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THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . August, 1970

VOLUME 25 NUMBER 8

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

The Fourth Dimension in Labeling: Trademark Consequences of an Improper Label—Part II.—This paper, by *Thomas G. Field, Jr.*, deals with the impact that improper labeling may have on a party's right to register his trademark. Beginning on page 372, Part II answers the questions: "Where does the trademark user stand today?" If a trademark user fails to catch any improprieties in his labeling, will his trademarks be regarded as *ab initio* invalid, cancelled, pirated away, refused enforcement, or what? Part I of the article appeared in the July issue of the JOURNAL. Mr. Field prepared his paper under the supervision of Professor James B. Gambrell, in partial fulfillment of requirements for an LL.M. at New York University School of Law, Graduate Division.

Sweden's New Food Law.—*Bengt Augustinsson* is Secretary General of the Swedish Food Law Committee, and Chairman of the Swedish Delegation to the Joint FAO/WHO Codex Alimentarius Commission. Mr. Augustinsson lists the essential aspects of Sweden's General Food Law, which is based upon the Food Standards Program of the Codex Alimentarius Commission, and explains the activities of the Food Board, which will oversee the application of the new law. The article begins on page 382.

Toxic Substances Naturally Present in Food.—In this paper, *Richard L. Hall* states that "there is a basic dichotomy in the Food, Drug, and Cosmetic Act respecting its treatment of imitation or synthetic foods as against 'natural' ones." The dichotomy is the consequence of an attempt to express a higher degree of confidence in the safety of "natural" foods and ingredients than in wholly synthetic ones, and to apply the results of human experience in the evaluation of safety. Rather than demonstrating the negative utility of such experience, however, Mr. Hall constructs a situation in which toxicological testing would be used to evaluate the safety of "natural" foods. His purpose is to show that all sources of relevant information should be used, and improved, in order to achieve a general recognition of safety. Mr. Hall, whose article begins on page 387, is Vice President of Research and Development for McCormick & Company, Inc.

Vol. 25, No. 8 August, 1970

Food Drug Cosmetic Law Journal

The Fourth Dimension in Labeling: Trademark Consequences of an Improper Label—Part II

By THOMAS G. FIELD, JR.

The First Part of This Paper Appeared in the July Issue of the JOURNAL.

VII. Summary Analysis of the Law

Where does the trademark user stand today? What should he do? Perhaps he should review all of his labeling in the very near future to try to catch any heretofore missed improprieties therein. If he should miss one or two, however, will his valuable trademarks be regarded as *ab initio* invalid? Will they be cancelled, pirated away, refused enforcement, or what?

In an attempt to answer those questions, it seems worthwhile to synthesize the law that has been heretofore covered, and, perhaps, try to condense it into a few meaningful principles by which the trademark user may be guided. Neither the case law nor the statutes seem to present a very clear picture of the situation where there is an unlawful or illegal use in commerce. A condensed analysis may be of value. As all lawyers know, however, *accurate* condensations are not easy to attain.

The first step in such a condensation seems to be an analysis of the case law. It is useful to reorganize the cases a bit differently from the order in which they were originally presented, and those cases may be arranged into three more or less cohesive groups:

(1) *Stellar* and *Zussman,* (2) *Levi* and *Coffin Redington,* and (3) *Coahoma, Taylor,* and *Strey.*

As was stated above, the basic issue taken for analysis here is the one of ex parte examination of an application for registration of a trademark in the Patent Office.[126] It will be recalled that it was also stated that a realistic analysis of such a problem must rest on the possibility of subsequent inter partes proceedings involving that mark and subsequent extra-Patent Office administrative action in regard to the trademark user's conduct, at least in interstate commerce.[127]

In regard to ex parte examination, *Stellar* and *Zussman* seem most directly in point. Of the cases considered, these present the purest analysis of unlawful commerce, and, like all of the Patent Office cases, the mark is sought to be registered on the principal register. This appears to be where all similarity stops; for example, their holdings on the issue of lawfulness of the commerce in question, it will be recalled, appear to be directly contra.

While there was a direct confrontation with a criminal statute in *Zussman,*[128] the Commissioner was able to skirt the issue for the reason that the mark, itself, was deceptively similar to another. This is specifically forbidden by the trademark act. Hence, the question of the lawfulness of applicant's commerce, with all of its difficult criminal ramifications, was avoided by finding the mark otherwise unregisterable.

This type of approach was not available in *Stellar,*[129] however. In that case, it was not the *mark* that was illegal; it was the *label.* All that was in issue was the failure of the applicant to list certain information on the labels as required by statute.[130] If registration was to be denied, in the opinion of the Board, it had to be denied on that ground alone, and it was so held.

Here, it might be noted that in certain instances where there might be doubt as to whether a given quasi-deceptive practice is forbidden under Sec. 2,[131] the Patent Office would seem able to argue that the presence of a statute, criminal or not,[132] forbidding

[126] See Part II, above, in general. See the language of the rule quoted, above, corresponding to footnote 20.

[127] See footnote 52, above.

[128] The detailed discussion of that case begins in the text corresponding to footnote 58, above.

[129] The detailed discussion of that case begins in the text corresponding to footnote 26, above.

[130] See footnote 38, above.

[131] See footnote 53, above; Sec. 2(a) forbids *Marks* which consist of or comprise "immoral, deceptive, or scandalous matter. . . ."

[132] For example, 35 U. S. C. 292 makes it an offense for which one may be fined to misrepresent that an article is patented or that an application is pending; but see footnote 7, above.

such practices makes it *per se* deceptive. But even that approach was not available in *Stellar,* for deceptive *labels* are not forbidden under Sec. 2. Its applicability appears to be limited to the *marks* themselves.[133] Hence, it is difficult to perceive how the failure to list certain information on a label could give rise to the finding that the mark was deceptive. But even that argument was not used in *Stellar,* and, thus, its authority must lie elsewhere.

Perhaps it can be found in *Levi*[134] and *Coffin Redington,*[135] for, in both of those cases, it was the labels, and not the marks, that were in issue. Additionally, not even the labels were *illegal,* they were merely deceptive, although apparently intentionally[136] so. At first glance, this would seem to present strong authority for the *Stellar* position. On second glance, however, the picture is not so encouraging. They may be distinguished.[137]

The position of the court in those cases, if limited to the facts before them, is amply supported in the present statutory scheme. The reason that they are supported, whereas it is doubtful that *Stellar* is, is that they are both inter partes situations. There are several references in the trademark act to rules permitting a "balancing of the equities" where there are two or more parties involved.[138]

This leaves *Coahoma,*[139] *Taylor,*[140] and *Strey*[141] to be discussed. They are important insofar as they are precursors of the *Stellar* holding and illustrate a variety of illegal conduct. On the other hand, they are of doubtful merit, if for no other reason than that there was a multiplicity of reasons for each holding. The amount of weight

[133] See footnote 131, above.

[134] The detailed discussion of that case begins in the text corresponding to footnote 112, above.

[135] The detailed discussion of that case begins in the text corresponding to footnote 117, above.

[136] See, for example, footnote 7, above, but such intention probably had a role in those cases. In *Levi,* the label was changed when the food and drug law went into effect, and in *Coffin Redington,* the appellee refused to testify. Apparently, the only express provision in regard to fraud appears in Sec. 14(c) of the Act at present, 15 U. S. C. 1064(c). But there it merely states that a mark may be cancelled if a fraud has been perpetrated *against the Patent Office* in securing the registration. One so damaged may recover, Sec. 38, 15 U. S. C. 1120.

[137] The ex parte v. inter partes distinction has been pointed out before. Rule 2.69, for example, is limited to the former situation. See footnote 21, above; footnote 119, above.

