Petition to Limit the Exposure of Refined Carbohydrates used in Industrial Processing in order to Prevent Obesity, Diabetes, and Cardiovascular Disease in Children and Adults

Submitted to the United States Department of Health and Human Services

Food and Drug Administration

Submitted by

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Date: August 6, 2025

The undersigned submits this petition under 21 C.F.R. 10.30 for which authority has been delegated by the Secretary of Health and Human Services to the Commissioner of Food and Drugs to request the Commissioner of Food and Drugs to amend regulations issued pursuant to 21 U.S.C. 321, 342, 348 and 371.

Summary

In the last several decades, a significant body of scientific research has emerged demonstrating that refined carbohydrates used in industrial processing (herein after, processed refined carbohydrates) put people at risk for increased caloric intake, weight gain, fat accumulation in the liver, pancreas, skeletal muscle, and heart, and metabolic abnormalities. These lead to a cascade of chronic diseases, including heart and kidney diseases, type 2 diabetes, certain cancers, and possibly neurodegenerative disease.[1]

There is increasing concern about the ill effects of ultraprocessed foods, which are usually composed of 1) refined sweeteners, 2) refined flours and starches, 3) added fats and oils, and/or 4) salt. This petition focuses on the first two categories, both of which are processed refined carbohydrates. These processed refined carbohydrates are central to the widespread availability of ultraprocessed foods.

This petition focuses on the regulatory status of the following substances: 1) refined sweeteners, including corn syrup, corn solids, glucose syrups, dextrose, invert sugar, xylose, maltose, and high fructose corn syrups; and maltodextrin[2] 2) refined flour and starches that are subjected to food extrusion technology, including wheat, corn, tapioca, oat and potato flour, and starches that are processed by extraction or similar technology, and 3) sucrose, refined flours, or starches that are used with emulsifiers (e.g. mono- and diglycerides of fatty acids, DATEM, sodium stearoyl lactylate,

[1] Kessler, D. A. (2025). *Diet, Drugs, and Dopamine.* Flatiron Books.

[2] These substances are all "starch conversion products."

polysorbates); dough conditioners and strengtheners (e.g. azodicarbonamide, L-cysteine, calcium peroxide); humectants (e.g. propylene glycol); stabilizers and gums (e.g. carboxymethylcellulose, methylcellulose); or modified starches and fillers (e.g. regelatinized starch, modified food starch, dextrins).

This petition focuses on processed refined carbohydrates that are primary causal determinants of metabolic harm. These processed refined carbohydrates can themselves be "markers" of ultraprocessed foods (e.g. corn syrup, maltodextrin), or they can be used with other markers of ultraprocessed foods (e.g. emulsifiers, stabilizers, humectants).

Ultraprocessed foods are harmful. Processed refined carbohydrates are harmful. This petition focuses on processed refined carbohydrates in an environment of ultraprocessed food.

This petition does not cover flour, table sugar (sucrose), starch, salt, or corn syrup when used at home.

Processed refined carbohydrates are allowed on the market because almost 50 years ago they were found to be "generally recognized as safe" but, as this petition demonstrates, the science no longer supports that determination.

In light of the substantial concerns regarding the safety of processed refined carbohydrates, there is no longer a basis for finding that these products are "generally recognized as safe." Past GRAS determinations are based on outdated data and fail to assess the long-term effects on insulin

dynamics, blood lipid parameters, energy partitioning, inflammatory markers, brain reward signaling, or visceral adiposity. These past determinations do not reflect chronic exposure, synergistic effects with other additives, or lifetime health consequences. Today there is no expert consensus that refined carbohydrates in ultraprocessed foods are safe under present conditions of use, as is required to find that use of refined carbohydrates is GRAS.

The law places a continuing burden of proof on industry for the safety of GRAS substances. In other words, GRAS status of a specific use of a particular substance in food is time dependent and a product is not GRAS if there is no longer consensus that the specific use is safe.

Further, to revoke GRAS status, FDA does not have to prove that the processed refined carbohydrates used in industrial processing are unsafe, but that their safety has not been established.

Processed refined carbohydrates can no longer be considered GRAS as a matter of science and law, and thus must be removed from commerce unless marketed as permitted by a food additive regulation.

This petition requests, among other items, that FDA should:

1. Declare that it no longer considers use of the processed refined carbohydrates identified in this petition to be GRAS based on the likelihood that they contribute to metabolic harm.

2. Promptly initiate proceedings to revoke any existing GRAS regulation for these processed refined carbohydrates used in industrial processing.

3. Inform industry that continued use of these products depends on the industry notifying FDA within 12 months of its intent to file a food additive petition.

4. Remove these products from commerce unless their use in food is authorized by a food additive petition.[3]

Four decades ago, FDA evaluated the science of these substances and affirmed their GRAS status. In 2015, the Dietary Guidelines Advisory Committee reevaluated that science and concluded that there is strong evidence that these substances increase risk of obesity, type 2 diabetes, and cardiovascular disease. Their findings mark a clear shift, showing that these substances can no longer be considered GRAS.

The current GRAS status of these substances is based on a finding that they are generally recognized as safe, which is no longer valid. In truth, especially when used in combination with fats and salt, and in a food

[3] Depending on the science and what the proponent of the food additive can show, it is conceivable that certain processed refined carbohydrates could, at low doses, and considering the cumulative effect with other related ingredients, meet the legal standard for approval of a food additive petition. Such a showing would need to be made in a food additive petition. It would need to demonstrate, taking into consideration the cumulative effects of all related ingredients, that there is "reasonable certainty of no harm."

environment that leads to chronic high consumption, processed refined carbohydrates pose a clear and demonstrable harm and do not meet the legal standards that require "reasonable certainty of no harm," taking into account the "cumulative effects" when combined with similar ingredients in this obesogenic environment.[4]

As a matter of science and law, processed refined carbohydrates can no longer be considered GRAS.

[4] To summarize, processed refined carbohydrates are harmful, in addition to their caloric load, because of their effects on:

1. Hyperinsulinemia and metabolic dysregulation
2. De novo lipogenesis, hepatic fat, ectopic fat deposition, and inflammation
3. Insulin clearance and resistance
4. Increased consumption independent of calorie content
5. Reward signaling, hedonic overdrive, loss of control over eating, and overconsumption
6. Speed of absorption and glycemic load
7. Eating rate
8. Hypertriglyceridemia
9. Nutrient dilution
10. Low satiety per calorie
11. Use in ultraprocessed foods with increased energy density
12. Synergistic rewarding effects with fat and salt
13. Gut microbiome dysbiosis
14. Lower dietary fiber intake

A. Actions Requested

This petition addresses the three groups of processed refined carbohydrates used in industrial processing: 1) starch conversion products, including maltodextrin and certain sweeteners, including corn syrup, corn solids, glucose syrups, dextrose, invert sugar, xylose, maltose, and high fructose corn syrups; and 2) refined flour and starches that are subjected to food extrusion technology, including wheat, corn, tapioca, oat and potato flour, and starches that are processed by extraction or similar technology, and 3) sucrose, refined flours, or starches that are used with emulsifiers (e.g. mono- and diglycerides of fatty acids, DATEM, sodium stearoyl lactylate, polysorbates); dough conditioners and strengtheners (e.g. azodicarbonamide, L-cysteine, calcium peroxide); humectants (e.g. propylene glycol); stabilizers and gums (e.g. carboxymethylcellulose, methylcellulose); or modified starches and fillers (e.g. regelatinized starch, modified food starch, dextrins).

This petition requests that FDA should declare that:

1. It no longer considers use of the processed refined carbohydrates that are identified in this petition to be GRAS based on the likelihood that they are contributing to metabolic harm.

2. It will promptly initiate proceedings to revoke any existing GRAS regulation for these processed refined carbohydrates used in industrial processing.

3. Continued use of these products depends on the industry notifying FDA within 12 months of their intent to file a food additive petition, and to file such petition within 24 months.

4. With revocation of GRAS status, announce that these substances are legally classified as a food additive and that absent a regulation that prescribes the conditions under which such an additive may be safely used, it is illegal to continue using those food additives.

5. These products must be removed from commerce unless they are eventually covered by a food additive petition.

6. That the Agency will work with the food industry to reduce the use of processed refined carbohydrates as rapidly as possible.

B. Statement of Grounds

I. The American body is ill

Only 12.2% of Americans are metabolically healthy.[5] Seventy-four percent are overweight or obese,[6] and about 38%[7] are insulin-resistant[8] or prediabetic.[9] About 1 in 3 adolescents 12 to 17 years old have prediabetes.[10] Americans have a 23–25% lifetime risk of developing heart failure.[11] They have a 40% lifetime chance of developing diabetes.[12]

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[5] Araújo, J., Cai, J., & Stevens, J. (2019). Prevalence of optimal metabolic health in American adults: National Health and Nutrition Examination Survey 2009–2016. *Metabolic syndrome and related disorders*, *17*(1), 46-52.

[6] CDC. National Center for Health Statistics. https://www.cdc.gov/nchs/fastats/obesity-overweight.htm. Oct. 25, 2024.

[7] CDC. Diabetes. https://www.cdc.gov/diabetes/communication-resources/1-in-3-americans.html. May 15, 2024.

[8] Parcha, V., Heindl, B., Kalra, R., Li, P., Gower, B., Arora, G., & Arora, P. (2022). Insulin resistance and cardiometabolic risk profile among nondiabetic American young adults: insights from NHANES. *The Journal of Clinical Endocrinology & Metabolism*, *107*(1), e25-e37.

[9] U.S. Centers for Disease Control and Prevention. (May, 2024). *Prediabetes – Your chance to prevent Type 2 Diabetes*. U.S. Department of Health and Human Services. https://www.cdc.gov/diabetes/prevention-type-2/prediabetes-prevent-type-2.html?CDC_AAref_Val=https://www.cdc.gov/diabetes/basics/prediabetes.html

[10] Cooney, E. (2025, July 9). *Nearly 1 in 3 teens have prediabetes, CDC finds, in 'wake-up call'.* Stat News. https://www.statnews.com/2025/07/09/prediabetes-in-teens-cdc-says-nearly-one-in-three-teenagers-at-risk-of-type-2-diabetes/

[11] Vasan RS, Enserro DM, Beiser AS, Xanthakis V. Lifetime Risk of Heart Failure Among Participants in the Framingham Study. J Am Coll Cardiol. 2022 Jan 25;79(3):250-263. doi: 10.1016/j.jacc.2021.10.043. PMID: 35057911; PMCID: PMC8820638.

[12] Gregg, E.W., Zhuo, X., Cheng, Y.J., Albright, A.L., Venkat Narayan, K.M., & Thompson, T.J. (2014). Trends in lifetime risk and years of life lost due to diabetes in the USA, 1985–2011: A modelling study. *The Lancet, 2*(11), 867-874. https://www.thelancet.com/journals/landia/article/PIIS2213-8587(14)70161-5/abstract; U.S. Centers for Disease Control and Prevention. (May, 2024). *2 in 5 Americans Expected to Develop Diabetes.* U.S. Department of Health and Human Services. https://www.cdc.gov/diabetes/communication-resources/2-in-5-americans.html

One in four will have a stroke.[13] Some will develop kidney failure.

Visceral fat in the abdomen causes cardiac and kidney diseases, diabetes, certain forms of cancer, and dementia.[14] Fifty to sixty percent of Americans will develop at least one of these conditions over their lifetime. Cardiologists, nephrologists, and endocrinologists are recognizing that the epidemic of obesity causes these diseases.[15]

According to the Centers for Disease Control (CDC), poor nutrition is at the center of this epidemic.[16] This epidemic rivals tobacco in its damage to human health.

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[13] American Heart Association. (2025). *World Stroke Day*. https://www.stroke.org/en/about-the-american-stroke-association/world-stroke-day (This statistic applies globally.)

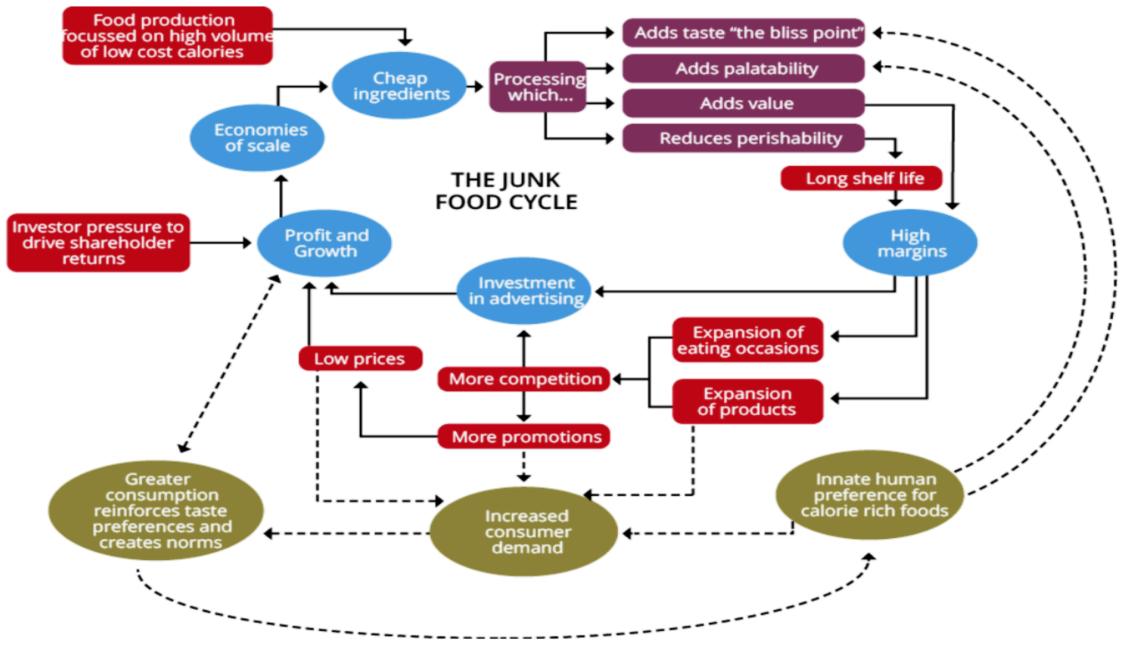
[14] Kessler, D. A. (2025). *Diet, Drugs, and Dopamine.* Flatiron Books.

