four Remedial Targets have been derived for the CNPI: i) treated materials which will be placed within 20m of Riddy Brook (Inner Zone), ii) treated materials which will be placed at least 20m from Riddy Brook (Outer Zone), iii) treated materials which will be placed at least 1 m below final site levels, after levels have been raised to account for flood risk, (controlled waters risk driven) and iv) treated materials which will be placed within 1 m of final site levels (human health risk driven). The CNPIs and derived/surrogate Remedial Targets will be added to the list of Contaminants of Concern for the relevant grid square and treatment bed validation suites.

Table 3 – Preliminary Remedial Targets

Contaminant	Remedial Targets (µg/kg)				LOD (µg/kg)
	Greater than 1m depth		Less than1m depth		
	Outer Zone	Inner Zone	Outer Zone	Inner Zone	
Nicotine	219	10	91.6	10	100* 10#

* LOD for soils to be backfilled at depths greater than 1m in the Outer Zone
# LOD for soils to be backfilled in the Inner Zone and in either zone at depths less than 1m.

The data collected, methods and models used in the derivation of Remedial Targets and identification of surrogates are detailed Annex 1: Derivation of Generic Assessment Criteria for the protection of Human Health, Annex 2: Human Health Toxicological Data, Annex 3: Human Health Physical and Chemical Data, Annex 4: Human Health Modelling, and Annex 5: Derivation of Generic Assessment Criteria for the protection of Controlled Waters.

The treatability of this compound has been reviewed by Vertase FLI and the remediation of the CNPI will be dealt with by the existing treatment train identified in the Remediation Method Statement (Version 6) and detailed in the Environmental Permit Deployment Form for the site.

Yours sincerely
For and on behalf of Atkins Limited

Mark Smith
Project Manager

Cc Eileen Young – Environment Agency
Nigel Blazeby - South Cambridgeshire District Council

Enc.

Annex 1: Derivation of Generic Assessment Criteria for the Protection of Human Health

Introduction

Laboratory analysis from soil characterisation at the site has identified one compound not previously identified (CNPI). This compound did not have available generic assessment criteria (GAC). The CNPI is:

- Nicotine (CAS No. 54-11-5)

A GAC has been derived for nicotine.

Methodology

The derivation of any GAC involves a number of steps including a toxicological assessment and the collation of physical and chemical data for each contaminant. In the derivation of such criteria the Environment Agency has released three guidance documents, namely:

- Science Report (SR)2 – Human Health toxicological assessment of contaminants in soil;
- SR3 – Updated technical background to the CLEA model; and
- SR7 – Compilation of Data for Priority Organic Pollutants for Derivation of Soil Guideline Values.

Following the methodology outlined in these documents, Atkins has carried out a toxicological search and review of physical and chemical data for the compounds identified, with each discussed in further detail below.

Toxicology

In order to evaluate the CNPI compounds appropriately, a number of steps were taken to ensure that these compounds were suitably assessed. The search was conducted as described in SR2, particularly an evaluation of the available data from all 33 sources listed, as advised. The checklist of the toxicological sources used for this research has been included in Annex 2.

For nicotine, suitable health criteria values (HCVs) were derived for oral and inhalation exposures, based on the principles for toxicological evaluation as outlined in SR2. A detailed summary of the data collated and the HCV obtained is included in Annex 2.

Physical and Chemical Data

In the derivation of appropriate physical and chemical data the methodology that the Environment Agency presented in SR7 was followed.

Each source was consulted and the available data collated as presented in Annex 3. Where more than one result was recorded, the selection process as presented in SR2 was followed for each parameter. A rationale for the use of each value is also presented in Annex 3.

Where a value was reported at 25°C, Atkins has retained this value. This is consistent with the approach that was carried out during evaluation of the previous GACs.

Modelling

Modelling was undertaken using CLEA v1.06 selecting the standard residential with the consumption of home-grown produce land use. In order to retain consistency with previous work undertaken at the site, a default sand soil type as defined in SR3 was selected. A soil organic matter of 1% was also selected.

A default soil to dust transport factor of 0.5 g/g was applied in the modelling.

The data available in relation to nicotine and its dermal toxicity was studied prior to selecting a dermal absorption factor (DAF). The DAF is used in the calculation of the assessment criteria for the dermal pathway. Limited data were available with regard to the dermal toxicity and therefore a decision was taken with regard to the DAF that would be applied. The structure and available data on dermal absorption from toxicokinetic evaluations within the toxicity data summary was taken into account, along with the fact that the criteria derived are being used at the generic stage of assessment. A DAF value of 0.5 was utilised and considered as a suitably conservative value based on an experimental study on dermal absorption. These decisions are documented in the substance specific toxicological data summaries available in Annex 2.

The modelling outputs are presented in Annex 4.

Results and conclusions

The results of the modelling are presented in Table 1 below.

Table 2 - Summary of Modelling Results

Compound	Oral Criteria mg/kg	Inhalation Criteria mg/kg	GAC mg/kg
Nicotine	9.17E-02	1.56E+02	9.16E-02

References

Environment Agency, 2008. Compilation of Data for Priority Organic Pollutants for Derivation of Soil Guideline Values Science Report Final SC050021/ SR7.

Environment Agency, 2009a. Human Health toxicological assessment of contaminants in soil. Science Report Final SC050021/SR2.

Environment Agency, 2009b. Updated technical background to the CLEA model Science Report Final SC050021/SR3.

Annex 2: Derivation of Generic Assessment Criteria the Protection of Controlled Waters

TOXICOLOGICAL DATA TEMPLATE

Chemical name: 3-[(2*S*)-1-methylpyrrolidin-2-yl]pyridine___

Common name: **Nicotine**_____

CAS RN: 54-11-5_____

Chemical Identification

Synonyms: -(-)Nicotine; (-)-3-(Methyl-2-pyrrolidyl)pyridine; (S)-3-(1-Methyl-2-pyrrolidinyl)pyridine; (S)-Nicotine; 1-Methyl-2-(3pyridyl)pyrrolidine; 3-(NMethylpyrrolidino) pyridine; beta-Pyridyl-alpha-Nmethylpyrrolidine; S-(-)Nicotine (Chemblink, 2008).