[138] See footnote 119, above. See also Sec. 2(d), 15 U. S. C. 1052(d), which seems to give the Commissioner quite a bit of latitude in concurrent use proceedings; Sec. 12(a) proviso, 15 U. S. C. 1062a; and footnote 11, above.

[139] The discussion of that case begins in the text corresponding to footnote 64, above.

[140] The discussion of that case begins in the text corresponding to footnote 98, above.

[141] The discussion of that case begins in the text corresponding to footnote 120, above.

that the issue of the lawfulness of the commerce played in those decisions is difficult to ascertain.[142] Further, the depth of the analysis of the issue as presented leaves much to be desired.

From the standpoint of authority, in none of those cases was any statutory authority cited for the conclusion reached. As was mentioned above, considerable leeway is allowed the Patent Office in inter partes matters under specific authority of the act. This was not discussed satisfactorily in *Coahoma;*[143] additionally, that case seems to present a harsh result for a misunderstanding of the law. The major deception in that case, apparently, was Smith's self-deception. He thought that *he* owned the mark. Apparently, too, he thought that use by *his* corporation inured to his benefit.[144] Is this any more reprehensible than a misunderstanding of the doctrine of adverse possession by the Commissioner?[145]

Taylor likewise recites no authority for the proposition that trademark rights cannot arise in "unlawful" commerce.

While *Strey* relied on the doctrine of unclean hands, that doctrine, apparently, is of little value in Patent Office ex parte matters.[146]

Those three cases, however, do present three different types of allegedly unlawful conduct and three ways to protect the public therefrom.

In *Coahoma,* apparently, the illegality was not based on a deceptive or illegal label or mark, but rather on a failure to promptly register that label.[147] This resulted in cancellation of registrant's mark from the register.

In *Taylor,* the illegality was based on a failure to inform as required by statute.[148] This resulted in refusal to register the applicant's mark.

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[142] See footnotes 82, 101, and the text corresponding to footnote 122, above.

[143] See footnote 95, above, and the text corresponding thereto.

[144] See the text corresponding to footnote 90, above. While the opinion is not too clear on the matter, it is possible that the Commissioner found that the illegality arose, in part, upon a reorganization of the North Carolina branch as a separate corporation in 1950 (113 USPQ at 416) and a failure to file new pesticide registrations. See footnote 74, above.

[145] See the text corresponding to footnote 87, above. It appears from that that this is the case. It was no defense to trespass, for example, to show title was other than in the possessor unless the defendant claimed thereunder. This was to prevent a succession of piracies with each pirate denying title in the one before him. But this doctrine has its limitations. See 55 Yale L. J. 842 (1946) for an excellent discussion where the property is in the public domain (where unconceived, unused trademarks would apparently be, if anywhere).

[146] See footnote 119, above.

[147] See footnote 74; see also footnote 144.

[148] See footnote 106, above. On the issue of packaging, see *United States v. Kocmond* (CA-7, 1952), 200 F. 2d 370, cert. denied 345 U. S. 924. See also Dunn, *Federal Food, Drug, and Cosmetic Act,* 1336 (1938) in regard to the "Kenyon Amendment."

Finally, in *Strey,* there were two violations of law. Not only was there a failure to inform as in *Taylor* and *Stellar,*[149] there was also a deceptive practice specifically forbidden by a state law. The latter practice, while not forbidden under the *Stellar* interpretation of Rule 2.69, is nevertheless probably forbidden under Sec. 2 of the act.[150] Those improprieties resulted in the mere failure to enforce registrant's mark even though it was only registered on the supplemental register.[151]

The express provisions that give rise to those three trademark sanctions have been considered in various places, above, as they arose in the cases. It seems useful here to review them prior to attempting to draw any conclusions. Under what circumstances does the trademark act specifically call for a refusal to register a mark or cancellation or non-enforcement of one already registered? These will be taken up in order.

In an ex partes examination, it appears that little is expressedly forbidden. Marks that are, for example, deceptive, scandalous, immoral, or merely descriptive, are unregistrable under Sec. 2. Sec. 2(f), on the other hand, specifically provides that:[152]

> (E)xcept as expressedly excluded in paragraphs (a), (b), (c), and (d) of this section, nothing herein shall prevent the registration of a mark used by the applicant which has become distinctive of the applicant's goods in commerce.

Additionally, however, there is a literal requirement in Sec. 23 that supplemental registrations shall be in "lawful use in commerce."[153]

The provisions for cancellation of a mark are likewise quite limited, at least in regard to principal registrations.[154] If less than five years have elapsed since the registration, cancellation may be had by one who believes, and, apparently, can prove, that he is or

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[149] See footnotes 9 and 38, above.

[150] The title, "Dr.," appears to be part of the mark. See footnote 131, above. Principal registration had been denied because the mark was dominated by descriptive material and primarily a surname.

[151] As will be recalled, this is one of only two references to the legality of applicant's commerce in the act. See, for example, footnote 16, above.

[152] 15 U. S. C. 1052(f). See also footnote 53, above.

[153] 15 U. S. C. 1091. That section reads in part: "All marks capable of distinguishing applicant's goods . . . and not registerable on the principal register . . . , except those declared to be unregisterable under . . . section 2 of this Act, which have been in lawful use in commerce by the proprietor thereof . . . may be registered. . . ."

[154] Cancellation of supplemental registrations needs only a petition filed by a party subject to being damaged therefrom. This may be done at any time. Sec. 24, 15 U. S. C. 1092.

will be likely to be damaged by the registration.[155] However, if five years have elapsed, cancellation of a mark from the principal register can result only:[156] (1) for a fraud on the Patent Office, (2) if the mark becomes the common descriptive name of the commodity,[157] (3) if the mark is used to misrepresent the source of the commodity,[158] or (4) the mark is abandoned through non-use.[159] Those limitations would appear to be equally binding on the Patent Office and the courts.

The fact that a mark is no longer subject to cancellation does not mean that the owner thereof is entitled to have his rights thereunder enforced. Either the Patent Office or the courts may refuse to enforce those rights for a wide variety of misconduct.[160] It must be remembered, however, that in such an instance there will always be three parties to such a proceeding. The third, of course, is the public, and the court is free to consider that interest as well as those of the litigating parties.[161] This would seem to be likewise true in a cancellation proceeding.[162] The law in these matters seems to be relatively clear, except as clouded by *Coahoma* and dicta from the *Stellar* decision.[163]

In regard to ex parte matters, the law is not quite so clear. As pertains to an unlawful use in commerce, *Stellar* seems quite definitive, but that holding has certain flaws, it seems. The real question, then, becomes, if not what the law appears to be, what it should be. The answers, to the extent that *answers* to those questions are possible, will be considered in the last section of this paper.

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[155] Sec. 14, 15 U. S. C. 1064.

[156] Sec. 14(c). See also Sec. 15, 15 U. S. C. 1065.

[157] See also Sec. 2(e), 15 U. S. C. 1052(e).

[158] See footnote 157, above.

[159] See also Secs. 8, 15 U. S. C. 1058, and 9, 15 U. S. C. 1059.

[160] See *Strey*, footnote 111, above. In *Independent Grocer's Alliance Distributing Co. v. Zayre Corp.*, 149 USPQ 229, 230 (POTT&AB, 1966), such a doctrine was urged to prevent the plaintiff from opposing applicant's registration. It failed on the merits. See also footnotes 119 and 7, above.

[161] See the quotation from *Morehouse*, corresponding to footnote 2, above. There, a cancellation was urged based on a fraud on the Patent Office (footnote 156, above). As Judge Rich said therein, above, "Assertions of 'fraud' should be dealt with realistically. . . ."