[15] Kessler, D. A. (2025). Sick Fat. In *Diet, Drugs, and Dopamine* (pp. 62-69). Flatiron Books.; Després, J.-P. (2012). Body fat distribution and risk of cardiovascular disease: An update. *Circulation, 126*(10), 1301–1313. https://doi.org/10.1161/CIRCULATIONAHA.111.067264; Bays, H.E. (2011). Adiposopathy: Is "Sick Fat" a Cardiovascular Disease? *JACC 57*(25), 2461–2473. https://doi.org/10.1016/j.jacc.2011.02.038; Ndumele, C. E., Rangaswami, J., Chow, S. L., Neeland, I. J., Tuttle, K. R., Khan, S. S., Coresh, J., Mathew, R. O., Baker-Smith, C. M., Carnethon, M. R., Despres, J. P., Ho, J. E., Joseph, J. J., Kernan, W. N., Khera, A., Kosiborod, M. N., Lekavich, C. L., Lewis, E. F., Lo, K. B., Ozkan, B., … American Heart Association (2023). Cardiovascular-Kidney-Metabolic Health: A Presidential Advisory From the American Heart Association. *Circulation, 148*(20), 1606–1635. https://doi.org/10.1161/CIR.0000000000001184; Bays, H. E., Bindlish, S., & Clayton, T. L. (2023). Obesity, diabetes mellitus, and cardiometabolic risk: An Obesity Medicine Association (OMA) Clinical Practice Statement (CPS) 2023. *Obesity pillars, 5,* 100056. https://doi.org/10.1016/j.obpill.2023.100056

[16] U.S. Centers for Disease Control and Prevention. (October, 2024). About Chronic Diseases. U.S. Department of Health and Human Services. https://www.cdc.gov/chronic-disease/about/index.html

II. There is increasing recognition that both foods and the food system contribute to this epidemic

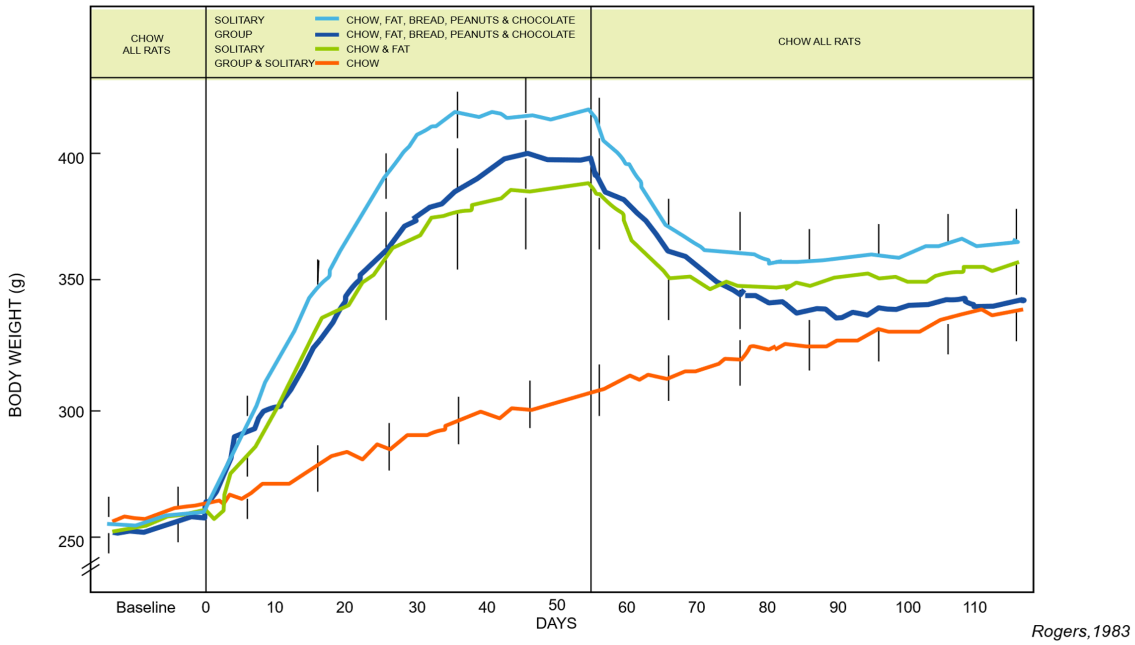
National and international authorities have observed that our current food system is locked in a "junk food cycle"[17] that not only fails to deliver healthy food, but provides cheap industrial foods that are energy-dense, highly palatable, and have extended shelf life.



Overview of the Junk Food Cycle, UK National Food Strategy, July 2021

[17] Adams, J. (2025, May 11). *Challenges for Public Health in comprehensive approaches to address obesity: Where we are and where do we need to be?* [Conference presentation]. European Congress on Obesity, Malaga, ES. https://eco2025.org/assets/docs/programme-at-a-glance.pdf?a=2345; The National Food Strategy. (July, 2021). *The Evidence.* https://www.nationalfoodstrategy.org/wp-content/uploads/2021/08/NFS_Evidence-Pack.pdf; Poti JM, Mendez MA, Ng SW, Popkin BM. Is the degree of food processing and convenience linked with the nutritional quality of foods purchased by US households? Am J Clin Nutr. 2015 Jun;101(6):1251-62. doi: 10.3945/ajcn.114.100925. Epub 2015 May 6. PMID: 25948666; PMCID: PMC4441809.

Fifty years ago, Dr. Anthony Sclafani observed that laboratory rats rapidly consumed the high-calorie, high-sugar breakfast cereal Fruit Loops that had fallen onto a laboratory bench. Since then, studies have shown that the consumption of highly palatable supermarket foods leads to increased food intake.[18]



Body weight of laboratory animals fed a "supermarket diet" versus traditional chow. Peter Rogers, 1983

[18] Kessler, D. A. (2009). Sugar, Fat, and Salt Make Us Eat More Sugar, Fat, and Salt. In *The End of Overeating* (pp. 12-17). McClelland and Stewart.; Rogers, P. An investigation of the effects of dietary manipulation, obesity and hunger on feeding behaviour [unpublished doctoral dissertation]. University of Leeds.; Sclafani, A., & Springer, D. (1976). Dietary obesity in adult rats: similarities to hypothalamic and human obesity syndromes. *Physiol Behav., 17*(3), 461-471. https://doi.org/10.1016/0031-9384(76)90109-8

At the center of the junk food cycle are ultraprocessed[19] foods that became "substitutes of whole foods and freshly prepared meals."[20] These products are made using ultraprocessed[21] food technology that utilizes:

1) Extraction of food substances (starches/sugars/oil/fats/protein isolates) from a few high-yield crops (wheat, sugar cane, corn, soy)
2) Chemical and physical modifications of food substances (extrusion, puffing, hydrolysis, hydrogenation, etc.)
3) Deconstructed food ingredients, destruction of natural food matrix[22]
4) Assemblage of food substances (molding, pre-frying, etc.)

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[19] I generally prefer the use of the term "ultraformulated" to ultraprocessed, as ultraformulated emphasizes formulation over processing and draws attention to specific ingredients and combinations of ingredients. Both terms correctly focus on the structure of food. I use the term ultraprocessed because much of the data on harms has been collected using that term.

[20] Monteiro, C.A. (2024, June 26-29). *Ultra-processed foods and the pandemic of obesity: the thesis and the evidence'* [Conference presentation]. International Congress on Obesity, São Paulo, Brazil; Popkin BM, Barquera S, Corvalan C, Hofman KJ, Monteiro C, Ng SW, Swart EC, Taillie LS. Towards unified and impactful policies to reduce ultra-processed food consumption and promote healthier eating. Lancet Diabetes Endocrinol. 2021 Jul;9(7):462-470. doi: 10.1016/S2213-8587(21)00078-4. Epub 2021 Apr 15. PMID: 33865500; PMCID: PMC8217149.

[21] Ultraprocessed foods are distinguished from unprocessed, minimally processed, processed culinary ingredients, and processed foods.

[22] Monteiro, C.A. (2024, June 26-29). *Ultra-processed foods and the pandemic of obesity: the thesis and the evidence'* [Conference presentation]. International Congress on Obesity, São Paulo, Brazil.; Vamos, E. (2024, May 12-15). *Ultra-processed foods: from a concept to epidemiological evidence* [Conference presentation]. European Congress on Obesity, Venice, IT. https://easo.org/wp-content/uploads/2024/04/ECO2024-Scientific-Programme-book.pdf

5) Use of additives to extend shelf life and alter texture

6) Use of cosmetic additives (flavors, colors, emulsifiers, etc.)

7) Sophisticated packaging using synthetic material[23]

Ultraprocessed foods account for approximately 58%[24] of America's total energy intake.[25] In contrast, ultraprocessed foods account for as little as 10% of energy intake in Italy.

The higher the exposure to ultraprocessed foods, the higher the dietary intake of saturated fat and added sugar, and the lower the intake of fiber, protein, and potassium.[26]

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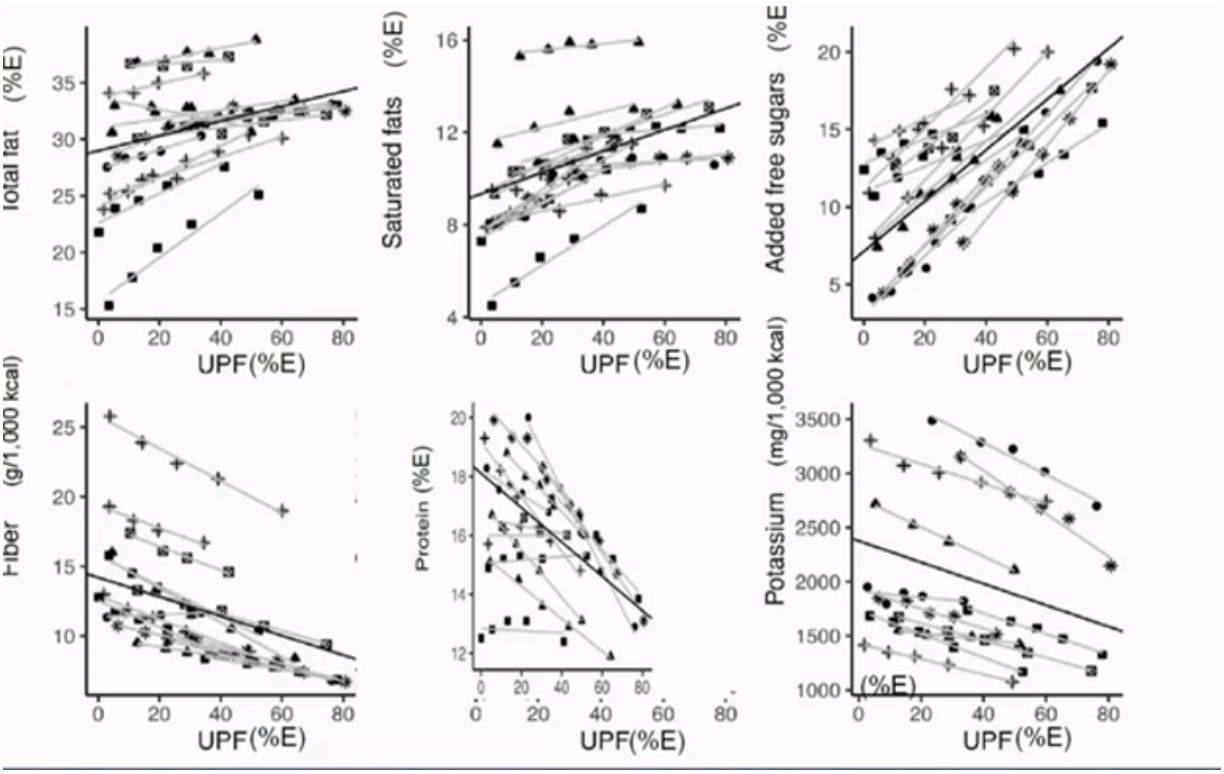
[23] This list has been modified from the original from Monteiro, C.A. (2024, June 26-29). *Ultra-processed foods and the pandemic of obesity: the thesis and the evidence'* [Conference presentation]. International Congress on Obesity, São Paulo, Brazil.

[24] Martínez Steele E, Baraldi LG, Louzada ML, Moubarac JC, Mozaffarian D, Monteiro CA. Ultra-processed foods and added sugars in the US diet: evidence from a nationally representative cross-sectional study. BMJ Open. 2016 Mar 9;6(3):e009892. doi: 10.1136/bmjopen-2015-009892. PMID: 26962035; PMCID: PMC4785287.

[25] In another study, "Across high-income countries, 'the share of dietary energy derived from ultraprocessed foods ranges from 42% and 58% in Australia and the United States, respectively, to as low as 10% and 25% in Italy and South Korea.' Lane, M. M., Gamage, E., Du, S., Ashtree, D. N., McGuinness, A. J., Gauci, S., Baker, P., Lawrence, M., Rebholz, C. M., Srour, B., Touvier, M., Jacka, F. N., O'Neil, A., Segasby, T., & Marx, W. (2024). Ultra-processed food exposure and adverse health outcomes: umbrella review of epidemiological meta-analyses. *BMJ (Clinical research ed.), 384,* e077310. https://doi.org/10.1136/bmj-2023-077310

[26]Martínez Steele E, Popkin BM, Swinburn B, Monteiro CA. The share of ultra-processed foods and the overall nutritional quality of diets in the US: evidence from a nationally representative cross-sectional study. Popul Health Metr. 2017 Feb 14;15(1):6. doi: 10.1186/s12963-017-0119-3. PMID: 28193285; PMCID: PMC5307821.



Scatter plots for the correlation between ultra-processed food consumption and selected food items in nationally representative samples. Martini, 2021

Ultraprocessed foods are generally carriers of combinations of fat, sugar, and salt that are formulated to produce hyperpalatable[27] foods. Ultraprocessed foods generally contain concentrated calories, making them

[27] Kessler, D. A. (2009). *The End of Overeating.* McClelland and Stewart.; Kessler, D. A. (2025). *Diet, Drugs, and Dopamine.* Flatiron Books; Fazzino TL, Rohde K, Sullivan DK. Hyper-Palatable Foods: Development of a Quantitative Definition and Application to the US Food System Database. Obesity (Silver Spring). 2019 Nov;27(11):1761-1768. doi: 10.1002/oby.22639. PMID: 31689013; Fazzino TL, Courville AB, Guo J, Hall KD. Ad libitum meal energy intake is positively influenced by energy density, eating rate and hyper-palatable food across four dietary patterns. Nat Food. 2023 Feb;4(2):144-147. doi: 10.1038/s43016-022-00688-4. Epub 2023 Jan 30. PMID: 37117850; Hall, Kevin. *Unraveling the Mechanisms of Ultraprocessed Foods.* https://www.foodpolitics.com/wp-content/uploads/Hall-ImperialUPF2024pdf.pdf.

more energy dense,[28] with enhanced palatability designed to achieve "bliss points" and optimal pleasure. These foods are engineered to deliver intense flavors and pleasurable eating experiences that often combine fat, sugar, salt, and refined[29] carbohydrates in ways that are not found in nature and are low in nutritional quality.[30]

Ultraprocessed foods are delivery devices for excess calories. They encourage people to absorb more calories. According to a study published by Dr. Kevin Hall, ultraprocessed diets lead to an excess of approximately 500 calories per day, resulting in weight gain.[31]

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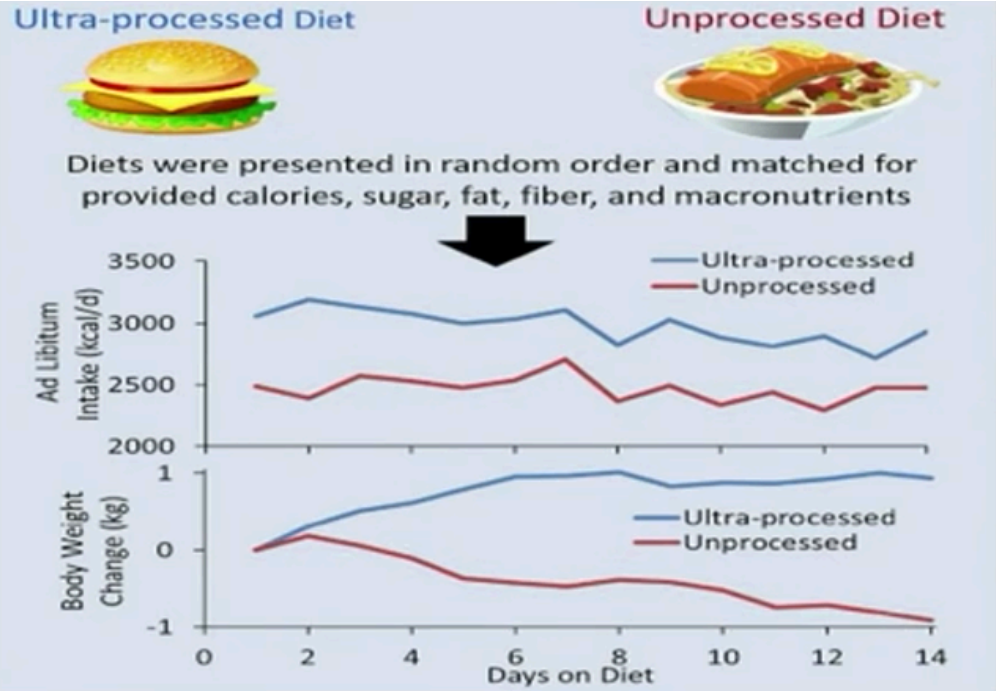
[28] Feskens, E. (2024, May 12-15). Why is UPF so Controversial? [Conference presentation]. European Congress on Obesity, Venice, IT. https://easo.org/wp-content/uploads/2024/04/ECO2024-Scientific-Programme-book.pdf; Increased energy density can occur from the macronutrient composition and the removal of water in the food that extend shelf life.

