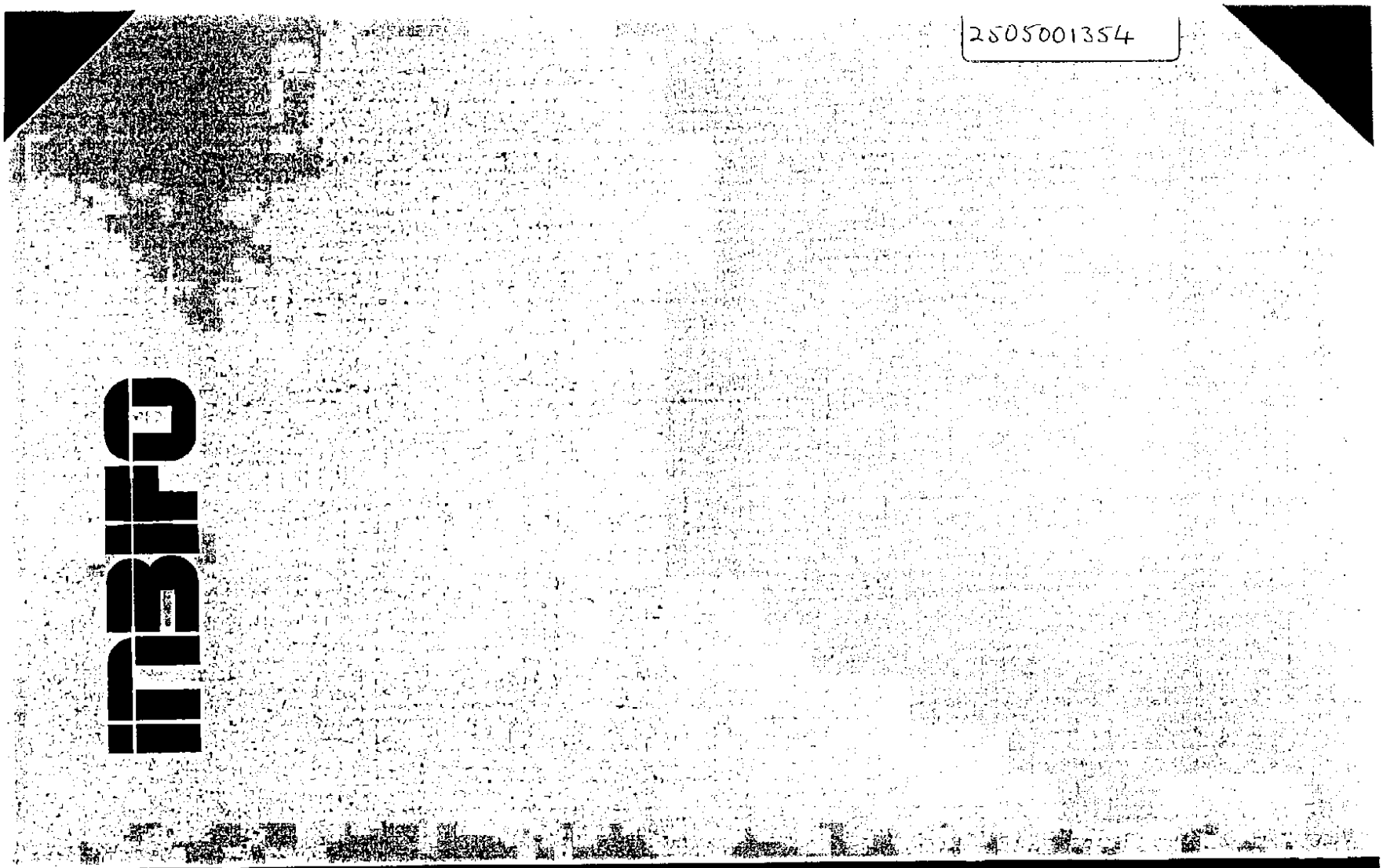

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INBIFO Institut für biologische Forschung GmbH

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Philip Morris U.S.A.
Research Center
Richmond, VA

13 Oct.2000
RST/MHA

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REPORT P 0500/3362

Chemical Analysis of Mainstream Smoke from HYDRA Cigarettes with and without AMP in the Cigarette Overwrap and from the 1R4F

Project HYDRA Series I (9575-18)

2505001354 E3

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1 Abstract

The objective of this study was to determine the influence of ammonium magnesium phosphate (AMP) in the cigarette overwrap on the composition of mainstream smoke (MS) by comparing research cigarettes from the project HYDRA series I (9575-18). MS from HYDRA cigarettes was also compared to that of the Reference Cigarette 1R4F which was investigated in parallel.

The cigarettes were conditioned following ISO standard 3402 (1991). The MS was generated in basic conformity with ISO standard 3308 (1991). The HYDRA cigarettes were smoked on a modified 30-port INBIFO smoking machine, type H2000, with modified F-series lighters (9575-6).

Compared with the 1R4F, MS yields for the HYDRA cigarettes (i.e., HYDRA-ST, with standard overwrap; and HYDRA-AMP, with AMP in the overwrap) were statistically significantly lower by 31 to 99 % for most constituents, except for water and formaldehyde. Water was 1.6 times higher for the HYDRA-ST and 1.8 times for the HYDRA-AMP. Formaldehyde was 4.6 times higher for the HYDRA-ST and not statistically different for the HYDRA-AMP.

A comparison of the 2 HYDRA cigarettes revealed the influence of the AMP overwrap through a decrease in almost all of the analytes, even though TPM and "tar" yields were similar. The decrease ranged from 10 % (acrolein) to 80 % (formaldehyde). The only analyte that was statistically significantly higher was 2-nitropropane, which was 22 % higher in MS from the HYDRA-AMP with a standard deviation of 16 % (propagation of error).

When the results for the HYDRA cigarettes were compared to the 1R4F on an equal TPM basis, the differences were smaller for most constituents than the differences on a per cigarette basis. This is due to the lower TPM yields (approximately 2 times lower) for the HYDRA cigarettes compared to the 1R4F. For the HYDRA-AMP compared to the 1R4F, several statistically significant differences were seen: 28 constituents were lower, and water and 2-nitropropane were higher. There were no statistically significant differences in either formaldehyde or acrolein for the HYDRA cigarettes compared to the 1R4F.

When the results for the 2 HYDRA cigarettes were compared on an equal TPM basis, the HYDRA cigarette with the AMP overwrap showed lower amounts for almost all of those smoke constituents classified as carcinogenic/irritating smoke constituents.

2 Objective

The objective of this study was to determine the influence of ammonium magnesium phosphate (AMP) in the cigarette overwrap on the composition of mainstream smoke (MS) by comparing research cigarettes from the project HYDRA series I (9575-18). MS from HYDRA cigarettes was also compared to that of the Reference Cigarette 1R4F, which was investigated in parallel.

3 Test Substance

The HYDRA cigarettes, approximately 220,000 per type, were provided by PM Richmond, VA, U.S.A. packed in cartons that hold approximately 4,000 cigarettes each. Each HYDRA cigarette type has 2 different rod print codes (**Table 1**), and an equal number of each were used for the generation of each individual sample. The cigarettes were received on 26 Feb.2000 (PM Richmond analytical data: **Table 2** and PM Richmond cigarette data: **Table 3**, fax dated 15 Mar.2000).

Code			Overwrap Paper [a]	Cigarette Short Name [b]	INBIFO Code
Cigarette	Rod Print	Lighter			
9575-1	A01, A02	9575-6	10-078A	HYDRA-ST (standard overwrap; control)	K1290
9575-2	A06, A07	9575-6	F1666 (AMP 30 %)	HYDRA-AMP (AMP overwrap)	K1291
1R4F	1R4F	-	-	1R4F	K1262

Table 1 Cigarette and Lighter Type, Supplier's Specification

All determinations were also performed on MS from the Reference Cigarette 1R4F [c] (for specifications see Tobacco and Health Research Institute, University of Kentucky, 1990).

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[a] supplier's specification dated 15 Mar.2000
[b] Cigarettes are also referred to in this report by their short name.
[c] manufactured in 1983

DATE: March 2, 2000

TO: Sue Wrenn, Gerry Nixon, and Kathy Fox

SUBJECT: Total Particulate Matter (TPM), and Whole Smoke for Inbifo Cigarettes

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The following data was collected using four inch puff sensor lighters with a cupped post and the peek simplified heater swoop design. The lighters were preheated twice for preheat of two cycles for two seconds. The cigarette samples used in smoking were 9575-1 and 9575-2.

TPM Data: (All values for TPM are in mg /cigarette)

Sample	TPM	Tar	Nicotine	Water
9575-1, average	6.03	2.55	0.21	3.27
9575-1, standard deviation	0.15	0.12	0.01	0.28
9575-2 , average	5.41	2.40	0.16	2.84
9575-2 , standard deviation	0.13	0.09	0.01	0.04

Whole Smoke Data: (All values for Whole Smoke are in ug /cigarette)

Sample	Formaldehyde	Acetaldehyde	Acrolein
9575-1, average	54.29	170.41	18.13
9575-1, standard deviation	5.44	14.95	2.63
9575-2 , average	9.33	98.26	19.11
9575-2 , standard deviation	2.14	8.92	3.28

All cigarette production and physical data is located in the series I design history file entitled Inbifo Inhalation Study.

Table 2 Analytical Data Provided by PM Richmond

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2000 INBIFO QA

	9575-1 Standard Overwrap		9575-2 AMP Overwrap	
	Average	St. Dev.	Avg.	St. Dev.
N=60, both samples				
ROD CIRC.	24.7	0.2	24.6	0.2
BITE CIRC.	24.8	0.1	24.7	0.1
STD. RTD	29	2	30	3
ENCAP. RTD	34	3	35	4
SYSTEM RTD	76	5	78	5
CIGT. LENGTH	68.1	0.1	68.1	0.2
TOBACCO LEN.	17.6	0.5	17.8	0.5
CAVITY LEN.	7.1	0.4	7.1	0.6
HAT LEN.	6.7	0.6	6.8	0.7
MP HOLLOW LEN.	28.3	0.7	28.7	0.6
MP SOLID LEN.	7.8	0.7	7.6	0.5
DAPTC POSITION	6.9	1.2	7.1	1.2
LASER POSITION	11.3	0.3	11.3	0.4

All length measurements in mm.

Table 3 Cigarette Data Provided by PM Richmond

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The cigarettes types are distinguishable by their rod print code. Determinations to confirm the composition of the blend and the uniformity and stability of the research cigarettes were not performed for reasons of feasibility.

As far as Good Laboratory Practice (GLP) requirements are concerned, the cigarettes that were used to generate MS samples for the required analyses are considered test substances. The reference substances for the analytes are the pure compounds, their derivatives, or solutions.

4 Experimental Conditions

The study was conducted in compliance with GLP principles (Grundsätze der Guten Laborpraxis, 1994).

4.1 Sample Generation

The cigarettes were conditioned following ISO standard 3402 (1991). Mainstream smoke was generated in basic conformity with ISO standard 3308 (1991), some deviations (e.g., rectangular puff profile, free smoking; for the HYDRA cigarettes: fixed 8 puffs/cigarette) being necessary for technical reasons. The HYDRA cigarettes were smoked on a modified 30-port INBIFO smoking machine, type H2000.

The smoking machine was equipped with 30 modified F-series lighters (9575-6). The lighters were modified by adding a sealing cup to the heater connector and enabling both remote initiation of product ID and remote puff triggering. The puff sensor gasket was removed and the sensor hole in the heater cartridge was sealed. Preheating was initiated twice after insertion of a new cigarette prior to the first puff. A 4-piston pump (Battelle type) was used for puff generation.

Lighters and heater cartridges were identified by individual serial numbers. Heater cartridges were cleaned in ethanol/water by sonication before each day's sample generation. Lighters were operated in a multi-phase heating mode (**Table 4**). The resistance to draw of each lighter and heater cartridge assembly with a cigarette inserted was between 600 and 1200 Pa.

Phase Number	Phase Length (s)	Phase Energy (J)	Power During the Phase (W)
1a	0.25	5.17	20.67
1b	0.25	4.89	19.53
1c	0.25	4.78	19.14
2a	0.4	3.16	7.90
2b	0.8	5.79	7.24
total	1.95	23.78	-

Table 4 Energy Profile for F-Series Lighters [a]

Lighter displays were inspected during smoking, and cigarettes were inspected after smoking to identify defective heater blades.