Easily soluble in diethyl ether. Soluble in cold water. Miscible with water below 60 deg. C. Very soluble in alcohol, chloroform, petroleum ether, kerosene oils. It is yellowish-brown in colour with a slight fish odour and an acrid, burning taste (Chemblink, 2008)

Nicotine has been reviewed recently by the European Food Safety Authority (EFSA) in order to evaluate risk from ingestion of wild mushrooms. The majority of the data in this summary relies on data contained within this report, in the absence of more recent data readily available in the open literature for this compound.

Occurrence and uses

Nicotine is found in tobacco which is used for chewing, snuffing or smoking (IPCS, 2009). It is is also inherently present in ceps and other wild mushrooms (EFSA, 2009). It can also be found in the *Solanaceae*[1] plant family, in crops such as pepper and potatoes.

In is used as an instillation of tobacco enemas for treatment of intestinal worms or constipation (IPCS, 2009), and as an insecticide (EFSA, 2009).

It appears that mushrooms are also more susceptible to nicotine contamination through handling and storage, either due to the disinfection of storage facilities with nicotine, simultaneous drying of tobacco and mushrooms in the same room or the presence of mushrooms in locations where smoking occurs (EFSA, 2009).

Toxicokinetics

Nicotine is a water and lipid soluble drug which, in the free base form, is readily absorbed via respiratory tissues, skin, and the gastrointestinal tract (IPCS, 1991).

Nicotine from patches is absorbed through the skin and passes into the systemic blood system, and is distributed throughout the body (EFSA, 2009). One study on skin permeability for nicotine shows that the permeation rate for different concentrations of nicotine in water could be up to a maximum at 50% (Zorin *et al*, 1999). This implies that up to 50% of a dermally applied dose may be absorbed, when nicotine is dissolved in water. Similarly, it has been reported in one experimental study that following application of a transdermal system (nicotine patch) a mean value of 68% was absorbed (Gupta *et al*, 1993).

However, although it is considered reasonable to assume that exposures from a soil source will not be as readily absorbed as from a water solution or transdermal system, **in the absence of any other soil-specific data a conservative dermal absorption fraction (ABS_d) of 0.5 can be applied for exposure estimation.**

[1] The plant family informally known as the nightshades which includes, amongst others, the *Capsicum* (paprika, chilli pepper), *Solanum* (potato, tomato, aubergine or eggplant) and *Nicotiana* (tobacco).

Following the administration of nicotine capsules or nicotine in solution, peak concentrations in blood are reached in about 1 h. The oral bioavailability of nicotine is incomplete because of the hepatic first-pass metabolism[2] and is reported to range between 20% and 45% (EFSA, 2009).

The half-life of nicotine in the body averages 2 h, although there is considerable variability among people (range: 1 to 4 h). Nicotine is rapidly and extensively metabolised (80 to 90%), primarily in the liver, but also to a small extent in the lungs and kidneys. Nicotine's primary metabolites are cotinine and nicotine-N-oxide, neither of which appears to be pharmacologically active. Their formation involves oxidation, demethylation and pyridine N-methylation (IPCS, 2009).

Due to the short biological half-life of nicotine in humans, it does not accumulate in the body and the most sensitive effect of nicotine is considered to be its pharmacological effect on the cardiovascular system.

Mechanism of action

The effects of nicotine alkaloid are a result of the summation of actions at ganglionic sites, motor end plates and smooth muscle. The central nervous system is affected, initially by stimulation, resulting in tremors and convulsions, progressing to depression. Death occurs from respiratory failure. Vomiting is a result of stimulation of the emetic chemoreceptor trigger zone (IPCS, 1991).

The cardiovascular responses are generally due to stimulation of sympathetic ganglia and adrenal medulla combined with discharge of catecholamines. The target organs are the nervous system and heart (IPCS, 1991).

Acute Toxicity

Nicotine is acutely toxic by all routes of exposure (oral, dermal, and inhalation). The oral LD50 of nicotine is 50 mg/kg for rats and 3 mg/kg for mice. A dose of 40–60 mg can be a lethal dosage for adult human beings and doses as low as 1-4 mg can be associated with toxic effects in some individuals (US EPA 2008). It has also been known in some cases to haveresulted in severe poisoning from percutaneous absorption (Zorin *et al*, 1999).

Ingestion of two to four drops of pure nicotine can prove lethal in humans (each drop: 23-33 mg). The ingestion of 30 g of tobacco or infusion of 15 to 20 g of tobacco resulted in death in human receptors. The administration of enemas of 8 g of or inhalation of 0.8 g of tobacco as snuff has been reported to be lethal in humans (IPCS, 2009).

An acute reference dose (ARfD) of 0.0008 mg/kg body weight (b.w.) per day was established by the EFSA. This value has been based on a lowest observed adverse effect level (LOAEL) of 0.0035 mg/kg b.w. for pharmacological effects after intravenous application of nicotine (i.e. slight, transient and rapidly reversible increase of the heart rate in humans), using an overall uncertainty factor of 10 and a correction factor of 0.44 for oral bioavailability of nicotine (extrapolation from the intravenous route to the oral route) (EFSA 2009).

Subacute Toxicity (short term repeat dose studies)

In a subacute study on nicotine effects on the rat liver, nicotine hydrogen tartrate was administered to pregnant (n=16/group) and non-pregnant (n=24/group) female rats at doses of 54 and 108 µmol/L of drinking water (equivalent to 1.25 and 2.5 mg/kg b.w. per day) for 10

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[2] Following ingestion of a substance, it is absorbed by the digestive system and enters into the liver before it reaches the rest of the body. Therefore, the enzymes of the gastrointestinal tract and liver may metabolise them, preventing a portion of the substance from reaching the rest of the circulatory system. This is known as **first pass metabolism** and may result in a reduced bioavailability of an ingested substance.

days. The animals exhibited mild fatty liver change, mild focal necrosis and mild dark cell change, with effects on the mitochondria, in a dose proportional manner. Effects at the lower dose were not statistically significant, so the no observed adverse effect level (NOAEL) was identified as 1.25 mg/kg bw/day; the lowest observed adverse effect level (LOAEL) was identified as 2.5 mg/kg bw/day (EFSA, 2009).