[162] See footnote 161, above. In a famous case concerning failure to enforce a party's rights because of his "unclean hands," it was remarked: "Undoubtedly 'equity does not demand that its suitors shall have led blameless lives,' . . . but additional considerations must be taken into account where maintenance of the suit concerns the public interest as well as the private interests of the suitors." *Morton Salt Co. v. G. S. Suppiger Co.* 314 U. S. 488 (1942).

[163] In regard to *Coahoma*, see footnote 95 and the quotation it refers to. In regard to *Stellar*, see the quotation corresponding to footnote 4, above.

VIII. Conclusions

It is doubtful that anyone would urge that the trademark act, said to be primarily designed to guard against public confusion and deception in the market place,[164] should be used or can be used to further the interest of those who are in violation of law, nor those in the business of deceiving the public, whether legally or not. Certainly, that conclusion is not urged here.

However, it is quite another thing to support the conclusion advanced in *Stellar,* albeit indirectly, that the Patent Office should, via the trademark registration procedure, attempt to enforce the multitude of laws regulating the content of labels[165] on goods moving in the flow of state and federal commerce. It seems useful to examine some of the arguments advanced for this position in the context of three considerations: (1) the statutory authority for it, (2) the case authority for it, and (3) the practical consequences of it.

In *Stellar,* the concept of power arose twice. First, it was urged that Congress does not have the power to regulate unlawful commerce.[166] Second, it was urged that movement of goods in commerce in violation of law does not give rise to a power in the Patent Office to recognize certain rights that might otherwise arise therefrom.[167] Neither of these arguments appear to be sound; the former most certainly is not.

If the argument is advanced that Congress does not have power to give rights to those in violation of laws that it has created, it seems to go without saying that Congress is going to be in a considerably more awkward position in attempting to give the same rights to those in violation of state laws. If anything, it would seem to demand that Rule 2.69 be amended to include the latter. Needless to say, it seems that that would be neither wise nor authorized. States would undoubtedly resent having their laws interpreted and applied by the Patent Office.

As for the argument that the Patent Office does not have power to recognize rights that may have arisen in illegal commerce, it seems

[164] See *Trademark Management,* p. 3 (1955), prepared and published by the United States Trademark Association. See also footnotes 161 and 162, above.

[165] See the text corresponding to footnote 38, above. From the standpoint of dicta, however, the Board doesn't appear to regard its opinion and conclusion as so limited. See also footnote 4, above, and the quotation it refers to.

[166] See footnote 4, above, and the quotation it refers to. Specific reference is made to the phrase, "commerce which may lawfully be regulated by Congress."

[167] See footnote 4, above; specific attention is drawn to the language dealing with the rights "which the Patent Office can properly recognize."

that the same things may be said. It can be argued with considerable force that not only does the Patent Office have such power, it also does not have the power to refuse to exercise it. A contrary conclusion seems neither supportable in law nor in practice.

The Board, in *Stellar,* relied on Rule 2.69 for its direct authority in this matter. The history of that rule, to the extent that it might be said to support anything, does not support the interpretation that was made. Again, it is quite one thing to refuse registration to marks which must, either themselves or the labels they appear on, be registered and precleared under the authority of a regulatory law, and yet another when they need not be so cleared.[168] The latter requires that Trademark Examiners interpret and apply unfamiliar law, the former does not. It is no simple matter, as has been amply demonstrated,[169] for an Examiner to decide whether a given label, for example, shows, even "on its face," a violation of law when that law is not one within the expertise of the Examiner.

Nor would even the cases before it seem to support the Board's conclusions as to how Rule 2.69 must be applied. There were two ex parte decisions before it on the matter of unlawful use in commerce. One, citing apparently sound reasons for doing so, refused to delve into such an inquiry.[170] The other case, without citing an iota of authority, was directly contra and apparently overruled the Commissioner.[171]

The other cases, either directly or indirectly before *Stellar,* were inter partes matters and may be distinguished. As has been pointed out, the Patent Office and the courts have broad authority to balance the equities of the parties in such a proceeding. Furthermore, the Patent Office in analogous situations does not seem to have arrived at the type of philosophy necessary to support *Stellar,* even in inter partes matters.[172]

The provisions of the trademark act would not seem to provide any meaningful authority for such a position either. Indeed, there is considerable evidence to the contrary. Of the two references in the act to "lawful use in commerce," only one deals with ex parte matters.[173] Even in that section, there is considerable doubt as to what is meant.[174] None of the cases supporting *Stellar* in any sense involve a

[168] See footnote 25, above.

[169] See, for example, footnotes 38, 74, and 148, above.

[170] *Zussman,* see the quotation corresponding to footnote 62, above.

[171] *Taylor,* see the discussion corresponding to footnote 106, above.

[172] See *Morehouse,* footnote 161, above.

[173] Sec. 23, see, for example, footnote 16, above.

[174] See, in general, Part V, above.

supplemental registration.[175] The rule relied on is apparently applicable to both supplemental and principal registrations.[176] The language dealing with "lawful use in commerce" seems to have been deliberately left out of the requirements dealing with ex parte principal registrations.[177]

At this point it might be urged that the authority question is not definitively settled; that is, that there is still some argument for the *Stellar* position. In the event that such doubt exists, and to the extent that it does, it seems useful to consider some further ramifications of the problem that have been largely avoided heretofore. They are practical matters, but while only practical as opposed to legal, they seem, nevertheless, worthy of some reflection.

The most practical matter of all concerns time and money, to the extent that they may be separated. It doesn't seem necessary to launch into an economic discourse to conclude that the result of the *Stellar* position is substantial waste. To the extent that there is a duplication of enforcement of the acts in question, there is most certainly waste. To the extent that those familiar principally with the trademark laws are forced to become expert on a wide variety of labeling provisions, for example, there is waste. Perhaps more reflection would yield more such examples, but that seems unnecessary.

There is also an element of unfairness in the *Stellar* position, whether one would characterize it as practical or legal in nature. There is little question that the Patent Office interpretation of the food laws, for example, will not be binding on the Food and Drug Administration.[178] Nor should they be. Expertise in that area was granted by Congress to that agency, and it will be recognized by courts. At present, registration is prima facie evidence of the validity of the mark registered.[179] Will it also become prima facie evidence of the legality of the labels that it appears on? The question seems to answer itself. Why should an applicant have to argue his compliance with regulatory acts twice? There are no ready answers to that.

This brings up a somewhat distinct but integrated third practical consideration: necessity. The use of Rule 2.69 as an enforcement tool

[175] While *Strey* involved a supplemental registration, it does not support *Stellar*. See the text corresponding to footnotes 123 and following, above. Also, *Coahoma* had, at one time, been involved with a concurrent use proceeding, but the language of Sec. 2(d) was not referred to. See footnote 70, above.

[176] See the text corresponding, for example, to footnote 42, above.

[177] See the text corresponding to footnote 53, above.

[178] See footnote 169, above. For what has been a somewhat analogous conflict between those agencies as to workload, see *In re Anthony*, 162 USPQ 594 (CCPA, 1969).

