# A N N E X E  2

## LE TABAC

**Le produit et ses composantes :**

Le produit au cœur du litige, le tabac, provient d'une plante dont le nom latin est *nicotiana tabaccum*. Le tabac est commercialisé sous diverses formes et vendu par les trois demanderesses ainsi que par d'autres fabricants (D-62, D-74). Les produits du tabac sont le suivants :

- Feuille de tabac non transformé (D-58)
- Tabac à chiquer (D-73)
- Tabac à pipe
- Tabac à rouler (D-66)
- Tabac gonflé (D-59)
- Tabac reconstitué
- Cigarettes manufacturées
- Batonnêt de tabac (D-63)
- Kretek (D-74)
- Bidies

À cette liste s'ajoutent de nouveaux produits qui ne sont pas encore vendus au Canada:

- Cigarettes Éclipse (D-76) et Accord Kit (D-77), dont le tabac est chauffé plutôt que brûlé pour en extraire la nicotine

Les produits du tabac dont il a surtout été question dans ce litige sont la cigarette manufacturée et le tabac à rouler. Les demanderesses n'ont présenté aucune preuve quant aux caractéristiques physiques ou chimiques des cigarettes qu'elles fabriquent et vendent à plus de 6 millions de Canadiens. Il est même étonnant que le seul représentant qu'ont fait entendre les demanderesses soit M. Ed Ricard, vice-président Marketing d'ITL, un témoin ayant plus de 25 ans d'expérience chez ITL et qui a été responsable du marketing de la cigarette Player's Première (P-29 et D-242 et D-243), une cigarette issue d'une supposée nouvelle technologie. M. Ricard a affirmé ne pas être au courant des caractéristiques physiques des cigarettes en général et de la cigarette Player's Première en particulier.

Comme l'a souligné le professeur André Castonguay, « la cigarette ressemble à une véritable usine chimique ». Il y a 2 500 substances différentes dans le tabac qui, lorsque qu'elles sont brûlées, « produisent plus de 4000 substances » (Surgeon General Report, 1989) (D-113, p. 6).

De plus, le tabac utilisé par les demanderesses pour manufacturer leurs diverses marques de cigarettes, comme les Du Maurier, Matinée, Player's, Export A, Craven A, Rothmans et autres contient des insecticides et des pesticides. Voilà pourquoi l'Allemagne et l'Italie ont fixé des limites ou niveaux de tolérance maximum quant aux résidus de pesticides que peut contenir le tabac. À elles deux, l'Allemagne et l'Italie réglementent environ 125 types de pesticides. Les États-Unis, pour leur part, ont établi des limites pour 16 pesticides prohibés contenus dans le tabac importé de l'étranger. Au Canada, il n'y a pas présentement de règlement concernant les quantités de pesticides et insecticides contenus dans le tabac utilisé par les demanderesses. Par contre, l'article 7 a) de la *Loi sur le tabac*, qui est contesté par les demanderesses, autorise l'adoption de règlements à ce sujet.

Dans une étude portant sur 360 marques de cigarettes canadiennes, menée en octobre 1995, la compagnie Labstat inc.– dont le président, M. Bill Rickert, jouit d'une grande réputation –, a notamment conclu ce qui suit :

> *1.1 "General Comments*
>
> *West Germany and Italy have set maximum permitted limits or tolerances for pesticide residues on tobacco and (or) tobacco products.*
>
> *For the two countries collectively, about 125 pesticides have been included. Other European countries may also adopt tolerances for tobacco products independently or jointly with Germany and Italy, through the European Economic Community. Although the United States has not established pesticide tolerances for tobacco products, it has set maximum allowable limits for 16 banned, cancelled, suspended, or otherwise prohibited pesticides (the so-called USDA Import List).*
>
> *Canada is well behind the rest of the world with respect to this issue since, once processed into cigarettes, there is not, nor has there ever been a program for the systematic assessment of pesticide residues in tobacco.*
>
> *There is not, nor has there ever been a requirement for the reporting of levels of pesticide residues in manufactured cigarette tobaccos, even though it could be argued that pesticides are "additives".*
>
> *1.6 Loss During Smoking*
>
> *The most unique factor relating to loss of pesticide residues on tobacco occurs during consumption, where the user either heats the product to 800°C or expectorates most of the product. The phosphate and carbamate insecticides are essentially destroyed during smoking. Available data indicate that 2% or less of presently recommended insecticides are likely to appear in the mainstream smoke. In the case of the chlorinated hydrocarbon insecticides, 5 to 20% of the parent molecule might be expected in the mainstream smoke.*
>
> *In addition to the active principals contained in pesticides, other substances such as surfactants or solubilizing agents of inert carriers may, if transferred to tobacco smoke, interact with compounds in the diet or undergo conversion to potentially hazardous substances in the tobacco leaf itself, e.g., nitrosation of diethnolamine which is used as a*

*solubilizing agent for maleic hydrazide. Very little is known regarding these potential interactions and the effects, if any, in humans.*

*1.7 Regulation of Tobacco Pesticide Residues*

*Agriculture Canada registers pesticides for use in Canadian on the basis of an evaluation that considers efficacy, safety of residue levels, safety of application, and environmental impact. Maximum residue limits (MRLs) are established by Health and Welfare Canada and published in the Food and Drugs Act. Division 15, Section B.15.002, of this Act establishes an adulteration limit of 0.1 ppm for all agricultural chemicals in foods except those specifically listed with their MRL in Division 15, Table II. Accordingly residues of pesticides not registered for use in Canada are subject to an MRL of 0.1 ppm.*