The Reference Cigarette 1R4F was smoked on a conventional 30-port INBIFO smoking machine, type SM85.

The analytes determined in the MS, the number of determinations, and the type of sample collection are given in **Table 5** and **Table 6**.

4.2 Methods

Total particulate matter (TPM) was determined gravimetrically from glass fiber filters used for sample collection. Nicotine was determined by capillary gas chromatography (CGC) with a nitrogen phosphorous detector (NPD) from a 2-propanol extract from the TPM filter. The samples were evaluated using isoquinoline as the internal standard for nicotine. Water was determined from the same 2-propanol extract by Karl Fischer titration. For the 1R4F, the puff count was counted from at least 10 cigarettes; for the HYDRA cigarettes, the puff count was fixed at 8 puffs per cigarette.

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[a] according to supplier's specifications (F-Series Final Specification, Rev. 8.03, rev. date: 29 Apr.1999)

Analyte Class	Individual Analytes
FTC parameters	TPM
	"tar" [a]
	nicotine
	water
	carbon monoxide
aliphatic hydrocarbons	1,3-butadiene
	isoprene
aldehydes	formaldehyde
	acetaldehyde
	acrolein
	propionaldehyde
aliphatic nitrogen compounds	acrylonitrile
	hydrogen cyanide
	2-nitropropane
aromatic amines	o-toluidine
	o-anisidine
	2-naphthylamine
	4-aminobiphenyl (4-ABP)
halogen compounds	vinyl chloride
inorganic compounds	nitrogen oxides
monocyclic aromatic hydrocarbons	benzene
	toluene

Table 5 Analytes Determined

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[a] calculated as TPM minus nicotine minus water

Analyte Class	Individual Analytes
N-nitrosamines	N-nitrosodimethylamine (NDMA) N-nitrosomethylethylamine (NMEA) N-nitrosodiethylamine (NDEA) N-nitrosodi-n-propylamine (NPRA) N-nitrosodi-n-butylamine (NBUA) N-nitrosopyrrolidine (NPY) N-nitrosopiperidine (NPI) N'-nitrosonornicotine (NNN) 4-(N-methyl-N-nitrosamino)-1,-(3-pyridyl)-1-butanone (NNK) N-nitrosodiethanolamine (NDELA)
phenols	phenol catechol
polycyclic aza-arenes	dibenz(a,h)acridine dibenz(a,j)acridine
polycyclic aromatic hydrocarbons	benzo(a)anthracene benzo(b)-fluoranthene benzo(j)-fluoranthene benzo(k)-fluoranthene benzo(a)pyrene dibenz(a,h)anthracene dibenz(a,e)pyrene dibenz(a,h) pyrene dibenz(a,i) pyrene dibenz(a,l) pyrene indeno(1,2,3-cd)pyrene 5-methyl chrysene

Table 5 (cont.) Analytes Determined

Analyte/ Analyte Class [a]	Number of Determinations per Cigarette Type	Number of Cigarettes per Determination		Sample Collection Method		
		HYDRA	1R4F	Glass Fiber Filter	Liquid Trap	Solid Trap
TPM, nicotine [b], water [b]	4	20	10	+	-	-
aldehydes	10	2	4	-	+	-
acrylonitrile [c], aliphatic hydrocarbons [c], monocyclic aromatic hydrocarbons [c], vinyl chloride [c]	4	20	10	-	+	-
hydrogen cyanide	4	20	10	-	+	-
2-nitropropane	4	20	20	-	-	+
N-nitrosamines	4	30	20	+	+	-
N-nitroso-diethanolamine	4	30	20	+	+	-
polycyclic aromatic hydrocarbons and polycyclic aza-arenes	4	20	10	+	-	-
phenols	4	20	10	+	+/- [d]	-
aromatic amines	4/5 [e]	15	4	+	-	-
carbon monoxide [f], nitrogen oxides [f]	4/10 [g]	5	1	-	-	-

Table 6 Analytical Sample Collection

[a] see Table 5 for details
[b] determination from the filter used for TPM collection
[c] determination from the same sample
[d] filter and wash bottle only for the HYDRA cigarettes
[e] 4 determinations for the HYDRA cigarettes and 5 for the 1R4F
[f] simultaneous on-line determination
[g] 4 determinations for the HYDRA cigarettes and 10 for the 1R4F

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Aldehydes were trapped in 2 wash bottles connected in series, both filled with 20 ml of a solution of 2,4-dinitrophenylhydrazine (DNPH) in acetonitrile. The DNPH derivatives were determined by reversed phase chromatography (RPC) and UV detection at 365 nm using the external standard method.

The dienes, 1,3-butadiene and isoprene, and the aromatics, benzene and toluene, vinyl chloride, and acrylonitrile were trapped in 3 microimpingers connected in series, each filled with 6 to 7 ml of methanol at -78 °C. An aliquot of the combined trapping solutions was analyzed by CGC with a mass selective detector (MSD) using benzene-d_6 as the internal standard.

Hydrogen cyanide was trapped in 2 wash bottles connected in series, each containing 40 ml of sodium hydroxide solution. The determination was performed by headspace CGC/NPD after acidification of the samples. For the evaluation, the external standard method was used.

For the determination of 2-nitropropane, MS was trapped on a silica cartridge. After elution, 2-nitropropane was determined by CGC with a thermal energy analyzer (TEA) using 2-methyl-2-nitropropane as the internal standard.

N-Nitrosamines were trapped in 2 wash bottles, each containing 100 ml of citrate/phosphate buffer with ascorbic acid, and on a glass fiber filter, all connected in series. The buffer solution and the glass fiber filter were extracted with dichloromethane, and the combined extracts were washed with sodium hydroxide solution. The sample was then concentrated in a Kuderna Danish concentrator and cleaned on an alumina column. The concentrated eluate of the alumina column was analyzed by CGC with a TEA using 2 different columns for the volatile and tobacco-specific nitrosamines using N-nitroso-N-methyl-(3-picolyl)-amine (NMPA) and N-nitrosodihexylamine (NDHA) as internal standards.

N-Nitrosodiethanolamine (NDELA) was trapped in 2 wash bottles, each containing 30 ml of ethyl acetate, an empty wash bottle at -78 °C, and a glass fiber filter, all connected in series. After extraction from the filter with ethyl acetate, filtration, and addition of the internal standard NDHA, the combined ethyl acetate solutions were concentrated and cleaned up by solid phase extraction (SPE). The eluate of the SPE column was concentrated to dryness and redissolved in acetonitrile. An aliquot of the acetonitrile solution was derivatized using N,O-*bis*(trimethylsilyl)trifluoroacetamide (BSTFA). The NDELA derivative was analyzed by CGC with a TEA.

Polycyclic aromatic hydrocarbons (PAHs) and polycyclic aza-arenes were extracted from a TPM-loaded glass fiber filter with methanol/water followed by back-extraction with n-hexane/toluene. The concentrated extracts were cleaned up by SPE. The concentrated eluate of the SPE column was analyzed by GC/MSD and evaluated using multiple internal standards.

Phenol and catechol were extracted with trichloromethane from a TPM-loaded glass fiber filter. An aliquot of the extract and the added internal standards, phenol-d_6 and catechol-d_6, was derivatized with BSTFA, resulting in the formation of trimethylsilyl ethers of the phenols. The derivatives were analyzed by CGC/MSD. For the HYDRA cigarettes, a wash bottle containing 15 ml acetone and the internal standards were placed behind the glass fiber filter. The solution was derivatized and analyzed separately.

The aromatic amines, o-toluidine, o-anisidine, 2-naphthylamine, and 4-aminobiphenyl, were extracted from a TPM-loaded glass fiber filter with hydrochloric acid followed by back-extraction with n-hexane after alkalization. After addition of the internal standards, o-toluidine-d_9, p-toluidine-d_9, 2-naphthylamine-d_7, and 4-aminobiphenyl-d_9, the sample was derivatized with perfluoropropionic anhydride (PFPA) and analyzed by CGC tandem mass spectrometry in the neutral loss scan mode to determine the aromatic amines via loss of hydrogen fluoride from their PFPA derivatives. Quantification was based on the standard addition method.

Carbon monoxide was determined by nondispersive infrared photometry. The nitrogen oxides were determined by chemiluminescence after reduction to nitrogen oxide and reaction with ozone. For calibration, certified reference gases were used.

5 Statistics and Evaluation

The results were expressed as yields on a per cigarette basis and as amounts on an equal "tar" basis and on an equal TPM basis.

The quantification limits on a per cigarette basis reported in this study are those determined in the process of method validation as signal-to-noise ratios (10 : 1). Quantification limits on an equal "tar" basis and on an equal TPM basis were calculated from these quantification limits. Detection limits are one third the quantification limit.

As descriptive statistics, the number of values, the arithmetic mean, and the standard deviation were given. For samples including at least 1 measured value below the quantification limit, only the median or the quantification limit was given, depending on whether the median is above or below the quantification limit. The ratio between 2 cigarette types was only calculated if the mean value or a median above the quantification limit was available for both cigarettes; SD of the ratio was only given if a mean value with SD was available for both cigarette types. For subsequent evaluation, values below the quantification limit were treated as zero.

The one-way analysis of variance (ANOVA) was used to compare the yields of all cigarettes on a per cigarette basis as well as the amounts on an equal "tar" basis and an equal TPM basis. When the overall comparison revealed a significant difference between the cigarettes, the Tukey test (Zar, 1984) was applied for pairwise comparison between the HYDRA-ST and the HYDRA-AMP and between each HYDRA cigarette and the 1R4F. For those parameters with at least 1 data value below the quantification limit, the Kruskal-Wallis H-test was used for the overall comparisons, and the pairwise comparison was performed according to Dunn (Zar, 1984).

Due to the insensitivity of the pairwise test of the HYDRA cigarettes after a multi-group test together with the 1R4F (large variance inhomogenicity), a separate t-test was performed for the comparison of the 2 HYDRA cigarettes. For those parameters with at least 1 data value below the quantification limit, the Mann-Whitney U-test was used instead (Mann and Whitney, 1947).

All tests were conducted at the level of significance of $\alpha = 0.05$, $\alpha = 0.01$, and $\alpha = 0.001$ (2-tailed). No adjustment for multiple testing was made. Results were considered statistically significant at $p \leq 0.05$.

Results obtained for the 1R4F were compared to historical 1R4F data.

6 Results

6.1 Results on a per Cigarette Basis

The results expressed as yields on a per cigarette basis are given in **Table 7.** Both HYDRA cigarettes (i.e., HYDRA-ST, with standard overwrap; and HYDRA-AMP, with AMP in the overwrap) delivered approximately 6 mg TPM per cigarette, which is in accordance with the data from PM Richmond (**Table 2**), although the PM data listed a slightly lower TPM yield for the HYDRA-AMP (5.4 mg/cig.). In both data sets, there were no differences between the two HYDRA cigarettes in the yields of "tar"; however, the yields of nicotine, formaldehyde, and acetaldehyde were lower in MS from the HYDRA-AMP compared to the HYDRA-ST.

Compared with the 1R4F (**Table 8**), MS yields for the HYDRA cigarettes were statistically significantly lower by 31 to 99 % for most constituents, except for water and formaldehyde. Water was 1.6 times higher for the HYDRA-ST and 1.8 times for the HYDRA-AMP. Formaldehyde was 4.6 times higher for the HYDRA-ST and not statistically different for the HYDRA-AMP. All volatile N-nitrosamines, some PAHs, and the aza-arenes were below the quantification limit for all 3 cigarettes; while NDELA, some PAHs, vinyl chloride, o-anisidine, and 4-aminobiphenyl were only below the quantification limit for the HYDRA cigarettes.

A comparison of the 2 HYDRA cigarettes (**Table 9**) revealed the influence of the AMP overwrap through a decrease in almost all of the analytes, even though TPM and "tar" yields were similar. The decrease ranged from 10 % (acrolein) to 80 % (formaldehyde). All volatile N-nitrosamines, NDELA, aza-arenes, most of the PAHs, o-anisidine, 4-aminobiphenyl, and vinyl chloride were below the quantification limit for both HYDRA cigarettes. The only analyte that was statistically significantly higher was 2-nitropropane, which was 22 % higher in MS from the HYDRA-AMP with a standard deviation of 16 % (propagation of error).