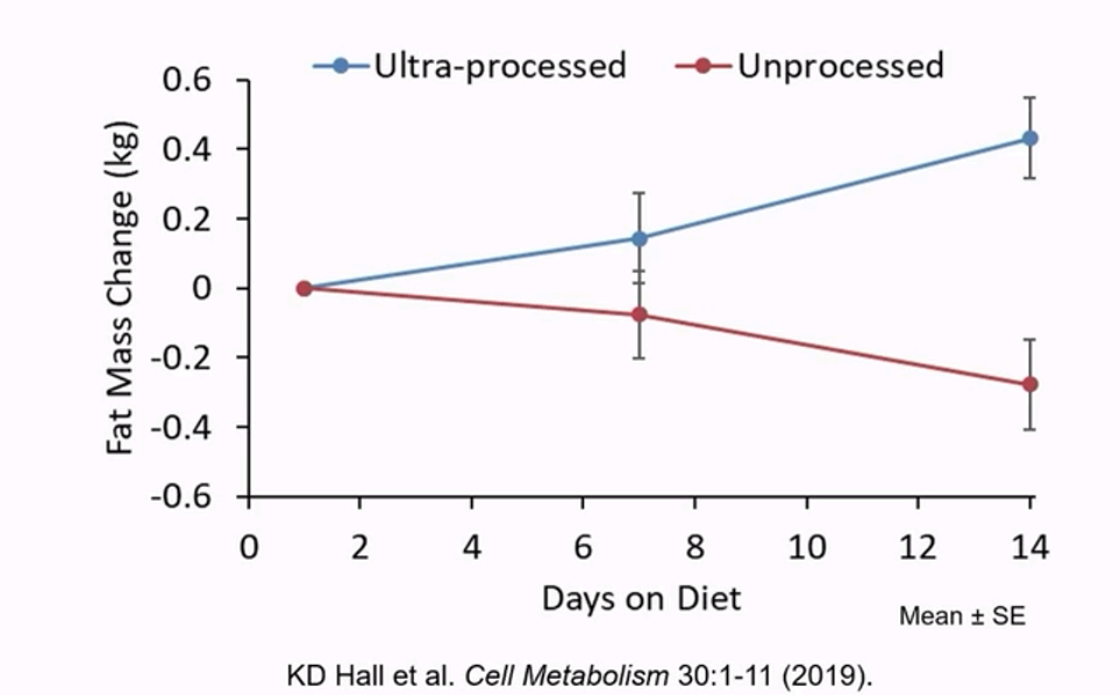
[29] Refined carbohydrates in addition to sugars include many types of starch. Refined carbohydrates are carbohydrates that have been heavily processed to remove their natural fiber, vitamins, and minerals.

[30] Vellinga, R.E., van Bakel, M., Biesbroek, S. et al. (2022). Evaluation of foods, drinks and diets in the Netherlands according to the degree of processing for nutritional quality, environmental impact and food costs. *BMC Public Health 22*, 877. https://doi.org/10.1186/s12889-022-13282-x; Feskens, E. (2024, May 12-15). Why is UPF so Controversial? [Conference presentation]. European Congress on Obesity, Venice, IT. https://easo.org/wp-content/uploads/2024/04/ECO2024-Scientific-Programme-book.pdf

[31] Hall, K. D., Ayuketah, A., Brychta, R., Cai, H., Cassimatis, T., Chen, K. Y., Chung, S. T., Costa, E., Courville, A., Darcey, V., Fletcher, L. A., Forde, C. G., Gharib, A. M., Guo, J., Howard, R., Joseph, P. V., McGehee, S., Ouwerkerk, R., Raisinger, K., Rozga, I., … Zhou, M. (2019). Ultra-Processed Diets Cause Excess Calorie Intake and Weight Gain: An Inpatient Randomized Controlled Trial of Ad Libitum Food Intake. *Cell metabolism, 30*(1), 67–77.e3. https://doi.org/10.1016/j.cmet.2019.05.008; A recent study that looked at 25 different populations for which dietary data were available, the researchers found a clear link between how much UPF people ate and how much body fat they had. TMcGrosky, A., Luke, A., Arab, L., Bedu-Addo, K., Bonomi, A. G., Bovet, P., ... & IAEA DLW Database Consortium. (2025). Energy expenditure and obesity across the economic spectrum. *Proceedings of the National Academy of Sciences*, *122*(29), e2420902122.; Dicken, S.J., Jassil, F.C., Brown, A. *et al.* Ultraprocessed or minimally processed diets following healthy dietary guidelines on weight and cardiometabolic health: a randomized, crossover trial. *Nat Med* (2025). https://doi.org/10.1038/s41591-025-03842-0



Ultra-Processed Diets Cause Excess Calorie Intake and Weight Gain:
An Inpatient Randomized Controlled Trial of Ad Libitum Food Intake. Hall et al. 2019



Body composition changes on ultraprocessed vs. unprocessed diets.

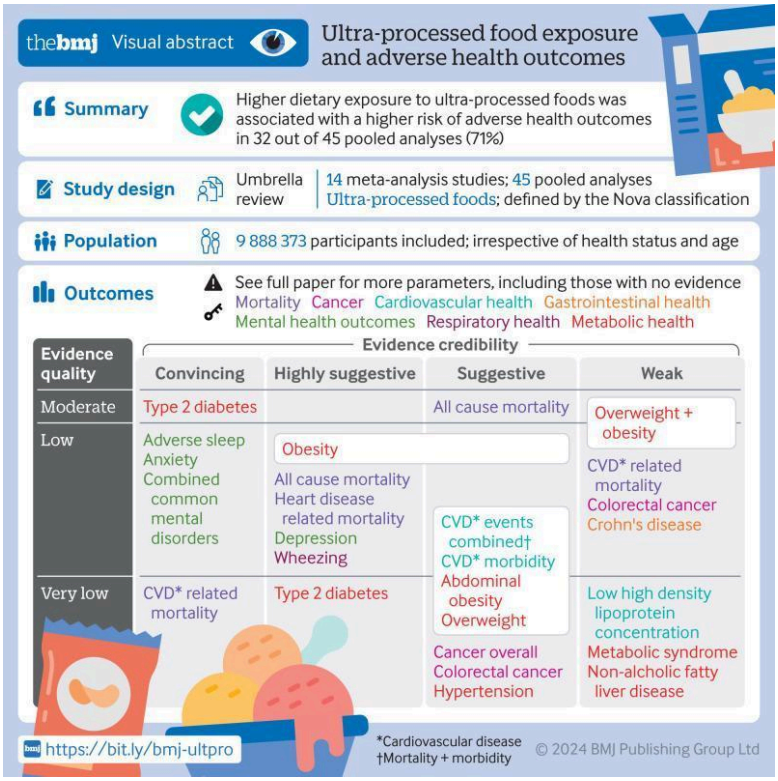
On average, Americans consume about 500 calories more daily than they did in 1970 (of which 210 are from carbohydrates, particularly flour, rice, and cereals).[32]

A food designer who worked in the industry for fifty years described the increase in caloric intake over time as "a kind of metamorphosis. Over the decades we have made food itself nothing but easy calories." He said that the food industry had removed anything that could stand in the way of rapid caloric absorption. "Mill the bran off the white rice, refine the flour so it's very light and doesn't obstruct you in any way. Light, easy to chew, easy to swallow. Make it more compelling by adding fat and sugar and salt: the perfect caloric torpedo."[33]

[32] Kessler, D.A. (2020). Fast Carbs, Slow Carbs: The Simple Truth about Food, Weight, and Disease. HarperWave, p. 26; See also: https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/2123/Tables_1-36%20and%2041-56_2123.pdf

[33] Kessler, D.A. (2020). Fast Carbs, Slow Carbs: The Simple Truth about Food, Weight, and Disease. HarperWave, p. 39.

Meta-analyses demonstrate an association between ultraprocessed foods and type 2 diabetes.[34]



Ultraprocessed foods and adverse health outcomes. Lawrence et al. 2024

[34] Lawrence, M., Rebholz, C. M., Srour, B., Touvier, M., Jacka, F. N., O'Neil, A., Segasby, T., & Marx, W. (2024). Ultra-processed food exposure and adverse health outcomes: umbrella review of epidemiological meta-analyses. *BMJ (Clinical research ed.), 384,* e077310. https://doi.org/10.1136/bmj-2023-077310; *See also: Moradi S, et al., Ultra-processed food consumption and adult obesity risk: a systematic review and dose-response meta-analysis. Crit Rev Food Sci Nutr. 2023;63(2):249-260. Epub 2021 Jun 30.; Lane MM, et al., Ultraprocessed food and chronic noncommunicable diseases: A systematic review and meta-analysis of 43 observational studies. Obes Rev. 2021 Mar;22(3):e13146. Epub 2020 Nov 9.; Pagliai G, et al., Consumption of ultra-processed foods and health status: a systematic review and meta-analysis. Br J Nutr. 2021 Feb 14;125(3):308-318. Epub 2020 Aug 14.; Dicken SJ, Batterham RL. Ultra-processed Food and Obesity: What Is the Evidence? Curr Nutr Rep. 2024 Mar;13(1):23-38. Epub 2024 Jan 31.; Zhang, J., Shu, L., & Chen, X. P. (2025). Ultra-processed foods and non-alcoholic fatty liver disease: An updated systematic review and dose-response meta-analysis. Frontiers in Nutrition, 12, 1631975.; Leonberg KE, et al. Ultra-Processed Food and Chronic Kidney Disease Risk: A Systematic Review, Meta-Analysis, and Recommendations. Nutrients. 2025 Apr 30;17(9):1560.*

A criticism of using the term "ultraprocessed foods" is that it utilizes elements of formulation, processing, economics, and food additives, which complicates the definition.[35]

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[35] Mattes, R., & Sanders, L. (2025, July 16). *Hot Topics Studio: Are Ultra-processed Foods Engineered to be Irresistible?* [Conference presentation]. IFT First, Chicago, IL. https://www.iftevent.org/schedule/agenda

Another criticism is the lack of mechanistic specificity, or that their negative effects may be due to specific mechanisms that have already been identified in the literature, such as increased energy density, glycemic load, or palatability, as well as nutrient composition.[1]

Moreover, critics have also pointed out that not all ultraprocessed foods are unhealthy and that some may be nutritious and deliver important nutrients and vitamins, including as a source of fortification, especially folic acid. Furthermore, when effects of ultraprocessed foods are stratified by type, sweetened beverages and processed meats are consistently driving the negative associations between ultraprocessed foods and chronic diseases (especially type 2 diabetes).

Additionally, there is a lack of consensus on what processing means, although destruction of the natural food structure is a sine qua non of processing.

Confounding the issue is that there is not just one processing technology that produces ultraprocessed foods, but many. How ultraprocessed foods overlap with traditional conceptions of "junk foods" is not clear. Some criticize the theory because it overstates industry intentions. Others raise concerns that the term demonizes foods and raises risk of eating disorders. There are also other dimensions within the category of ultraprocessed food, such as ratio of or characteristics of certain ingredients such as fat, sugar, and salt, that may be operative.[2] Questions also exist about the epidemic parallels of increasing obesity rates over the last several decades and change in use of ultraprocessed foods. Questions have been raised about how long lasting the effects of ultraprocessed food are on energy intake. There are also unanswered questions about the effects of ultraprocessed foods in populations such as vegetarians.[3]

On the other hand, there are data to suggest that the notion of limiting ultraprocessed foods has been embraced by many people who wish to avoid these foods and want information about what processing is used.[4]

[1] Astrup, A., & Monteiro, C. A. (2022). Does the concept of "ultra-processed foods" help inform dietary guidelines, beyond conventional classification systems? Debate consensus. *The American journal of clinical nutrition, 116*(6), 1489–1491. https://doi.org/10.1093/ajcn/nqac230; Sadler, C.R., Grassby, T., Hart, K., Raats, M., Sokolović, M., & Timotijevic, L. (2021). Processed food classification: Conceptualisation and challenges. *Trends in Food Science & Technology*, *112*, 149-162. https://doi.org/10.1016/j.tifs.2021.02.059; Visioli, F., Marangoni, F., Fogliano, V., Del Rio, D., Martinez, J. A., Kuhnle, G., Buttriss, J., Da Costa Ribeiro, H., Bier, D., & Poli, A. (2023). The ultra-processed foods hypothesis: a product processed well beyond the basic ingredients in the package. *Nutrition research reviews, 36*(2), 340–350. https://doi.org/10.1017/S0954422422000117; Feskens, E. (2024, May 12-15). *Why is UPF so Controversial?* [Conference presentation]. European Congress on Obesity, Venice, IT. https://easo.org/wp-content/uploads/2024/04/ECO2024-Scientific-Programme-book.pdf
Fazzino, T. L., Rohde, K., & Sullivan, D. K. (2019). Hyper-Palatable Foods

[2] Fazzino, T. L., Rohde, K., & Sullivan, D. K. (2019). Hyper-Palatable Foods: Development of a Quantitative Definition and Application to the U.S. Food System Database. *Obesity (Silver Spring, Md.), 27*(11), 1761–1768. https://doi.org/10.1002/oby.22639.

[3] Mattes, R., & Sanders, L. (2025, July 16). *Hot Topics Studio: Are Ultra-processed Foods Engineered to be Irresistible?* [Conference presentation]. IFT First, Chicago, IL. https://www.iftevent.org/schedule/agenda

One of the most important criticisms is that the concept of ultraprocessed foods is too difficult to define and too broad for regulatory action.

For all these reasons, and the fact that the Federal Food, Drug and Cosmetic Act has as its framework focus on specific food substances, this petition focuses specifically on processed refined carbohydrates.

III. Refined Carbohydrates Used in Industrial Food Processing

This petition focuses on refined carbohydrates[36] used in industrial food processing (hereafter referred to as processed refined carbohydrates), not in home cooking. It focuses on key markers of ultraprocessed foods. Over the years, these carbohydrates have been referred to as "refined carbohydrates," "fast carbs," and "rapidly absorbable carbohydrates." The FDA's 1976 Select Committee on GRAS Substances referred to this group of carbohydrates as "nutritive saccharides."[37] They include carbohydrates that are considered by the agency as "added sugars," but also include starch derived polysaccharides such as maltodextrin, which the select committee recognized may differ in "the extent of hydrolysis" but are closely related. This group of processed ingredients act metabolically in a similar fashion to "added sugars" and small chain saccharides.

Ultraprocessed foods contain many types of processed refined carbohydrates, which are rapidly absorbed into the circulation. In contrast

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[4] Dornblaser, L. (2025, July 16). *Solutions Showcase: Rethinking Ultra-Processed Foods: Taste, Function, and Consumer Expectations.* [Conference presentation]. IFT First, Chicago, IL. https://www.iftevent.org/schedule/agenda

[36] Hu FB. Are refined carbohydrates worse than saturated fat? Am J Clin Nutr. 2010 Jun;91(6):1541-2. doi: 10.3945/ajcn.2010.29622. Epub 2010 Apr 21. PMID: 20410095; PMCID: PMC2869506.

[37] Report no. FDA/BF-77/28, Evaluation of the Health Aspects of Corn Sugar (Dextrose), Corn Syrup, and Invert Sugar as Food Additives. 1976 Select Committee on GRAS Substances (SCOGS). Jan 13, 1977

to vegetables and fruits, which retain their food matrix, these processed carbohydrates rapidly release glucose (and fructose), which are quickly absorbed into the bloodstream.[38]

As a group, these refined carbohydrates used in industrial processing are conducive to rapid eating, rapid digestion, fast gastrointestinal transit time, and rapid absorption, and they stimulate blood insulin and glucose.[39] These are ultraformulated[40] foods; they are formulated for palatability with other fats, sugars, and salt in the absence of natural intact food matrices. As such, they can be part of a food system that contributes to fast gastric emptying and decreased satiety.