*Agriculture Canada is responsible for ensuring that food commodities, either shipped interprovincially or imported, comply with these MRL's.*

*Since tobacco is not a food commodity, it does not come under the provisions of the Food and Drugs Act. Commercial brands of Canadian cigarettes have not been investigated in a systematic way for pesticide levels. The present investigation would provide the first comprehensive data base in that regard."*

*A Historical Survey of Levels of Selected Pesticides in Canadian Cigarette Tobaccos*, Labstat Incorporated, October 31, 1995 (ED-192)

Au fil des ans, les demanderesses ont modifié les caractéristiques physiques et chimiques des cigarettes canadiennes sans en informer les consommateurs. Par exemple, l'utilisation de différentes sortes de papier ou d'additifs, la perforation du papier et de l'embout de ventilation ont modifié le contenu ou le nombre de substances toxiques que l'on retrouve dans la fumée principale et secondaire de la cigarette (D-113, p. 7).

Les cigarettes de plusieurs marques canadiennes sont ventilées au moyen de minuscules orifices qui se trouvent sur l'embout. En théorie, la ventilation a pour effet de diminuer la quantité de fumée principale. Toutefois, ce principe ne vaut que dans les analyses faites à partir d'une machine à fumer. Dans le cas des êtres humains, le comportement des fumeurs et le phénomène de compensation font en sorte qu'un consommateur de cigarettes légères absorbera autant de fumée et de substances toxiques qu'un fumeur de cigarettes à haute teneur en nicotine et en goudron (D-113, p. 13).

Par ailleurs, le tabac utilisé par les demanderesses dans la fabrication de leurs produits a lui aussi été modifié au fil des ans. Les manufacturiers de tabac ont notamment sélectionné certaines parties de la plante de tabac qui contiennent davantage de nicotine afin de conserver les mêmes taux de nicotine qu'auparavant vu que les cigarettes canadiennes sont ventilées en plus de contenir moins de tabac que par le passé.(D-113, p. 13).

*Historical Study of Nicotine Yields of Canadian Cigarettes in Relation to the Composition and Nicotine Content of Cigarette Tobacco* (1968-1995) by W.S. (Bill) Rickert (D-118, p. 2, par. 2.1, 2.2, 5.5.5 et 7):

*2.1 "Physiological Properties of Nicotine*

*Nicotine is one of the most powerful of all drugs. Two or three drops placed on the tongue would rapidly kill an adult, and the nicotine content of one cigar, about 60 mg, would be fatal to a human if injected intravenously. The actions of nicotine in the body are so complex and multitudinous that there are few other psychoactive drugs about which so much is known, though so little understood. Nicotine reaches and can have an effect on every organ in the body.*

*Nicotine has both peripheral and central effects. It can stimulate. It can sedate. It induces tolerance. Physical as well as psychological effects occur on withdrawal. More importantly, unlike some addictive drugs, it does not impair the capacity to work or to socialize appropriately. Social disapproval is the only contiguous negative consequence and this does not operate all the time.*

*Some of the effects of nicotine, not necessarily addictive, include:increase in heart rate and blood pressure, release of epinephrine from the adrenal medulla and 11 hydroxycorticosteroids from the adrenal cortex, increase in serum free fatty acids and triglycerides, inhibition of stomach contractions and gastric secretions, delay in the emptying time of the stomach, impairment of pyloric competence with increase in duodenogastric reflux, increase in the activity of the colon, inhibition of appetite, and an effect of reducing body weight by some process over and above the effect on appetite.*

*Finally, it is possible that the dependence-producing potential of psychoactive drugs is partly due to their pharmacological ability directly or indirectly to influence the hypothalamic reward system. Activity in this system, it seems, is mediated by catecholamine release. Doses of nicotine not only release catecholamines in these areas, but nicotine actually influences hypothalamic electrical self-stimulating behaviour.*

*2.2 Addictive Properties of Nicotine*

*Why is cigarette smoking so addictive? The short answer is because the modern cigarette is such a highly efficient device for delivering nicotine to the brain. By inhaling tobacco smoke, the smoker can get nicotine to his brain more rapidly than the heroin addict can get a "buzz" when he shoots heroin into a vein. It takes only 7 seconds for inhaled nicotine to reach the brain compared to 14 seconds for blood to flow from arm to brain. Furthermore, the smoker gets a "shot" of nicotine after each inhaled puff. The number of rapid pharmacological reinforcements is quite staggering. The pack-a-day smoker gets through 7300 cigarettes a year. At 10 puffs per cigarette this means more than 70,000 shots of nicotine to the brain in a year.*

*Added to this are other factors such as taste, aroma, the social and other nonpharmacological rewards, and the fact that smoking combines a pharmacological effect with a sensorimotor ritual which provides an elaborate network of sensory and motor stimuli to act as substrate for secondary conditioning. It is hardly surprising that cigarette smoking is so addictive.*

*5.5.5 Conclusions*

*The nicotine content of cigarette tobacco has been increasing roughly in a linear way since about 1980. This increase is most evident in the lamina fraction but is also noticeable in fractions of midrib and stem. With respect to individual brands of cigarettes, there are impressive differences; the nicotine content of Player's RSFT manufactured by Imperial Tobacco increased rapidly from about 1980 to 1995 compared with Rothmans KSFT manufactured by Rothmans B&H. This suggests significant differences in cigarette design strategies among Canadian manufacturers which is further emphasized by the recent use of a "brown" component in the manufacture of many Imperial Tobacco brands.*