Chronic Toxicity (long-term toxicity data)
Chronic exposure to nicotine is considered to lead to cardiovascular disease, hypertension, peptic ulcers and effects on the immune system (EFSA, 2009).

Reproductive and Developmental Toxicity

There is some evidence that adverse effects may occur only at high nicotine doses. A 6 mg/kg bw per day nicotine dose administered throughout gestation to rats implanted with osmotic mini-pumps (plasma concentrations >100 ng/ml), did not result in any relevant adverse effects in the offspring (IPCS, 2009).

Another study in rats reported that low doses of nicotine injected subcutaneously (0.1 mg/ kg b.w. per day) from day 14 to the end of pregnancy had no effect on litter size or foetal development, but higher doses (1 mg/kg b.w. per day), comparable to those consumed by heavy smokers, reduced litter size and increased the number of still births (EFSA, 2009).

Genotoxicity

The EFSA report that on the basis of the information reviewed in the published literature, nicotine was not considered to be mutagenic (EFSA, 2009).

Carcinogenicity

On the basis of the information reviewed in the published literature, nicotine was considered not to be carcinogenic. (EFSA, 2009). Literature reports indicate that nicotine is neither an initiator nor a promoter of tumours in mice. There is inconclusive evidence to suggest that cotinine, an oxidised metabolite of nicotine, may be carcinogenic in the rat (IPCS, 1991).

Other

Background exposure (food, drinking water, air)

Food

There are no readily available data for concentrations of nicotine in UK diet. However, the EFSA has undertaken a study of dietary exposure to nicotine found in wild mushrooms. The long term exposure to nicotine in wild mushrooms using the consumption recorded in Italy was for adults a mean of 0.026 µg/kg bw/ day and a 95th percentile of 0.172 µg/kg bw/ day, and for children a mean of 0.026 µg/kg bw/ day and a 95th percentile of 0.281 µg/kg b.w. per day. The highest calculated acute exposure to nicotine in wild mushrooms was for Italian children at 6.708 µg/kg bw/ day. The adult mean intake for Finland was 0.0135 µg/kg bw/day, the child mean in Denmark and the Netherlands was 0.0031 µg/kg bw/day and 0.0003 µg/kg bw/day, respectively and the general mean of the total population in the Netherlands was 0.001 µg/kg bw/day (EFSA, 2009).

A similar study on dietary nicotine intake through consumption of *Solanaceae* concluded that the mean daily dietary nicotine intake for the population of the countries for which consumption data were available is approximately 1.4 µg/person per day and 2.25 µg/person per day at the 95th percentile. However, the EFSA report that the measured nicotine concentrations were neither consistent nor reliable enough to include in long-term exposure assessments (EFSA, 2009).

Drinking Water

There are no readily available data in open literature sources.

Air

There are no readily available data for the UK in open literature sources for ambient or indoor levels of nicotine. Indoor air nicotine concentrations ranged from the laboratory limit of detection, LOD (0.08 µg/m³) to 14.3 mg/m³, 10.2 mg/m³, and 3.2 mg/m³ in Germany, the Netherlands, and Sweden (Gehring *et al*, 2006) in various types of homes. Data was obtained from homes of both smokers and non-smokers, and the levels at which nicotine was measured in non-smokers' homes was not explicitly stated. Another study of low-income multi-unit housing reports a mean value of 0.08 µg/m³ in indoor air of non-smokers' homes (Kraev *et al*, 2009).

No data on ambient air levels of nicotine have been identified at the time of data collation.

Other sources
The amount of nicotine contained in cigarettes varies, with the lowest nicotine reported to be approximately 0.1 mg to the highest of 0.9–2.4 mg per cigarette (Atsuko *et al* 2004). One study reports that based on the the daily intake of nicotine in 22 subjects, daily intake of nicotine averaged 37.6 mg (±17.7, SD) but varied widely among subjects from 10.5 to 78.6 mg (Benowitz and Peyton, 1983). However, these exposures are not considered within the background exposures, based on current UK guidance (EA, 2009).

Nicotine patches typically come in three different dosage strengths of 21mg, 14mg and 7mg. It is advised that one is used per day. However, these exposures are not considered within the background exposures, based on current UK guidance (EA, 2009).

Reviews by authoritative bodies

German Federal Institute for Risk Assessment
In February 2009, the German Federal Institute for Risk Assessment (BfR) published a report concerning the potential acute risks deriving from the consumption of nicotine-contaminated mushrooms. The BfR established an ARfD for nicotine of 0.0008 mg/kg b.w. on the basis of a study in humans who were injected nicotine intravenously. The lowest systemic nicotine dose, which caused an increase of heart rate, namely 0.0035 mg/kg b.w., was taken as the LOAEL (lowest observed adverse effect level) for humans. By applying a safety factor of 10 to account for the differences in sensitivity within the human population, and by assuming an oral bioavailability of 44%, the final value of 0.0008 mg/kg b.w. was derived for the ARfD. (cited in EFSA, 2009).

European Food Safety Authority
EFSA established an acute reference dose (ARfD) of 0.0008 mg/kg, based on work undertaken by the BfR. EFSA also state that due to the short biological half-life of nicotine in humans, it does not accumulate in the body and the most sensitive effect of nicotine is considered to be its pharmacological effect on the cardiovascular system. Therefore, avoiding acute effects of nicotine would also protect from its chronic effects and EFSA established an acceptable daily intake (ADI) for nicotine at 0.0008 mg/kg bw/ day that is at the same level as the ARfD (EFSA, 2009).