These processed refined carbohydrates used in industrial processing include maltodextrin, corn syrup, corn solids, glucose syrups, dextrose, invert sugar, xylose, maltose, fruit concentrates, and high fructose corn syrups. They also include flours and starches that are altered in industrial processing, such as by extrusion, which markedly changes the structure of the ingredient. For purposes of this petition, processed refined carbohydrates used in industrial processing do not include sugar, flour, or native starches commonly used in the home.

[38] Kessler, D.A. (2020). *Fast Carbs, Slow Carbs: The Simple Truth about Food, Weight, and Disease*. HarperWave.
[39] Ibid.
[40] Kessler, D. A. (2025). *Diet, Drugs, and Dopamine*. Flatiron Books.

IV. The Central Role of Processed Refined Carbohydrates: From Industrial Production to Metabolic Harm

A. The Industrial Transformation of Carbohydrates

In the 1980s, a major change occurred in the way that starch was processed from corn and chemically processed to produce sweeteners. Known as corn wet milling, it became the backbone in industrial food processing and allowed for the production of synthetic, highly palatable, energy-dense shelf foods. Estimates are that about 25% of grocery store items come from the products produced by corn milling.[41]

In 1984, Professor Roy Whistler of Purdue University understood the major revolution that was occurring:

> Innovations have now brought the industry to a highly sophisticated level with up-to-date, state-of-the-art, continuous, economical processes for conversion of corn to starch and on to D-glucose of excellent quality. A significant further development was the introduction of advanced enzyme engineering to convert high-purity D-glucose to a mixture of D-glucose and D-fructose equivalent to invert sugar from sucrose, thereby opening to the corn industry the hitherto unavailable but enormous market in sweeteners. Solid entry into this market is provided by the stability of corn supply and the low cost of producing D-glucose–D-fructose syrup.[42]

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[41] https://michaelpollan.com/articles-archive/whats-eating-america/

[42] Whistler, R. L., BeMiller, J. N (Eds.). (1984).*Starch: chemistry and technology*. Academic Press, p. xvii.

The products that are the focus of this petition are enzymatically, chemically, and physically made from cornstarch into readily absorbable glucose polymers or simple sugars.[43]

These industrial starch-derived chemicals range in their level of sweetness. They were key to the emergence of ultraprocessed foods by increasing shelf stability, moisture and texture control, cost reductions, and customization of sweetness.[44]

Unlike sucrose, these products do not crystallize but do retain moisture, allowing greater shelf life. They can act as humectants, emulsifiers, and bulking agents, resulting in softness, smoothness, and chewiness in a great variety of products.[45]

Also unlike sucrose, these processed refined carbohydrates can be blended to achieve a range of sweetness in everything from bread, cereals, ketchup, sauces, yogurts, bars, shakes, and sodas.[46]

Unlike traditional cornstarch that was used in home cooking, these processed refined carbohydrates are derived first by breaking down that starch and altering it chemically and then recombining it with fat, salt, and other food substances into ultraprocessed food-like structures that have none of the food matrix structure of traditional food and deliver increased carbohydrate loads. That food matrix structure had for thousands of years

[43] Whistler, R. L., BeMiller, J. N. (Eds.). (1984) *Starch: chemistry and technology*. Academic Press.
[44] ibid
[45] ibid
[46] ibid

naturally controlled the release of sugars that result in insulin and glucose stimulation. Processing's effects on the food matrix eliminates those natural "brakes" on insulin and glucose release.[47]

These processed refined carbohydrates are readily and frequently combined with other refined carbohydrates, industrial fats, emulsifier gums, flavor enhancers, and color additives.

Three industrial ingredients make up the backbone of many ultraprocessed foods: added fats and oils, refined sweeteners,[48] and refined flours and starches from wheat and corn, much of which are subjected to extrusion processing.

The introduction of corn syrups—particularly high-fructose corn syrup (HFCS),[49] glucose syrup, and maltodextrin—marked a pivotal shift in the scale, form, and economics of food manufacturing in the United States. While these ingredients did not increase the total amount of agricultural food mass grown, they played a central role in expanding the production and distribution of shelf-stable, calorie-dense, and highly processed foods. Their chemical and physical properties, coupled with their affordability and

[47] Kessler, D.A. (2020). *Fast Carbs, Slow Carbs: The Simple Truth about Food, Weight, and Disease*. HarperWave.
[48] In addition, salt is a key functional additive in ultraprocessed foods, but it's not one of the three ingredients that form the caloric backbone of ultraprocessed foods.
[49] Kay Parker, Michelle Salas and Veronica C. Nwosu. "*High fructose corn syrup: Production, uses and public health concerns*." Biotechnology and Molecular Biology Review Vol. 5(5), pp. 71 - 78 December 2010. https://doi.org/10.5897/BMBR2010.0009

integration into industrial food systems, made it possible to produce more processed food more quickly, cheaply, and optimized for modern markets.[50]

B. How Corn Syrups Give Rise to Ultraprocessed Foods

Corn syrups were key to the increased availability of many ultraprocessed foods in part by improving the efficiency and functionality of food manufacturing. Unlike crystalline sucrose, which must be dissolved and carefully handled to prevent recrystallization, corn syrups are flowable liquids that can be directly metered into continuous production systems. Corn syrups are made by breaking down cornstarch through acid or enzymatic hydrolysis, producing a mixture of glucose and other saccharides. These mixtures resist crystallization, unlike sucrose, allowing the syrup to remain liquid and smooth, which makes it easier to handle in industrial food manufacturing without clogging equipment. This makes them especially compatible with large-scale processes like extrusion, spray drying, and aseptic packaging. Their resistance to crystallization made them ideal for soft drinks, baked goods, frozen desserts, and syrups—products that require stable textures and extended shelf lives under a range of storage conditions. Because these syrups are liquid at room temperature, they are particularly valuable for products like sweet baked goods because, along with the addition of oils (also liquid at room temperature), they can keep a product like a cake or muffin moist for 30

[50] Pollan, M. (2006). *The Omnivore's Dilemma: A Natural History of Four Meals.* Penguin Books.; Moss, M. (2013). *Salt, Sugar, Fat: How the Food Giants Hooked Us.* Random House Trade Paperbacks.

days or more in contrast to a homemade cake, which might be stale in a matter of days.[51]

In addition to ease of handling, corn syrups offered chemical flexibility. Produced by hydrolyzing cornstarch, they can be tailored to have different levels of sweetness, viscosity, and browning potential depending on the degree of hydrolysis—measured as dextrose equivalent (DE). High-DE syrups like glucose syrup are highly sweet and hygroscopic, contributing to moisture retention and sweetness; low-DE syrups like maltodextrin provide bulk and body with little sweetness. This tunability allowed food manufacturers to precisely control product characteristics and tailor ingredients to specific formulations, something sucrose alone could not offer.[52]

Perhaps most significantly, corn syrups enabled the creation of more energy-dense foods—that is, foods that deliver more calories per gram or per serving—by facilitating the formulation of high-solids products that retained desirable textures and stability. This was not simply due to their caloric value, which is similar to that of sucrose, but because of their

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[51] Whistler, R. L., BeMiller, J. N., & Paschall, E. F. (Eds). (1984). *Starch: Chemistry and Technology* (2nd ed). Academic Press.; BeMiller, J. N., & Whistler, R. L. (Eds.). (2009). *Starch: Chemistry and Technology* (3rd ed.). Academic Press.; Parkin, K. L., & Fennema, O. R. (Eds.). (2007). *Fennema's Food Chemistry* (4th ed.). CRC Press.; Hui, Y. H. (Ed). (2006). *Handbook of Food Science, Technology, and Engineering* (vol. 3). Taylor & Francis.; Belitz, H.-D., Grosch, W., & Schieberle, P. (2009). *Food Chemistry* (4th ed). Springer Berlin Heidelberg.; Goff, H. D., & Hartel, R. W. (7th ed). (2013). *Ice Cream*. Springer.

[52] BeMiller, J. N., & Whistler, R. L. (Eds.). (2009). *Starch: Chemistry and Technology* (3rd ed.). Academic Press.; Chronakis I. S. (1998). On the molecular characteristics, compositional properties, and structural-functional mechanisms of maltodextrins: a review. *Critical reviews in food science and nutrition, 38*(7), 599–637. https://doi.org/10.1080/10408699891274327; Parker, K., Salas, M., & Nwosu, V. C. (2010). High fructose corn syrup: production, uses and public health concerns. *Biotechnol Mol Biol Rev*, *5*(5), 71-78.

physical properties, such as low crystallization tendency and moisture-binding capacity, which permitted the inclusion of higher concentrations of sugar-equivalent solids without compromising texture or palatability. Unlike sucrose, which can crystallize at high concentrations and sometimes produce gritty or brittle textures in certain formulations, corn syrups remain smooth and stable, making them ideal for dense confections, snack bars, syrups, and beverages.[53]

Additionally, corn syrups are hygroscopic, meaning they draw and retain moisture. This moisture-binding property made it possible to produce soft, chewy, shelf-stable foods—a key feature of modern ultraprocessed snack items. Foods such as energy bars, soft cookies, and gummy candies rely on this combination of high caloric density and pleasant texture, which corn syrup facilitates. Sucrose lacks comparable moisture retention and can cause foods to dry out over time if not carefully formulated. Again, compare the texture of a homemade cake made with butter and sugar a week after baking to a sweet snack cake that may be palatable—or perhaps still tasty—even a year after it's been produced. Corn syrup's compatibility with fats and its role in extrusion processes also allowed the fusion of carbohydrates and lipids in products like frosted cereals, pastries, and

[53] Parkin, K. L., & Damodaran, S. (2017). *Fennema's Food Chemistry* (5th ed). CRC Press.; Labuza, T. P., Altunakar, B. (2007). Water Activity Prediction and Moisture Sorption Isotherms. In Barbosa-Canovas, G. V., Fontana, A. J., Schmidt, S. J., & Labuza, T. P. (Eds.), *Water Activity in Foods: Fundamentals and Applications* (pp. 109-154). Blackwell Publishing. https://doi.org/10.1002/9780470376454.ch5

snack cakes—many of which deliver high calories in compact, portable formats.[54]

These functional advantages were reinforced by the economic incentives built into the U.S. food system. Corn-derived products are made artificially cheap through federal subsidies and market interventions such as sugar import quotas and price supports, which created strong incentives to substitute HFCS for sucrose. This cost advantage encouraged widespread substitution of HFCS for sucrose in sweetened beverages, condiments, and baked goods. By the mid-1980s, HFCS had surpassed sucrose as the primary sweetener in U.S. soft drinks. Its high solubility, clarity, and stability in cold liquids—with the addition of its artificially low cost thanks to indirect subsidies—made it the preferred sweetener for soda production, helping make sweetened beverages one of the most calorie-dense and widely consumed sources of sugar in the American diet.[55]

Importantly, corn syrups did not expand the total agricultural output of food in the traditional sense. Rather, they rechanneled existing corn crops—primarily field corn used for feed or industrial purposes—into the

[54] Parkin, K. L., & Damodaran, S. (2017). *Fennema's Food Chemistry* (5th ed). CRC Press.; BeMiller, J. N., & Whistler, R. L. (Eds.). (2009). *Starch: Chemistry and Technology* (3rd ed). Academic Press.; Pyler, E. J., & Gorton, L. A. (2008). *Baking Science & Technology: Fundamentals and Ingredients* (4th ed). Sosland Publishing.
[55] Bray, G. A., Nielsen, S. J., & Popkin, B. M. (2004). Consumption of high-fructose corn syrup in beverages may play a role in the epidemic of obesity. *The American journal of clinical nutrition, 79*(4), 537-543.; Popkin, B. M., & Nielsen, S. J. (2003). The sweetening of the world's diet. *Obesity research, 11*(11), 1325-1332.; Abadam, V. (2025, July 17). *Sugar and Sweeteners Outlook.* United States Department of Agriculture, Economic Research Service (USDA, ERS). https://usda.library.cornell.edu/concern/publications/pv63g024f?locale=en (These reports are publicly available on the ERS website and provide ongoing data and analysis of the policies mentioned).

production of refined caloric ingredients. This helped shift the U.S. food supply toward more processed, energy-dense formulations, contributing to the growing availability of ultraprocessed foods. According to USDA data, the total number of calories available in the U.S. food supply increased substantially from the 1970s to the early 2000s, with added sugars, grains, and fats all contributing. While corn syrups were not the sole driver of this trend, they were a critical enabler of the industrial systems that made such products possible.[56]

In sum, corn syrups expanded the capacity of the food industry not by increasing the sheer amount of food grown, but by enabling the mass production, distribution, and shelf stability of highly engineered, affordable, and calorie-dense foods. Their unique physical and chemical properties allowed manufacturers to scale up production with greater control over texture, taste, and preservation, adding high levels of moist sweetness to products consumers like, from beverages to baked goods. These characteristics add to the rewarding and hedonic properties of these

[56] Bray, G. A., Nielsen, S. J., & Popkin, B. M. (2004). Consumption of high-fructose corn syrup in beverages may play a role in the epidemic of obesity. *The American Journal of Clinical Nutrition, 79*(4), 537-543.; Putnam, J., Allshouse, J., & Kantor, L. S. (2002). US Per Capita Food Supply Trends: More Calories, Refined Carbohydrates. *FoodReview, 25*(3), 2-15.; Stuckler, D., & Nestle, M. (2012). Big food, food systems, and global health. PLoS medicine, 9(6), e1001242.; Economic Research Service. (2025, June 26). *Food Availability (Per Capita) Data System.* U.S. Department of Agriculture. https://www.ers.usda.gov/data-products/food-availability-per-capita-data-system; Wells, H. F., & Buzby, J. C. (March 2008). *Dietary assessment of major trends in US food consumption, 1970-2005.* Economic Information Bulletin No. 33, U.S. Department of Agriculture. https://ers.usda.gov/sites/default/files/_laserfiche/publications/44217/EIB-33.pdf?v=25327

products.[57] Most importantly, they allowed for the efficient concentration of calories into compact, palatable forms, ushering in a new era of industrialized food that helped define the modern American diet.

C. Refined Ingredients and the Growth of Ultraprocessed Foods

Together, refined flours and starches, added fats, and sweeteners form the foundation of ultraprocessed foods—products that now dominate the American diet. Since 1970, intake of each of these components has risen

[57] While this petition highlights the metabolic harms associated with processed refined carbohydrates, the FDA needs to evaluate the substantial body of knowledge that processed refined carbohydrates have a unique role in the reward system, leading to increased sensitization and overconsumption.[1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]

[1]Ahmed, S. H., Avena, N. M., Berridge, K. C., Gearhardt, A. N., & Guillem, K. (2022). Food addiction. In *Neuroscience in the 21st century: From basic to clinical*, p. 4193-4218. Cham: Springer International Publishing.

[2]Berridge KC. The debate over dopamine's role in reward: the case for incentive salience. Psychopharmacology (Berl). 2007 Apr;191(3):391-431. doi: 10.1007/s00213-006-0578-x. Epub 2006 Oct 27. PMID: 17072591.

[3]Berridge KC, Robinson TE. Liking, wanting, and the incentive-sensitization theory of addiction. Am Psychol. 2016 Nov;71(8):670-679. doi: 10.1037/amp0000059. PMID: 27977239; PMCID: PMC5171207.

[4]Cornwell TB, McAlister AR. Alternative thinking about starting points of obesity. Development of child taste preferences. Appetite. 2011 Apr;56(2):428-39. doi: 10.1016/j.appet.2011.01.010. Epub 2011 Jan 14. PMID: 21238522.

[5]Figlewicz DP, Bennett-Jay JL, Kittleson S, Sipols AJ, Zavosh A. Sucrose self-administration and CNS activation in the rat. Am J Physiol Regul Integr Comp Physiol. 2011 Apr;300(4):R876-84. doi: 10.1152/ajpregu.00655.2010. Epub 2011 Feb 9. PMID: 21307361; PMCID: PMC3075076.

[6]Hutter JA, Chapman CA. Exposure to cues associated with palatable food reward results in a dopamine D_2 receptor-dependent suppression of evoked synaptic responses in the entorhinal cortex. Behav Brain Funct. 2013 Oct 4;9:37. doi: 10.1186/1744-9081-9-37. PMID: 24093833; PMCID: PMC3852587.