[179] Sec. 7(b), 15 U. S. C. 1057b.

for the various regulatory acts need not be so far-reaching. It is doubtful that Rule 2.69, taken at face value, need be one of dubious authority nor of dubious practical impact. It would seem a simple matter for an Examiner, who believes applicant to be in violation of a regulatory act, to so inform him. There are so many, it is not easy to be aware of them all. But the Examiner need not even stop at that point. If the violation seems to be a serious one, it would be a simple matter to send out an inter-agency memorandum to that effect; that is, turn the matter over to those most qualified to, and paid to, cope with it. Inspection of the applicant's labels for such purposes does not seem to be a waste of time and effort.[180]

Finally, the Board in *Stellar* should have considered the effect of its language on inter partes matters. If, indeed, lawful commerce is a "condition precedent to registration,"[181] this would seem to give rise to a questionable technique for avoiding the cancellation provisions of the act.[182] From that language, it seems possible to argue that it is not necessary to "cancel" a mark that is "ab initio void." Without considering the full legal ramifications of such an argument,[183] it can, nevertheless, be concluded that such a technique, if successful, would yield a bad result. That result, it seems, would be a succession of pirates with each finding his predecessor's mark void ab initio, for example, because of its being used in "unlawful commerce." It is doubtful, at best, that this would serve the public interest that the act is said to guard. That is to say that the public would hardly be secure in the knowledge of the constancy of the source of its goods.[184]

The *Stellar* position as to the effect of a user's unlawful conduct in commerce should be reconsidered and overruled. The legality of a party's use in commerce should only be considered in inter partes matters, and even then, only to the extent that it bears on the mala fides of the parties and the overwhelming interest of the public.

[The End]

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[180] *Stellar,* see the quotation corresponding to footnote 32, above.

[181] *Stellar,* footnote 4, above.

[182] See the discussion of Sec. 14(c), corresponding to footnote 156, above. For an instance of the discussion of the cancellation of a mark on the principal register in excess of five years, see *Bart Schwartz International Textiles, Ltd. v. F. T. C.*, 289 F. 2d 665, 129 USPQ 258 (CCPA, 1961).

[183] The real issue, of course, is what the language "condition precedent to registration" means. Similarly, what is the full impact of the term, "ab initio void?" Can an ab initio void mark be "stricken from the record," as opposed to "cancelled?" The answer to that is not considered here, but see footnote 95, above, for some further discussion that may be illuminating.

[184] See footnote 164, above, and the discussion pertaining thereto.

Sweden's New Food Law

By BENGT AUGUSTINSSON

Mr. Augustinsson Is Secretary General of the Swedish Food Law Committee, and Chairman of the Swedish Delegation to the Joint FAO/WHO Codex Alimentarius Commission.

THE SWEDISH FOOD LAW COMMITTEE presented its report to the Swedish Government in March, 1970. The report includes proposals for new legislation and for a new official organization for food control.

The proposed food legislation is divided into two parts: on the one hand, a General Food Law with fundamental principles meant to be adopted by the Swedish Parliament; and on the other hand, detailed regulations concerning the application of that law set forth in an Implementing Ordinance and proposed to be issued by the new Food Board. This board will become the central food-controlling authority and will oversee the 24 Swedish County Administrative Boards and the 800 Municipal Health Boards in their regional and local food-control work.

The new legislation is built on two main principles; namely, to secure a wholesome and nutritious quality and composition of foodstuffs, and to assure fair practices in the food trade. These principles are basically the same as those drawn up by the Food and Agriculture Organization (FAO) and World Health Organization (WHO) for the Food Standards Program of the Codex Alimentarius Commission. This approach was mainly intended to protect the interests of the consumers. Looked upon from other angles, the proposal is obviously of great interest to the authorities concerned and to all those branches of industry and commerce which deal with the handling of food products and their importation into Sweden.

Essential Aspects

Among the more important points in the proposal, the following should be mentioned:

(1) The *food concept* is widened and will include all substances, except drugs, which are intended to be consumed by human beings. Consequently, drinking water will be regarded as food.

(2) The regulations governing *food additives* are completed with provisions concerning vitamins and other *enriching substances,* pesticide residues and other *foreign substances* in foodstuffs. With this arrangement, all kinds of substances which intentionally or unintentionally might appear in or on foods can be regulated by the food legislation.

(3) *Compulsory enrichment* is proposed for some essential foods; for example, vitamins A and D to margarine and milk, iron to flour and iodine to salt. The purpose is to require that these and other foods, which most people consume every day, shall contain some essential nutrients in a proportion satisfactory in regard to the public health point of view.

(4) The Food Board is authorized to prescribe *food standards* for various products. In this way a formal authority is established for the legal approval and application within Sweden of the food standards adopted by the Codex Alimentarius Commission. In Sweden the prescription of a food standard will indicate that the product concerned will be regarded as fit for human consumption in those respects which are dealt with in the standard.

(5) The *name of a food* is required to be specific and if possible descriptive. The use of fanciful names alone will not be allowed, but they may be used together with an appropriately descriptive term for the food. The Food Board may prescribe special descriptive names which will be exclusive and mandatory for certain foods.

(6) Provisions are made for information on the label of prepackaged foods about the *essential composition* of the products. This means, in fact, a declaration of ingredients which aims to give the consumer a satisfactory and meaningful conception of the usefulness and value of a food. Together with the descriptive name of the food, this declaration will help the consumer to distinguish products which look the same but differ in quality; for example, well-known and traditional foodstuffs contra substitute foods and other new food products. This kind of information also gives the consumer a better opportunity to choose that product which will fit his needs best at the time. For some

products, the demand for information about a food's essential composition will require a declaration of its *nutritive value.* This will be the case for sausages and certain mixed-meat products.

(7) The label of a prepackaged food must always bear the *name of the producer or the packer.* Imported foods must also be labelled with the *name of the importer.* The purpose is to prevent the sale of "anonymous" products and to ensure that there will always be somebody in Sweden responsible for the quality of the food.

(8) Prepackaged foods must be labelled with satisfactory *storage instructions* if it is of essential importance for the durability of the product that it be kept in a special way, for example, at a certain temperature in a refrigerator, in a freezer, or in a dry place.

(9) Perishable foods with a durability of 30 days or less must always be labelled with *durability information* following one uniform system, and showing the estimated latest *day of consumption.* This kind of compulsory labelling will replace the present voluntary date-marking, which in Sweden has been very heterogeneous. Deep-frozen foods will be required to be labelled with their estimated durability at different temperatures. The Food Board is authorized to prescribe durability information for types of food products other than those perishable within 30 days, for example, semipreserved meat or fish products. Even when a food is being voluntarily labelled with its durability, this information must indicate the latest day of consumption.

(10) The requirements concerning *food localities* are expanded to include any kind of facility, which is mainly intended for the permanent handling of foods, whether it is located in a building, ship, train, airplane or motor vehicle. These food localities must be approved by the food authorities before they are allowed to be used.

(11) A special permit from the food authorities is required for *selling foods* in places other than in approved food localities, for example, in the *open air,* in *markets, camping places, exhibitions* or in *vending machines.* The same requirement is applied to "ambulatory salesmen" with hot dogs, ice cream, etc.

(12) More stringent requirements are proposed for *food carriers.* Transport vehicles for some perishable foods, for example, meat, fish, milk and bread, must as a rule be furnished with a closed storage space. Carcasses and cuts of meat must be kept

hanging when transported. Some meat, fish and milk products have to be transported at certain low temperatures. Deep-frozen food products must be transported in such a way that their temperature does not exceed —18°C (O°F).

(13) A special permit from the Food Board is required for *claims*—on the label, or in advertising in daily papers, weeklies, radio, television or cinemas—that a product is especially suitable as *food for babies or children* or for persons with a certain disease or weakness, for example, *diabetes*. Such a permit is not to be given unless the Board has examined the product concerned and has concluded that its ingredients will be declared in a satisfactory way.

(14) Compulsory *medical examination* and *health control* at least once a year is proposed for workers at those plants, and other localities where food is handled, where there is a high risk of contamination. This examination will be performed in slaughter-houses, dairy plants, bakeries and all kinds of restaurants, canteens and catering establishments. The purpose is to attain a better opportunity to discover and diminish the risk of dissemination of salmonelloses and other similar infections.

(15) All laws and regulations concerning food will be gathered in a special publication called the *Swedish Codex Alimentarius*.