6.2 Results on an Equal TPM Basis

The results expressed on an equal TPM basis are given in **Table 10.**

When the results for the HYDRA cigarettes were compared to the 1R4F on an equal TPM basis (**Table 11**), the differences were smaller for most constituents than the differences on a per cigarette basis. This is due to the lower TPM yields (approximately 2 times lower) for the HYDRA cigarettes compared to the 1R4F. For the HYDRA-AMP compared to the 1R4F, several statistically significant differences were seen: 28 constituents were lower, and water and 2-nitropropane were higher. There were no statistically significant differences in either formaldehyde or acrolein for the HYDRA cigarettes compared to the 1R4F.

When the results for the 2 HYDRA cigarettes were compared on an equal TPM basis (**Table 12, Figure 1**), almost all the constituents above the quantification limit were statistically significantly lower for the HYDRA-AMP; however, no statistically significant differences were seen for "tar" or 2-nitropropane. There was a reduction of almost all carcinogenic/irritating smoke constituents on an equal TPM basis – especially an 80 % reduction in formaldehyde.

6.3 Results on an Equal "Tar" Basis

The results on an equal "tar" basis are given in **Table 13.**

On an equal "tar" basis, 4 analytes were statistically significantly higher in MS from the HYDRA-AMP compared to the 1R4F: TPM, water, acrolein, and 2-nitropropane (**Table 14**); while 26 analytes were statistically significantly lower. Of the latter, some, e.g., vinyl chloride, were only quantifiable in 1R4F-MS.

On an equal "tar" basis, the analytes determined were similar or even lower in amount for the HYDRA-AMP compared to the HYDRA-ST (**Table 15**).

6.4 Comparison with Historical 1R4F Data

All yields found in the present study for the 1R4F were within the 95 % confidence limit of the historical data (**Table 16**).

7 Tables and Figures

PARAMETER	UNIT	HYDRA-ST			HYDRA-AMP		
		M	SD	N	M	SD	N
FTC parameters:							
puff count	-	8.00	0.00	4	8.00	0.00	4
TPM	mg/cig.	5.65	0.36	4	5.90	0.27	4
"tar"	"	3.08	0.20	4	3.14	0.15	4
nicotine	"	0.305	0.005	4	0.268	0.014	4
water	"	2.27	0.18	4	2.49	0.13	4
carbon monoxide	"	0.710	0.019	4	0.414	0.017	4
Aliphatic hydrocarbons:							
1,3-butadiene	ug/cig.	5.73	0.29	4	2.96	0.14	4
isoprene	"	80.2	3.1	4	54.9	4.1	4
Aldehydes:							
formaldehyde	ug/cig.	54.1	10.2	10	10.7	2.0	8
acetaldehyde	"	255	21	10	157	10	8
acrolein	"	30.6	2.0	10	27.5	1.7	8
propionaldehyde	"	17.3	2.0	10	9.2	0.9	8
Aliphatic nitrogen compounds:							
acrylonitrile	ug/cig.	1.44	0.08	4	0.79	0.05	4
hydrogen cyanide	"	4.42	0.46	4	3.64	0.15	4
2-nitropropane	ng/cig.	7.87	0.50	4	9.61	1.07	4
Aromatic amines:							
o-toluidine	ng/cig.	1.29	0.01	4	0.86	0.06	4
o-anisidine	" <	0.200	*	4 <	0.200	*	4
2-naphthylamine	"	0.118	0.003	4	0.099	0.004	4
4-aminobiphenyl	" <	0.113	*	4 <	0.113	*	4
Halogen compounds:							
vinyl chloride	ng/cig. <	12.4	*	4 <	12.4	*	4
Inorganic compounds:							
nitrogen oxides	ug/cig.	40.8	1.7	4	27.3	1.1	4
Monocyclic aromatic hydrocarbons:							
benzene	ug/cig.	3.35	0.13	4	2.06	0.11	4
toluene	"	7.41	0.37	4	4.32	0.30	4

Table 7 YIELDS ON CIGARETTE BASIS

Remarks: N is the number of determinations.
*: at least 1 single value below QL, therefore, the median and no SD given

2000/09/06 08:59:47 P. 1 USER_DISK:[AC]YLD1_CIG_3362.LIS;18

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PARAMETER	UNIT	1R4F		
		M	SD	N
FTC parameters:				
puff count	-	9.30	0.08	4
TPM	mg/cig.	11.3	0.5	4
"tar"	"	9.13	0.39	4
nicotine	"	0.817	0.036	4
water	"	1.38	0.09	4
carbon monoxide	"	11.2	1.0	10
Aliphatic hydrocarbons:				
1,3-butadiene	ug/cig.	43.0	3.2	4
isoprene	"	419	14	4
Aldehydes:				
formaldehyde	ug/cig.	11.7	1.1	8
acetaldehyde	"	615	39	8
acrolein	"	58.4	3.6	8
propionaldehyde	"	54.0	3.5	8
Aliphatic nitrogen compounds:				
acrylonitrile	ug/cig.	11.6	0.6	4
hydrogen cyanide	"	96.0	3.9	4
2-nitropropane	ng/cig.	14.0	0.7	4
Aromatic amines:				
o-toluidine	ng/cig.	42.5	2.0	5
o-anisidine	"	2.13	0.28	5
2-naphthylamine	"	5.24	0.34	5
4-aminobiphenyl	"	1.12	0.09	5
Halogen compounds:				
vinyl chloride	ng/cig.	35.3	2.2	4
Inorganic compounds:				
nitrogen oxides	ug/cig.	362	29	10
Monocyclic aromatic hydrocarbons:				
benzene	ug/cig.	47.5	2.5	4
toluene	"	86.5	8.3	4

Table 7 (cont.) YIELDS ON CIGARETTE BASIS

Remarks: N is the number of determinations.

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2000/08/25 12:42:02 P. 1 USER_DISK:[AC]YLD1_CIGR_3362.LIS;11

PARAMETER		HYDRA-ST M	SD	N		HYDRA-AMP M	SD	N
N-nitrosamines (ng/cig.):								
NDMA	<	5.00	*	4	<	5.00	*	4
NMEA	<	10.0	*	4	<	10.0	*	4
NDEA	<	7.00	*	4	<	7.00	*	4
NPRA	<	11.0	*	4	<	11.0	*	4
NBUA	<	9.00	*	4	<	9.00	*	4
NPY	<	7.00	*	4	<	7.00	*	4
NPI	<	8.00	*	4	<	8.00	*	4
NNN		22.3	0.5	4		17.6	3.0	4
NNK		14.1	0.5	4	<	12.0	*	4
NDELA	<	10.5	*	4	<	10.5	*	4
Phenols (ug/cig.):								
phenol		0.119	0.01	4		0.081	0.01	4
catechol		6.52	0.46	4		5.03	0.13	4
Polycyclic aza-arenes (ng/cig.):								
dibenz(a,h)acridine	<	0.620	*	4	<	0.620	*	4
dibenz(a,j)acridine	<	0.600	*	4	<	0.600	*	4
Polycyclic aromatic hydrocarbons (ng/cig.):								
benz(a)anthracene		0.665	0.05	4		0.290	0.01	4
benzo(b)fluoranthene		0.308	0.00	4	<	0.230	*	4
benzo(k)fluoranthene	<	0.120	*	4	<	0.120	*	4
benzo(j)fluoranthene	<	0.200	*	4	<	0.200	*	4
benzo(a)pyrene		0.515	0.02	4		0.248	0.02	4
indeno(1,2,3-cd)pyrene		0.165	0.01	4	<	0.130	*	4
dibenz(a,h)anthracene	<	0.130	*	4	<	0.130	*	4
dibenz(a,l)pyrene	<	0.260	*	4	<	0.260	*	4
dibenz(a,e)pyrene	<	0.290	*	4	<	0.290	*	4
dibenz(a,i)pyrene	<	0.340	*	4	<	0.340	*	4
dibenz(a,h)pyrene	<	0.430	*	4	<	0.430	*	4
5-methylchrysene	<	1.70	*	4	<	1.70	*	4

Table 7 (cont.) YIELDS ON CIGARETTE BASIS

Remarks: N is the number of determinations.
*: at least 1 single value below QL,
therefore, the median and no SD given

2505001374

PARAMETER		1R4F M	SD	N
N-nitrosamines (ng/cig.):				
NDMA	<	5.00	*	4
NMEA	<	10.0	*	4
NDEA	<	7.00	*	4
NPRA	<	11.0	*	4
NBUA	<	9.00	*	4
NPY	<	7.00	*	4
NPI	<	8.00	*	4
NNN		77.9	4.2	4
NNK		73.5	3.3	4
NDELA		16.4	*	4
Phenols (ug/cig.):				
phenol		11.1	0.4	4
catechol		47.4	2.1	4
Polycyclic aza-arenes (ng/cig.):				
dibenz(a,h)acridine	<	6.70	*	4
dibenz(a,j)acridine	<	2.72	*	4
Polycyclic aromatic hydrocarbons (ng/cig.):				
benz(a)anthracene		10.7	0.2	4
benzo(b)fluoranthene		3.89	0.32	4
benzo(k)fluoranthene	<	1.30	*	4
benzo(j)fluoranthene		2.22	0.21	4
benzo(a)pyrene		5.84	0.45	4
indeno(1,2,3-cd)pyrene		2.75	0.15	4
dibenz(a,h)anthracene	<	0.60	*	4
dibenz(a,l)pyrene	<	1.10	*	4
dibenz(a,e)pyrene		0.935	*	4
dibenz(a,i)pyrene		1.83	0.47	4
dibenz(a,h)pyrene		1.65	0.44	4
5-methylchrysene	<	7.60	*	4

Table 7 (cont.) YIELDS ON CIGARETTE BASIS

Remarks: N is the number of determinations.
*: at least 1 single value below QL,
therefore, the median and no SD given

2505001375

PARAMETER	HYDRA-AMP VERSUS HYDRA-ST			HYDRA-AMP VERSUS 1R4F			HYDRA-ST VERSUS 1R4F		
	RATIO (%)	SD	SIG.	RATIO (%)	SD	SIG.	RATIO (%)	SD	SIG.
FTC parameters:									
TPM	104	8	=	52	3	+++	50	4	+++
"tar"	102	8	=	34	2	+++	34	3	+++
nicotine	88	5	=	33	2	+++	37	2	+++
water	110	10	=	180	16	+++	164	17	+++
carbon monoxide	58	3	=	4	0	+++	6	1	+++
Aliphatic hydrocarbons:									
1,3-butadiene	52	4	=	7	1	+++	13	1	+++
isoprene	68	6	++	13	1	+++	19	1	+++
Aldehydes:									
formaldehyde	20	5	+++	91	19	=	462	97	+++
acetaldehyde	62	7	+++	26	2	+++	41	4	+++
acrolein	90	8	+	47	4	+++	52	5	+++
propionaldehyde	53	8	+++	17	2	+++	32	4	+++
Aliphatic nitrogen compounds:									
acrylonitrile	55	5	=	7	1	+++	12	1	+++
hydrogen cyanide	82	9	=	4	0	+++	5	1	+++
2-nitropropane	122	16	+	69	8	+++	56	5	+++
Aromatic amines:									
o-toluidine	67	5	=	2	0	+++	3	0	+++
o-anisidine	*	-	=	*	-	+	*	-	+
2-naphthylamine	84	4	=	2	0	+++	2	0	+++
4-aminobiphenyl	*	-	=	*	-	+	*	-	+
Halogen compounds:									
vinyl chloride	*	-	=	*	-	+	*	-	+
Inorganic compounds:									
nitrogen oxides	67	4	=	8	1	+++	11	1	+++
Monocyclic aromatic hydrocarbons:									
benzene	61	4	=	4	0	+++	7	0	+++
toluene	58	5	=	5	1	+++	9	1	+++

Table 8 RELATIVE YIELDS ON CIGARETTE BASIS

Remarks: analysis of variance followed by Tukey test
* : at least 1 median <QL, therefore, no ratio and SD given; Kruskal-Wallis followed by Dunn test with single values <QL set to zero