*The tobacco which is found in Canadian cigarettes is relatively homogeneous in comparison with the constituents of American cigarettes. This means that most of the brand differentiation must come from cigarette design rather than through the use of a variety of starting materials. Since the distribution of alkaloids among the various fractions is rather similar, in the authors opinion, it would appear that:*

*The main vehicle for increasing the nicotine content of the tobacco in Canada cigarettes has been through selection of appropriate leaves (nicotine content varies with leaf position) and genetic manipulation of cultivars. However, if the "brown" fraction represents reconstituted material, the nicotine content of that material would be subject to a far greater control by the manufacturer.*

*7.0 Nicotine in Cigarette Tobacco in Relation to Nicotine in Cigarette Smoke*

*[…]*

*It is extremely important to remember that the amount of tobacco per cigarette actually decreased in this time period. Thus, in order to maintain levels of nicotine per cigarette it was necessary to increase the amount of nicotine per gram."*

Par ailleurs, certaines marques de cigarettes et de tabac à rouler vendues par les demanderesses ITL et Rothmans Benson & Hedges sont identiques. Autrement dit, ces produits n'ont de différents que le nom et l'emballage; il sont en fait identiques, ce dont les consommateurs ne sont pas informés (D-270, D-279).

Les cigarettes canadiennes contiennent du tabac de Virginie, dont une quantité de tabac reconstitué à partir des déchets produits lors du processus de fabrication. Les fabricants incorporent un ou des additifs à ce tabac reconstitué (D-115, p. 51 et suivantes, p. 58).

*«2. Physical Characterization of Tobacco Sheet*

*Because of the possible effects that the physical and structural characteristics of reconstituted cigarette tobacco sheet can have on the combustion process in the formation of cigarette tobacco smoke, a somewhat detailed description of reconstituted tobacco sheets appears warranted. It would be an oversimplification to consider reconstituted tobacco sheets as a generic heading. Reconstituted tobacco sheets differ as widely from each other as Burley tobacco differs from flue-cured*

> *and oriental tobaccos. Each of the sheet processes forms its own unique kind of tobacco sheet, with different structural, physical, and chemical characteristics. With the exception of sheets produced by those processes that employ no added ingredients, that is, the all-tobacco sheets, the reconstituted sheets owe their physical structure and tensile properties to non-tobacco adhesive and to the reinforcing fibers that are added. The reinforcing fibers are usually cellulose, although in some instances they may be inorganic or ceramic fibers."*

À la p. 83 :

> *"Little has been published concerning the chemical composition of smoke from reconstituted sheets. The gross condensate, nicotine, and carbonyl levels are reduced. There is strong inferential evidence that the composition of sheet smoke condensate is also qualitatively altered. The chemical and physical make-up of reconstituted sheets can be altered within wide limits as a result of the advanced sheet-forming technology that has been developed in the past 15 years. Reconstituted sheet technology will permit the tobacco scientist and technologist to superimpose structural and compositional variations in the manufacture of reconstituted sheet. These variations could have profound effects upon the composition and the chemical and biological properties of the smoke obtained from cigarettes made of these products."*

Les papiers, filtres et embouts de ventilation des cigarettes manufacturées contiennent toutes sortes de produits chimiques qui s'ajoutent aux substances contenues dans le tabac et qui sont libérées lors de la combustion (D-84, D-85, D-240).

Le contenu des cigarettes canadiennes n'a pas été divulgué aux consommateurs; il s'agit pourtant de renseignements tout aussi utiles que les quantités de substances toxiques contenues dans la fumée principale et secondaire des cigarettes (D-120).

Au cours des années 1996 et 1997, la demanderesse ITL a fabriqué et promu, à l'échelle nationale, la cigarette Player's Première (D-29, D-237), présentée comme étant moins irritante. Or, l'analyse comparative de ses constituants toxiques effectuée par le professeur André Castonguay démontre ce qui suit :

1. *« La cigarette Player's Première annoncée comme moins irritante contenait plus de NNK (un puissant cancérigène) que les autres marques de cigarettes canadiennes (D-113, D-120) (transcription p. 2888, 2891 et 2893).*
2. *Le filtre prétendu «unique» de la Player's Première n'avait rien d'innovateur puisqu'il était utilisé au Portugal depuis 20 ans.*
3. *La cigarette Player's Première, supposée moins irritante, contenait des quantités de substances chimiques irritantes égales ou supérieures à celles qui sont contenues dans les autres marques de cigarette (D-241, annexe Toxicity/Carcinogenicity Assessment Yields of Selected Constituents by Popular or « Innovative» Cigarettes », Labstat Inc., April 30, 1998.).*

4. *De 1999 à 2001, les rendements en substances toxiques de la cigarette Player's Première ont varié parce qu'on aurait apporté des changements à cette marque (Q 187-197). »*

Dans une étude intitulée «Toxicity/Carcinogenicity Assessment Yields of Selected Constituents by Popular or « Innovative cigarettes», Labstat Inc., April 30, 1998 (Pièce D-241), on y constate :