Function of the Food Board

The Swedish *Food Board* will, as a new central authority, take over most activities concerning foodstuffs which hitherto have been dealt with by many other authorities, for example, the Medical and Social Board, the Veterinary Board, the Institute of Public Health, the Agricultural Marketing Board and the Board of Commerce. The purpose is to bring to an end the present lack of uniformity in the decision-making procedures concerning food subjects, and to have all these questions considered and administered by a single authority at the central level.

The leadership of the Food Board will be entrusted to a central management committee and a director general, who will be advised by a scientific council. The management committee will consist of representatives from other authorities concerned and from industry, trade, employees and consumers. The staff of the Board will be made up of civil service officers with different kinds of education of value in considering food problems. The three main categories are planned

to be medical and veterinary-hygiene officers and food technologists. There will also be a need for chemists, bacteriologists, agronomists, economists and persons with practical experience from the food industry and trade and with a good knowledge of different food products.

The County Administrative Boards and the Municipal Health Boards will be reinforced in order to intensify their food control activities in the regional and local areas. In order to do this they will employ officers with medical, veterinarian-hygienic and food technological education.

Special *laboratories* will be authorized to take care of the examination of food products as one of the most important parts of the official food control. For this purpose, two central laboratories will be established at the Institute for Public Health, which will work exclusively for the Food Board. Several regional and local laboratories will be reserved for food examination in the regional and local areas.

Internal Supervision

As a very important complement to the official food control by the regulatory authorities it is proposed that every concern in the food business shall be obliged to arrange a continuous "internal supervision" of its activity. This new type of control will be compulsory and will be handled in different ways, depending upon the kind of food treatment in which the concern is engaged. This procedure will include laboratory control in a food plant, hygienic control of food localities, surveillance of the health and personal care among the employees, etc.

The compulsory internal supervision will be paid for by the food concern. The reason for this is that those who have chosen to produce, sell, import, transport or handle foods in other ways, with the many sanitary risks which are connected with this activity for most parts of the population, obviously must take upon themselves the economic responsibility for the quality of the food products they handle, and therefore make certain that this activity can be considered as fully satisfactory from the hygienic point of view. The purpose of the demand for internal supervision is also to make the food concern's responsibility more stringent and to assure that it offers the consumers good and sound food products which have been treated in a hygienically proper and safe way.

The proposals of the Swedish Food Law Committee are intended to be brought into effect on July 1, 1971. **[The End]**

Toxic Substances Naturally Present in Food

By RICHARD L. HALL

Mr. Hall, Who Is Vice President of Research and Development for McCormick & Company, Inc., Presented This Paper at the Food Update Program Held in Chicago, Illinois, on March 23, 1970.

IT IS NO NEWS TO ANYONE that there is a basic dichotomy in our Food, Drug, and Cosmetic Act respecting its treatment of imitation or synthetic foods as against "natural" ones. This statutory posture is not peculiar to the United States; many European countries, Germany for example, go even further in according favored treatment to "natural" foods and food ingredients. Even in its extremes, such a policy must still permit the manufacture and supply of food in an industrialized economy, and this often requires a definition of "natural" as remarkable for its ingenuity as for its comprehensiveness. We play this game, too; the law says in Section 402:

> A food shall be deemed to be adulterated—(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance (i. e., a "natural" one) such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not *ordinarily* render it injurious to health. . . .

An *"added* poisonous or deleterious substance," however, renders the food adulterated unless the additive is used within the other provisions of the Act, such as the Pesticide, the Food Additive, and the Color Additive Amendments. The regulations issued under these amendments extend, though they do not clarify, this distinction between "added" and "not added," or, as it is more often said, between "natural" and "synthetic." An example is the listing of synthetic and natural flavorings in CFR 121.1163 and 121.1164. Successive hair-splittings have finally brought us to the point where purification by

distillation results in a "natural" product, while crystallization generally produces a "synthetic" one. We might as well say of these distinctions themselves, that some are natural, and some are synthetic.

Now ridiculous as this becomes, by the time we have expended our legal and administrative ingenuity on it, there is a substantial underlying reason. We are attempting, in a fumbling way, to express a higher degree of confidence in the safety of "natural" foods and ingredients than in wholly synthetic ones. This confidence often has an emotional and irrational basis, as in the case of the organic gardener. But there is a more scientifically respectable basis for much of it. It is an attempt to apply the results of human experience in the evaluation of safety. If it lacks precision and consistency, and occasionally even common sense, we should consider the alternatives and what can be done by refinement before we abandon the concept.

There is an alternative, or rather a complex and expensive set of alternatives, with which we have become increasingly, but often only superficially, familiar. This is the approach of toxicological investigation, primarily employing animal feeding studies. These are extremely useful tools, providing valuable insights into the degree and nature of hazards which may be associated with a particular substance. But now we are seeing the development of a new breed of fanatic, comparable in his messianic enthusiasm to the organic gardener, who insists that every ingredient must be "thoroughly tested" until it is "proved safe." A thorough examination of this pathetic folly would carry us far beyond present limits of time and subject. First, I should like to comment briefly on the strengths and limitations of both testing and experience. Then, in a somewhat whimsical example, I would like to explore the impact and contradictions involved in their application to safety evaluation.

Strengths and Limitations

The advantages of human experience in assessing safety are:

1. The experience is gained with the species with which we are concerned—avoiding the problem of interspecific differences.

2. The experience is with the diet composition and within the range of dietary levels normally consumed—avoiding the problems of the consequences of untypical methods of administration and of metabolism by pathways not involved in normal feeding levels.

The disadvantages or limitations of human experience are:

1. Controlled experiments cannot ordinarily be run, although comparative epidemiological studies can sometimes be made.

2. It is not possible to determine the limits of safety by test. Such information ordinarily comes from the study of accidental over-consumption or industrial exposure, or from results in some other application, such as drug use.

The advantages of animal studies are that:

1. Controlled experiments can be run—meaning that one can isolate the use or non-use of a particular substance as the single test variable and determine how the response varies with the dose. In observations on humans, this is usually impossible because of the complexity of both our human genetic makeup and our environment.

2. One can determine the nature and extent of the hazard—and damage—to the test animal with a precision limited only by the skill and equipment of the experimenter, since risk to the animal is of no consequence and the pre- and post-mortem observation may be as extensive as necessary and desired.

3. One can do lifetime, and even multigeneration, studies in animals with a short life-span.

These are large advantages, but they are balanced by serious disadvantages:

1. The test animal is not the same as the human animal—not even the same as a miniature human would be. The metabolic pathways may, and often do, differ; the susceptibility to damage of the individual organs, or of more generalized bodily functions, will almost certainly differ from those of the human. The susceptibility may be greater or less, and usually in a manner and extent impossible to predict beforehand.

In part, because of these differences, it is customary to apply a safety factor, often 1/100, to "no-effect" levels observed in animals, when using these experimental results to estimate safe levels in humans. The result of this is to require in animals doses at least 100 times higher than the functionally effective level intended for human food. And here, in avoiding one trap, we fall into another.

Any substance that any animal consumes is either excreted unchanged, or in a few cases, is stored (accumulated), or is modified by the body in some way prior to excretion or storage. This modification, or metabolism, generally takes place by one or a few processes, or metabolic pathways, which the organism favors over other paths, presumably because in evolving, these have worked out to the least disadvantage to the organism. As the level of intake of a substance increases, these normal pathways become loaded to capacity, and the organism calls upon other pathways or the substance temporarily accumulates. These other paths will often involve intermediate stages which are more toxic, or mechanisms which place a greater strain on the animal. In any case, they are not necessarily related to the paths, and effects, encountered at lower levels. Thus, the second disadvantage of animal testing is that:

2. In order to obtain an adverse effect, and to provide an arbitrary but large safety factor, feeding levels must be so high, compared with intended human consumption, that valid analogies very often cannot be made.