2505001376

M 2000/09/06 08:02:24 P. 1 USER_DISK:[AC]YLD1CIGTUK_3362.LIS;8

PARAMETER	HYDRA-AMP VERSUS HYDRA-ST			HYDRA-AMP VERSUS 1R4F			HYDRA-ST VERSUS 1R4F		
	RATIO (%)	SD	SIG.	RATIO (%)	SD	SIG.	RATIO (%)	SD	SIG.
N-nitrosamines:									
NDMA	*	-	=	*	-	=	*	-	=
NMEA	*	-	=	*	-	=	*	-	=
NDEA	*	-	=	*	-	=	*	-	=
NPRA	*	-	=	*	-	=	*	-	=
NBUA	*	-	=	*	-	=	*	-	=
NPY	*	-	=	*	-	=	*	-	=
NPI	*	-	=	*	-	=	*	-	=
NNN	79	13	=	23	4	+++	29	2	+++
NNK	*	-	=	*	-	++	19	1	=
NDELA	*	-	=	*	-	=	*	-	=
Phenols:									
phenol	68	13	=	1	0	+++	1	0	+++
catechol	77	6	=	11	1	+++	14	1	+++
Polycyclic aza-arenes:									
dibenz(a,h)acridine	*	-	=	*	-	=	*	-	=
dibenz(a,j)acridine	*	-	=	*	-	=	*	-	=
Polycyclic aromatic hydrocarbons:									
benz(a)anthracene	44	4	++	3	0	+++	6	1	+++
benzo(b)fluoranthene	*	-	=	*	-	++	8	1	=
benzo(k)fluoranthene	*	-	=	*	-	=	*	-	=
benzo(j)fluoranthene	*	-	=	*	-	+	*	-	+
benzo(a)pyrene	48	5	=	4	1	+++	9	1	+++
indeno(1,2,3-cd)pyrene	*	-	=	*	-	++	6	0	=
dibenz(a,h)anthracene	*	-	=	*	-	=	*	-	=
dibenz(a,l)pyrene	*	-	=	*	-	=	*	-	=
dibenz(a,e)pyrene	*	-	=	*	-	=	*	-	=
dibenz(a,i)pyrene	*	-	=	*	-	+	*	-	+
dibenz(a,h)pyrene	*	-	=	*	-	+	*	-	+
5-methylchrysene	*	-	=	*	-	=	*	-	=

Table 8 (cont.) RELATIVE YIELDS ON CIGARETTE BASIS

Remarks: analysis of variance followed by Tukey test
* : at least 1 median <QL, therefore, no ratio and SD given; Kruskal-Wallis followed by Dunn test with single values <QL set to zero

2505001377

PARAMETER	HYDRA-AMP VERSUS HYDRA-ST RATIO (%)	SD	SIG.
FTC parameters:			
TPM	104	8	=
"tar"	102	8	=
nicotine	88	5	++
water	110	10	=
carbon monoxide	58	3	+++
Aliphatic hydrocarbons:			
1,3-butadiene	52	4	+++
isoprene	68	6	+++
Aldehydes:			
formaldehyde	20	5	+++
acetaldehyde	62	7	+++
acrolein	90	8	++
propionaldehyde	53	8	+++
Aliphatic nitrogen compounds:			
acrylonitrile	55	5	+++
hydrogen cyanide	82	9	+
2-nitropropane	122	16	+
Aromatic amines:			
o-toluidine	67	5	+++
o-anisidine	*	-	=
2-naphthylamine	84	4	+++
4-aminobiphenyl	*	-	=
Halogen compounds:			
vinyl chloride	*	-	=
Inorganic compounds:			
nitrogen oxides	67	4	+++
Monocyclic aromatic hydrocarbons:			
benzene	61	4	+++
toluene	58	5	+++

Table 9 RELATIVE YIELDS ON CIGARETTE BASIS, t-TEST

Remarks: t-test
* : at least 1 median <QL, therefore, no ratio and SD given; Mann-Whitney U-test used instead of t-test with single values <QL set to zero

M 2000/09/06 08:37:30 P. 1 USER_DISK:[AC]YLD1CIG_TT_3362.LIS;6

2505001378

PARAMETER	HYDRA-AMP VERSUS HYDRA-ST RATIO (%)	SD	SIG.
N-nitrosamines:			
NDMA	*	-	=
NMEA	*	-	=
NDEA	*	-	=
NPRA	*	-	=
NBUA	*	-	=
NPY	*	-	=
NPI	*	-	=
NNN	79	13	+
NNK	*	-	++
NDELA	*	-	=
Phenols:			
phenol	68	13	++
catechol	77	6	+++
Polycyclic aza-arenes:			
dibenz(a,h)acridine	*	-	=
dibenz(a,j)acridine	*	-	=
Polycyclic aromatic hydrocarbons:			
benz(a)anthracene	44	4	+++
benzo(b)fluoranthene	*	-	++
benzo(k)fluoranthene	*	-	=
benzo(j)fluoranthene	*	-	=
benzo(a)pyrene	48	5	+++
indeno(1,2,3-cd)pyrene	*	-	++
dibenz(a,h)anthracene	*	-	=
dibenz(a,l)pyrene	*	-	=
dibenz(a,e)pyrene	*	-	=
dibenz(a,i)pyrene	*	-	=
dibenz(a,h)pyrene	*	-	=
5-methylchrysene	*	-	=

Table 9 (cont.) RELATIVE YIELDS ON CIGARETTE BASIS, t-TEST

Remarks: t-test
* : at least 1 median <QL, therefore, no ratio and SD given; Mann-Whitney U-test used instead of t-test with single values <QL set to zero

2505001379

M 2000/09/06 08:14:01 P. 1 USER_DISK:[AC]YLD2CIG_TT_3362.LIS;3

PARAMETER	UNIT		HYDRA-ST M	SD	N		HYDRA-AMP M	SD	N
FTC parameters:									
TPM	mg/mg		1.00	0.09	4		1.00	0.07	4
"tar"	"		0.545	0.050	4		0.532	0.035	4
nicotine	"		0.054	0.004	4		0.045	0.003	4
water	"		0.402	0.041	4		0.422	0.030	4
carbon monoxide	"		0.126	0.009	4		0.070	0.004	4
Aliphatic hydrocarbons:									
1,3-butadiene	ug/mg		1.01	0.08	4		0.50	0.03	4
isoprene	"		14.2	1.1	4		9.3	0.8	4
Aldehydes:									
formaldehyde	ug/mg		9.57	1.91	10		1.81	0.34	8
acetaldehyde	"		45.0	4.8	10		26.6	2.1	8
acrolein	"		5.41	0.50	10		4.67	0.36	8
propionaldehyde	"		3.07	0.40	10		1.56	0.16	8
Aliphatic nitrogen compounds:									
acrylonitrile	ug/mg		0.255	0.022	4		0.135	0.011	4
hydrogen cyanide	"		0.782	0.096	4		0.617	0.038	4
2-nitropropane	ng/mg		1.39	0.13	4		1.63	0.20	4
Aromatic amines:									
o-toluidine	ng/mg		0.227	0.015	4		0.146	0.013	4
o-anisidine	"	<	0.035	*	4	<	0.034	*	4
2-naphthylamine	"		0.021	0.001	4		0.017	0.001	4
4-aminobiphenyl	"	<	0.020	*	4	<	0.019	*	4
Halogen compounds:									
vinyl chloride	ng/mg	<	2.19	*	4	<	2.10	*	4
Inorganic compounds:									
nitrogen oxides	ug/mg		7.21	0.55	4		4.63	0.28	4
Monocyclic aromatic hydrocarbons:									
benzene	ug/mg		0.592	0.045	4		0.349	0.025	4
toluene	"		1.31	0.11	4		0.73	0.06	4

Table 10 AMOUNTS CALCULATED ON EQUAL TPM BASIS

Remarks: N is the number of determinations.
*: at least 1 single value below QL, therefore, the median and no SD given

2505001380

PARAMETER	UNIT	1R4F		
		M	SD	N
FTC parameters:				
TPM	mg/mg	1.00	0.06	4
"tar"	"	0.81	0.05	4
nicotine	"	0.072	0.005	4
water	"	0.122	0.010	4
carbon monoxide	"	0.98	0.10	10
Aliphatic hydrocarbons:				
1.3-butadiene	ug/mg	3.80	0.33	4
isoprene	"	37.0	2.1	4
Aldehydes:				
formaldehyde	ug/mg	1.03	0.10	8
acetaldehyde	"	54.3	4.2	8
acrolein	"	5.16	0.39	8
propionaldehyde	"	4.77	0.38	8
Aliphatic nitrogen compounds:				
acrylonitrile	ug/mg	1.03	0.07	4
hydrogen cyanide	"	8.5	0.5	4
2-nitropropane	ng/mg	1.23	0.09	4
Aromatic amines:				
o-toluidine	ng/mg	3.75	0.25	5
o-anisidine	"	0.188	0.026	5
2-naphthylamine	"	0.462	0.036	5
4-aminobiphenyl	"	0.099	0.009	5
Halogen compounds:				
vinyl chloride	ng/mg	3.12	0.24	4
Inorganic compounds:				
nitrogen oxides	ug/mg	32.0	3.0	10
Monocyclic aromatic hydrocarbons:				
benzene	ug/mg	4.19	0.29	4
toluene	"	7.63	0.81	4

Table 10 (cont.) AMOUNTS CALCULATED ON EQUAL TPM BASIS

Remarks: N is the number of determinations.

2505001381

M 2000/08/30 16:48:13 P. 1 USER_DISK:[AC]YLD1_TPMR_3362.LIS;1

PARAMETER		HYDRA-ST M	SD	N		HYDRA-AMP M	SD	N
N-nitrosamines (ng/mg):								
NDMA	<	0.884	*	4	<	0.848	*	4
NMEA	<	1.77	*	4	<	1.70	*	4
NDEA	<	1.24	*	4	<	1.19	*	4
NPRA	<	1.95	*	4	<	1.87	*	4
NBUA	<	1.59	*	4	<	1.53	*	4
NPY	<	1.24	*	4	<	1.19	*	4
NPI	<	1.41	*	4	<	1.36	*	4
NNN		3.95	0.27	4		2.98	0.52	4
NNK		2.50	0.18	4	<	2.03	*	4
NDELA	<	1.86	*	4	<	1.78	*	4
Phenols (ug/mg):								
phenol		0.021	0.003	4		0.014	0.002	4
catechol		1.15	0.11	4		0.85	0.05	4
Polycyclic aza-arenes (ng/mg):								
dibenz(a,h)acridine	<	0.110	*	4	<	0.105	*	4
dibenz(a,j)acridine	<	0.106	*	4	<	0.102	*	4
Polycyclic aromatic hydrocarbons (ng/mg):								
benz(a)anthracene		0.118	0.013	4		0.049	0.003	4
benzo(b)fluoranthene		0.054	0.004	4	<	0.039	*	4
benzo(k)fluoranthene	<	0.021	*	4	<	0.020	*	4
benzo(j)fluoranthene	<	0.035	*	4	<	0.034	*	4
benzo(a)pyrene		0.091	0.007	4		0.042	0.004	4
indeno(1,2,3-cd)pyrene		0.029	0.003	4	<	0.022	*	4
dibenz(a,h)anthracene	<	0.023	*	4	<	0.022	*	4
dibenz(a,l)pyrene	<	0.046	*	4	<	0.044	*	4
dibenz(a,e)pyrene	<	0.051	*	4	<	0.049	*	4
dibenz(a,i)pyrene	<	0.060	*	4	<	0.058	*	4
dibenz(a,h)pyrene	<	0.076	*	4	<	0.073	*	4
5-methylchrysene	<	0.301	*	4	<	0.288	*	4

Table 10 (cont.) AMOUNTS CALCULATED ON EQUAL TPM BASIS

Remarks: N is the number of determinations.
*: at least 1 single value below QL, therefore, the median and no SD given

2505001382

PARAMETER (UNIT)		1R4F M	SD	N
N-nitrosamines (ng/mg):				
NDMA	<	0.441	*	4
NMEA	<	0.883	*	4
NDEA	<	0.618	*	4
NPRA	<	0.971	*	4
NBUA	<	0.794	*	4
NPY	<	0.618	*	4
NPI	<	0.706	*	4
NNN		6.88	0.48	4
NNK		6.49	0.41	4
NDELA		1.45	*	4
Phenols (ug/mg):				
phenol		0.981	0.054	4
catechol		4.18	0.27	4
Polycyclic aza-arenes (ng/mg):				
dibenz(a,h)acridine	<	0.591	*	4
dibenz(a,j)acridine	<	0.240	*	4
Polycyclic aromatic hydrocarbons (ng/mg):				
benz(a)anthracene		0.942	0.047	4
benzo(b)fluoranthene		0.344	0.033	4
benzo(k)fluoranthene	<	0.115	*	4
benzo(j)fluoranthene		0.196	0.021	4
benzo(a)pyrene		0.515	0.046	4
indeno(1,2,3-cd)pyrene		0.243	0.017	4
dibenz(a,h)anthracene	<	0.053	*	4
dibenz(a,l)pyrene	<	0.097	*	4
dibenz(a,e)pyrene		0.083	*	4
dibenz(a,i)pyrene		0.161	0.042	4
dibenz(a,h)pyrene		0.145	0.040	4
5-methylchrysene	<	0.671	*	4