Regulatory guidelines/ advisories/ guideline values

The Health and Safety Executive (HSE) has published workplace exposure limits (WELs) for nicotine. The EH40 workplace inhalation exposure limits for nicotine have been set for long term exposure (8-hour time weighted average, TWA) limits and for short term exposure (15

minute period). For long term exposure the limit has been set at 0.5mg/m^3 and for short term exposure the limit has been set at 1.5 mg/m^3. (HSE, 2007).

The Table below summarises established health based guidelines for several organisations, as detailed by the EFSA (EFSA, 2009).

Organisation	**Key study**	**Administration**	**Endpoint**	**NOAEL** (mg/kg b.w.)	**UF***	**ARfD** (mg/kg bw)	**ADI** (mg/kg bw/ day)
UK PSD, 2007 AFFSA, 2009	Woolf *et al*. 1997 (human study)	Dermal, acute	Clinical symptoms	0.01 (lowest observed effect limit, LOEL)	100	0.0001	0.0001
US EPA, 2008	Yuen *et al*. 1995 (rat study)	Oral, 10 days	Hepatotoxicity	1.25	1000	Only acute occupational exposure limit, AOEL derived (0.00125 mg/kg bw/ day).	
						No consumer exposure expected	
BfR, 2009	Lindgren *et al*. 1999 (human study)	Intravenous , acute	EEG and heart rate frequency changes	0.0035 (LOAEL)	10; 44% oral bioavailability	0.0008	0.0008

It is noted that the ADI reported by EFSA from the Pesticides Safety Directorate (PSD) has since been updated in line with the ADI derived by EFSA.

Health Criteria Values (HCV)

Oral exposure

EFSA established an acceptable daily intake (ADI) for nicotine at 0.0008 mg/kg b.w. per day that is at the same level as the ARfD. This is preferred to the value presented above by the PSD which is based on dermal exposure data, and has since been withdrawn by the PSD. Therefore, a TDI_{oral} of **0.0008 mg/kg bw/day (0.8 µg/kg bw/day)** has been adopted as the TDI**.**

Mean Daily Intake (MDI)

Drinking water

In light of the likely sources of nicotine, it is assumed that its concentration in drinking water is negligible.

Dietary sources

There are no data available on nicotine levels in UK diet. However, the EFSA report that long term exposure to nicotine in wild mushrooms using the consumption recorded in Italy was for adults a mean of 0.026 and a 95th percentile of 0.172 µg/kg bw/ day, and for children a mean of 0.026 and a 95th percentile of 0.281 µg/kg b.w. per day.Mean intake levels in Finland were 0.0135 µg/kg bw/day for adults, which is considered more likely to be similar to UK exposure patterns. It is noted that UK diets are unlikely to contain a similar level of exposure from this source (wild mushrooms) as Italy and there is considerable uncertainty involved in evaluating exposures from other components of diets in the UK. However, as this is the reported concentration from one dietary source alone, it is reasonable to assume that a higher concentration may be present in the average UK diet from a number of different sources, such as from potatoes, tomatoes, and other members of the *Solanaceae plant group*. Such intakes have been estimated to be up to 2.25 µg/person (0.032 µg/kg bw/day, assuming a 70 kg adult). In the absence of other data, assuming this estimate is accurate the total nicotine exposure from the diet could be up to 0.204 µg/kg bw.day for an adult receptor eating a high proportion of wild mushrooms (similar to Italy) or 0.045 for more moderate wild mushroom

intake. A higher intake of potentially 0.029 – 0.2841 µg/kg bw/day could be expected for a child receptor, based on the available intake estimates.

In the light of this, an allocation of 10% of the TDI is selected as the MDI from oral sources. This is 0.08 µg/kg bw/day, or 5.6 µg/day for a 70kg adult.

MDI_{oral} = 0.08 µg/kg bw/ day (5.6 µg/ day)
Tolerable daily soil intake (TDSI)
= TDI – MDI
= (0.8 – 0.08) µg/kg bw/day
= 0.72 µg/kg bw/day (0.00072 mg/kg bw/day).

Inhalation
There are no readily available guidelines for inhalation of nicotine. However, occupational guidelines are available for use as a point of departure (POD). The HSE WEL of 0.5 mg/m³ is adopted as a POD for nicotine. Standard safety factors of 10 each for extrapolation from occupational to continuous exposure and for sensitive individuals in the human population have been selected, as well as a factor of 2 to account for the limited database. The factor of 2 is considered sufficient to account for the use of a published WEL, which should be based on health-based data according to the updates made in 2005, although they have in the past been based on other factors such as technological feasibility. This factor has been applied to account for the fact that the background data on which the WEL was based have not been made available.

POD = 0.5 mg/m³
SF = 200
$TDI_{inhalation}$ = 0.0025 mg/m³ (2.5 µg/m³)

Assuming a 70 kg man inhales 20m³ air per day, this is equivalent to a dose of **0.000714 mg/kg bw/day (0.714 µg/kg bw/day**) for an adult receptor.

$MDI_{inhalation}$
Indoor air exposures from non-smokers homes are likely to be represented by the 'LOD' /mean concentration of 0.08 µg/m³. This is equal to a dose of 0.023 µg/kg bw/day (1.6 µg/day), assuming a 70kg adult inhales 20m³ per day.

It is deemed inappropriate to include data from smoking, or from smokers' homes within background exposure estimations, based on current UK guidance (EA, 2009). This is also supported by the fact that smoking is no longer permitted in places of work in the UK, including many areas where smoking often occurs such is restaurants and bars. In the absence of any other data, these data may be used as a guide on the potential minimum exposure that may be expected in outdoor air,

There are no data available for ambient air concentrations of nicotine. However, it is expected that some nicotine from smoking will be present in ambient air, as well as potential exposures indoors.

The TDSI = TDI – MDI

Therefore, the $MDI_{inhalation}$ is set at 20% of the TDI (0.143 µg/kg bw/day; 9.996 µg/day).