The demand that everything be "thoroughly tested" until "safety is proved" actually comes from a naive, desperate, and quite unsupportable faith in the extent and certainty of the conclusions which may be drawn from animal tests.

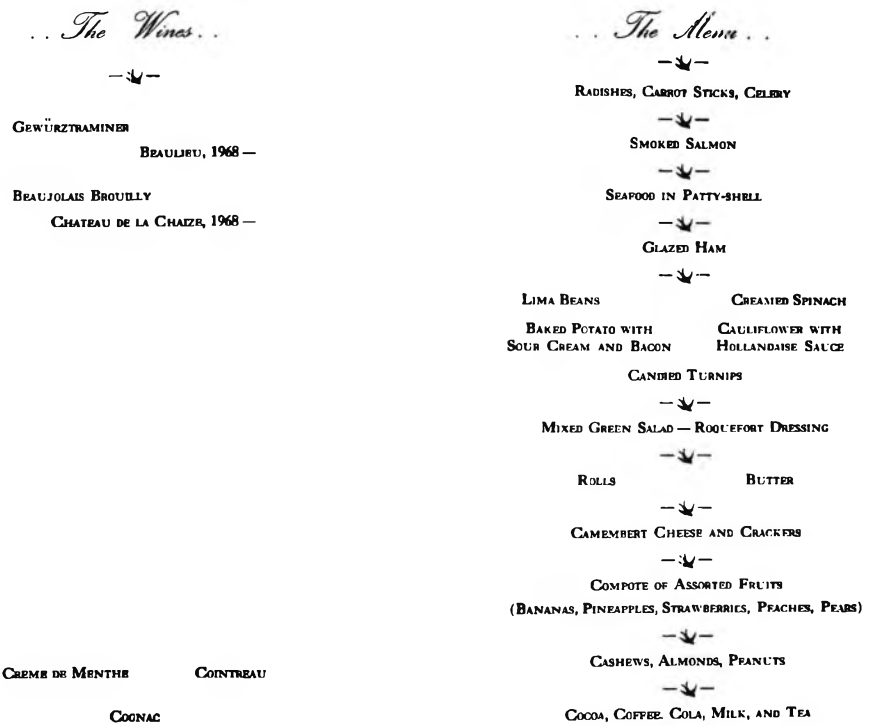
One may well point out that where doubt exists about the applicability of animal data to humans, the decision should always be made conservatively; and if this is the case, why all the fuss? There are at least two rejoinders to this, one of which is obvious from recent events. "No effect" in animal studies has every limitation of negative evidence. It simply means that under conditions of that experiment, that experimenter did not find anything. It provides no reason to assume that under some different set of experimental conditions, or with better analytical tools, or a more skilled observer, an effect could not have been found.

We should not ignore another aspect. Not to use a particular substance because a more or less thorough investigation showed some significant potential of hazard is not to avoid a danger. It merely exchanges one risk, recently estimated, for another risk which is often unknown. Nowhere is this more apparent than in the attitudes, congealed into regulation, with which we regard "natural" and "synthetic" food ingredients. For like an old tintype, our food

laws, regulations, and company policies present these attitudes as they once were, their rigidity exaggerated, as in a tintype, by the laborious process of recording them.

The Toxicological Approach

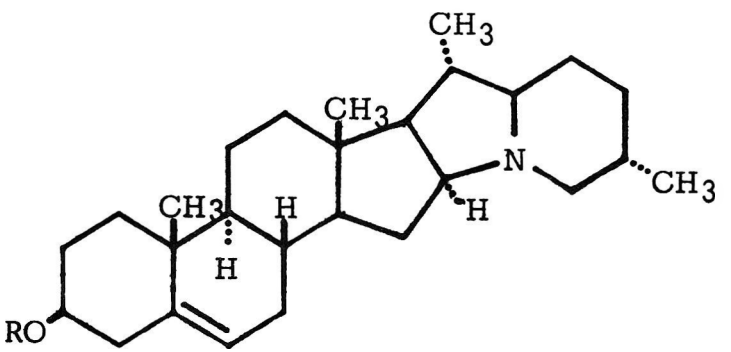
Let us consider a reasonably elaborate and attractive, but not at all exotic dinner menu.



And let us approach it, not with the infectious, rules-be-damned enthusiasm of Graham Kerr, the Galloping Gourmet, but with the flinty-eyed inflexibilty of Dr. Constance Care, the Galloping Toxicologist. Connie, of course, reads the literature and has heard of the concept of toxicological insignificance, so she concedes that a trace—or possibly the shadow of a trace—may indeed be negligible. But she thinks about carcinogens, teratogens, and mutagens; and she vows never to depart from the 100-fold safety factor which stands between us and disaster. Natural or synthetic, it will kill us all the same. We shall

evaluate our menu from Connie's point of view, as if we must regard each food not as it is treated under the law as "natural" food, but as it would be treated if manufactured from "added" ingredients. We will become alarmed only by foods containing substances which, following the assumptions inherent in present toxicological protocols, could not survive these assumptions and safety factors. The Delaney Clause will be applied with the reverent concern properly due revealed truth.

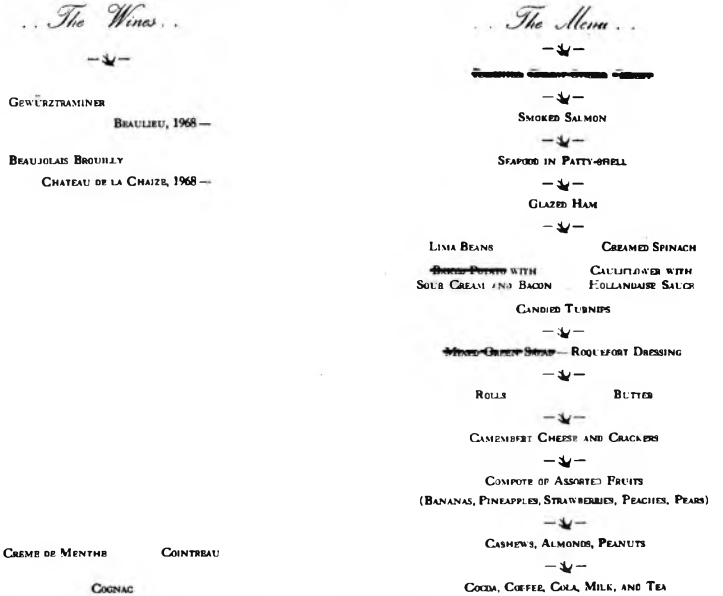
Among the toxic substances naturally present in certain foods are some cholinesterase inhibitors of unknown structure. Cholinesterase inhibitors interfere with the transmission of nerve impulses; many potent modern pesticides are based on such activity. These are present in measurable quantity in radishes, carrots, celery, and most particularly, in potatoes. In the case of potatoes, the alkaloid solanine is responsible, and is often present with less than a ten-fold safety factor between the normal level and levels that have caused human poisoning.