Table 10 (cont.) AMOUNTS CALCULATED ON EQUAL TPM BASIS

Remarks: N is the number of determinations.
*: at least 1 single value below QL,
therefore, the median and no SD given

2505001383

PARAMETER	HYDRA-AMP VERSUS HYDRA-ST			HYDRA-AMP VERSUS 1R4F			HYDRA-ST VERSUS 1R4F		
	RATIO (%)	SD	SIG.	RATIO (%)	SD	SIG.	RATIO (%)	SD	SIG.
FTC parameters:									
TPM	100	11	=	100	9	=	100	11	=
"tar"	98	11	=	66	6	+++	68	7	+++
nicotine	84	8	+	63	6	+++	75	7	+++
water	105	13	=	346	37	+++	329	43	+++
carbon monoxide	56	5	=	7	1	+++	13	2	+++
Aliphatic hydrocarbons:									
1,3-butadiene	50	5	+	13	1	+++	27	3	+++
isoprene	66	8	++	25	3	+++	38	4	+++
Aldehydes:									
formaldehyde	19	5	+++	175	37	=	926	207	+++
acetaldehyde	59	8	+++	49	5	+++	83	11	+++
acrolein	86	10	++	91	10	=	105	13	=
propionaldehyde	51	8	+++	33	4	+++	64	10	+++
Aliphatic nitrogen compounds:									
acrylonitrile	53	6	++	13	1	+++	25	3	+++
hydrogen cyanide	79	11	=	7	1	+++	9	1	+++
2-nitropropane	117	18	=	132	18	+	113	13	=
Aromatic amines:									
o-toluidine	64	7	=	4	0	+++	6	1	+++
o-anisidine	*	-	=	*	-	+	*	-	+
2-naphthylamine	80	7	=	4	0	+++	5	0	+++
4-aminobiphenyl	*	-	=	*	-	+	*	-	+
Halogen compounds:									
vinyl chloride	*	-	=	*	-	+	*	-	+
Inorganic compounds:									
nitrogen oxides	64	6	=	14	2	+++	23	3	+++
Monocyclic aromatic hydrocarbons:									
benzene	59	6	=	8	1	+++	14	1	+++
toluene	56	7	=	10	1	+++	17	2	+++

Table 11 RELATIVE AMOUNTS ON EQUAL TPM BASIS

Remarks: analysis of variance followed by Tukey test
* : at least 1 median <QL, therefore, no ratio and SD given; Kruskal-Wallis followed by Dunn test with single values <QL set to zero

M 2000/09/06 08:06:17 P. 1 USER_DISK:[AC]YLD1TPMTUK_3362.LIS;7

2505001384

PARAMETER	HYDRA-AMP VERSUS HYDRA-ST			HYDRA-AMP VERSUS 1R4F			HYDRA-ST VERSUS 1R4F		
	RATIO (%)	SD	SIG.	RATIO (%)	SD	SIG.	RATIO (%)	SD	SIG.
N-nitrosamines:									
NDMA	*	-	=	*	-	=	*	-	=
NMEA	*	-	=	*	-	=	*	-	=
NDEA	*	-	=	*	-	=	*	-	=
NPRA	*	-	=	*	-	=	*	-	=
NBUA	*	-	=	*	-	=	*	-	=
NPY	*	-	=	*	-	=	*	-	=
NPI	*	-	=	*	-	=	*	-	=
NNN	76	14	+	43	8	+++	57	6	+++
NNK	*	-	=	*	-	++	39	4	=
NDELA	*	-	=	*	-	=	*	-	=
Phenols:									
phenol	65	14	=	1	0	+++	2	0	+++
catechol	74	8	=	20	2	+++	28	3	+++
Polycyclic aza-arenes:									
dibenz(a,h)acridine	*	-	=	*	-	=	*	-	=
dibenz(a,j)acridine	*	-	=	*	-	=	*	-	=
Polycyclic aromatic hydrocarbons:									
benz(a)anthracene	42	5	+	5	0	+++	12	2	+++
benzo(b)fluoranthene	*	-	=	*	-	++	16	2	=
benzo(k)fluoranthene	*	-	=	*	-	=	*	-	=
benzo(j)fluoranthene	*	-	=	*	-	+	*	-	+
benzo(a)pyrene	46	6	=	8	1	+++	18	2	+++
indeno(1,2,3-cd)pyrene	*	-	=	*	-	++	12	1	=
dibenz(a,h)anthracene	*	-	=	*	-	=	*	-	=
dibenz(a,l)pyrene	*	-	=	*	-	=	*	-	=
dibenz(a,e)pyrene	*	-	=	*	-	=	*	-	=
dibenz(a,i)pyrene	*	-	=	*	-	+	*	-	+
dibenz(a,h)pyrene	*	-	=	*	-	+	*	-	+
5-methylchrysene	*	-	=	*	-	=	*	-	=

Table 11 (cont.) RELATIVE AMOUNTS ON EQUAL TPM BASIS

Remarks: analysis of variance followed by Tukey test
* : at least 1 median <QL, therefore, no ratio and SD given; Kruskal-Wallis followed by Dunn test with single values <QL set to zero

PARAMETER	HYDRA-AMP VERSUS HYDRA-ST RATIO (%)	SD	SIG.
FTC parameters:			
TPM	100	11	=
"tar"	98	11	=
nicotine	84	8	+
water	105	13	=
carbon monoxide	56	5	+++
Aliphatic hydrocarbons:			
1,3-butadiene	50	5	+++
isoprene	66	8	+++
Aldehydes:			
formaldehyde	19	5	+++
acetaldehyde	59	8	+++
acrolein	86	10	++
propionaldehyde	51	8	+++
Aliphatic nitrogen compounds:			
acrylonitrile	53	6	+++
hydrogen cyanide	79	11	+
2-nitropropane	117	18	=
Aromatic amines:			
o-toluidine	64	7	+++
o-anisidine	*	-	=
2-naphthylamine	80	7	++
4-aminobiphenyl	*	-	=
Halogen compounds:			
vinyl chloride	*	-	=
Inorganic compounds:			
nitrogen oxides	64	6	+++
Monocyclic aromatic hydrocarbons:			
benzene	59	6	+++
toluene	56	7	+++

Table 12 RELATIVE AMOUNTS ON EQUAL TPM BASIS, t-TEST

Remarks: t-test
* : at least 1 median <QL, therefore, no ratio and SD given; Mann-Whitney U-test used instead of t-test with single values <QL set to zero

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PARAMETER	HYDRA-AMP VERSUS HYDRA-ST RATIO (%)	SD	SIG.
N-nitrosamines:			
NDMA	*	-	=
NMEA	*	-	=
NDEA	*	-	=
NPRA	*	-	=
NBUA	*	-	=
NPY	*	-	=
NPI	*	-	=
NNN	76	14	+
NNK	*	-	++
NDELA	*	-	=
Phenols:			
phenol	65	14	++
catechol	74	8	++
Polycyclic aza-arenes:			
dibenz(a,h)acridine	*	-	=
dibenz(a,j)acridine	*	-	=
Polycyclic aromatic hydrocarbons:			
benz(a)anthracene	42	5	+++
benzo(b)fluoranthene	*	-	++
benzo(k)fluoranthene	*	-	=
benzo(j)fluoranthene	*	-	=
benzo(a)pyrene	46	6	+++
indeno(1,2,3-cd)pyrene	*	-	++
dibenz(a,h)anthracene	*	-	=
dibenz(a,l)pyrene	*	-	=
dibenz(a,e)pyrene	*	-	=
dibenz(a,i)pyrene	*	-	=
dibenz(a,h)pyrene	*	-	=
5-methylchrysene	*	-	=

Table 12 (cont.) RELATIVE AMOUNTS ON EQUAL TPM BASIS, t-TEST

Remarks: t-test
* : at least 1 median <QL, therefore, no ratio and SD given; Mann-Whitney U-test used instead of t-test with single values <QL set to zero

PARAMETER	UNIT	HYDRA-ST			HYDRA-AMP		
		M	SD	N	M	SD	N
FTC parameters:							
TPM	mg/mg	1.84	0.17	4	1.88	0.12	4
"tar"	"	1.00	0.09	4	1.00	0.07	4
nicotine	"	0.099	0.007	4	0.085	0.006	4
water	"	0.737	0.075	4	0.794	0.057	4
carbon monoxide	"	0.231	0.016	4	0.132	0.008	4
Aliphatic hydrocarbons:							
1,3-butadiene	ug/mg	1.86	0.15	4	0.94	0.06	4
isoprene	"	26.0	2.0	4	17.5	1.5	4
Aldehydes:							
formaldehyde	ug/mg	17.6	3.5	10	3.4	0.6	8
acetaldehyde	"	82.7	8.8	10	50.0	4.0	8
acrolein	"	9.94	0.92	10	8.77	0.68	8
propionaldehyde	"	5.63	0.73	10	2.93	0.31	8
Aliphatic nitrogen compounds:							
acrylonitrile	ug/mg	0.467	0.040	4	0.253	0.021	4
hydrogen cyanide	"	1.44	0.18	4	1.16	0.07	4
2-nitropropane	ng/mg	2.56	0.23	4	3.06	0.37	4
Aromatic amines:							
o-toluidine	ng/mg	0.417	0.027	4	0.275	0.024	4
o-anisidine	"	< 0.065	*	4 <	0.064	*	4
2-naphthylamine	"	0.038	0.003	4	0.031	0.002	4
4-aminobiphenyl	"	< 0.037	*	4 <	0.036	*	4
Halogen compounds:							
vinyl chloride	ng/mg	< 4.03	*	4 <	3.95	*	4
Inorganic compounds:							
nitrogen oxides	ug/mg	13.2	1.0	4	8.7	0.5	4
Monocyclic aromatic hydrocarbons:							
benzene	ug/mg	1.09	0.08	4	0.65	0.05	4
toluene	"	2.41	0.20	4	1.38	0.12	4

Table 13 AMOUNTS CALCULATED ON EQUAL "TAR" BASIS

Remarks: N is the number of determinations.
*: at least 1 single value below QL, therefore, the median and no SD given

PARAMETER	UNIT	1R4F		
		M	SD	N
FTC parameters:				
TPM	mg/mg	1.24	0.08	4
"tar"	"	1.00	0.06	4
nicotine	"	0.089	0.005	4
water	"	0.152	0.012	4
carbon monoxide	"	1.22	0.12	10
Aliphatic hydrocarbons:				
1,3-butadiene	ug/mg	4.71	0.40	4
isoprene	"	45.9	2.5	4
Aldehydes:				
formaldehyde	ug/mg	1.28	0.13	8
acetaldehyde	"	67.4	5.1	8
acrolein	"	6.40	0.47	8
propionaldehyde	"	5.92	0.46	8
Aliphatic nitrogen compounds:				
acrylonitrile	ug/mg	1.28	0.08	4
hydrogen cyanide	"	10.5	0.6	4
2-nitropropane	ng/mg	1.53	0.10	4
Aromatic amines:				
o-toluidine	ng/mg	4.66	0.30	5
o-anisidine	"	0.234	0.032	5
2-naphthylamine	"	0.574	0.044	5
4-aminobiphenyl	"	0.123	0.011	5
Halogen compounds:				
vinyl chloride	ng/mg	3.87	0.29	4
Inorganic compounds:				
nitrogen oxides	ug/mg	39.7	3.6	10
Monocyclic aromatic hydrocarbons:				
benzene	ug/mg	5.20	0.35	4
toluene	"	9.47	0.99	4

Table 13 (cont.) AMOUNTS CALCULATED ON EQUAL "TAR" BASIS

Remarks: N is the number of determinations.