- *"The so called "less hazardous" cigarette would seem to be the solution to a number of dilemmas. For the smoker who is both strongly attracted or habituated to continued smoking but also desires to reduce the hazard to his or her health, it offers the promise of compromise. For the manufacturers, reducing "tar" and nicotine (T/N) has proved an important marketing tool to reach an increasingly health-conscious public and to reduce criticism in the biomedical community, without serious economic loss to interests dependent on tobacco sales. The less hazardous cigarette has been seen, by some, as a compromise between the statutory commitments of the Government to public health (and thus antismoking efforts) on one hand and to agriculture and other economic activity on the other.*

- *The logic that lower T/N yields equal less harmful smoking seems simple and persuasive. But, as noted in "Tobacco Control: A Blueprint to Protect the Health of Canadians", there are a number of ways in which this logic may be misleading. First, the measurements of T/N are performed by analyzing smoke drawn by a machine that simulates smoking with a simple and unchanging program. Human smokers and their cigarettes, however, are neither simple nor unchanging. Lowering the T/N of cigarettes typically results in people's smoking more of them or smoking them differently. Machine yields, as currently published, have little to do with human exposure.*

- *Second, there is the complexity of the product itself. Tobacco smoke contains several thousand distinct compounds. While the particulate condensate ("tar") is clearly carcinogenic, and pure nicotine and carbon monoxide both have well-demonstrated effects of the cardiovascular system, the quantities of these components, as now reported, does not give adequate information relevant to the potential toxicity of cigarettes. In particular, the numbers do not take into account the yield of gases formaldehyde, hydrogen cyanide, NOx and others in cigarette smoke, which may not parallel T/N yields as the cigarette is smoked. This point can be illustrated by a plot of pyridine in relation to yields of nicotine under current standard Canadian conditions (data from a 1995 Labstat report to Health Canada).*

- *In addition, flavourings are added to tobacco to modify the taste for consumer satisfaction. As a rule these additives are not under the purview of regulations and are held as industrial secrets. It is known that some flavourings designed to offset reduced T/N taste give rise to toxic constituents when burned.*

- *However, yields of tar, nicotine and CO from the second «unique » brand (Player's Premiere) were not significantly different from the other popular Canadian brands which were tested in this project. Consequently, the properties of the filter (described by the manufacturer as "incorporating the dispersion qualities of granular semonlina, a grain product made from wheat, with beads of charcoal, an effective natural*

*filtering agent") were not sufficient to differentiate this brand from the others.*

- *The data for the two innovative brands tested in this project establish the upper and lower bounds for phenolic deliveries in this project. Player's Premiere (brand 292) was consistently the highest and Eclipse the lowest.*
- *There is very little difference among the popular brands of Canadian cigarettes which were tested in this project. There is no evidence for a difference in the innovative Canadian brand (Player's Premiere) and the highest yielding popular brand in this test set. Yields of bezo[a]pyrene from the cigarette which primarily heats tobacco were very in comparison with those of typical Canadian tobacco burning cigarettes small(~6% of the average for the 4 Canadian brands).*
- *In most cases, yields obtained for Player's Premiere (brand number 292) were indistinguishable from those produced by the more popular member of the Player's family (i.e. Player's Light (Re) Regular Filter. With respect to Eclipse (brand number 308), deliveries of hydrogen cyanide under standard test conditions are about 10 fold less than the other brands which were tested in this project.*
- *Yields of ammonia from Player's Premiere (brand no 292, the cigarette with the innovative filter) are higher than those observed for the "regular" Player's brand (brand no 114). As a group, the traditional tobacco burning cigarettes evaluated in this series, all have very similar yields of mainstream ammonia. Yields for the tobacco heating cigarette are about ¼ of those obtained from the other products.*
- *Yields for compounds classified, as "miscellaneous volatile organics" are all very similar with the exception of Brand number 308 (Eclipse). Yields for brand 292 (Player's Premiere), described by the manufacturer as giving "reduced irritation" were very similar to those of the other two popular brands which were tested. In most cases, yields obtained for Player's Premiere were indistinguishable from those produced by the more popular member of the Player's family (i.e. Player's Light Regular Filter)"*

Au sujet des cigarettes qualifiées de légères, le Surgeon General des États-Unis a émis les commentaires suivants en 1981 (D-121) :

1. *"There is no safe cigarette and no safe level of consumption.*
2. *Smoking cigarettes with lower yields of "tar" and nicotine reduces the risk of lung cancer and, to some extent, improves the smoker's chance for longer life, provided there is no compensatory increase in the amount smoked. However, the benefits are minimal in comparison with giving up cigarettes entirely. The single most effective way to reduce hazards of smoking continues to be that of quitting entirely.*
3. *It is not clear what reductions in risk may occur in the case of diseases other than lung cancer. The evidence in the case of cardiovascular disease is too limited to warrant a conclusion, nor is there enough information on which to base a judgment in the case of chronic obstructive lung disease. In the case of smoking's effects on the foetus and newborn, there is no evidence that changing to a lower "tar" and nicotine cigarette has any effect at all on reducing risk.*

4. *Carbon monoxide has been impugned as a harmful constituent of cigarette smoke. There is no evidence available, however, that permits a determination of changes in the risk of diseases due to variations in carbon monoxide levels.*

5. *Smokers may increase the number of cigarettes they smoke and inhale more deeply when they switch to lower yield cigarettes. Compensatory behaviour may negate any advantage of the lower yield product or even increase the health risk.*

6. *The "tar" and nicotine yields obtained by present testing methods do not correspond to the dosages that the individual smokers receive: in some cases they may seriously underestimate these dosages.*