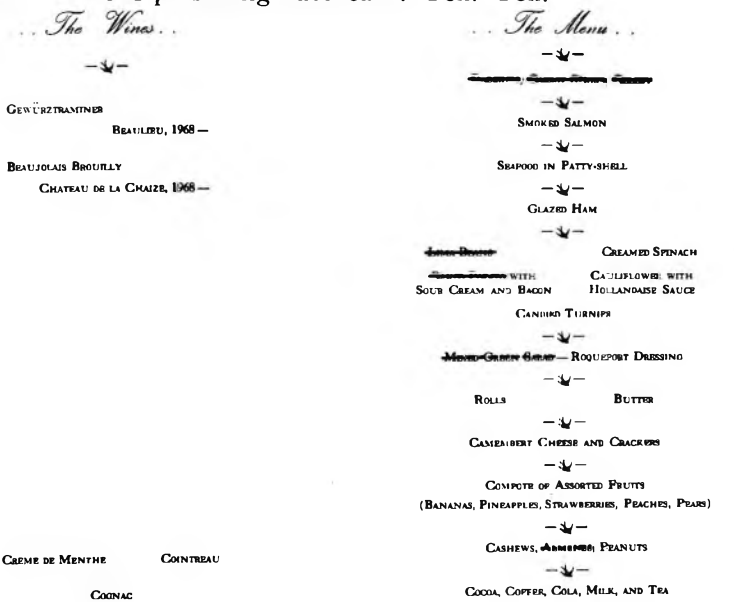
Solanine - R = l-rhamnosyl-d-galactosyl-d-glucosyl-

Solanidine - R = H

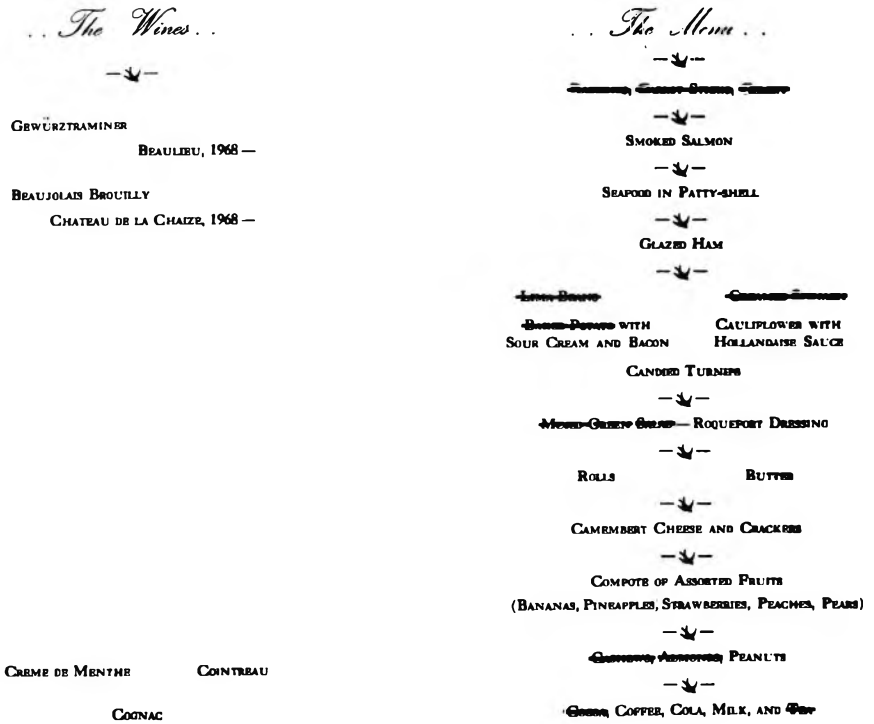
Thus fall the first items from our menu.



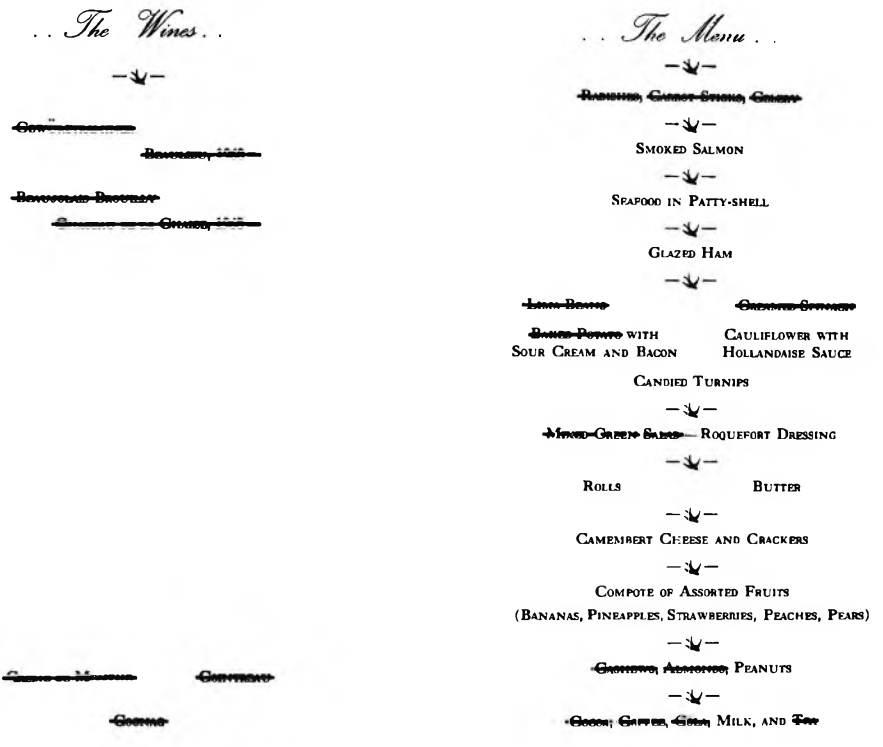
A number of foods contain glycosides which break down during cooking or digestion to yield hydrogen cyanide. Among those with this disconcerting property are almonds and lima beans. This is no idle concern; strains of lima beans high in HCN have been the cause of several serious poisoning outbreaks. Tch. Tch.



Oxalates and free oxalic acid occur in a number of foods—spinach, cashews, almonds, cocoa, and tea. Our menu is beginning to suffer.



Stimulants occur widely in foods. Nutmeg contains myristicin; tea, coffee, cola, and cocoa contain caffeine. Tea contains theophylline and coca, theobromine. Even more ominously, myristicin is a hallucinogen, and occasionally abused for that purpose. But nutmeg also contains small quantities of safrole, a carcinogen. Unfortunately, we used nutmeg on our spinach, and of course the depressant, alcohol, is not tolerable with a reasonable safety factor, and its hazards are well known.



That alone would rule out the liqueurs, but high intakes of menthol have caused cardiac arrythmia, and the glycerine in Cointreau is toxic at only small multiples of normal use.

Goitrogens, substances which promote goiter, are present in many foods. The white turnip contains *l*-5-vinyl-2-thiooxazolidone, and cauliflower contains a thiocyanate. It would only take about 22 pounds per day of cauliflower to cause thyroid enlargement, and as careful readers of recent adverse toxicological reports know, this is a wholly inadequate margin of safety. The peach, pear, strawberry, brussel sprouts, spinach, and carrot have all been shown to demonstrate goitrogenic activity in man. A shame.

. . The Wines . .

—

[illegible]

. . The Menu . .

