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Cara Welch, Ph.D.
Acting Director
Office of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition
Food and Drug Administration Department of Health and Human Services
5100 Campus Drive
College Park, MD 20740

August 3, 2021

Dear Dr. Welch,

As you know, on March 31, 2021, we submitted a New Dietary Ingredient Notification (NDI 1202) for our Charlotte's Web full spectrum hemp extract (FSHE) product. Pursuant to questions from FDA, we amended the NDI on May 12, 2021. We filed the NDIN after two pre-submission meetings and other discussions with CFSAN. Those discussions included the reasoning behind our position that a full spectrum product such as ours is a different article from CBD isolate and thus not precluded from the dietary supplement definition under 21 USC 321 (ff)(3)(B). We also discussed the ample evidence supporting the safety of our product.

We have reviewed the letter that FDA sent on July 23, 2021 (FDA letter) regarding NDI 1202 and are disappointed in, and strongly disagree with, not just FDA's conclusion and reasoning but in the fact that FDA's letter contains significant factual inaccuracies. We ask that FDA correct the inaccuracies, which we detail below, before the agency publicly releases the letter. We also ask that FDA reconsider its conclusion in light of these corrections.

1. Provision/availability of data.

   The FDA letter states: "…FDA requested that you provide the agency with the supporting or underlying data that formed the basis for the Dziwenka et al. 2020 study, but you did not provide FDA with this data."

   The specific request your office made per the letter FDA provided on May 4th, 2021, was: "You provided a bacterial reverse mutation test, 14-day range-finding oral study and 90-day sub-chronic oral study in rodents performed on Charlotte's Web FSHE and published in Dziwenka et al. (2020). However, the supplemental material in the Dziwenka et al. (2020) publication could not be accessed. Please provide the supplemental information to this publication."

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Charlotte's Web responded to this specific request in an Amendment to the NDIN on May 12, 2012. The response was: "No supplemental information was provided with the manuscript submission. The link included in the publication for supplemental data is in error. A signed statement from the corresponding author confirming this is included in Appendix Safety Concern 1."

To clarify this response, the "supplemental information" as noted in the published article does not exist - the statement was an error introduced by the publisher. Your office did not specifically request the full study reports, nor did your office request summary data tables from the study reports. Therefore, the statement "…you did not provide FDA with this data." is not an accurate statement.

1.1. Correction request.

Charlotte's Web requests a formal correction to the FDA letter to remove or clarify the statement "…you did not provide FDA with this data."

2. Evidence of Safety.

The FDA letter dated July 23, 2021 includes several statements related to evidence of safety, specifically:
"FDA was unable to accept your proposed no-observed adverse effect level (NOAEL), which was based on the publication by Dziwenka et al., 2020, because the publication included inadequate information for the purposes of assessing the reliability of the conclusions in the publication." and "…none of the clinical and pre-clinical studies that you provided adequately address certain reported toxicity endpoints of CBD such as hepatotoxicity and reproductive toxicity."

We are providing a response to each of the following points along with a request for reconsideration and correction.

2.1. NOAEL determination.

The Dziwenka et al., 2020 paper was published in a peer reviewed journal which is standard practice within the scientific community to allow for expert scrutiny of scientific findings during the peer review process and following publication. The peer reviewers for this publication were selected by the journal, Toxicology Reports. Toxicology Reports is an Elsevier open access journal that is included in PubMed Central (US National Library of Medicine National Institutes of Health). Per the PubMed Central website[1] journals included in the PubMed database undergo an

[1] How to Include a Journal in PMC (nih.gov)

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evaluation process which includes a review of the scientific and editorial quality of the publication as well as technical quality.

As described in the NDI 1202, the NOAEL established for males was 400 mg/kg body weight (bw) per day and was based on body weight loss in the high dose group being approximately 11% lower as compared to concurrent controls. There were no adverse findings in any of the other endpoints evaluated. Establishing the NOAEL at the 400 mg/kg body weight (bw) per day was a conservative measure because, as stated in the notification, "…this level of body weight loss (>10%) is generally accepted to be an adverse effect in short term studies." This conclusion has not been challenged by the scientific community at large nor by a panel of experts convened to review the safety data specific to Charlotte's Web FSHE.

It is unclear as to why the conclusions of a 90-day study conducted under Good Laboratory Practice (GLP) and to Organisation for Economic Co-operation and Development (OECD) guidelines for testing that have been subjected to an unbiased peer review and published in a journal vetted and accepted for indexing in the PubMed Central database are "…inadequate information for the purposes of assessing the reliability of the conclusions…". It is also unclear as to what data your Office requires to assess the reliability of the conclusions in the peer reviewed publication as we did not receive any specific data requests. To immediately provide the following summary tables for body weights, we have included the following Business Confidential summary tables related to body weight directly from the final report "Everyday Advanced Olive Oil: A 90-Day Repeat Dose Oral Gavage Duty in Rats with a 28-Day Recovery Period", referred to hereafter as "90-Day Final Report".