7. *A final question is unresolved, whether the new cigarettes being produced today introduce new risks through their design, filtering mechanisms, tobacco ingredients, or additives. The chief concern is additives. The Public Health Service has been unable to assess the relative risks of cigarette additives because information was not available from manufacturers as to what these additives are.*

*In evaluating the public health significance of the finding of reduced risk of lung cancer, it is important to recognize that the largest component of excess mortality caused by smoking is cardiovascular disease deaths. There is no sufficient evidence to conclude that use of lower "tar" and nicotine cigarettes causes any reduction in this burden. The same is true of the other major diseases caused by cigarette smoking, most notably chronic obstructive lung disease and adverse effects on pregnancy."*

Étant donné que les fumeurs fument pour combler leur besoin en nicotine, ils auront tendance à ajuster leurs habitudes de consommation de façon à maintenir la dose de nicotine à laquelle ils sont habitués :

*"[…] In a practical sense, if someone smokes for nicotine, they will obtain whatever amount is necessary to satisfy their need independent of what the smoking machine number happens to be. […]*

Statement from the Ad Hoc Committee of the President's Cancer Panel to Consider the FTC Test Method for Determining Tar, Nicotine, and Carbon Monoxide Levels in Cigarettes
December 6, 1994, 2:30 pm

A. *"The smoking of cigarettes with lower machine-measured yields has a small effect in reducing the risk of cancer caused by smoking, no effect on the risk of cardiovascular disease, and an uncertain effect on the risk of pulmonary disease. A reduction in machine-measured tar yield from 15 mg tar to 1 mg tar does not reduce relative risk from 15 to 1.*

B. *The FTC test protocol was based on cursory observations of human smoking behaviour. Actual human smoking behaviour is characterized by wide variations in smoking patterns which result in wide variations in tar and nicotine exposure. Smokers who switch to lower tar and nicotine cigarettes frequently change their smoking behaviour which may negate potential health benefits.*

> *C. Accordingly, the committee recommends the following changes to the FTC protocol:*
>
> *1. This system should also measure and publish information on the range of Tar, Nicotine, and Carbon Monoxide yields that most smokers should expect from each cigarette sold in the U.S.*
>
> *2. This information should be clearly communicated to smokers."*
>
> Smoking under realistic conditions: development of minimum and maximum values for toxic constituents in Tobacco smoke, September 30, 1996 (ED-187, p. 3 et 4).

Voilà pourquoi il a été recommandé d'adopter une nouvelle méthode de calcul en ce qui a trait aux niveaux de goudron, de nicotine et de monoxyde de carbone émis par la cigarette. La méthode qui avait été utilisée au Canada de 1969 à l'an 2000 datait des années 1930, d'où le besoin d'avoir une nouvelle réglementation sur le contenu des cigarettes :

> *"[…] FDA agrees that accurate information about the tar, nicotine, and carbon monoxide delivery from a cigarette to the user would be useful information. FDA is aware of the Federal Trade Commission's (FTC's) recent efforts to develop a system to measure, more accurately than the current test, the tar, nicotine, and carbon monoxide delivered by cigarettes. […]"*
>
> Health Food and Drug Administration, August 28, 1996 (ED-47, p. 44463)

En 1997, la Federal Trade Commission s'est aussi prononcée sur la question :

> *"Despite these substantial decreases in machine-measured yields, the Commission has been concerned for some time that the current test method may be misleading to individual consumers who rely on the ratings it produces as indicators of how much tar and nicotine they actually get from their cigarettes. In fact, the current ratings tend to be relatively poor predictors of tar and nicotine exposure. This appears to be due primarily to compensation – the tendency of smokers of lower rated cigarettes to take bigger or more frequent puffs, or otherwise alter their smoking behaviour to get the amount of nicotine they need. Such variations in the way people smoke can have significant effects on the amount of tar, nicotine, and carbon monoxide they get from any particular cigarette. The Commission is concerned that smokers may incorrectly believe, for example, that they will get three times as much tar from a 15 mg. tar cigarette as from a 5 mg. tar cigarette. In fact, if compensation is sufficiently great, it is possible for smokers to get as much tar and nicotine from relatively low rated cigarettes as from higher rated ones. Although these limitations have been present in the system since its initiation in 1967, they have become of substantial concern more recently because of changes in modern cigarette design and a better understanding of the effects of compensatory smoking behaviour.*
>
> *Some public health agencies have also expressed concerns that new studies may question the basic assumption underlying cigarette testing – that cigarettes with lower machine-measured tar and nicotine ratings are less harmful than ones with higher ratings. For example, in 1997, the National Cancer Institute issued a monograph noting that the apparent mortality risk*

> *among current smokers has risen in the last forty to fifty years, even though machine-measured tar and nicotine yields have fallen during the same period. In attempting to understand this fact, the monograph suggested that the increased mortality risk might be due to increases in current smokers' lifetime exposure to cigarette smoke or that the reduced tar levels of modern cigarettes may have less benefit than previously believed. In addition, a number of studies have also found that changes in smoking behaviour and cigarette design appear to have resulted in an increase in a type of cancer that occurs deeper in the lung than the lung cancer traditionally associated with smoking."*
>
> Federal Trade Commission, Report to Congress (1997) (ED-46, p. 3, 4 et 5).