Therefore, the TDSI is 0.5712 µg/kg bw/day (0.0005712 mg/kg bw/day) for an adult receptor.

Dermal
It is deemed inappropriate to include data from nicotine patches within background exposure estimations, based on current UK guidance (EA, 2009). No other data are available and background dermal exposures are assumed to be negligible.

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Zorin Sara, Fredrik Kuylenstierna and Hans Thulin, 1999. *In Vitro Test of Nicotine's Permeability through Human Skin. Risk Evaluation and Safety Aspects*. Ann. occup. Hyg., Vol. 43, No. 6, pp. 405±413, 1999.
http://annhyg.oxfordjournals.org/content/43/6/405.full.pdf+html

Originated By: __Z A Rostance_____ Date: 25/10/2010_____

Checked By: ____TA_____ Date: 26/10/2010 ___

Annex 3: Physical and Chemical Data

Nicotine (C10 H14 N2) CAS 54-11-5							http://webbook.nist.gov/chemistry/ http://srdata.nist.gov/solubility/			http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@na+NICOTINE			http://www.inchem.org/documents/icsc/icsc/eics0519.htm					
	B			D			No Info			OTHER SOURCES			OTHER SOURCES			Decision		
	HAYNES, 2010-2011 (replaced LIDE, 2008)			MERCK, 2006			NIST, 2005			OECD, 2000 (HSDB)			INCHEM (ICSC)					
	Value	**Units**	**Temp if present**	**Value**	**Units**	**Temp if present**	**Value**	**Units**	**Temp if present**	**Value**	**Units**	**Temp if present**	**Value**	**Units**	**Temp if present**	**Value Selected**	**Units**	**Justification**
Relative Molecular Mass	162.231			162.23			162.2316			162.23			162.2			162.231	g/mol	Central value from consistent range
Henry's Law Constant (HLC)										8.1 E^{-9} 3.0E^{-9}	atm-cu m/mole atm-cu m/mole	25°C 25°C				8.10E-09	atm m^3/mol	Values presented are sourced from EPIWIN (estimated, 2009) and a literature paper (estimated, 1999). Both are at the same temperature. Most recent estimated value selected.
Solubility (S) 10 oC where possible. (Use unit converter if source provides different units)										1 E^{6}	mg/L	25°C				1.00E+06	mg/L	Single value selected.
Chemical Boiling Point (ambient pressure)	247	°C		247	°C					247	°C		247	°C		247	°C	All values the same.
Chemical Melting Point (ambient pressure)	-79	°C								-79	°C		-80	°C		-79	°C	Most consistent value selected, also most recently cited value.
Log Octanol - Water Coefficient (Kow)										1.17			1.2	log Pow		1.17		When rounded to two significant figures, both values are the same. More precise value selected.
Molar Volume (Le Bas method)																		
Enthalpy of Vaporisation at normal boiling point (EVNBP)																		
Chemical Critical Point temperature (ambient pressure)																		
Critical Pressure																		
Diffusion Coefficient in Air																		
Diffusion Coefficient in Water																		
Log (organic carbon-water partition coefficient)(Koc)																		
Vapour Pressure										0.038 1	mmHg mmHg	25°C 61.8°C	0.006	kPa	20°C	6	Pa	Value at 20°C and 25°C are very similar at 6 Pa and 5.1 Pa respectively. Value at 20°C selected as temperature of 20°C more similar to that of soil.
Air-water partition coefficient (Kaw)																		
Density	1.00972		20°	1.00925		20°				1.00925		20°	1.01			1.00925	g/cm^3	Most common value from consistent range. It should be noted that there is a very small difference between the values reported.
Melting point																		
Critical Temp																		

Vapour Pressure

0.038	mmHg	convert to Pascals, multiply by	133.3224	5.07	Pa
0.006	KPa	convert to Pascals, multiply by	1000	6	Pa

Henry's Law Constant

8.10E-09	atm m^3/mol	convert to Pa m^3/mol, multiply by	101325	8.21E-04	Pa m3/mol

Diffusion Coefficient in Air

Nicotine
Based on SR7 Section 2.4

	Answer	Units	Calcs		Parameter
Eqn 2-13	0.040682517	mol g-1	0.040682517		Mr
Eqn 2.15	0.00206915	Unitless	0.00206915		B'
Eqn 2.17	1.305846326	Unitless	1.305846326		T*
eqn 2.16	1.272115282	Unitless	1.272115282		Ω
eqn 2.14	**6.04995E-06**	**m2 s-1**	**6.05E-06**		**Da**
eqn 2.18	5.083014768	Å	5.083014768		δAB
	163.7	$cm^3\ mol^{-1}$	163.7		Vb

Parameters

	Units			
Mole Weight	g mol-1	162.231		
Boiling point	Kelvin	520.15	247	oC
Density	g cm3	1.00925		
tamb	Kelvin	283.15	10	oC
Molcular weight of air	g mol-1	28.97		
Vb	$cm^3\ mol^{-1}$	164		

C10 H14 N2	
C	16.5
H	1.98
N	5.69
ring	-20.2

Vb calculation source: Fuller, E.N., Schettler, P.D., and Giddings, J.C., A New Method for Prediction of Binary Gas-Phase Diffusion Coefficients, Ind. Eng. Chem., 58, 19-27 (1966). Cited in Lyman, W. J., Reehl, W.F., Rosenblatt, D, H., Handbook for Chemical Property Estimation Methods: Enviornemental Behaviour of Organic Compounds. American Chemical Society, Washington DC., 1990.