[7]Levy, A. (2018). *Behaviour and Neural Indices of the Abuse Liability associated with Intraoral Self-administration of High Fructose Corn Syrup* (Doctoral dissertation, University of Guelph).

[8]Naleid AM, Grimm JW, Kessler DA, Sipols AJ, Aliakbari S, Bennett JL, Wells J, Figlewicz DP. Deconstructing the vanilla milkshake: the dominant effect of sucrose on self-administration of nutrient-flavor mixtures. Appetite. 2008 Jan;50(1):128-38. doi: 10.1016/j.appet.2007.06.011. Epub 2007 Jul 18. PMID: 17707949; PMCID: PMC2266682.

[9]Robinson TE, Berridge KC. The Incentive-Sensitization Theory of Addiction 30 Years On. Annu Rev Psychol. 2025 Jan;76(1):29-58. doi: 10.1146/annurev-psych-011624-024031. Epub 2024 Dec 3. PMID: 39094061; PMCID: PMC11773642.

[10]Sun X, Kroemer NB, Veldhuizen MG, Babbs AE, de Araujo IE, Gitelman DR, Sherwin RS, Sinha R, Small DM. Basolateral amygdala response to food cues in the absence of hunger is associated with weight gain susceptibility. J Neurosci. 2015 May 20;35(20):7964-76. doi: 10.1523/JNEUROSCI.3884-14.2015. PMID: 25995480; PMCID: PMC4438134.

[11]Wyvell CL, Berridge KC. Incentive sensitization by previous amphetamine exposure: increased cue-triggered "wanting" for sucrose reward. J Neurosci. 2001 Oct 1;21(19):7831-40. doi: 10.1523/JNEUROSCI.21-19-07831.2001. PMID: 11567074; PMCID: PMC6762900.

sharply: Americans consume over 200 additional daily calories from added[58] fats (primarily industrial seed oils), nearly 190 more from refined grains, and about 75 to 90 more from caloric sweeteners. These three inputs account for the vast majority of the roughly 450 to 500 calorie increase in the average American's daily intake. Today, ultraprocessed foods make up more than half of total caloric intake and nearly three-quarters of all packaged foods sold. Even as the use of caloric sweeteners has leveled off or declined slightly in recent years, that drop has been offset by the rise of non-caloric sweeteners, which still help drive consumption by enhancing the palatability of foods high in refined grains and added fats. In this way, sweeteners—both caloric and non-caloric—continue to play a pivotal role in shaping the modern food environment, reinforcing the overconsumption of the industrial ingredients that define ultraprocessed products.[59]

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[58] These data compare 1970 to 2017/18. Economic Research Service. (2019). *Calories* [data set]. U.S. Department of Agriculture. https://www.ers.usda.gov/data-products/food-availability-per-capita-data-system.

[59] Economic Research Service. (2019). *Calories* [data set]. U.S. Department of Agriculture. https://www.ers.usda.gov/data-products/food-availability-per-capita-data-system; Economic Research Service. (2022). *Dairy (fluid milk, cream, and other products)* [data set]. U.S. Department of Agriculture. https://www.ers.usda.gov/data-products/food-availability-per-capita-data-system; Economic Research Service. (2019). *Fats and oils (added)* [data set]. U.S. Department of Agriculture. https://www.ers.usda.gov/data-products/food-availability-per-capita-data-system; Economic Research Service. (2023). *Fruit* [data set]. U.S. Department of Agriculture. https://www.ers.usda.gov/data-products/food-availability-per-capita-data-system; Economic Research Service. (2024). *Grains* [data set]. U.S. Department of Agriculture. https://www.ers.usda.gov/data-products/food-availability-per-capita-data-system; Economic Research Service. (2024). *Sugar and sweeteners (added)* [data set]. U.S. Department of Agriculture. https://www.ers.usda.gov/data-products/food-availability-per-capita-data-system; Economic Research Service. (2024). *Vegetables* [data set]. U.S. Department of Agriculture. https://www.ers.usda.gov/data-products/food-availability-per-capita-data-system

D. The Effects of Ultraprocessed Food and Processed Refined Carbohydrates on Eating Rate

Refined processed carbohydrates in ultraprocessed foods are characterized by their soft, easy to chew nature that allows for food to be eaten quickly, swallowed effortlessly, and absorbed rapidly. In a controlled feeding study, researchers studied how fast people ate meals consisting of ultraprocessed versus unprocessed foods. The diets were matched for their calories, macronutrients, sugar, sodium, and fiber, but not their oral-sensory properties. The structure and texture of the foods in the ultraprocessed versus unprocessed test meals was different. Participants ate the ultraprocessed meals significantly faster.[60]

Speed eating is no accident. The food industry designs food to go down in a whoosh. A patent application to produce[61] corn chips that are as friction-free as potato chips makes this clear. The patent specifies the desired textural attributes: crispness, crunchiness, and lightness. The challenge in meeting those goals is that conventional corn chips and tortilla chips are "undesirably gritty." The thicker cell walls of corn make these snack foods slower to break down as we chew, and they do not melt in our mouths. Like the potato chips and Goldfish crackers that were included

[60] Hall, K. D., Ayuketah, A., Brychta, R., Cai, H., Cassimatis, T., Chen, K. Y., Chung, S. T., Costa, E., Courville, A., Darcey, V., Fletcher, L. A., Forde, C. G., Gharib, A. M., Guo, J., Howard, R., Joseph, P. V., McGehee, S., Ouwerkerk, R., Raisinger, K., Rozga, I., … Zhou, M. (2019). Ultra-Processed Diets Cause Excess Calorie Intake and Weight Gain: An Inpatient Randomized Controlled Trial of Ad Libitum Food Intake. *Cell metabolism, 30*(1), 67–77.e3. https://doi.org/10.1016/j.cmet.2019.05.008

[61] Gage et al., Extrusion cooked snack chips.

among the ultraprocessed snacks in the NIH study, these corn chips would achieve a high degree of "mouthmelt." They would disappear into the gut much faster than fresh fruit, raisins, or nuts, all snacks that actually require us to chew.[62, 63]

Light in the hand, the improved corn chip is crisp without being hard in the mouth, and crunchy but not gritty in the gut. Producing that structure begins with crushing the kernels into minute particles. In a separate step, starch is cooked in water and similarly pulverized, and the corn and starch are commingled and fed into extruders that break down the grain's structure into "a highly gelatinized plasticized mass." The resulting starch is a pale imitation of its molecular ancestor. Almost pre-chewed, it is quickly dissolved, swallowed, and absorbed in the upper GI tract, never reaching the colon. The gelatinous mass might have imparted "a distinct fresh roasted taste to corn chips and a toasted taste to wheat chips," as the industry boasts, but satiety never sets in no matter how many chips are consumed. Rather, we consume chip after chip after chip.[64]

E. Processing and its Effects on Metabolism

As we've seen, ultraprocessed foods are harmful. The components of ultraprocessed foods, processed refined carbohydrates, are also harmful. These include refined sweeteners and refined flours and starches that are

[62] Paragraph excerpted from Fast Carbs, Slow Carbs, page 86 (with permission).

[63] Forde, C. G., Mars, M., & De Graaf, K. (2020). Ultra-processing or oral processing? A role for energy density and eating rate in moderating energy intake from processed foods. *Current Developments in Nutrition*, *4*(3), nzaa019.

[64] Paragraph excerpted from Fast Carbs, Slow Carbs, page 87 (with permission).

subjected to extrusion. The effects of extrusion technology on human metabolism have not been fully studied and understood. The following insert describes the extrusion process—which exposes food ingredients to high temperatures and shear forces, disrupts the food matrix, and makes the food into new shapes with new texture:[65]

[65] Kessler, D.A. (2020). Fast Carbs, Slow Carbs: The Simple Truth about Food, Weight, and Disease. HarperWave, p. 48.; O'Connor, A., & Steckelberg, A. (2023, June 27). Melted, pounded, extruded: Why many ultra-processed foods are unhealthy. The Washington Post. https://www.washingtonpost.com/wellness/2023/06/27/ultra-processed-foods-predigested-health-risks/

Food Processing Technology: Extrusion

Grains are no longer ground by large stones powered by water wheels, as they were in the not-so-distant past, but instead are milled by high-speed steel rollers. Although this milling disrupts the tight, compact bonds of starch granules, it doesn't dramatically transform them. It is a second step, called extrusion cooking, that upends the granules, virtually pulverizing the amylose and amylopectin contained in glucose molecules. These processes result in dextrinization, the fragmentation of the starch molecule into chains of shorter length called dextrin, which enables faster absorption in the small intestine. (One of my scientific colleagues told me that some extruded starches can be absorbed even faster than that great American invention, Wonder Bread.) Glance at many food labels and somewhere you will see the word "dextrose." That's glucose, the shortest-chain fast carb created by processing.

Cooking extruders, which transform every part of the molecular matrix of starch, are widely used by the food industry today. Most of the grains in breakfast cereals are processed in cooking extruders, as are corn chips and other snack foods. Even the rye in many whole grain flatbreads is pummeled in extruders. The label on the package may claim that the bread is made from 100 percent rye and salt, but it doesn't say anything about how much the rye has been transformed. Extrusion is also used to create some of the vegetable proteins found in the increasingly popular vegetarian products designed as meat substitutes.

The attraction of such aggressive processing to corporations is obvious. The ultraprocessed powder that results is easily mixed and combined to make thousands of products. It's a classic example of "value added" manufacturing that allows food companies to charge more for the same raw ingredients. Moreover, it's a way to create an aerated structure that delivers a desirable mouthfeel, or "pleasurable masticatory sensations," as Dr. Martin Scanlon, professor of nutrition at the University of Manitoba, explained to me.

Developed in the 1940s, extrusion cooking uses both thermal and mechanical techniques to process ingredients for cereal and many other types of food. After the endosperm of the wheat kernel is milled into powder, the resulting flour is poured as a stream into a tube or barrel at the back of the extruder. A stream of water is added for hydration, and other ingredients are likely to be added for flavor. Rotating screws blend the ingredients, producing the shear force that twists bits of starch molecules in opposite directions to fragment them. Intense pressure, sometimes exceeding 100 times atmospheric pressure, forces the resultant mix up and down the tube, where it is kneaded over and over again.

The initial mixing is done in a cold environment, but the pulp is soon pushed into the heating section, where temperatures can exceed 300°F. The heat and moisture, coupled with the shear force, lead to gelatinization—the destruction of the semicrystalline structure that characterizes unprocessed starch granules. The amylopectin component of the granule swells, its molecular chains break apart, and the amylose leaches out. Additional heating and shearing promote further swelling and leaching of the starch.

Now in paste form and still under extreme pressure, the mixture is moved toward the front of the machine, where it is extruded through a die. If an O-shaped breakfast cereal is being processed, for example, it passes through a circular die. Once the molten product is released from the tube, the pressure suddenly plummets and the liquid within vaporizes, causing a massive expansion of the surface area. It is now in a highly viscous, plastic-like state, which quickly hardens into a solid that will eventually become your breakfast.

According to the scientist I spoke with, when they entered the extruder, the amylose chains had a molecular weight between 10^5 and 10^6, while the amylopectin weighed approximately 10^8 to 10^9. The weight of starch molecules as they emerge from the extruder will vary, depending on the temperature and pressure within the machine. The higher the speed of the rotating screws and the greater the shear force, the more fully the starch granule will have been degraded. While the final molecular weight varies, it can drop to 10^3 to 10^5. From a practical standpoint, these processes increase how quickly we digest these foods.

Excerpt from Fast Carbs, Slow Carbs, David Kesler, MD Harper 2020 (with permission)

In contrast to unprocessed foods, ultraprocessed foods that contain refined carbohydrates increase postprandial blood insulin levels.[66] High consumption of carbohydrates and excess energy intake hinder the body's clearance of insulin, resulting in increased blood insulin levels and hyperinsulinemia.[67] A reduced carbohydrate diet lowers post-meal insulin spikes[68] and alters the endocrine input into the portal circulation.[69, 70]

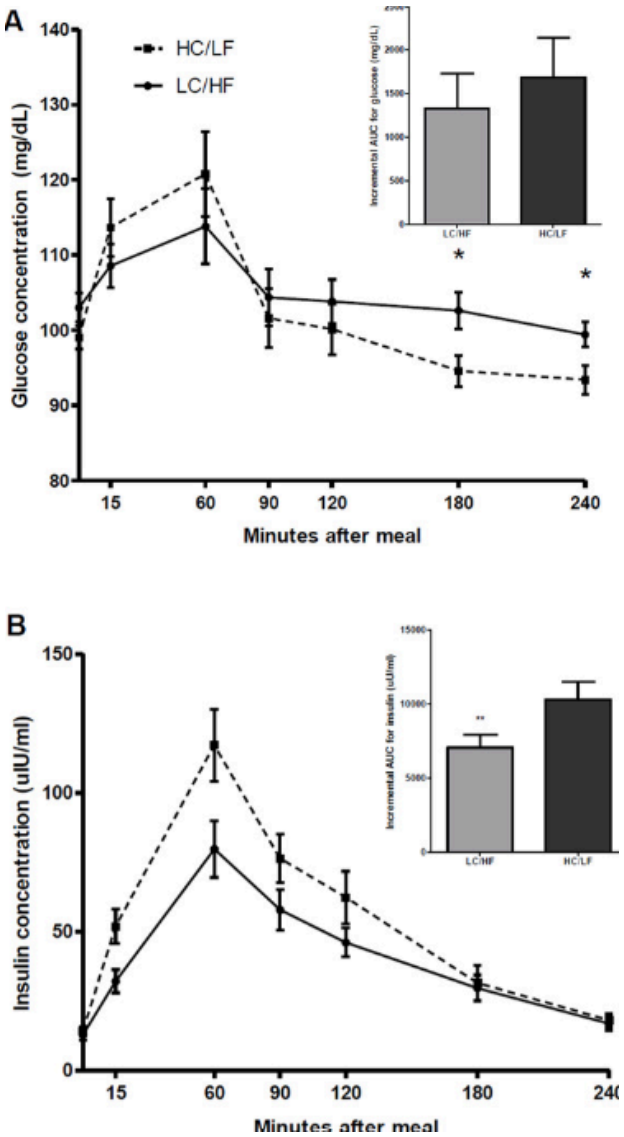
[66] Oettle, G. J., Emmett, P. M., & Heaton, K. W. (1987). Glucose and insulin responses to manufactured and whole-food snacks. *The American journal of clinical nutrition*, *45*(1), 86-91.

[67] Bojsen-Møller, K. N., Lundsgaard, A. M., Madsbad, S., Kiens, B., & Holst, J. J. (2018). Hepatic insulin clearance in regulation of systemic insulin concentrations—role of carbohydrate and energy availability. Diabetes, 67(11), 2129-2136; Kessler, D. A. (2025). *Diet, Drugs, and Dopamine*. Flatiron Books, p. 173.ki

[68] Hall, K. D., Guo, J., Courville, A. B., Boring, J., Brychta, R., Chen, K. Y., ... & Chung, S. T. (2021). Effect of a plant-based, low-fat diet versus an animal-based, ketogenic diet on ad libitum energy intake. *Nature medicine, 27*(2), 344-353.; Chandler-Laney, P. C., Morrison, S. A., Goree, L. L. T., Ellis, A. C., Casazza, K., Desmond, R., & Gower, B. A. (2014). Return of hunger following a relatively high carbohydrate breakfast is associated with earlier recorded glucose peak and nadir. *Appetite, 80*, 236-241.

[69] Gower, Barbara. "Hepatic Ketone Production as the Governing Factor in Determining Fatty Liver and Type 2 Diabetes." Lecture presented at Nutrition by the American Society for Nutrition, Chicago, IL, June 29-July 2, 2024.