## Le tabac et la science de la toxicologie

La cigarette étant un produit extrêmement toxique, sa fumée contenant près de 4 000 produits chimiques dont 250 causent du dommage génétique ou sont toxiques et dont 43 sont reconnus comme étant cancérigènes[1], elle se prête au modèle du Risk Assessment Paradigm[2] utilisé en toxicologie pour décrire le risque associé à l'usage d'un produit toxique. Ce modèle est utilisé pour déterminer si, malgré qu'un produit soit toxique, il peut néanmoins être utlisé, ou si en limitant l'exposition au produit on peut en arriver à un niveau où les avantages découlant de son usage seront plus importants que les désavantages découlant de l'exposition au produit, rendant de ce fait son usage acceptable malgré les risques qui y sont associés. Suivant ce modèle, le risque est donc défini par deux variables, soit la toxicité et l'exposition.

Or, compte tenu qu'elle découle directement de l'usage de la cigarette, l'exposition à la fumée de cigarette ne peut être réduite. Combiné à la deuxième variable qu'est la grave toxicité de la fumée de cigarette, la conclusion irréfutable à laquelle mène cet exercice est que l'énorme risque associé à la cigarette ne peut être réduit. Il est donc impossible suivant ce modèle d'atteindre un niveau de risque acceptable.

Au surplus, puisqu'aucun bénéfice ne peut être dérivé de l'usage du tabac[3], le risque associé à son usage ne peut se justifier.

L'application de ce modèle au tabac permet de conclure qu'il s'agit d'un produit qui n'a aucun niveau sécuritaire d'exposition, qui entraine des risques

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[1] IARC (International Agency for Research on Cancer). 1986. IARC Monographs on the Evaluation of the carcinogenic Risk of Chemicals to Humans – Tobacco Smoking, Volume 38, Lyon, France, pièce D-109

[2] "Risk assessment is used as part of the decision-making progress to ensure public protection against unacceptable risks and to allow the use of products whose benefits outweigh the risks associated with their use, SOT (Society of Toxicology). 2000. Risk Assessment: What's it all about? Society of Toxicology, Reston, Virginia dans "Toxicology and Tobacco", Leonard Ritter, pièce D-107.

[3] "Toxicology and Tobacco", Leonard Ritter, pièce D-107, Q. 251ss, p. 2362ss.

extrêmement importants pour la santé lesquels ne peuvent absolument pas se justifier vu l'absence de bénéfices découlant de l'usage du tabac.

D'ailleurs, l'absence de bénéfices associés à l'usage du tabac a essentiellement été confirmé par la Cour Suprême des États-Unis dans l'affaire Food and Drug Administration et al. v. Brown and Williamson Corp. et al. 529 U.S. (2000) où la Cour a invalidé le Food and Drug Administration's «Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents» au motif d'absence de juridiction puisqu'il n'était pas du ressort de la FDA de réglementer un produit dont l'on sait d'ores et déjà qu'il devrait être prohibé compte tenu des risques associés à son usage et en l'absence de quelconque effet bénéfique pour la santé. Madame la Juge O'Connor pour la majorité explique:

> *"Viewing the FDCA as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is "safe" and "effective" for its intended use.*
>
> *Thus, the Act generally requires the FDA to prevent the marketing of any drug or device where the "potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit."*
>
> *In its rulemaking proceeding, the FDA quite exhaustively documented that "tobacco products are unsafe," "dangerous," and "cause great pain and suffering from illness." 61 Fed. Reg. 44412 (1996). It found that the consumption of tobacco products "presents extraordinary health risks," and that "tobacco use is the single leading cause of preventable death in the United States."* Id. *, at 44398. It stated that "[m]ore than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths," and that "[t]obacco alone kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined."* Ibid. *Indeed, the FDA characterized smoking as "a pediatric disease,"* id. *, at 44421, because "one out of every three young people who become regular smokers ... will die prematurely as a result,"* id. *, at 44399.*
>
> *These findings logically imply that, if tobacco products were "devices" under the FDCA, the FDA would be required to remove them from the market. Consider, first, the FDCA's provisions concerning the misbranding of drugs or devices. The Act prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adultered or misbranded." 21 U. S. C. §331(a). In light of the FDA's findings, two distinct FDCA provisions would render cigarettes and smokeless tobacco misbranded devices. First, §352(j) deems a drug or device misbranded "[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." The FDA's findings make clear that tobacco products are "dangerous to health" when used in the manner prescribed. Second, a drug or device is misbranded under the Act "[u]nless its labeling bears ... adequate directions for use ... in such manner and form, as are necessary for the protection of users," except where such directions are "not necessary for the protection of the public health." §352(f)(1). Given the FDA's conclusions concerning the health consequences*

*of tobacco use, there are no directions that could adequately protect consumers. That is, there are no directions that could make tobacco products safe for obtaining their intended effects. Thus, were tobacco products within the FDA's jurisdiction, the Act would deem them misbranded devices that could not be introduced into interstate commerce.*

*Second, the FDCA requires the FDA to place all devices that it regulates into one of three classifications. See §360c(b)(1). … Given the FDA's findings regarding the health consequences of tobacco use, the agency would have to place cigarettes and smokeless tobacco in Class III because, even after the application of the Act's available controls, they would "presen[t] a potential unreasonable risk of illness or injury." 21 U. S. C. §360c(a)(1)(C). As Class III devices, tobacco products would be subject to the FDCA's premarket approval process. See 21 U. S. C. §360c(a)(1)(C) (1994 ed., Supp. III); 21 U. S. C. §360e; 61 Fed. Reg. 44412 (1996). Under these provisions, the FDA would be prohibited from approving an application for premarket approval without "a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested on the labeling thereof." 21 U. S. C. §360e(d)(2)(A). In view of the FDA's conclusions regarding the health effects of tobacco use, the agency would have no basis for finding any such reasonable assurance of safety. Thus, once the FDA fulfilled its statutory obligation to classify tobacco products, it could not allow them to be marketed.*