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PARAMETER	HYDRA-ST			HYDRA-AMP		
	M	SD	N	M	SD	N
N-nitrosamines (ng/mg):						
NDMA	< 1.62	*	4	< 1.59	*	4
NMEA	< 3.25	*	4	< 3.19	*	4
NDEA	< 2.27	*	4	< 2.23	*	4
NPRA	< 3.57	*	4	< 3.50	*	4
NBUA	< 2.92	*	4	< 2.87	*	4
NPY	< 2.27	*	4	< 2.23	*	4
NPI	< 2.60	*	4	< 2.55	*	4
NNN	7.25	0.49	4	5.61	0.98	4
NNK	4.59	0.34	4	< 3.82	*	4
NDELA	< 3.41	*	4	< 3.34	*	4
Phenols (ug/mg):						
phenol	0.039	0.005	4	0.026	0.004	4
catechol	2.12	0.20	4	1.60	0.09	4
Polycyclic aza-arenes (ng/mg):						
dibenz(a,h)acridine	< 0.201	*	4	< 0.198	*	4
dibenz(a,j)acridine	< 0.195	*	4	< 0.191	*	4
Polycyclic aromatic hydrocarbons (ng/mg):						
benz(a)anthracene	0.216	0.024	4	0.092	0.006	4
benzo(b)fluoranthene	0.100	0.007	4	< 0.073	*	4
benzo(k)fluoranthene	< 0.039	*	4	< 0.038	*	4
benzo(j)fluoranthene	< 0.065	*	4	< 0.064	*	4
benzo(a)pyrene	0.167	0.013	4	0.079	0.008	4
indeno(1,2,3-cd)pyrene	0.054	0.005	4	< 0.041	*	4
dibenz(a,h)anthracene	< 0.042	*	4	< 0.041	*	4
dibenz(a,l)pyrene	< 0.084	*	4	< 0.083	*	4
dibenz(a,e)pyrene	< 0.094	*	4	< 0.092	*	4
dibenz(a,i)pyrene	< 0.110	*	4	< 0.108	*	4
dibenz(a,h)pyrene	< 0.140	*	4	< 0.137	*	4
5-methylchrysene	< 0.552	*	4	< 0.542	*	4

Table 13 (cont.) AMOUNTS CALCULATED ON EQUAL "TAR" BASIS

Remarks: N is the number of determinations.
*: at least 1 single value below QL,
therefore, the median and no SD given

2505001390

PARAMETER (UNIT)		1R4F M	SD	N
N-nitrosamines (ng/cig.):				
NDMA	<	0.548	*	4
NMEA	<	1.10	*	4
NDEA	<	0.767	*	4
NPRA	<	1.20	*	4
NBUA	<	0.986	*	4
NPY	<	0.767	*	4
NPI	<	0.876	*	4
NNN		8.54	0.58	4
NNK		8.05	0.50	4
NDELA		1.79	*	4
Phenols (ug/cig.):				
phenol		1.22	0.06	4
catechol		5.19	0.32	4
Polycyclic aza-arenes (ng/cig.):				
dibenz(a,h)acridine	<	0.734	*	4
dibenz(a,j)acridine	<	0.298	*	4
Polycyclic aromatic hydrocarbons (ng/cig.):				
benz(a)anthracene		1.17	0.05	4
benzo(b)fluoranthene		0.426	0.040	4
benzo(k)fluoranthene	<	0.142	*	4
benzo(j)fluoranthene		0.243	0.025	4
benzo(a)pyrene		0.639	0.057	4
indeno(1,2,3-cd)pyrene		0.302	0.021	4
dibenz(a,h)anthracene	<	0.066	*	4
dibenz(a,l)pyrene	<	0.120	*	4
dibenz(a,e)pyrene		0.102	*	4
dibenz(a,i)pyrene		0.200	0.053	4
dibenz(a,h)pyrene		0.180	0.049	4
5-methylchrysene	<	0.833	*	4

Table 13 (cont.) AMOUNTS CALCULATED ON EQUAL "TAR" BASIS

Remarks: N is the number of determinations.
*: at least 1 single value below QL,
therefore, the median and no SD given

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PARAMETER	HYDRA-AMP VERSUS HYDRA-ST			HYDRA-AMP VERSUS 1R4F			HYDRA-ST VERSUS 1R4F		
	RATIO (%)	SD	SIG.	RATIO (%)	SD	SIG.	RATIO (%)	SD	SIG.
FTC parameters:									
TPM	102	12	=	151	14	+++	148	16	+++
"tar"	100	11	=	100	9	=	100	11	=
nicotine	86	8	+	95	9	=	111	10	=
water	108	13	=	524	56	+++	487	63	+++
carbon monoxide	57	5	=	11	1	+++	19	2	+++
Aliphatic hydrocarbons:									
1,3-butadiene	51	5	++	20	2	+++	39	5	+++
isoprene	67	8	+++	38	4	+++	57	5	+++
Aldehydes:									
formaldehyde	19	5	+++	265	57	=	1371	306	+++
acetaldehyde	60	8	+++	74	8	+++	123	16	+++
acrolein	88	11	++	137	15	+++	155	18	+++
propionaldehyde	52	9	+++	49	6	+++	95	14	=
Aliphatic nitrogen compounds:									
acrylonitrile	54	6	+++	20	2	+++	37	4	+++
hydrogen cyanide	81	11	=	11	1	+++	14	2	+++
2-nitropropane	120	18	=	200	28	+++	167	19	+++
Aromatic amines:									
o-toluidine	66	7	=	6	1	+++	9	1	+++
o-anisidine	*	-	=	*	-	+	*	-	+
2-naphthylamine	82	8	=	5	1	+++	7	1	+++
4-aminobiphenyl	*	-	=	*	-	+	*	-	+
Halogen compounds:									
vinyl chloride	*	-	=	*	-	+	*	-	+
Inorganic compounds:									
nitrogen oxides	66	6	=	22	2	+++	33	4	+++
Monocyclic aromatic hydrocarbons:									
benzene	60	6	+	13	1	+++	21	2	+++
toluene	57	7	=	15	2	+++	25	3	+++

Table 14 RELATIVE AMOUNTS ON EQUAL "TAR" BASIS

Remarks: analysis of variance followed by Tukey test
* : at least 1 median <QL, therefore, no ratio and SD given: Kruskal-Wallis followed by Dunn test with single values <QL set to zero

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PARAMETER	HYDRA-AMP VERSUS HYDRA-ST			HYDRA-AMP VERSUS 1R4F			HYDRA-ST VERSUS 1R4F		
	RATIO (%)	SD	SIG.	RATIO (%)	SD	SIG.	RATIO (%)	SD	SIG.
N-nitrosamines:									
NDMA	*	-	=	*	-	=	*	-	=
NMEA	*	-	=	*	-	=	*	-	=
NDEA	*	-	=	*	-	=	*	-	=
NPRA	*	-	=	*	-	=	*	-	=
NBUA	*	-	=	*	-	=	*	-	=
NPY	*	-	=	*	-	=	*	-	=
NPI	*	-	=	*	-	=	*	-	=
NNN	77	15	+	66	12	+++	85	8	=
NNK	*	-	=	*	-	++	57	5	=
NDELA	*	-	=	*	-	=	*	-	=
Phenols:									
phenol	66	14	=	2	0	+++	3	0	+++
catechol	76	8	+	31	3	+++	41	5	+++
Polycyclic aza-arenes:									
dibenz(a,h)acridine	*	-	=	*	-	=	*	-	=
dibenz(a,j)acridine	*	-	=	*	-	=	*	-	=
Polycyclic aromatic hydrocarbons:									
benz(a)anthracene	43	6	++	8	1	+++	18	2	+++
benzo(b)fluoranthene	*	-	=	*	-	++	23	3	=
benzo(k)fluoranthene	*	-	=	*	-	=	*	-	=
benzo(j)fluoranthene	*	-	=	*	-	+	*	-	+
benzo(a)pyrene	47	6	+	12	2	+++	26	3	+++
indeno(1,2,3-cd)pyrene	*	-	=	*	-	++	18	2	=
dibenz(a,h)anthracene	*	-	=	*	-	=	*	-	=
dibenz(a,l)pyrene	*	-	=	*	-	=	*	-	=
dibenz(a,e)pyrene	*	-	=	*	-	=	*	-	=
dibenz(a,i)pyrene	*	-	=	*	-	+	*	-	+
dibenz(a,h)pyrene	*	-	=	*	-	+	*	-	+
5-methylchrysene	*	-	=	*	-	=	*	-	=

Table 14 (cont.) RELATIVE AMOUNTS ON EQUAL "TAR" BASIS

Remarks: analysis of variance followed by Tukey test
* : at least 1 median <QL, therefore, no ratio and SD given; Kruskal-Wallis followed by Dunn test with single values <QL set to zero

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PARAMETER	HYDRA-AMP VERSUS HYDRA-ST RATIO (%)	SD	SIG.
FTC parameters:			
TPM	102	12	=
"tar"	100	11	=
nicotine	86	8	+
water	108	13	=
carbon monoxide	57	5	+++
Aliphatic hydrocarbons:			
1,3-butadiene	51	5	+++
isoprene	67	8	+++
Aldehydes:			
formaldehyde	19	5	+++
acetaldehyde	60	8	+++
acrolein	88	11	++
propionaldehyde	52	9	+++
Aliphatic nitrogen compounds:			
acrylonitrile	54	6	+++
hydrogen cyanide	81	11	+
2-nitropropane	120	18	=
Aromatic amines:			
o-toluidine	66	7	+++
o-anisidine	*	-	=
2-naphthylamine	82	8	++
4-aminobiphenyl	*	-	=
Halogen compounds:			
vinyl chloride	*	-	=
Inorganic compounds:			
nitrogen oxides	66	6	+++
Monocyclic aromatic hydrocarbons:			
benzene	60	6	+++
toluene	57	7	+++

Table 15 RELATIVE AMOUNTS ON EQUAL "TAR" BASIS, t-TEST

Remarks: t-test
* : at least 1 median <QL, therefore, no ratio and SD given; Mann-Whitney U-test used instead of t-test with single values <QL set to zero

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PARAMETER	HYDRA-AMP VERSUS HYDRA-ST RATIO (%)	SD	SIG.
N-nitrosamines:			
NDMA	*	-	=
NMEA	*	-	=
NDEA	*	-	=
NPRA	*	-	=
NBUA	*	-	=
NPY	*	-	=
NPI	*	-	=
NNN	77	15	+
NNK	*	-	++
NDELA	*	-	=
Phenols:			
phenol	66	14	++
catechol	76	8	++
Polycyclic aza-arenes:			
dibenz(a,h)acridine	*	-	=
dibenz(a,j)acridine	*	-	=
Polycyclic aromatic hydrocarbons:			
benz(a)anthracene	43	6	+++
benzo(b)fluoranthene	*	-	++
benzo(k)fluoranthene	*	-	=
benzo(j)fluoranthene	*	-	=
benzo(a)pyrene	47	6	+++
indeno(1,2,3-cd)pyrene	*	-	++
dibenz(a,h)anthracene	*	-	=
dibenz(a,l)pyrene	*	-	=
dibenz(a,e)pyrene	*	-	=
dibenz(a,i)pyrene	*	-	=
dibenz(a,h)pyrene	*	-	=
5-methylchrysene	*	-	=

Table 15 (cont.) RELATIVE AMOUNTS ON EQUAL "TAR" BASIS, t-TEST

Remarks: t-test
* : at least 1 median <QL, therefore, no ratio and SD given; Mann-Whitney U-test used instead of t-test with single values <QL set to zero

PARAMETER	UNIT	YIELD ACTUAL	HISTORICAL		95%-CONFIDENCE LIMIT		
		M	M	SD	LOWER	UPPER	N
FTC parameters:							
puff count	-	9.30	9.16	0.16	8.84	9.48	10
TPM	mg/cig.	11.3	10.9	0.6	9.7	12.1	10
"tar"	"	9.13	8.98	0.54	7.93	10.03	10
nicotine	"	0.817	0.894	0.07	0.754	1.035	10
water	"	1.38	1.04	0.25	0.56	1.52	10
carbon monoxide	"	11.2	11.3	1.4	8.6	13.9	8
Aliphatic hydrocarbons:							
1.3-butadiene	ug/cig.	43.0	48.3	7.8	33.1	63.6	8
isoprene	"	419	394	47	301	486	8
Aldehydes:							
formaldehyde	ug/cig.	11.7	15.5	3.7	8.3	22.7	10
acetaldehyde	"	615	734	110	518	949	10
acrolein	"	58.4	65.6	10.1	45.7	85.5	10
propionaldehyde	"	54.0	60.7	7.6	45.9	75.6	6
Aliphatic nitrogen compounds:							
acrylonitrile	ug/cig.	11.6	11.1	1.4	8.3	13.9	5
hydrogen cyanide	"	96.0	100.6	13.2	74.7	126.5	9
2-nitropropane	ng/cig.	14.0	13.8	-	-	-	1
Aromatic amines:							
o-toluidine	ng/cig.	42.5	52.4	-	-	-	1
o-anisidine	"	2.13	-	-	-	-	-
2-naphthylamine	"	5.24	5.17	-	-	-	1
4-aminobiphenyl	"	1.12	1.02	-	-	-	1
Halogen compounds:							
vinyl chloride	ng/cig.	35.3	38.5	5.9	26.9	50.1	5
Inorganic compounds:							
nitrogen oxides	ug/cig.	362	328	50	230	427	8
Monocyclic aromatic hydrocarbons:							
benzene	ug/cig.	47.5	50.4	4.9	40.8	60.1	8
toluene	"	86.5	86.8	10.2	66.9	106.8	8