Diffusion Coefficient in Water

Based on equation in SR7 Section 2.5 EQN 2.20

Eqn 2.20

Nicotine	4.85E-10	m2/s

Koc Value Calculated from Kow Value

	Pesticides	Predominantly Hydrophobics	
	Eqn. 4	Eqn. 1	
Compound	**log Koc**	**log Koc**	**log Kow**
Nicotine	1.64	1.05	1.17

Henry's Law Constant

Contaminant	H' (H'=H/RT)	H
	(dimensionless)	(Pa m3 mol-1)
Nicotine	3.31E-07	8.21E-04

Annex 4: Modelling

CLEA Software Version 1.06

Report generated 05/11/2010

Report title Hauxton Nicotine modelling

Created by LM at Atkins

BASIC SETTINGS

Land Use Residential with homegrown produce

Building Small terraced house
Receptor Female (res) Start age class 1 End age class 6 Exposure Duration 6 years
Soil Sand

Exposure Pathways

Direct soil and dust ingestion	✓	Dermal contact with indoor dust	✓	Inhalation of indoor dust	✓
Consumption of homegrown produce	✓	Dermal contact with soil	✓	Inhalation of soil dust	✓
Soil attached to homegrown produce	✓			Inhalation of indoor vapour	✓
				Inhalation of outdoor vapour	✓

Land Use Residential with homegrown produce

Age Class	Exposure Frequencies (days yr^{-1})						Occupation Periods (hr day^{-1})		Soil to skin adherence factors (mg cm^2)		Direct soil ingestion rate (g day^{-1})
	Direct soil ingestion	Consumption of homegrown produce	Dermal contact with indoor dust	Dermal contact with soil	Inhalation of dust and vapour, indoor	Inhalation of dust and vapour, outdoor	Indoors	Outdoors	Indoor	Outdoor	
1	180	180	180	180	365	365	23.0	1.0	0.06	1.00	0.10
2	365	365	365	365	365	365	23.0	1.0	0.06	1.00	0.10
3	365	365	365	365	365	365	23.0	1.0	0.06	1.00	0.10
4	365	365	365	365	365	365	23.0	1.0	0.06	1.00	0.10
5	365	365	365	365	365	365	19.0	1.0	0.06	1.00	0.10
6	365	365	365	365	365	365	19.0	1.0	0.06	1.00	0.10
7	0	0	0	0	0	0	0.0	0.0	0.00	0.00	0.00
8	0	0	0	0	0	0	0.0	0.0	0.00	0.00	0.00
9	0	0	0	0	0	0	0.0	0.0	0.00	0.00	0.00
10	0	0	0	0	0	0	0.0	0.0	0.00	0.00	0.00
11	0	0	0	0	0	0	0.0	0.0	0.00	0.00	0.00
12	0	0	0	0	0	0	0.0	0.0	0.00	0.00	0.00
13	0	0	0	0	0	0	0.0	0.0	0.00	0.00	0.00
14	0	0	0	0	0	0	0.0	0.0	0.00	0.00	0.00
15	0	0	0	0	0	0	0.0	0.0	0.00	0.00	0.00
16	0	0	0	0	0	0	0.0	0.0	0.00	0.00	0.00
17	0	0	0	0	0	0	0.0	0.0	0.00	0.00	0.00
18	0	0	0	0	0	0	0.0	0.0	0.00	0.00	0.00

Environment Agency

Receptor Female (res)

Age Class	Body weight (kg)	Body height (m)	Inhalation rate (m^3 day^{-1})	Max exposed skin factor: Indoor (m^2 m^{-2})	Max exposed skin factor: Outdoor (m^2 m^{-2})	Total skin area (m^2)	Consumption rates (g FW kg^{-1} BW day^{-1}): Green vegetables	Root vegetables	Tuber vegetables	Herbaceous fruit	Shrub fruit	Tree fruit
1	5.60	0.7	8.5	0.32	0.26	3.43E-01	7.12	10.69	16.03	1.83	2.23	3.82
2	9.80	0.8	13.3	0.33	0.26	4.84E-01	6.85	3.30	5.46	3.96	0.54	11.96
3	12.70	0.9	12.7	0.32	0.25	5.82E-01	6.85	3.30	5.46	3.96	0.54	11.96
4	15.10	0.9	12.2	0.35	0.28	6.36E-01	6.85	3.30	5.46	3.96	0.54	11.96
5	16.90	1.0	12.2	0.35	0.28	7.04E-01	3.74	1.77	3.38	1.85	0.16	4.26
6	19.70	1.1	12.2	0.33	0.26	7.94E-01	3.74	1.77	3.38	1.85	0.16	4.26
7	22.10	1.2	12.4	0.22	0.15	8.73E-01	3.74	1.77	3.38	1.85	0.16	4.26
8	25.30	1.2	12.4	0.22	0.15	9.36E-01	3.74	1.77	3.38	1.85	0.16	4.26
9	27.50	1.3	12.4	0.22	0.15	1.01E+00	3.74	1.77	3.38	1.85	0.16	4.26
10	31.40	1.3	12.4	0.22	0.15	1.08E+00	3.74	1.77	3.38	1.85	0.16	4.26
11	35.70	1.4	12.4	0.22	0.14	1.19E+00	3.74	1.77	3.38	1.85	0.16	4.26
12	41.30	1.4	13.4	0.22	0.14	1.29E+00	3.74	1.77	3.38	1.85	0.16	4.26
13	47.20	1.5	13.4	0.22	0.14	1.42E+00	3.74	1.77	3.38	1.85	0.16	4.26
14	51.20	1.6	13.4	0.22	0.14	1.52E+00	3.74	1.77	3.38	1.85	0.16	4.26
15	56.70	1.6	13.4	0.21	0.14	1.60E+00	3.74	1.77	3.38	1.85	0.16	4.26
16	59.00	1.6	13.4	0.21	0.14	1.63E+00	3.74	1.77	3.38	1.85	0.16	4.26
17	70.00	1.6	14.8	0.33	0.27	1.78E+00	2.94	1.40	1.79	1.61	0.22	2.97
18	70.90	1.6	12.0	0.33	0.27	1.80E+00	2.94	1.40	1.79	1.61	0.22	2.97