*The FDCA's misbranding and device classification provisions therefore make evident that were the FDA to regulate cigarettes and smokeless tobacco, the Act would require the agency to ban them.*

*Several provisions in the Act require the FDA to determine that the* product itself *is safe as used by consumers. That is, the product's probable therapeutic benefits must outweigh its risk of harm. See* United States *v.* Rutherford, *442 U. S., at 555 ("[T]he Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use").*

*…the FDA must weigh the probable therapeutic benefits of the device to the consumer against the probable risk of injury. Applied to tobacco products, the inquiry is whether their purported benefits--satisfying addiction, stimulation and sedation, and weight control--outweigh the risks to health from their use. To accommodate the FDA's conception of safety, however, one must read "any probable benefit to health" to include the benefit to public health stemming from adult consumers' continued use of tobacco products, even though the* reduction *of tobacco use is the* raison d'être *of the regulations. In other words, the FDA is forced to contend that the very evil it seeks to combat is a "benefit to health." This is implausible.*

*As the FDA has documented in great detail, cigarettes and smokeless tobacco are an unsafe means to obtaining* any *pharmacological effect.*

*The FDA, consistent with the FDCA, may clearly regulate many "dangerous" products without banning them. Indeed, virtually every drug or device poses dangers under certain conditions. What the FDA may not do is conclude that a drug or device cannot be used safely for any therapeutic purpose and yet, at the same time, allow that product to remain on the market. Such regulation is incompatible with the FDCA's core objective of ensuring that every drug or device is safe and effective.*

> *Considering the FDCA as a whole, it is clear that Congress intended to exclude tobacco products from the FDA's jurisdiction. A fundamental precept of the FDCA is that any product regulated by the FDA--but not banned--must be safe for its intended use. Various provisions of the Act make clear that this refers to the safety of using the product to obtain its intended effects, not the public health ramifications of alternative administrative actions by the FDA. That is, the FDA must determine that there is a reasonable assurance that the product's therapeutic benefits outweigh the risk of harm to the consumer. According to this standard, the FDA has concluded that, although tobacco products might be effective in delivering certain pharmacological effects, they are "unsafe" and "dangerous" when used for these purposes. Consequently, if tobacco products were within the FDA's jurisdiction, the Act would require the FDA to remove them from the market entirely. But a ban would contradict Congress' clear intent as expressed in its more recent, tobacco-specific legislation. The inescapable conclusion is that there is no room for tobacco products within the FDCA's regulatory scheme. If they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit.*
>
> *The agency has amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States.Nonetheless,… an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress."*

La Cour Suprême des États-Unis a donc conclu que c'est l'absence de quelconque bénéfice découlant de l'usage du tabac conjugé au risque y associé qui faisait en sorte que la FDA n'avait juridiction pour légiférer comme elle entendait le faire puisque cela aurait entrainé la prohibition du produit alors que le rôle de la FDA est de s'assurer que tout produit non-prohibé doit être sécuritaire pour l'usage auquel il est destiné. La réalité du produit qu'est le tabac ne cadrait donc pas avec la mission de la FDA.

Cette décision permet de conclure que si l'on tentait pour la première fois de mettre le tabac sur le marché aujourd'hui, sa commercialisation et son usage seraient interdit.

Par ailleurs, la toxicologie des produits du tabac est bien connue des compagnies de tabac, en particulier ITL, et ce depuis des dizaines d'années, tel qu'il appert des pièces.

- D-108, «A Review of the Biological Activity of Smoke», préparé par G. Smith pour le compte de B.A.T et daté du 1er novembre 1990

- Report # 164 "Summary of Ames Tests for Mutagenicity of Smoke Condensates", ITL Montreal, July 2 1981, pièce D-110C

- Report T-234 "Bioassays of Mainstream and Sidestream Condensate from a Product with Total Sidestream Reduction and from Commercial Cigarettes", B.A.T, February 5 1992, pièce D-110A, à la page i

- Report # 165 “Ames Mutagenicity of Mainstream and Sidestream Smoke Condensates”, ITL Montreal, May 13 1981, pièce D-110B

- Report T.153-C “Ames Mutagenic Activity of Mainstream Condensate of Six Commercial Cigarettes for Imperial Tobacco Ltd. (Canada) – Project RIO”, B.A.T., October 1984, pièce D-110D

- Report # 146 “The Use of the Freiri Slave Smoker to Investigate Changes in Smoking Behaviour” ITL Montreal, March 25 1975, pièce D-110E

- Imperial Tobacco Ltd., Research Development Division, Montreal, Progress Report June 1987 – January 1988, pièce D-110H

En plus de démontrer que les compagnies de tabac connaissent la grave toxicité de leurs produits depuis des décennies, ces rapports confirment la nécessité de continuer de tester toutes les composantes de la cigarette et de sa fumée. Ce produit demeure toujours en constante évolution et compte tenu de sa toxicité, ses caractéristiques se doivent d’être testées et évaluées, d’où la nécessité du Règlement sur les rapports qui permettra au Gouvernement de contrôler ce qui est mis sur le marché.