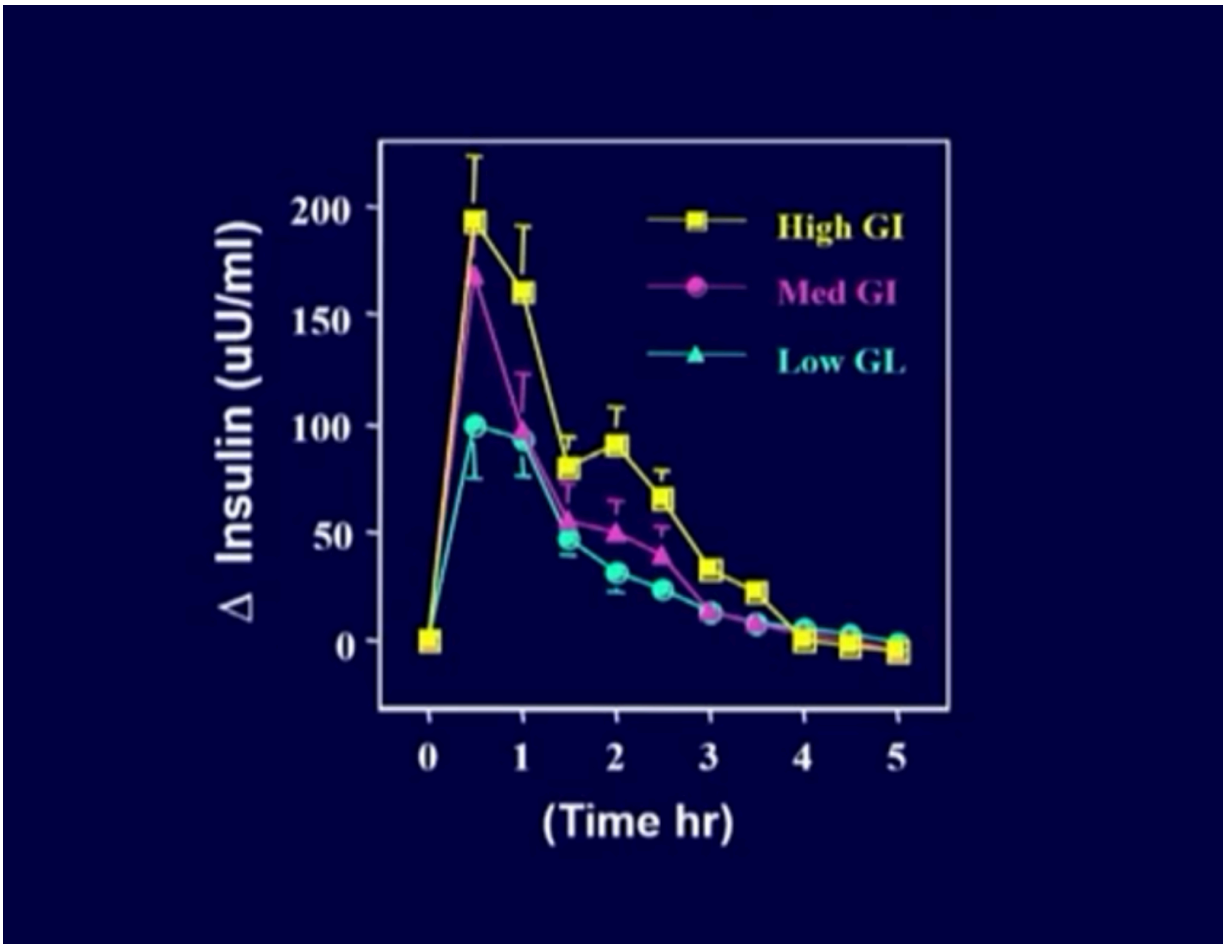
[70] The following graphs are from Chandler-Laney PC et al. Return of hunger following a relatively high carbohydrate breakfast is associated with earlier recorded glucose peak and nadir. Appetite. 2014 Sep;80:236-41. doi: 10.1016/j.appet.2014.04.031. Epub 2014 May 10. PMID: 24819342; PMCID: PMC4204795.



Insulin and glucose response following high and low-carb meals.
Chandler-Laney et al. 2014

A study by Dr. David Ludwig comparing breakfasts with highly processed and refined carbohydrates, minimally processed carbohydrates, or no processed carbohydrates demonstrates that the greater the processing and glycemic index, the greater the insulin response.[71]

[71] Ludwig, D. S., Majzoub, J. A., Al-Zahrani, A., Dallal, G. E., Blanco, I., & Roberts, S. B. (1999). High glycemic index foods, overeating, and obesity. *Pediatrics*, *103*(3), e26-e26.



Change in insulin after test breakfast. Ludwig, 1999.

Elevated insulin levels lead to increased production of fatty acids, which are released into circulation and contribute to a proinflammatory state. Hyperinsulinemia is thought to drive the accumulation of visceral fat and the resulting inflammatory and metabolic damage associated with obesity. A recent study by UCLA's Chuyue Wu shows the prevalence of

hyperinsulinemia increased dramatically, from 28% to 41%, from 1999 to 2018.[72]

In the face of elevated insulin levels, dietary carbohydrates are directed to glucose production and de novo lipogenesis[73] which results in fat deposition in the liver,[74] pancreas, heart, and skeletal muscle. This can lead to metabolic syndrome, with increased waist circumference, elevated triglycerides,[75] abnormal lipid patterns, and hypertension, ultimately increasing risk of insulin resistance, prediabetes or type 2 diabetes, and fatty liver disease.[76]

Americans suffering from insulin resistance, obesity, and type 2 diabetes need less refined carbohydrates in their diets. Excessive refined carbohydrate intake fuels high insulin levels.[77]

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[72] Wu, C., Ke, Y., & Nianogo, R. A. (2025). Trends in hyperinsulinemia and insulin resistance among nondiabetic U.S. adults, NHANES, 1999–2018. Journal of Clinical Medicine, 14(9), 3215.; Kessler, D. A. (2025). Diet, Drugs, and Dopamine. Flatiron Books, p. 177.

[73] Gower, Barbara. "Hepatic Ketone Production as the Governing Factor in Determining Fatty Liver and Type 2 Diabetes." Lecture presented at Nutrition by the American Society for Nutrition, Chicago, IL, June 29-July 2, 2024.

[74] Orliacq, J., Pérez-Cornago, A., Parry, S.A. *et al.* Associations between types and sources of dietary carbohydrates and liver fat: a UK Biobank study. *BMC Med* 21, 444 (2023). https://doi.org/10.1186/s12916-023-03135-8

[75] Sanders FWB, Acharjee A, et al. Hepatic steatosis risk is partly driven by increased de novo lipogenesis following carbohydrate consumption. Genome Biol. 2018 Jun 20;19(1):79. doi: 10.1186/s13059-018-1439-8. PMID: 29925420; PMCID: PMC6009819.; Giacco R, Costabile G, et al. A whole-grain cereal-based diet lowers postprandial plasma insulin and triglyceride levels in individuals with metabolic syndrome. Nutr Metab Cardiovasc Dis. 2014 Aug;24(8):837-44. doi: 10.1016/j.numecd.2014.01.007. Epub 2014 Jan 28. PMID: 24598599.

[76] Neeland, I.J., Lim, S., Tchernof, A. *et al.* Metabolic syndrome. *Nat Rev Dis Primers* 10, 77 (2024). https://doi.org/10.1038/s41572-024-00563-5.; Chu NHS, Yu Y, He J, Li CRH, Pai SI, Leung KHT, Ma RCW, Chan JCN, Chow E. Carbohydrate Quality Is Independently Associated with Cardiometabolic Risk in Chinese Individuals with Impaired Glucose Tolerance. Nutrients. 2025 Mar 24;17(7):1123. doi: 10.3390/nu17071123. PMID: 40218881; PMCID: PMC11990533.

[77] Kessler, D. A. (2025). *Diet, Drugs, and Dopamine.* Flatiron Books.

Research suggests that metabolic damage can begin very early in life. Children consume 67% of their calories from ultraprocessed foods.[78] It can even begin as early as the first days of life. Over the last several decades, according to an analysis by Dr. Dina DiMaggio of NYU Langone Medical Center, about half of all formulas contain corn syrup solids or similar refined carbohydrates.[79] Dr. Nancy Krebs at the University of Colorado showed that a measurement of insulin release called C-peptide quadruples in infants consuming such formulas with corn syrups.[80] The long-term consequences of formula-induced elevated insulin levels is unknown and must be studied.

[78] Wang, L., Steele, E. M., Du, M., Pomeranz, J. L., O'Connor, L. E., Herrick, K. A., ... & Zhang, F. F. (2021). Trends in consumption of ultraprocessed foods among U.S. youths aged 2-19 years, 1999-2018. *Jama, 326*(6), 519-530.; Kessler, D. A. (2025). *Diet, Drugs, and Dopamine.* Flatiron Books, p. 176.

[79] DiMaggio, D. M., Abersone, I., & Porto, A. F. (2024). Infant consumption of 100% lactose-based and reduced lactose infant formula in the United States: Review of NHANES data from 1999 to 2020. *Journal of Pediatric Gastroenterology and Nutrition*, *79*(5), 1017-1023.; Kessler, D. A. (2025). *Diet, Drugs, and Dopamine.* Flatiron Books, p. 176.

[80] Young, B. E., Tang, M., Griese, K., & Krebs, N. F. (2016). Consumption of a Corn-Sugar Based Infant Formula Is Associated with Higher C-peptide Secretion Compared to Lactose Based Formula among Exclusively Formula Fed Infants. *The FASEB Journal*, *30*, 673-7.; Kessler, D. A. (2025*). Diet, Drugs, and Dopamine.* Flatiron Books, p. 176.

The American Heart Association,[81] beginning in 2021, and the U.S. Dietary Guidance in 2015[82] and 2020[83] recommend limiting the amount of refined carbohydrates in the diet.[84] Studies by Dr. Walter Willett's group at Harvard have shown that refined carbohydrates are linked to increased weight gain.[85]

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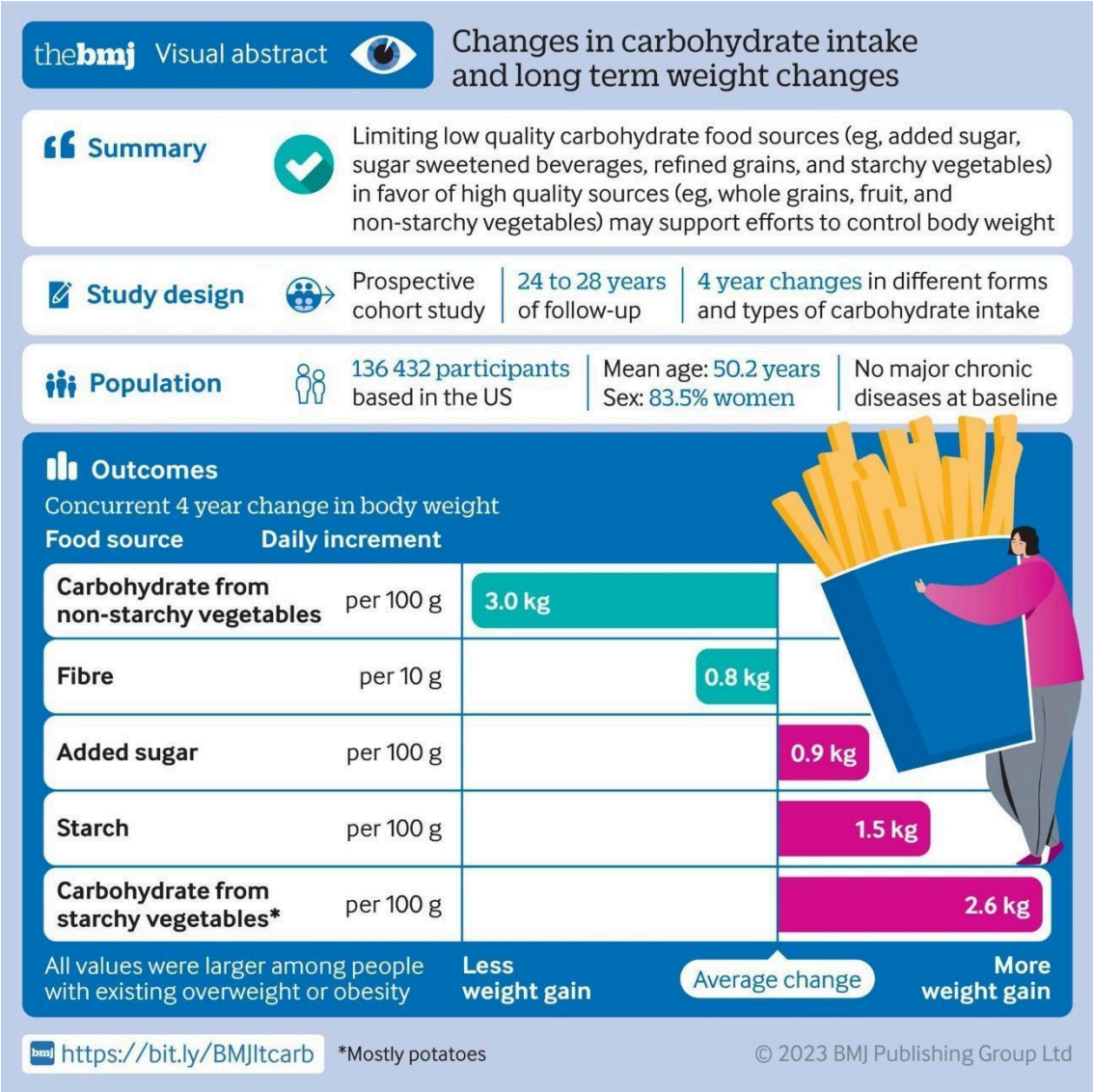
[81] Lichtenstein, A. H., Appel, L. J., Vadiveloo, M., Hu, F. B., Kris-Etherton, P. M., Rebholz, C. M., Sacks, F. M., Thorndike, A. N., Van Horn, L., & Wylie-Rosett, J. (2021). 2021 Dietary Guidance to Improve Cardiovascular Health: A Scientific Statement From the American Heart Association. *Circulation, 144*(23), e472–e487. https://doi.org/10.1161/CIR.0000000000001031

[82] U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015–2020 Dietary Guidelines for Americans. 8th Edition. December 2015. Available at http://health.gov/dietaryguidelines/2015/guidelines/.

[83] U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf.

[84] Rachel K. Johnson, PhD, MPH, RD, Chair, Lawrence J. Appel, MD, MPH, FAHA, Michael Brands, PhD, FAHA, Barbara V. Howard, PhD, FAHA, Michael Lefevre, PhD, FAHA, Robert H. Lustig, MD, Frank Sacks, MD, FAHA, Lyn M. Steffen, PhD, MPH, RD, FAHA, Judith Wylie-Rosett, EdD, RD, and on behalf of the American Heart Association Nutrition Committee of the Council on Nutrition, Physical Activity, and Metabolism and the Council on Epidemiology and Prevention. "*Dietary Sugars Intake and Cardiovascular Health: A Scientific Statement From the American Heart Association.*" Circulation. Volume 120, Number 11. https://doi.org/10.1161/CIRCULATIONAHA.109.192627; see also Hofman DL, van Buul VJ, Brouns FJ. Nutrition, Health, and Regulatory Aspects of Digestible Maltodextrins. Crit Rev Food Sci Nutr. 2016 Sep 9;56(12):2091-100. doi: 10.1080/10408398.2014.940415. PMID: 25674937; PMCID: PMC4940893: "The rise in consumption of refined CHO sources has been linked to an increased health risk (Johnson et al., 2009; Parker et al., 2010; Welsh et al., 2010). Although no causal relationship between the consumption of MDs and negative health effects has been reported, this does not mean that overconsumption of foods containing MDs will have no effect."