Environment Agency

Building Small terraced house

Soil Sand

Building footprint (m^2)	2.80E+01
Living space air exchange rate (hr^{-1})	5.00E-01
Living space height (above ground, m)	4.80E+00
Living space height (below ground, m)	0.00E+00
Pressure difference (soil to enclosed space, Pa)	3.10E+00
Foundation thickness (m)	1.50E-01
Floor crack area (cm^2)	4.23E+02
Dust loading factor (µg m^{-3})	5.00E+01

Porosity, Total (cm^3 cm^{-3})	5.40E-01
Porosity, Air-Filled (cm^3 cm^{-3})	3.00E-01
Porosity, Water-Filled (cm^3 cm^{-3})	2.40E-01
Residual soil water content (cm^3 cm^{-3})	7.00E-02
Saturated hydraulic conductivity (cm s^{-1})	7.36E-03
van Genuchten shape parameter *m* (dimensionless)	3.51E-01
Bulk density (g cm^{-3})	1.18E+00
Threshold value of wind speed at 10m (m s^{-1})	7.20E+00
Empirical function (F_x) for dust model (dimensionless)	1.22E+00
Ambient soil temperature (K)	2.83E+02
Soil pH	7.00E+00
Soil Organic Matter content (%)	1.00E+00
Fraction of organic carbon (g g^{-1})	5.80E-03
Effective total fluid saturation (unitless)	3.62E-01
Intrinsic soil permeability (cm^2)	9.83E-08
Relative soil air permeability (unitless)	7.68E-01
Effective air permeability (cm^2)	7.54E-08

Environment Agency

Soil - Vapour Model

Depth to top of source (no building) (cm)	0
Depth to top of source (beneath building) (cm)	65
Default soil gas ingress rate?	**No**
Soil gas ingress rate ($cm^3\ s^{-1}$)	3.54E+01
Building ventilation rate ($cm^3\ s^{-1}$)	1.87E+04
Averaging time surface emissions (yr)	6
Finite vapour source model?	No
Thickness of contaminated layer (cm)	200

Air Dispersion Model

Mean annual windspeed at 10m ($m\ s^{-1}$)	5.00
Air dispersion factor at height of 0.8m *	2400.00
Air dispersion factor at height of 1.6m *	0.00
Fraction of site cover ($m^2\ m^{-2}$)	0.75

* Air dispersion factor in $g\ m^{-2}\ s^{-1}$ per $kg\ m^{-3}$

Soil - Plant Model

	Dry weight conversion factor	Homegrown fraction Average	Homegrown fraction High	Soil loading factor	Preparation correction factor
	$g\ DW\ g^{-1}\ FW$	dimensionless		$g\ g^{-1}\ DW$	dimensionless
Green vegetables	0.096	0.05	0.33	1.00E-03	2.00E-01
Root vegetables	0.103	0.06	0.40	1.00E-03	1.00E+00
Tuber vegetables	0.210	0.02	0.13	1.00E-03	1.00E+00
Herbaceous fruit	0.058	0.06	0.40	1.00E-03	6.00E-01
Shrub fruit	0.166	0.09	0.60	1.00E-03	6.00E-01
Tree fruit	0.157	0.04	0.27	1.00E-03	6.00E-01

Gardener type Average

CLEA Software Version 1.06

Report generated	05-Nov-10
Report title	Hauxton Nicotine modelling
Created by	LM at Atkins

RESULTS

Environment Agency

		Assessment Criterion (mg kg^{-1})			Ratio of ADE to HCV			Saturation Limit (mg kg^{-1})	50% rule?	
		oral	inhalation	combined	oral	inhalation	combined		Oral	Inhal
1										
2	Nicotine	9.17E-02	1.56E+02	9.16E-02	1.00	0.00	1.00	2.68E+05 (sol)	Yes	Yes
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4										
5										
6										
7										
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20										

Environment Agency

	Assessment Criterion (mg kg^{-1})			Ratio of ADE to HCV			Saturation Limit (mg kg^{-1})	50% rule?	
	oral	inhalation	combined	oral	inhalation	combined		Oral	Inhal
21									
22									
23									
24									
25									
26									
27									
28									
29									
30									

Environment Agency

		Soil Distribution				Media Concentrations													
		Sorbed	Dissolved	Vapour	Total	Soil	Soil gas	Indoor Dust	Outdoor dust at 0.8m	Outdoor dust at 1.6m	Indoor Vapour	Outdoor vapour at 0.8m	Outdoor vapour at 1.6m	Green vegetables	Root vegetables	Tuber vegetables	Herbaceous fruit	Shrub fruit	Tree fruit
		%	%	%	%	mg kg^{-1}	mg m^{-3}	mg kg^{-1}	mg m^{-3}	mg m^{-3}	mg m^{-3}	mg m^{-3}	mg m^{-3}	mg kg^{-1} FW	mg kg^{-1} FW	mg kg^{-1} FW	mg kg^{-1} FW	mg kg^{-1} FW	mg kg^{-1} FW
1																			
2	Nicotine	24.2	75.8	0.0	100.0	9.16E-02	1.13E-04	4.58E-02	3.90E-11	0.00E+00	2.24E-07	2.50E-08	0.00E+00	2.15E-01	1.43E+00	2.84E-01	0.00E+00	0.00E+00	4.16E-01
3																			
4																			
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18																			
19																			
20																			

Environment Agency

	Soil Distribution				Media Concentrations													
	Sorbed	Dissolved	Vapour	Total	Soil	Soil gas	Indoor Dust	Outdoor dust at 0.8m	Outdoor dust at 1.6m	Indoor Vapour	Outdoor vapour at 0.8m	Outdoor vapour at 1.6m	Green vegetables	Root vegetables	Tuber vegetables	Herbaceous fruit	Shrub fruit	Tree fruit
	%	%	%	%	mg kg^{-1}	mg m^{-3}	mg kg^{-1}	mg m^{-3}	mg m^{-3}	mg m^{-3}	mg m^{-3}	mg m^{-3}	mg kg^{-1} FW	mg kg^{-1} FW	mg kg^{-1} FW	mg kg^{-1} FW	mg kg^{-1} FW	mg kg^{-1} FW
21																		
22																		
23																		
24																		
25																		
26																		
27																		
28																		
29																		
30																		