Table 16 ACTUAL AND HISTORICAL DATA OF MAINSTREAM SMOKE ANALYSIS OF THE REFERENCE CIGARETTE 1R4F

Remarks: all data: rectangular puff profile
actual data from the present study
historical data: mean from several former studies
(N = number of studies)

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PARAMETER (UNIT)	YIELD ACTUAL		HISTORICAL		95%-CONFIDENCE LIMIT		
	M		M	SD	LOWER	UPPER	N
N-nitrosamines (ng/cig.):							
NDMA	< 5.00	<	5.00	*	*	*	6
NMEA	< 10.0	<	10.0	*	*	*	2
NDEA	< 7.00	<	7.00	*	*	*	2
NPRA	< 11.0	<	11.0	*	*	*	3
NBUA	< 9.00	<	9.00	*	*	*	3
NPY	< 7.00		7.02	*	*	*	6
NPI	< 8.00	<	8.00	*	*	*	3
NNN	77.9		103.2	29.1	46.1	160.2	8
NNK	73.5		102.3	32.7	38.1	166.4	8
NDELA	16.4		21.9	*	*	*	5
Phenols (ug/cig.):							
phenol	11.1		9.4	1.4	6.6	12.1	8
catechol	47.4		42.3	3.9	34.6	49.9	8
Polycyclic aza-arenes (ng/cig.):							
dibenz(a,h)acridine	< 6.70		-	-	-	-	-
dibenz(a,j)acridine	< 2.72	<	2.72	*	*	*	5
Polycyclic aromatic hydrocarbons (ng/cig.):							
benz(a)anthracene	10.7		11.5	1.4	8.7	14.3	8
benzo(b)fluoranthene	3.89		-	-	-	-	-
benzo(k)fluoranthene	< 1.30						-
benzo(j)fluoranthene	2.22						-
benzo(a)pyrene	5.84		6.16	1.22	3.76	8.55	8
indeno(1,2,3-cd)pyrene	2.75		3.18	0.84	1.54	4.83	8
dibenz(a,h)anthracene	< 0.600		-	-	-	-	-
dibenz(a,l)pyrene	< 1.10		-	-	-	-	-
dibenz(a,e)pyrene	0.935		-	-	-	-	-
dibenz(a,i)pyrene	1.83		-	-	-	-	-
dibenz(a,h)pyrene	1.65		-	-	-	-	-
5-methylchrysene	< 7.60	<	7.60	*	*	*	5

Table 16 (cont.) ACTUAL AND HISTORICAL DATA OF MAINSTREAM SMOKE ANALYSIS OF THE REFERENCE CIGARETTE 1R4F

Remarks: all data: rectangular puff profile
actual data from the present study
historical data: mean from several former studies
(N = number of studies)
*: at least 1 single value below QL, therefore, the median, no SD and no confidence limits given

2000/09/01 09:07:12 P. 1 USER_DISK:[AC]YLD2_HIST_3362.LIS;15

2505001397

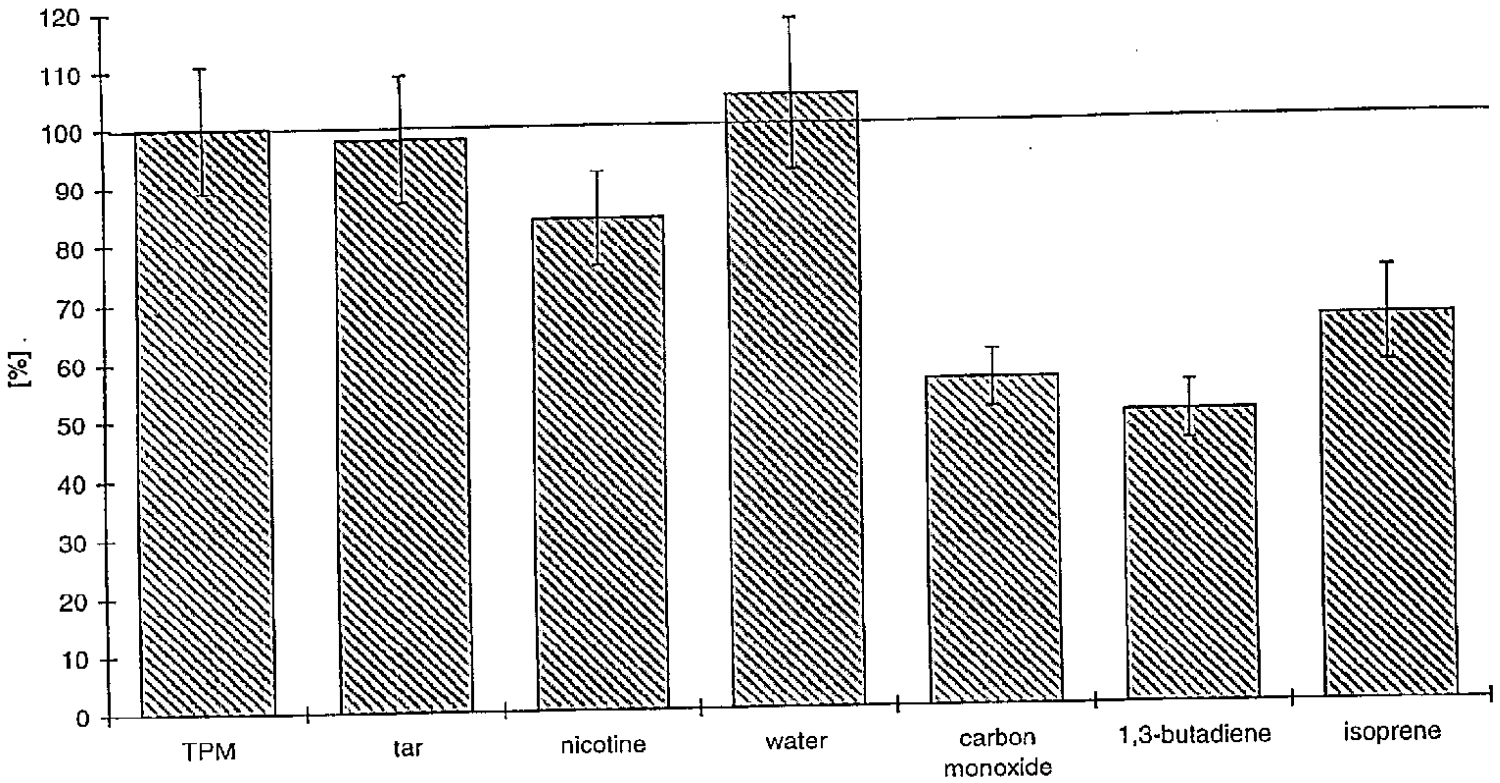

Figure 1 HYDRA-AMP vs HYDRA-ST on an Equal TPM Basis

Remarks: Columns with error bars represent means and standard deviations

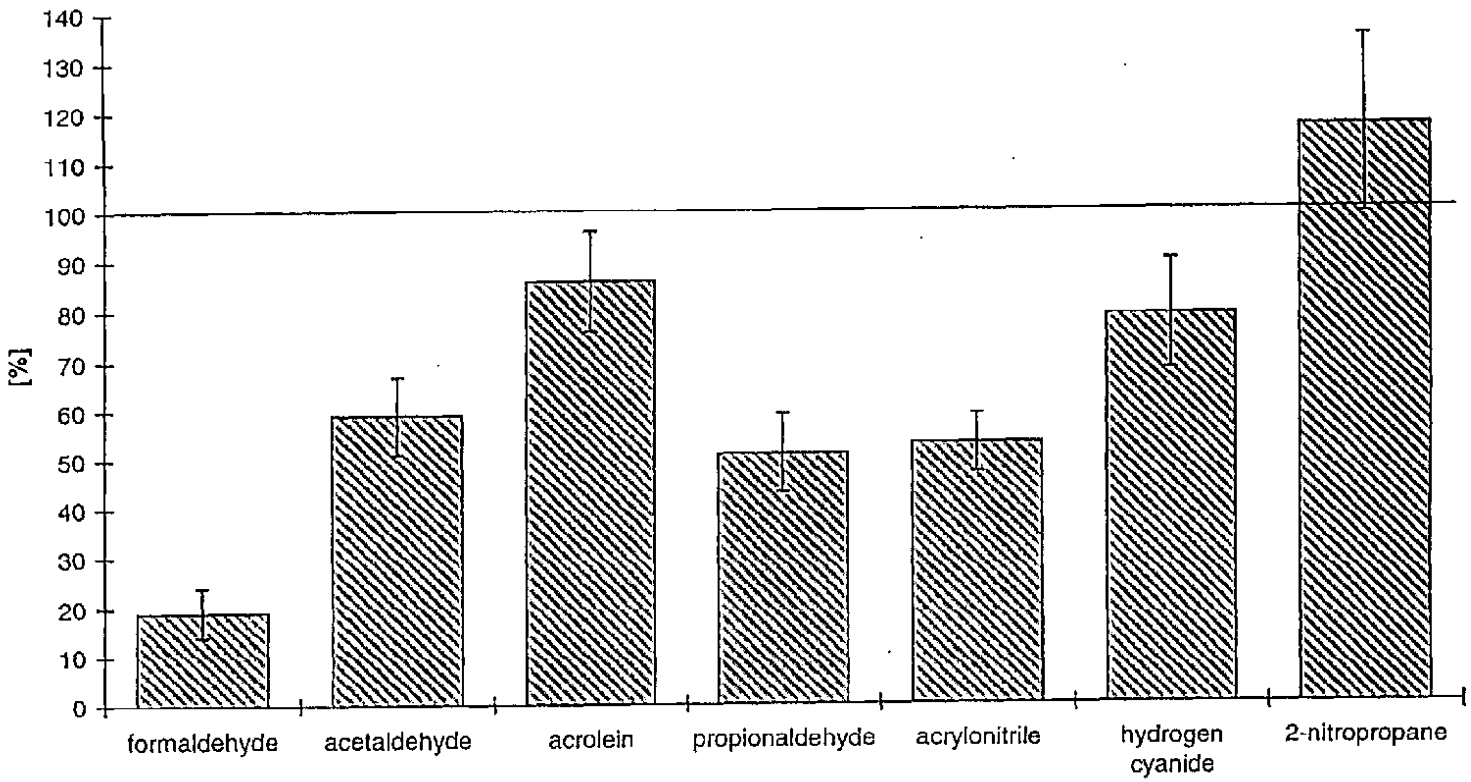

Figure 1 (cont.) **HYDRA-AMP vs HYDRA-ST on an Equal TPM Basis**

Remarks: Columns with error bars represent means and standard deviations.