[85] Wan, Y., Tobias, D. K., Dennis, K. K., Guasch-Ferré, M., Sun, Q., Rimm, E. B., Hu, F. B., Ludwig, D. S., Devinsky, O., & Willett, W. C. (2023). Association between changes in carbohydrate intake and long term weight changes: prospective cohort study. *BMJ (Clinical research ed.), 382*, e073939. https://doi.org/10.1136/bmj-2022-073939



Association between changes in carbohydrate intake and long term weight changes: prospective cohort study. Wan et al. 2023

F. FDA Recognition and the Need for Regulatory Oversight

Only recently, in 2016, did FDA define a category of "added sugar" for food labelling purposes, which includes these processed refined carbohydrates, and during rule-making, they included the following non-exhaustive list of

ingredients: brown sugar, corn sweetener, corn syrup, dextrose, fructose, fruit juice concentrates, glucose, high-fructose corn syrup, honey, invert sugar, lactose, maltose, malt sugar, molasses, raw sugar, turbinado sugar, trehalose, and sucrose.[86]

FDA also noted how corn syrup is more energy dense than table sugar or sugar. According to FDA, "a teaspoon of sucrose or table sugar weighs 4.2 grams, but a teaspoon of corn syrup weighs 7.3 grams and has 1.5 grams of water and 5.1 grams of sugar."[87]

While there is debate about what foods qualify as "ultraprocessed foods," processed refined carbohydrates used in industrial processing are detrimental to public health and are actionable from a regulatory perspective. Just as nicotine was central to FDA regulation of tobacco products,[88] processed refined carbohydrates used in industrial food processing are a key component[89] of ultraprocessed foods that the agency needs to address in order to protect the public from the health risks of these products. Society came to view nicotine in tobacco differently over

[86] Food and Drug Administration. (2016). *Food Labeling: Revision of the Nutrition and Supplement Facts Labels.* U.S. Department of Health and Human Services. Federal Register, 81(103), p. 33742. https://www.govinfo.gov/content/pkg/FR-2016-05-27/pdf/2016-11867.pdf; Not included in this definition are the sugars produced from starch that result from the use of enzymes that are added to a food. For example, pizza dough has enzymes added that can result in starch conversion in the food. FDA has stated "we do not have information suggesting that sugars produced through incidental hydrolysis of complex carbohydrates results in a significant increase in the sugar content of foods."

[87] Food and Drug Administration. (2016). *Food Labeling: Revision of the Nutrition and Supplement Facts Labels.* U.S. Department of Health and Human Services. Federal Register, 81(103), p. 33742. https://www.govinfo.gov/content/pkg/FR-2016-05-27/pdf/2016-11867.pdf

[88] Kessler, D. (2001). *A Question of Intent: A Great American Battle with a Deadly Industry.* Public Affairs.

[89] Nothing in this petition should be interpreted to diminish the important role of salt in ultraprocessed foods. Interestingly, hyperpalatable combinations of fat and salt also often contain a starch component.

the last century. Similarly, we need to view processed refined carbohydrates not as something we want or need, but as something that we have allowed to be widely used without appropriate regulatory oversight and which has and continues to cause and contribute to great harm. As with nicotine in cigarettes and tobacco, use of processed refined carbohydrates begins first in childhood. In this case, it begins as early as infancy.[90]

The actions requested in this petition are intended to remedy that harm.

V. Prior Regulatory Review of Processed Refined Carbohydrates

In 1976, under the direction of the FDA as part of a broader review of GRAS substances, a group of qualified scientists, designated the Select Committee on GRAS Substances, reviewed the safety of a group of ingredients that were "purified concentrated solutions" (or dry products made from them) of nutritive saccharides that were obtained from starch. These products are also referred to as starch conversion products and fall within a category of refined carbohydrates. They include corn sugar, corn syrup, invert sugar, high fructose corn syrup, and maltodextrin. FDA has referred to these products as "sweeteners" and "sugars" (except for maltodextrin).[91] The common thread of how these products are produced is the process of hydrolysis that breaks down larger carbohydrate molecules into simpler sugars. These products differ by the degree of breakdown and contain

[90] See below for discussion of the fact that over the last several decades, about half of all infant formulas contain corn syrup solids. and that a measurement of insulin release called C-peptide quadruples in infants consuming such formulas with corn syrups.

[91] Food and Drug Administration. (1988). *GRAS Status of Corn Sugar, Corn Syrup, Invert Sugar, and Sucrose*. U.S. Department of Health and Human Services. Federal Register, 53(215), p. 44862.

monosaccharides, disaccharides, and higher saccharides. At the time, some of these products were presumed to be GRAS but, according to the Agency, were "unpublished."

Regarding metabolic effects of these ingredients, the Committee noted that "fructose-dextrose mixtures have been observed to have hyperlipemic effects when fed at high levels in fat-free diets to adult males and postmenopausal women. There is no evidence, however, that the levels of invert sugar and high-fructose corn syrup in the average diet cause significant elevations in blood lipids and it is unlikely that the consumption of fructose or glucose ingested as monosaccharides has a role in coronary heart disease." The Select Committee concluded: "Other than the contribution made to dental caries, there is no evidence in the available information on corn sugar (dextrose), corn syrup, and invert sugar that demonstrates a hazard to the public when they are used at levels that are now current and in the manner now practiced. However, it is not possible to determine, without additional data, whether an increase in consumption—that would result if there were a significant increase in the total of corn sugar, corn syrup, invert sugar, and sucrose added to foods—would constitute a dietary hazard."[92]

Specifically, the Select Committee recommend a Grade 2 conclusion, which meant that, "There is no evidence in the available information that demonstrates a hazard to the public when it is used at levels that are now

[92] Food and Drug Administration. (1988). *GRAS Status of Corn Sugar, Corn Syrup, Invert Sugar, and Sucrose*. U.S. Department of Health and Human Services. Federal Register, 53(215), p. 44862.

current and in the manner now practiced. However, it is not possible to determine, without additional data, whether a significant increase in consumption would constitute a dietary hazard."[93]

In 1983, the FDA established a Sugars Task Force, which also found that the available data support the view that sugars do not have a unique role in the etiology of obesity. This finding of the Sugars Task Force is in agreement with the finding of the Select Committee, which noted that excessive consumption of sucrose may contribute to obesity as a nonspecific source of calories.[94]

As summarized by the FDA in 1988[95] as part of a final rule to affirm the GRAS status of these products, the Agency stated the following with regard to:

> **Obesity**: The Sugars Task Force found that the available data support the view that sugars do not have a unique role in the etiology of obesity. This finding of the Task Force is in agreement with the finding of the Select Committee, which noted that excessive consumption of sucrose may contribute to obesity as a nonspecific source of calories.
>
> **Diabetes and Cardiovascular Disease**: "Sugars have not been shown to present an increased risk of diabetes or coronary heart disease in this population." The Agency also concludes that current data do not support

[93]https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=SCOGS&sort=Sortsubstance&order=ASC&startrow=1&type=basic&search=corn%20syrup

[94] Food and Drug Administration. (1988). GRAS Status of Corn Sugar, Corn Syrup, Invert Sugar, and Sucrose. U.S. Department of Health and Human Services. Federal Register, 53(215), p. 44862.

[95] ibid

the contention that sugars are a primary or an independent risk factor for cardiovascular disease such that the reduction in current levels of sugars intake in the general population would reduce the risk of this disease.

Blood Lipids: Because of the myriad of factors that influence blood lipid levels and because of inconsistency in the results from different experiments, the Agency concludes that the available data are not adequate to demonstrate that a causal relationship exists between levels of sugars consumption and blood lipid levels in the normal population.

Interestingly, the Agency did note that "although there is evidence that a subset of the U.S. population experiences an elevation in serum lipids in response to a sucrose load, the data do not establish the size of this subset. Furthermore, based on the Task Force report, the agency finds that the available data do not demonstrate that sugars (including fructose), at current levels of consumption, had any different effects than other carbohydrates in inducing abnormal insulin and lipid levels in carbohydrate-sensitive individuals."[96]

Based on these findings, the Agency affirmed the GRAS status of these products in 1988.[97] The FDA affirmed the GRAS status of maltodextrin

[96] Food and Drug Administration. (1988). *GRAS Status of Corn Sugar, Corn Syrup, Invert Sugar, and Sucrose*. U.S. Department of Health and Human Services. Federal Register, 53(215), p. 44862.

[97] Ibid; Separately, on February 8, 1983, FDA issued a final rule on high fructose corn syrup that listed the substance as GRAS. 47 Federal Register 5716; Food and Drug Administration. (1996). *Direct Food Substances Affirmed as Generally Recognized as Safe; High Fructose Corn Syrup*. U.S. Department of Health and Human Services. Federal Register, 61(165), p. 43447.

separately in a proposed rule in 1982[98] and a final rule in 1983.[99] Maltodextrin is affirmed as GRAS at 21 CFR 184.1444, dextrose at 21 CFR 184.1857, corn syrup at 21 CFR 184.1865 (which may contain maltose and glucose), invert sugar 21 at CFR 184.1859, and high fructose corn syrup at 21 CFR 184.1866. Sucrose's GRAS affirmation is set out in 21 CFR 184.1854. There is no GRAS affirmation for flour or starch, nor for flour or starch that is used in extrusion cooking.

VI. Refined Flour and Starches that are Subjected to Food Extrusion Technology

This petition also includes refined flour and starches that are utilized in food extrusion technology as a processed refined carbohydrate. The Select Committee on GRAS Substances reviewed the GRAS status of wheat starch as a packaging material.[100] It did not review the effects of extrusion processing on flour and starch.

As noted above, extrusion is a mechanical process widely used in food and feed production to enhance the digestibility and absorption of starch. By subjecting cereals to high temperatures, pressure, and mechanical shear, extrusion alters the physical and chemical properties of starch, making it more accessible to digestive enzymes. This transformation not only accelerates the breakdown and absorption of starch in the gastrointestinal

[98] Food and Drug Administration. (1982). *GRAS Status of Corn Sugar, Corn Syrup, Invert Sugar, and Sucrose*. U.S. Department of Health and Human Services. Federal Register, 47, p. 36443.
[99] Food and Drug Administration. (1983). *GRAS Status of Maltodextrin*. U.S. Department of Health and Human Services. Federal Register, 48(221), p. 51911.
[100] FDA, SCOGS =-Report Number 115 , 1979 Id Code 977052-26-8; 21 CFR 182.70

tract, but also impacts blood glucose levels by accelerating the release of glucose during digestion.[101]

[101] Zhao, Y., Dang, X., Du, H., Wang, D., Zhang, J., Liu, R., ... & Zhong, Q. (2024). Understanding the Impact of Extrusion Treatment on Cereals: Insights from Alterations in Starch Physicochemical Properties and In Vitro Digestion Kinetics. *Animals*, *14*(21), 3144, 1-16.; Kessler, D.A. (2020). Fast Carbs, Slow Carbs: The Simple Truth about Food, Weight, and Disease. HarperWave; Chinnaswamy, R., & Hanna, M. A. (1990). Macromolecular and functional properties of native and extrusion-cooked corn starch. Cereal Chemistry, 67(5), 490–499. https://www.aaccnet.org/publications/cc/backissues/1990/Documents/67_490.pdf; Dreher, M. L., Dreher, C. J., Berry, J. W., & Fleming, S. E. (1984). Starch digestibility of foods: A nutritional perspective. CRC Critical Reviews in Food Science and Nutrition, 20(1), 47–71. https://doi.org/10.1080/10408398409527383; Einde, R. van den. (2004). Molecular modification of starch during thermomechanical treatment [Doctoral thesis, Wageningen University]; Forte, D., & Young, G. (2016). Food and extrusion technology: An applied approach to extrusion theory. Food Industry Engineering;Grayson, A. (2013, October 17). Invention blasts off our cereal business. General Mills Blog. https://blog.generalmills.com;Guha, M., & Ali, S. Z. (2002). Molecular degradation of starch during extrusion cooking of rice. International Journal of Food Properties, 5(3), 509–521. https://doi.org/10.1081/jfp-120015488; Guy, R. (2001). Extrusion cooking: Technologies and applications. Woodhead; Holm, J., Hagander, B., Björck, I., Eliasson, A.-C., & Lundquist, I. (1989). The effect of various thermal processes on the glycemic response to whole grain wheat products in humans and rats. Journal of Nutrition, 119(11), 1631–1638. https://doi.org/10.1093/jn/119.11.1631; Maskan, M. (2012). Advances in food extrusion technology. CRC Press; Miller, K. (2018, November 5). Does processing grains impact nutrition? Lecture presented at the Whole Grains Council Conference, Seattle, WA; Moscicki, L. (2011). Extrusion-cooking techniques. Wiley–VCH Verlag & Co. KGaA; Singh, J., Dartois, A., & Kaur, L. (2010). Starch digestibility in food matrix: A review. Trends in Food Science & Technology, 21(4), 168–180. https://doi.org/10.1016/j.tifs.2009.12.001; Svihus, B., Uhlen, A. K., & Harstad, O. M. (2005). Effect of starch granule structure, associated components and processing on nutritive value of cereal starch: A review. Animal Feed Science and Technology, 122(3–4), 303–320. https://doi.org/10.1016/j.anifeedsci.2005.02.025; Tamura, M., Singh, J., Kaur, L., & Ogawa, Y. (2016). Impact of the degree of cooking on starch digestibility of rice: An in vitro study. Food Chemistry, 191, 98–104. https://doi.org/10.1016/j.foodchem.2015.03.127; White, G. A., Doucet, F. J., Hill, S. E., & Wiseman, J. (2008). Physicochemical changes to starch granules during micronisation and extrusion processing of wheat, and their implications for starch digestibility in the newly weaned piglet. Animal, 2(9), 1312–1323. https://doi.org/10.1017/s1751731108002553; Ye, J., Hu, X., Luo, S., Liu, W., et al. (2018). Properties of starch after extrusion: A review. Starch–Stärke, 70(11–12). https://doi.org/10.1002/star.201700110; Zhang, G., & Hamaker, B. R. (2016). The nutritional property of endosperm starch and its contribution to the health benefits of whole grain foods. Critical Reviews in Food Science and Nutrition, 57(18), 3807–3817. https://doi.org/10.1080/10408398.2015.1130685; Zhu, L.-J., Shukri, R., de Mesa-Stonestreet, N. J., Alavi, S., et al. (2010). Mechanical and microstructural properties of soy protein: High amylose cornstarch extrudates in relation to physiochemical changes of starch during extrusion. Journal of Food Engineering, 100(2), 232–238. https://www.sciencedirect.com/science/article/pii/S0260877410001858.

The extrusion process involves passing cereals through a twin-screw extruder, where they are exposed to high temperatures ranging from 120 to 200 degrees Celsius, along with controlled moisture levels. The combination of heat, pressure, and mechanical forces disrupts the dense, crystalline structure of starch granules, converting them into a gelatinized and amorphous form. This structural change is critical because it increases the surface area available for enzyme action, making the starch easier to digest. After extrusion, the cereals are air dried to stabilize their altered structure.

The impact of extrusion on starch digestibility is profound.[102] The process significantly reduces the crystalline order of starch, as evidenced by a decrease in the short-range order of starch molecules. For example, a study by Yufei Zhao and colleagues showed a 43% reduction in the structural order of cornstarch after extrusion.[103] Additionally, scanning electron microscopy revealed that extruded cereals develop a loose and porous texture, which further facilitates enzyme penetration and digestion.

Extrusion also accelerates the digestion rate of starch.[104] The proportion of rapidly digestible starch increases dramatically, while slowly digestible starch and resistant starch, which are harder to break down, decrease significantly. For instance, the study found that extruded corn, wheat, and

[102] Zhao at p. 18; Kessler, D.A. (2020). Fast Carbs, Slow Carbs: The Simple Truth about Food, Weight, and Disease. HarperWave; Ibid

[103] Ibid.