Environment Agency

		Average Daily Exposure (mg kg^{-1} bw day^{-1})							Distribution by Pathway (%)							
		Direct soil ingestion	Consumption of homegrown produce and attached soil	Dermal contact with soil and dust	Inhalation of dust	Inhalation of vapour	Background (oral)	Background (inhalation)	Direct soil ingestion	Consumption of homegrown produce and attached soil	Dermal contact with soil and dust	Inhalation of dust	Inhalation of vapour (indoor)	Inhalation of vapour (outdoor)	Background (oral)	Background (inhalation)
1																
2	Nicotine	6.80E-07	4.82E-04	1.75E-06	2.16E-09	2.08E-07	3.15E-04	6.06E-04	0.08	60.28	0.22	0.00	0.03	0.00	39.37	0.03
3																
4																
5																
6																
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18																
19																
20																

Environment Agency

	Average Daily Exposure (mg kg^{-1} bw day^{-1})							Distribution by Pathway (%)							
	Direct soil ingestion	Consumption of homegrown produce and attached soil	Dermal contact with soil and dust	Inhalation of dust	Inhalation of vapour	Background (oral)	Background (inhalation)	Direct soil ingestion	Consumption of homegrown produce	Dermal contact with soil and dust	Inhalation of dust	Inhalation of vapour (indoor)	Inhalation of vapour (outdoor)	Background (oral)	Background (inhalation)
21															
22															
23															
24															
25															
26															
27															
28															
29															
30															

Environment Agency

		Oral Health Criteria Value (µg kg^{-1} BW day^{-1})		Inhalation Health Criteria Value (µg kg^{-1} BW day^{-1})		Oral Mean Daily Intake (µg day^{-1})	Inhalation Mean Daily Intake (µg day^{-1})	Air-water partition coefficient (K_{aw}) (cm^3 cm^{-3})	Coefficient of Diffusion in Air (m^2 s^{-1})	Coefficient of Diffusion in Water (m^2 s^{-1})	log K_{oc} (cm^3 g^{-1})	log K_{ow} (dimensionless)	Dermal Absorption Fraction (dimensionless)	Soil-to-dust transport factor (g g^{-1} DW)	Sub-surface soil to indoor air correction factor (dimensionless)	Relative bioavailability via soil ingestion (unitless)	Relative bioavailability via dust inhalation (unitless)
1																	
2	Nicotine	TDI	0.8	TDI	0.714	5.6	9.996	3.31E-07	6.05E-06	4.85E-10	1.05	1.17	0.5	0.5	1	1	1
3																	
4																	
5																	
6																	
7																	
8																	
9																	
10																	
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16																	
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Environment Agency

	Oral Health Criteria Value (µg kg^{-1} BW day^{-1})		Inhalation Health Criteria Value (µg kg^{-1} BW day^{-1})		Oral Mean Daily Intake (µg day^{-1})	Inhalation Mean Daily Intake (µg day^{-1})	Air-water partition coefficient (K_{aw}) (cm^3 cm^{-3})	Coefficient of Diffusion in Air (m^2 s^{-1})	Coefficient of Diffusion in Water (m^2 s^{-1})	log K_{oc} (cm^3 g^{-1})	log K_{ow} (dimensionless)	Dermal Absorption Fraction (dimensionless)	Soil-to-dust transport factor (g g^{-1} DW)	Sub-surface soil to indoor air correction factor (dimensionless)	Relative bioavailability via soil ingestion (unitless)	Relative bioavailability via dust inhalation (unitless)
21																
22																
23																
24																
25																
26																
27																
28																
29																
30																

Environment Agency

		Soil-to-water partition coefficient ($cm^3 g^{-1}$)	Vapour pressure (Pa)	Water solubility (mg L^{-1})	Soil-to-plant concentration factor for green vegetables (mg g^{-1} plant DW or FW basis over mg g^{-1} DW soil)	Soil-to-plant concentration factor for root vegetables (mg g^{-1} plant DW or FW basis over mg g^{-1} DW soil)	Soil-to-plant concentration factor for tuber vegetables (mg g^{-1} plant DW or FW basis over mg g^{-1} DW soil)	Soil-to-plant concentration factor for herbaceous fruit (mg g^{-1} plant DW or FW basis over mg g^{-1} DW soil)	Soil-to-plant concentration factor for shrub fruit (mg g^{-1} plant DW or FW basis over mg g^{-1} DW soil)	Soil-to-plant concentration factor for tree fruit (mg g^{-1} plant DW or FW basis over mg g^{-1} DW soil)
1										
2	Nicotine	6.51E-02	6.00E+00	1.00E+06	model	model	model	model	model	model
3										
4										
5										
6										
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12										
13										
14										
15										
16										
17										
18										
19										
20										

Environment Agency

	Soil-to-water partition coefficient ($cm^3\ g^{-1}$)	Vapour pressure (Pa)	Water solubility ($mg\ L^{-1}$)	Soil-to-plant concentration factor for green vegetables (mg g^{-1} plant DW or FW basis over mg g^{-1} DW soil)	Soil-to-plant concentration factor for root vegetables (mg g^{-1} plant DW or FW basis over mg g^{-1} DW soil)	Soil-to-plant concentration factor for tuber vegetables (mg g^{-1} plant DW or FW basis over mg g^{-1} DW soil)	Soil-to-plant concentration factor for herbaceous fruit (mg g^{-1} plant DW or FW basis over mg g^{-1} DW soil)	Soil-to-plant concentration factor for shrub fruit (mg g^{-1} plant DW or FW basis over mg g^{-1} DW soil)	Soil-to-plant concentration factor for tree fruit (mg g^{-1} plant DW or FW basis over mg g^{-1} DW soil)
21									
22									
23									
24									
25									
26									
27									
28									
29									
30									