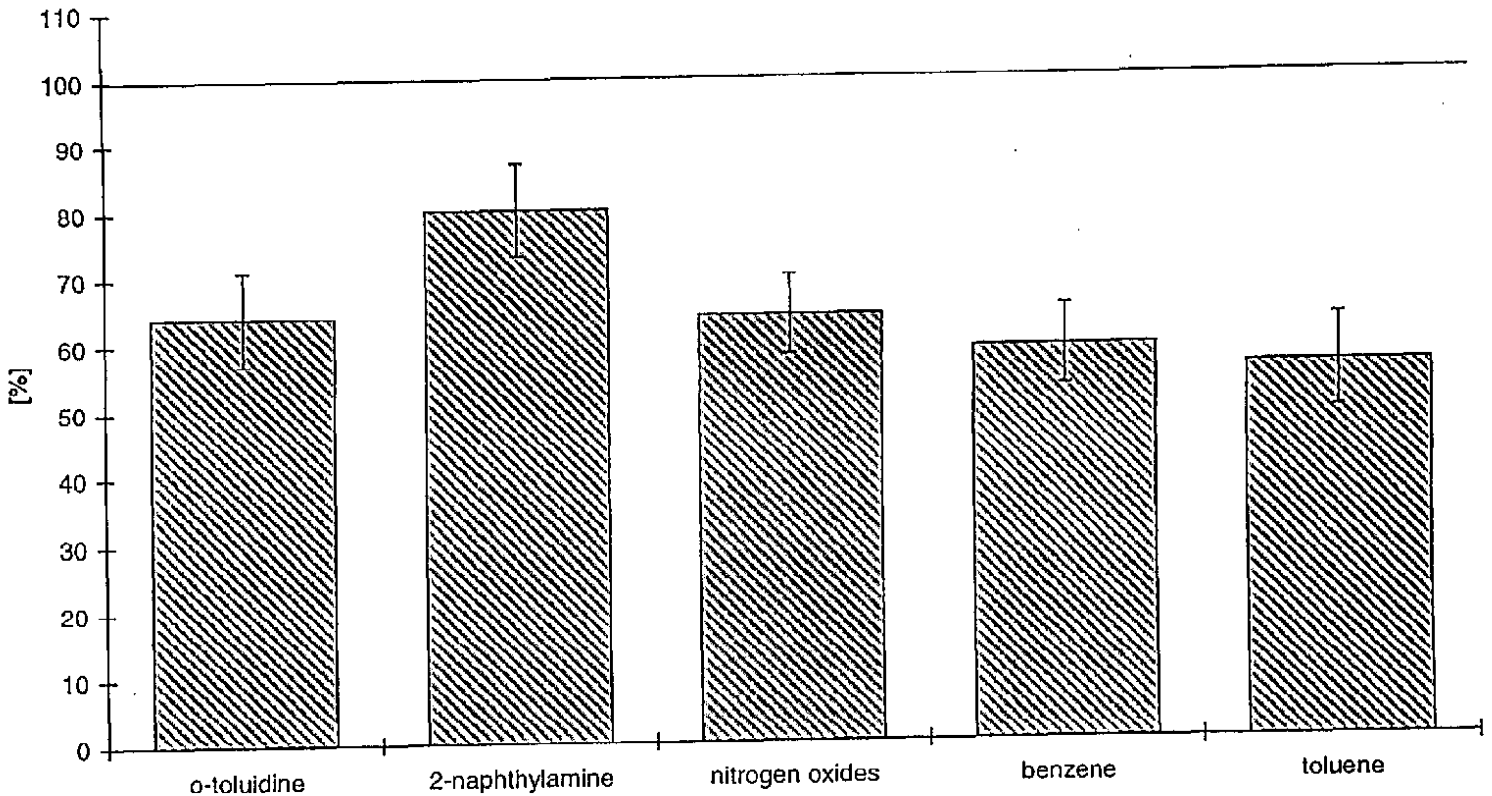

Figure 1 (cont.) HYDRA-AMP vs HYDRA-ST on an Equal TPM Basis

Remarks: Columns with error bars represent means and standard deviations.

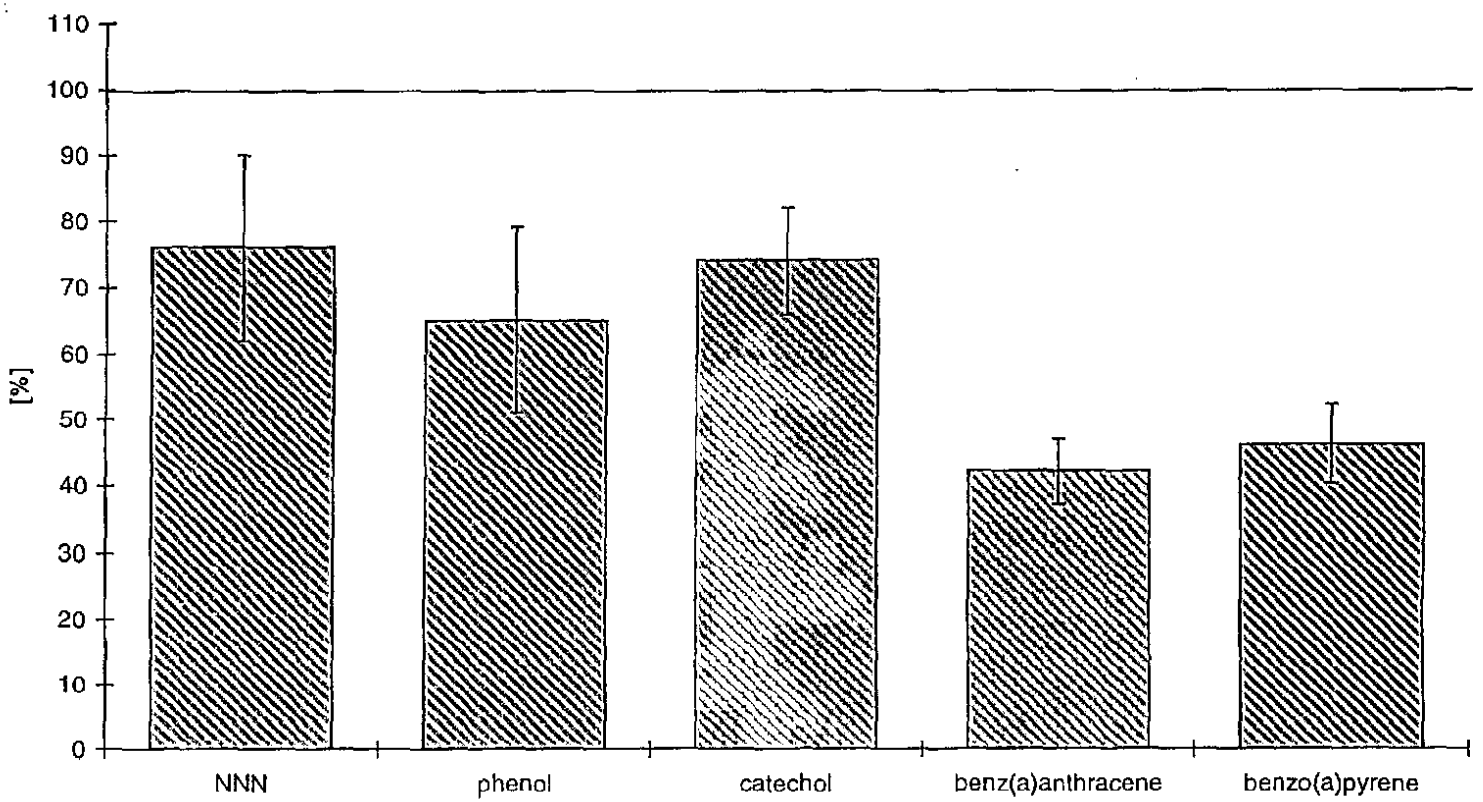

Figure 1 (cont.) HYDRA-AMP vs HYDRA-ST on an Equal TPM Basis

Remarks: Columns with error bars represent means and standard deviations.

8 Study Organization and Responsibilities

8.1 Study Organization

The study was performed by INBIFO Institut für biologische Forschung GmbH at Fuggerstraße 3, D-51149 Köln.

Start of experimental part:	16 CW 2000
End of experimental part:	33 CW 2000
Name and address of sponsor:	G. J. Patskan, Ph.D., D.A.B.T. Director, Product Integrity Philip Morris U.S.A. Research Center Richmond, VA
Address of study director and responsible scientists:	INBIFO Institut für biologische Forschung GmbH Fuggerstr. 3 D-51149 Köln

8.2 Responsibilities

The following teams were involved in this study: Analytical Chemistry (AC), Information Systems (IS), and Instrumentation (IN). The respective team manager is responsible for the performance of the methods.

Study Director:	13. Okt. 2000 Date	R. Stabbert Dr.rer.nat. R. Stabbert Chemist (Diplomchemiker)
Analytical Chemistry:	16 Okt. 00 Date	K. Rustemeier Dr.rer.nat. K. Rustemeier Chemist (Diplomchemiker)
Information Systems:	13 oct 00 Date	W. Gomm Dr.rer.nat. W. Gomm Mathematician (Diplommathematiker)
Instrumentation:	17. Okt. 2000 Date	i. A. SM F. Radtke Engineer (Diplomingenieur)
General Manager:	16.Okt.00 Date	W. Reininghaus Dr.rer.nat. W. Reininghaus Physicist (Diplomphysiker)

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9 Study Director Statement

The study director acknowledges responsibility for the validity of the study and confirms that it was conducted in accordance with Good Laboratory Practice (GLP) principles (Grundsätze der Guten Laborpraxis, 1994).

13. Okt. 2000
Date

R. Stabbert
Dr.rer.nat. R. Stabbert
Chemist (Diplomchemiker)

10 Quality Assurance Statement

Inspections on this study were performed by the INBIFO Quality Assurance unit for the following:

Parameter Inspected	Date (2000)		Remarks
	Inspection	QA Report	
study plan	13 Apr.	14 Apr.	-
smoke generation	5 May, 11 May, 25 May	11 May, 17 May, 13 Jul.	-
analytical procedures	8 May, 12 May, 25 May	11 May, 17 May, 13 Jul.	-
report	15 Sep.	18 Sep.	-

All findings were reported to the study director and to the general management. This report accurately reflects the study carried out and the results obtained.

13.10.00
Date

i. A. v. Holt
Quality Assurance Manager
Dr.med. Dr.rer.nat. K. von Holt, MSc
Medical Doctor, Physicist, Toxicologist
(Arzt, Diplomphysiker, Toxikologe)

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11 Storage of Records and Materials

Records are stored in the archives of INBIFO in room R021 for at least 15 years after delivery of the final report to the client. Samples of cigarettes are stored in the archives of INBIFO in room F58 as long as their quality under state-of-the-art storage conditions allows further evaluations, but not longer than 15 years. All cigarettes can be claimed by the client.

12 Study Plan Amendments

Change No.	Date of Study Director's Approval (2000)	Change	Author of Change
1	26 Apr.	SOP RM IN6/4 will be added to the SOPs listed in the study plan.	RST
2	26 Apr.	The permitted RTD range will be changed from 800 to 1300 Pa to 600 to 1200 Pa.	"
3	2 May	For the determination of N-nitrosamines in 1R4F MS, 20 instead of 30 cigarettes per sample will be smoked.	"
4	21 Aug.	In addition to the multi-group comparison of all 3 cigarette types, a comparison only between the 2 HYDRA cigarette types will be performed with the t-test.	WGO

13 References

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14 Abbreviations [a] [b]

AMP:	ammonium magnesium phosphate
BSTFA:	N,O-*bis*(trimethyl-silyl)trifluoroacetamide
CGC:	capillary gas chromatography
CW:	calendar week
FTC:	Federal Trade Commission
GC:	gas chromatography
GLP:	Good Laboratory Practice
ISO:	International Organization for Standardization
M:	arithmetic mean, for groups having values below the detection limit the median is given
MS:	mainstream smoke
MSD:	mass selective detector
NBUA:	N-nitrosodi-n-butylamine
NDEA:	N-nitrosodiethylamine
NDELA:	N-nitrosodiethanolamine
NDMA:	N-nitrosodimethylamine
NMEA:	N-nitrosomethylethylamine
NNK:	4-(N-methyl-N-nitrosamino)-1,-(3-pyridyl)-1-butanone
NNN:	N-nitrosonornicotine
NPD:	nitrogen phosphorous detector
NPI:	N-nitrosopiperidine
NPRA:	N-nitrosodi-n-butylamine
NPY:	N-nitrosopyrrolidine
PAHs:	polycyclic aromatic hydrocarbons
QL:	quantification limit
RTD:	resistance to draw
SD:	standard deviation
SPE:	solid phase extraction
TPM:	total particulate matter
UV:	ultraviolet

[a] in addition to those explained immediately on the same page
[b] Units are given in accordance with SI units (Système International d'Unités).

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Statistical Analysis

p:	probability of receiving the value of the test statistic or a more extreme value of the test statistic, if the null hypothesis holds
=:	$p > 0.05$, not statistically significant
+:	$p \leq 0.05$
++:	$p \leq 0.01$
+++:	$p \leq 0.001$
-:	not evaluated (e.g., no value available)

End of Report

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