—

[illegible]

—

Smoked Salmon

—

Seafood in Patty-shell

—

Glazed Ham

—

[illegible] with Sour Cream and Bacon

[illegible] with Hollandaise Sauce

—

Mixed Green Salad — Roquefort Dressing

—

Rolls Butter

—

Camembert Cheese and Crackers

—

Compote of Assorted Fruits
(Bananas, Pineapples, [illegible])

—

[illegible]

—

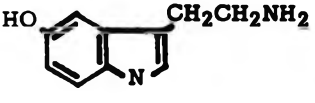
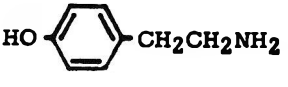
[illegible], Milk, and Tea

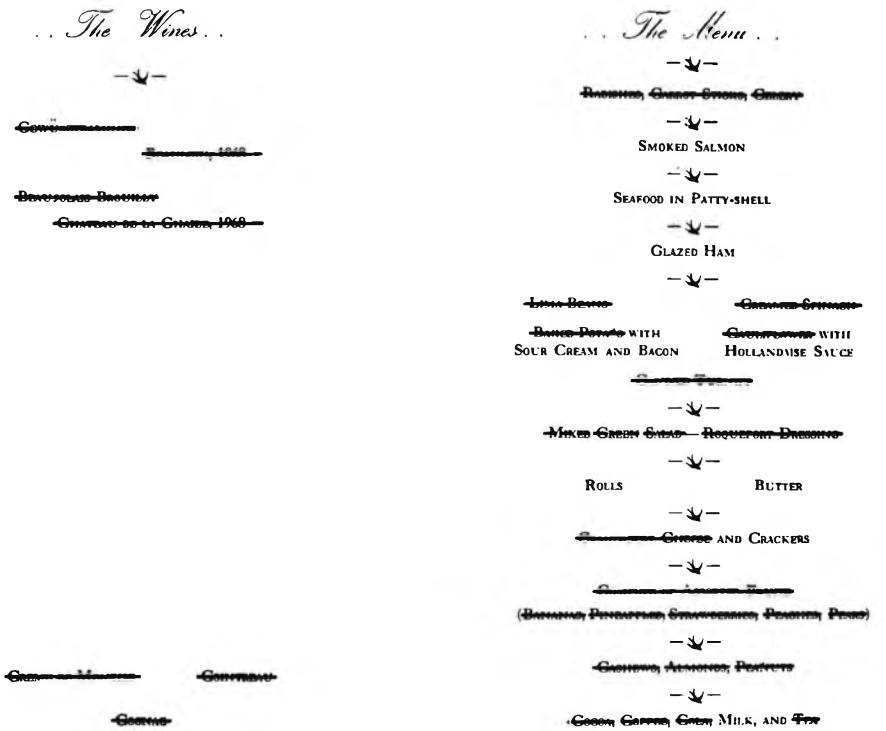
[illegible]

[illegible]

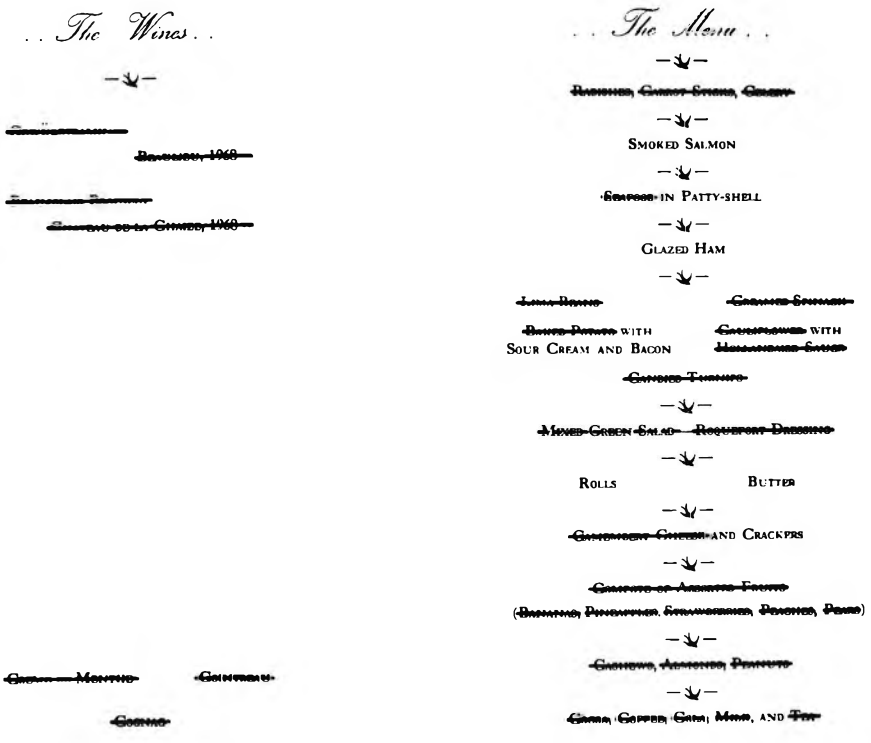
Pressor amines, which raise the blood pressure, are common, and present a real hazard to susceptible persons, and especially to those who are taking drugs such as the tranquilizer, Parnate. Since, by this time, we are sufficiently worried to be gobbling tranquilizers, we should eliminate bananas, pineapples, and cheese, especially Camembert cheese, and wine.

PRESSOR AMINES

Banana Pineapple Tomato	Serotonin (5-Hydroxytryptamine)	
Camembert Cheese	Tyramine	



Now, we probably need pressor amines, though their essentiality has not been conclusively demonstrated. But this dilemma is presented even more sharply by several of the Vitamins—A, D, and K—and several of the essential minerals, which we could not begin to tolerate at 100-x normal consumption levels. But our rule is sacred, and the Vitamin D and A in egg yolk and butter, the D in milk, and the zinc (and arsenic!) in seafood rule them out. Also, egg yolk is reportedly carcinogenic in the diet of mice.



Most of you have heard of the recent concern over the nitrite or nitrate content of foods, and the proved capability of these substances for causing methemoglobinemia in man. There is substantial evidence that they can be transformed in the stomach to the potent carcinogens, the nitrosamines.

These involve not only the cured meats such as ham and bacon, but certain vegetables if they have been fertilized—spinach particularly. Finally, smoked foods almost inevitably contain small amounts of the polynuclear aromatic hydrocarbons, and the role of these as dietary carcinogens in man is confirmed by epidemiological surveys of the northern European countries where smoked foods are much consumed, and cancer of the stomach is unusually common. Out with the smoked salmon.

We can, perhaps, retain the rolls, if we can ignore the ricket-promoting factor in yeast, and the hazards of amino-acid imbalance. Butter has been eliminated, although, if it were devitaminized, we could retain it, labeling it, of course, for added color. The sour cream is left, although we are probably stretching a point in view of its content of saturated fats and lactic acid. In order to provide a vestigial reminder of gracious living, these and the lettuce and crackers can be served in the now-empty patty shell.

If time permitted, it would be interesting to speculate on how foods would be labeled, if complete declarations of naturally-occurring ingredients were required, as in the case of added substances. Some interesting warning statements would be needed—ones that would make the cigarette warning seem hesitant by comparison. Since some of the toxins we have discussed are a characteristic and even essential component of the foods in which they occur, we would have to take steps to eliminate these, with appropriate labeling; degoitrogenized "imitation cauliflower," for example. Hazardous, but essential, substances, like the fat-soluble vitamins, could be available on a prescription basis. Those of less clearly justified merit, for example, the pressor amines and alcohol, would be available on a nonrefillable prescription only. We can't have people taking these things indiscriminately!

Conclusion

In all this nonsense, however, there is a serious point. For safety is a serious matter. The whole thrust of this discussion is that all sources of relevant information should be used. Indeed, this is the underlying concept of general recognition of safety (GRAS), in which both experience based on common use in food, and scientific procedures may be used. Combined, they are still insufficient, and always open to new evidence. Animal testing may be of crucial value—but it may also be irrelevant to human safety. Human experience, for all its directness, may remain an enigma. The utility of both should be improved. In part, this may be achieved by using in animal tests those species previously shown for each substance to be suitable metabolic models for man, instead of those that are handy, cheap, or customary. We need more, and more detailed, national dietary studies coupled with better reporting and analysis of individual health. Let there be no misunderstanding on one point. We must use the mass of human experience, not mass human experiments. By this, I mean that prior to the broad intentional use of a material in human food, we should have information from animal and human studies, which allows expert judgment to conclude with confidence that use of the material will not significantly increase overall risk. But, we must recognize that experience is the final determinant, no matter how encouraging the results from animal tests. We need not only to recognize this, but to improve our utilization of feedback from human experience, in improving our quality of life. **[The End]**

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