[104] Zhao at 13; Kessler, D.A. (2020). Fast Carbs, Slow Carbs: The Simple Truth about Food, Weight, and Disease. HarperWave; Ibid

broken rice reached their maximum digestibility within 15 minutes of intestinal digestion, whereas raw cereals required at least two hours for complete digestion. This rapid breakdown of starch in extruded cereals ensures quicker glucose release, which is absorbed in the small intestine to provide immediate energy.[105]

The faster digestion and absorption of starch in extruded cereals have a direct impact on blood glucose levels. The predicted glycemic index, which measures how quickly a food raises blood sugar, increases significantly after extrusion. Corn's glycemic index rose from 53 to 83, wheat's glycemic index increased from 59 to 83, and broken rice's glycemic index went from 63 to 81. These changes indicate that extruded cereals are more likely to cause a rapid rise in blood glucose levels.[106]

As extrusion is a transformative process—that enhances the digestibility and absorption of starch by altering its structure and composition, increasing the proportion of rapidly digestible starch, accelerating digestion rates, and increasing the absorption into the bloodstream, thus stimulating insulin and glucose—refined flour and starches that are utilized in food extrusion technology are included as processed refined carbohydrates in this petition.

[105] Zhao at 12; Kessler, D.A. (2020). Fast Carbs, Slow Carbs: The Simple Truth about Food, Weight, and Disease. HarperWave

[106] Ibid

VII. Legal Requirements for GRAS Status

FDA may not approve a food additive for a particular use unless the data presented to the agency establish that the additive is safe for that use. [21 U.S.C. § 348(c)(3)(A) (1994).]

Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not require proof beyond any possible doubt that no harm will result under any conceivable circumstance. [H.R. REP. NO. 2284, 85th Cong., 2d Sess. 4-5 (1958); accord S. REP. NO. 2422, 85th Cong., 2d Sess. 6 (1958)]

Substances that are "generally recognized as safe" (GRAS) are not food additives.[107, 108]

According to FDA's regulations, 21 CFR 170.30 (b), the quantity and quality of safety evidence is the same for GRAS substances and food additives. Those regulations: "General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive. General recognition of safety through scientific procedures shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods."

[107] Kessler, D. A. (1984). Food safety: revising the statute. *Science*, *223*(4640), 1034-1040.
[108] 21 U.S.C. 321(s).

FDA's statute and regulations require that GRAS status be based on how the ingredient is actually used in the real world, not in isolation, not at lower doses, and not divorced from real world consumption patterns. [21 USC 321 (s)][109]

Since the standards for food additives apply in determining safety of a GRAS substance, the Secretary is required to consider, among other relevant factors: the probable consumption of the additive and the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet. [21 USC 348]

In determining the safety of GRAS, according to FDA guidance, the effects of manufacturing on the physiochemical structure and bioavailability and toxicity of the substance and any evolution of those manufacturing processes need to be taken into consideration in evaluating and determining the safety of food additives.[110]

FDA has the authority to restrict the uses or conditions of use of GRAS substances. Federal regulations explicitly state that substances may be affirmed as GRAS for specific use.[111]

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[109] 21 USC 321 (s) requires a food additive and GRAS substances "to be safe under the conditions of its intended use." 21 CFR 170.3 (i) requires evaluation of safety based on 1) the conditions of its intended use; 2) the probable consumption of the substance; and 3) the cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in the diet.
[110]Food and Drug Administration. (June 2014). Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives. U.S. Department of Health and Human Services. https://www.fda.gov/media/115075/download
[111] 21 CFR 170.30 (k).

Importantly, FDA has stated that GRAS status of a specific use of a particular substance in food is time dependent and that a product cannot be GRAS if there is no longer consensus that the specific use is safe.[112]

Moreover, the burden to establish that a substance is "generally recognized as safe" rests with the industry, not with the FDA. FDA need only show that there are substantial questions concerning the safety of a product to determine that the product is no longer GRAS.[113]

VIII. The scientific evidence no longer supports the GRAS status of processed refined carbohydrates, which include corn syrup, corn solids, glucose syrups, dextrose, invert sugar, xylose, maltose, and high fructose corn syrups when used in industrial processing, nor can flour and starch be considered GRAS when used in extrusion processing

Evidence over the last several decades since the GRAS evaluation of processed refined carbohydrates used in industrial processing demonstrates that ultraprocessed foods that contain these ingredients put people at risk for increased caloric intake, weight gain, and metabolic abnormalities. That weight gain and elevated insulin responses are part of a vicious cycle that includes increased visceral and ectopic fat, which causes

[112] Federal Register, "Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information." Volume 78; no. 217. Nov 8, 2013 67169 at p. 67170

[113] UNITED STATES of America, Plaintiff, Appellee, v. AN ARTICLE OF FOOD, Etc., Et Al., Defendants, Appellees. Coco Rico, Inc., Claimant, Appellant "752 F.2d 11, 1985 U.S. App. LEXIS 27849 ("The burden of proving general recognition of safe use is placed on the proponent of the food substance in question. *See 21 U.S.C. § 348*(a); *Fmali Herb, Inc. v. Heckler,* 715 F.2d 1385, 1391 (9th Cir.1983); *United States v. An Article of Food,* 678 F.2d 735, 739 (7th Cir.1982)")

cardiac and kidney disease, diabetes, certain forms of cancer, and potentially neurodegenerative disease.

Previously, in evaluating corn syrups and similar ingredients, which they refer to as sugars (and later referred to as added sugars), FDA found that these substances posed no independent risk factor for obesity, diabetes, cardiovascular disease, and abnormal blood lipids.

However, in an extensive review of these ingredients, the 2015 U.S. Dietary Guidelines Advisory Committee (DGAC)[114] concluded that ingredients, which they categorize as added sugars, are in fact independent risk factors for obesity, diabetes, cardiovascular disease, and abnormal blood lipids.

Specifically, the Committee stated with regard to:

> **Obesity**: Strong and consistent evidence shows that intake of added sugars from food and/or sugar-sweetened beverages are associated with excess body weight in children and adults. The reduction of added sugars and sugar-sweetened beverages in the diet reduces body mass index (BMI) in both children and adults. **DGAC Grade: Strong**[115]
>
> **Diabetes**: Strong evidence shows that higher consumption of added sugars, especially sugar-sweetened beverages, increases the risk of type 2

[114] Dietary Guidelines Advisory Committee. 2015. Scientific Report of the 2015 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC

[115] Ibid at 342

diabetes among adults and this relationship is not fully explained by body weight. **DGAC Grade: Strong**[116]

Cardiovascular Disease (**and Blood Lipids**): Moderate evidence from prospective cohort studies indicates that higher intake of added sugars, especially in the form of sugar-sweetened beverages, is consistently associated with increased risk of hypertension, stroke, and CHD in adults. Observational and intervention studies indicate a consistent relationship between higher added sugars intake and higher blood pressure and serum triglycerides. **DGAC Grade: Moderate**[117]

These findings by the 2015 Dietary Guidelines Advisory Committee, compared to the FDA's 1988 affirmation that these substances were "generally recognized as safe" (which was based on its 1976 Select Committee on GRAS Substances and the 1983 Sugars Task Force), demonstrate a profound shift in the scientific consensus and establish that the safety of these substances can no longer be considered GRAS.

The U.S. Dietary Guidelines Advisory Committee has stated that the U.S. population's intake of refined grains and added sugars is too high and recommended a limit on their consumption.[118]

Another important change since the Agency did its full scientific reviews in the 1970s and 1980s, one that draws into question the continued validity of

[116] Ibid at 343
[117] Ibid at 343
[118] Ibid at 2

the Agency's prior decisions to affirm the GRAS status of these compounds, is the change in the metabolic status of Americans' health. Today, 74% of Americans are overweight or obese, and about 38% are insulin resistant or prediabetic. Those numbers are far different today than five decades ago, when obesity rates were 13%.[119]

A 2024 study found that insulin levels rose from 28% to 41% between 1998 and 2018.[120] High carbohydrate consumption reduces the clearance of insulin from the body, which further increases blood lipid levels. Studies show that reduced carbohydrate and increased fat intake for as little as four days induced a marked reduction in liver triglyceride content and increased hepatic insulin sensitivity.[121]

FDA saw hints of this in its original analysis back in the 1970s and 1980s when it pointed out the effects of these processed refined carbohydrates in a subset of the population that it identified as having carbohydrate sensitivity. In people with insulin resistance and obesity, visceral fat accumulates in the abdomen and infiltrates the liver, pancreas, and heart, leading to a dysregulated metabolic state and, in some cases, type 2 diabetes. A vicious circle of fatty acid release, insulin resistance, obesity,

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[119] Kessler, D.A. (2020). Fast Carbs, Slow Carbs: The Simple Truth about Food, Weight, and Disease. HarperWave,

[120] Wu, C., Ke, Y., & Nianogo, R. A. (2025). Trends in hyperinsulinemia and insulin resistance among nondiabetic U.S. adults, NHANES, 1999–2018. Journal of Clinical Medicine, 14(9), 3215.; Kessler, D. A. (2025). Diet, Drugs, and Dopamine. Flatiron Books, p. 177.

[121] London, A., Richter, M. M., Sjøberg, K. A., Albrechtsen, N. J. W., Považan, M., Drici, L., ... & Bojsen-Møller, K. N. (2024). The impact of short-term eucaloric low-and high-carbohydrate diets on liver triacylglycerol content in males with overweight and obesity: a randomized crossover study. *The American Journal of Clinical Nutrition, 120*(2), 283-293.

and organ damage ensues. While it is difficult to sort out what occurs first, eating processed refined carbohydrates fuels this fire. When metabolically vulnerable people consume less carbohydrates, or, as with the GLP-1 drugs, there is reduced gastric emptying with a concomitant decreased glucose absorption rate, insulin levels decrease. The sine qua non of processed refined carbohydrates is their fast transit times and rapid absorption. When nearly half the adult population is insulin resistant, consuming more rapidly absorbable carbohydrates into the GI tract is a recipe for disaster.[122]

It has been four decades since the FDA has reviewed the scientific basis of GRAS status of processed refined carbohydrates. It has been during those four decades that America's obesity crisis has emerged. Compared to forty years ago, obesity and severe obesity have risen sharply among both adults and children in the United States. In the late 1970s, about 15% of adults had obesity and just over 1% had severe obesity. As of 2018, over 40% of adults have obesity, and nearly 10% are severely obese. Among children, the obesity rate has quadrupled—from around 5% in 1980 to nearly 20% in 2018.[123]

This petition demonstrates that, based on the lack of scientific evidence to assure the American public that these products are safe and there is "reasonable certainty of no harm" from these processed refined

[122] Kessler, D. A. (2025). *Diet, Drugs, and Dopamine*. Flatiron Books.

[123] Fryar, C. D., Carroll, M. D., & Afful, J. (2020). *Prevalence of Overweight, Obesity, and Severe Obesity Among Children and Adolescents Aged 2–19 Years: United States, 1963–1965 Through 2017–2018*. NCHS Health E-*Stat; Fryar CD, Carroll MD, Afful J. Prevalence of overweight, obesity, and severe obesity among adults aged 20 and over: United States, 1960–1962 through 2017–2018. NCHS Health E-Stats. 2020.*

carbohydrates when evaluated, as the statute requires, in the context of how they are used and consumed in the food system, continued GRAS affirmation is neither legal nor credible.[124]

If the intended use of processed refined carbohydrates are not recognized as safe, the substance is no longer GRAS. Under 21 CFR § 170.18, even if a substance is safe at one level, it may not be GRAS at higher or more frequent exposures. The regulation states: "The quantity of any substance

[124] Unlike the drug provisions of the Federal Food, Drug, and Cosmetic Act, which define safety as a risk-benefit analysis, the food provisions of the Act require "reasonable certainty of no harm" without a weighing of the benefits. There is no way the Agency can waive the GRAS standards and substitute a labeling system instead.
Congress could give the Agency the authority to establish a food information system, not just a label. One possible idea to provide transparency would be a full product dossier to match the complexity of today's highly processed foods. that lists all the ingredients, their function, and their potential impact on our health. Such a label would require more space than is available on most packages—but that's fine, as many people now carry a smartphone. The agency should list the questions companies must answer about the products they sell, so consumers don't have to rely on company virtue signaling and marketing in choosing what to buy. There is a great opportunity to make a new digital food-information system compatible with emerging systems that provide consumers with mobile access to their health records. In this way, food nutrition information, warnings, and recommendations could be tailored to the health status of each. Consumers should know about the function and health impact of every ingredient in the packaged foods they buy. A truly transparent system needs to ask and answer the following questions: What is each ingredient in this product? Why is it there? Does it have an established health benefit or present a health concern? Does the food contain pairs of fat and sodium, fat and simple sugars, or carbohydrates and sodium? Are these translated on the packaging into simple numerical values that indicate hyperpalatable foods? Is the product energy-dense? What is its glycemic load (an estimate of how much a food will raise a person's blood sugar level after they eat it)? What are the processing steps for this product? How does processing change the food matrix (how food is digested and metabolized), and how does that affect eating rate, satiety, and human health? Where was the food produced (from farm to the grocery shelf)? Is this product sweet (with sweetness measured on a scale of 1 to 5, where 1 is not sweet and 5 is very sweet)? Does it include added sweeteners? Refined carbohydrates? Has this product or its combination of ingredients been shown in valid studies to be healthy or potentially harmful?

added to food must not exceed the amount reasonably required to accomplish the intended effect." In fact, many GRAS notices do specify a maximum level of use.

In its rulemaking for adding disclosure of "added sugars" to the nutrition facts label, FDA discussed whether there was a linear relationship between these substances and chronic disease. In that rulemaking, FDA took a "dietary pattern approach" to rulemaking rather than a "specific nutrient-disease approach."

In that dietary approach, based on the U.S. Dietary Guidelines Advisory Committee findings, FDA cited that 10% of the diet as "added sugars" still allowed the public to meet its nutrient needs within caloric limits. While that approach sidesteps the metabolic burden imposed by these substances, it is important to note that this petition's requested actions do not involve sucrose, fructose, lactose, glucose, or honey.

While the standard for inclusion in labeling is different from the standard of "reasonable certainty of no harm" to affirm GRAS status of an ingredient, it is reasonable to inquire whether there is a threshold use below which these substances provide "reasonable certainty of no harm."

In any case, there is no basis for FDA to assume that the general population is currently healthy, as there is widespread metabolic disease. The statute explicitly mandates that the FDA consider "the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet" (21

U.S.C. § 348(c)(5)).This standard applies to both food additives and GRAS ingredients.

As demonstrated, FDA's past GRAS determinations are based on outdated data that did not properly assess the biological effects of these processed refined carbohydrates on blood insulin, blood lipid parameters, energy partitioning, inflammatory markers, brain reward[125] signaling, or visceral adiposity. These past determinations do not reflect synergistic effects[126] with other macronutrients such as fat and salt, and effects on overconsumption, eating rate, and satiety. The combination of processed refined carbohydrates with fat and salt dysregulates appetite and leads to weight gain.[127]

There is no expert consensus that refined carbohydrates in ultraprocessed foods are safe under present conditions of use.

Some may claim that ultraprocessed foods are important because they are cheap and convenient. While this petition calls into question the GRAS status of some, but not all, core ingredients of ultraprocessed foods, those arguments must be critically evaluated. Succinctly, while the ultraprocessed foods are cheap and profitable, they are not nutritionally adequate.[128] While

[125] For a discussion of food addiction, see Diet, Drugs, and Dopamine.

[126] Fazzino TL, Rohde K, Sullivan DK. Hyper-Palatable Foods: Development of a Quantitative Definition and Application to the US Food System Database. Obesity (Silver Spring). 2019 Nov;27(11):1761-1768. doi: 10.1002/oby.22639. PMID: 31689013

[127] Kessler, D. A. (2009). *The End of Overeating.* McClelland and Stewart.; Kessler, D.A. (2020). Fast Carbs, Slow Carbs: The Simple Truth about Food, Weight, and Disease. HarperWave.; Kessler, D. A. (2025). *Diet, Drugs, and Dopamine.* Flatiron Books.

[128] Although these products may be more accessible to low-income groups based on their price and convenience, access to nutritionally inadequate foods is not a benefit.

plentiful, they are highly palatable and drive overconsumption. While they may be convenient in the short term, they cause devastating long-term health consequences.

C. Environmental Impact

The action requested is subject to a categorical exclusion under 21 C.F.R. 25.30 and 25.32 and therefore does not require the preparation of an environmental assessment.

D. Economic Impact

No statement of the economic impact of the requested action is presented because none has been requested by the Commissioner.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signature: 

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