Référant à la pièce D-108 “A Review of the Biological Activity of Smoke” de M. G. Smith, le témoignage du Dr. Ritter est on ne peut plus éloquent à ce sujet, tout comme les propos du tribunal. M. Ritter explique dans le passage suivant l’importance d’obtenir le résultat des recherches scientifiques des compagnies de tabac sur une base continuelle:

> *“But I think there is an interesting message here, particularly as we go to some of the other sections in the report itself, because it indicates that there is value in carrying out these studies on an ongoing basis.*
>
> *I mean, what he reports is that these are differences with different products, there are differences with different additives, there are differences in toxicity with different manufacturing constituents in the tobacco products, and what he’s saying here is that this review has allowed for a comparison of what those differences mean in terms of the ultimate toxicity of the product. So he really argues, I think, quite convincingly that ongoing studies are useful, because it allows you to compare the impact of changing things.*
>
> *Q- All righ. How would you … or can you apply this statement or this conclusion to our present situation here? What it the relevance that, in fact, it allows … or continuous studies are relevant? I mean, it’s a toxicological product, we all know that. So what would be the point of continuing evaluations?*
>
> *A- Well, I think continuing evaluations serve perhaps one (12) or two (2) very clear purposes, and perhaps a number of others as well. Most of our attention really for the last twenty-five (25) or thirty (30) years on the toxicity of tobacco has focused predominantly on cancer and on mutagenicity.*

*Now, what if there was a change in the tobacco that was used, or there was a change in the curing process, or there was a change in the part of the plant which was being used to manufacture the tobacco product? Or what if there was a change in the composition of the paper? I can go on and on and on. And what if that change resulted in a profile change that now made a product which was capable of causing cancer also very capable of causing birth defects?*

*Now, it we didn't have these studies continue on an ongoing basis and if we couldn't evaluate the results of those studies on an ongoing basis, how would we detect a change in the toxicity as a result of the change in the profile of the manufacturing process, so to speak?*

*Because Smith has provided very nice data which demonstrates that there are changes as a function of these variables, and so we have no way of knowing that there couldn't be other changes that would produce even greater toxicity or produce toxicity in other health end points that we have not yet identified.*

*Q- And in order to do that, to minotor that, what information would on need?*

*A- Ongoing studies that really demonstrate or investigate the profile of the tobacco smoke.*

*Q- And those would be? Profile of tobacco smoke would be?*

*A- Well, the sorts of studies that have been described here, but newer studies reflecting some of the newer technology as well.*

*Q- But in order to do those things, what information do you need?*

*A- The …*

*Me SIMON POTTER:*

*My Lord this goes quite beyond what was the subject of the expert's report. I object. There's been no indication in the expert's report as to what kinds of studies would be necessary on an ongoing basis to examine end points, health end points, as Dr. Ritter calls them, which are also not mentioned in the report. The expert is off the point. And we understand the expert's report to be that cigarettes are toxic, using his vernacular. We understood that report, but now we're off the point.*

*THE COURT:*

*You have reached your point.*

*Me JEAN LECLERC:*

*Well, with all due respect, My Lord, if I may answer that? In his qualification Dr. Ritter clearly stated that as part of this work in toxicology applying toxicants and chemicals to … or evaluating those to find out if they can be used by the human population, he referred to pesticides, he referred to drugs, he specifically mentioned on a number of occasions the fact that he was involved in information labelling issues of these products. This relates directly to that part of his qualifications.*

*In that context, I really feel it is quite relevant to have the opinion of one that has been involved in this type of work and tell us how it is relevant with respect to tobacco smoke in view of the fact that the industry own experts tell us that this product is not stagnant, I mean, it evolves.*

*THE COURT:*

*But the answer is obvious.*

*Me JEAN LECLERC:*

*Pardon?*

*THE COURT:*

*The answer is obvious."*

## CONCLUSION

La cigarette n'est pas un produit banal, même si sa présence est familière à tous. La cigarette, lorsqu'elle est fumée –puisque tel est le seul usage que l'on peut en faire –, produit un véritable cocktail de substances chimiques toxiques que les fumeurs inhalent. Quant aux non fumeurs, ils inhalent involontairement la fumée secondaire qui contient davantage de substances chimiques toxiques que la fumée principale.

Ce n'est que depuis peu que le monde scientifique connaît les substances toxiques qui sont contenues dans la fumée de cigarette. Dorénavant on ne parle plus simplement de goudron, de nicotine et de monoxyde de carbone, de cigarettes «légères» ou «douces», mais d'hydrocarbures polynucléaires aromatiques (une substance cancérogénique), de benzène (une substance causant la leucémie) de 4 -aminophyllines (une substance causant le cancer de la vessie), de formaldéhyde (une substance causant le cancer de la cavité nasale), de mercure (une substance absorbée par les tissus et les os des fumeurs), de nickel (une substance causant le cancer du poumon), de chrome, de plomb (une substance qui affecte notamment le système nerveux et les nerfs périphériques), de cadmium (une substance qui cause le cancer et la maladie de itai-itai, qui est associée à l'ostéoporose ostéomalacia et à des changements tubulaires au niveau des reins), de cyanure d'hydrogène ou d'acide cyanhydrique (une substance toxique).

Les demanderesses n'ont pas donné d'information aux consommateurs sur leurs produits, notamment sur leurs caractéristiques physiques et chimiques et sur leur toxicité.