- Summary of mean weekly body weights for main test animals
- Summary of mean weekly body weights for recovery animals
- Summary of mean daily body weight gain for main test animals
- Summary of mean daily body weight gain for recovery animals
- Summary of mean terminal body and organ weights for main test animals
- Summary of mean terminal body and organ weights for recovery animals.

2.2. Hepatotoxicity.

The Dzweika et al. 2020 published article includes data from the clinical chemistry and hematology and show no elevation of liver enzymes that would indicate hepatoxicity. As described in the publication and as stated in the NDI 1202, "Test substance-related microscopic observations were noted in the liver and were limited to hypertrophy in centrilobular hepatocytes in all male and female rats at all dose levels which correlated with dose-dependent increases in absolute liver weight for low, mid and high dose females, liver-to-body weight ratios for the mid dose females,

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and liver-to-body/brain weight ratios in the high dose females. At the end of the recovery period, no changes in absolute liver weight and relative liver-to-body/brain ratios were noted in all test substance recovery females, as compared to controls. There also was no evidence of centrilobular hepatocyte hypertrophy in any dose levels in both the males and females, which indicated complete recovery. In the Hall et al. (2012) review of adaptive (adverse and non-adverse) changes with liver hypertrophy, the reviewers concluded that hepatomegaly, as a consequence of hepatocellular hypertrophy without histologic or clinical pathology alterations indicative of liver toxicity, can be considered an adaptive and a non-adverse reaction. In this sub-chronic study, the changes noted in response to hemp extract exposure fit this criterion and were considered non-adverse."

To immediately provide data related to evaluation of the liver to further support the NOAEL conclusion and the lack of liver toxicity, we have included the following information from the 90-Day Final Report:

- Summary of mean terminal body and organ weights for main test animals
- Summary of mean terminal body and organ weights for recovery animals
- Summary of mean organ-to-body weight ratios for main test animals
- Summary of mean organ-to-body weight ratios for recovery animals
- Summary of mean organ-to-brain weight ratios for main test animals
- Summary of mean organ-to-brain weight ratios for recovery animals
- Histopathology Report Appendix A. Histopathology Incidence Tables (Expanded Summary Report of Histopathology Day 94/95 Animals).
- Appendix B. Histopathology Incidence Tables (Expanded Summary Report of Histopathology Day 126 Animals).

While the Charlotte's Web FSHE contains a low amount of CBD, it is a different article than CBD isolate and therefore safety data specific to this article was generated. The conservative NOAEL established in the Dziwenka et al. 2020 publication for the article subject of the NDIN is 400 mg/kg bw/day. By applying uncertainty factors, this can be extrapolated to a human dose. If a standard "safety factor" of 100 is applied, the human dose equates to 0.4 mg/kg bw/day. Considering that the CBD content is 6.27% of the Charlotte's Web FSHE tincture, this equates to CBD intake of 0.25 mg/kg bw/day for a human (equivalent to 17.5 mg CBD per day for a 70 kg (154 lb.) person).

We consider data generated specific to the article subject of the NDIN to be more relevant to the safety of the article than information related to CBD isolate. However, as FDA has made the comparison to CBD isolate, we can compare the above intake of CBD from the Charlotte's Web FSHE (article subject of the NDIN) to the recommended doses of the highly purified CBD isolate drug Epidiolex. Per the

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dosage and administration instructions for Epidiolex[2], the starting dose is 2.5 mg/kg by mouth twice daily, to escalate up to a maximum recommended dose of 20 mg/kg bw/day (or 1400 mg for a 70 kg person). By comparison, the amount of CBD that would be ingested per the maximum recommended intake in the NDI 1202 is 19.5 mg per day (0.28 mg/kg bw/day for a 70 kg person). **The 19.5 mg of CBD from the Charlotte's Web FSHE is 1.4 percent of the amount of CBD provided for in the Epidiolex dosage instructions for an average size adult**.

The NDI 1202 also included data related to a yet unpublished Valid Care, LLC review of data collected from consumers of various CBD containing products to assess liver function. The investigators found under the conditions of the decentralized observational study, the intake of these products is safe and does not cause clinical liver disease. It is Charlotte's Web's understanding that FDA has been provided the full dataset from Valid Care, LLC. Charlotte's Web provided data specific to the Charlotte's Web products that were included into this study in the NDI 1202.

FDA notes that Epidiolex "caused liver injury, generally mild…"[3] which is presumably the reason for raising the concern for hepatotoxicity related to the NDI 1202 in the FDA Letter of July 23, 2021. We contend that while there is a known safety concern related to CBD intake related to high doses of CBD isolate, based on the results of the 90-day oral toxicity study, there are no safety concerns for hepatoxicity under the intake suggested in the labeling for the Charlotte's Web NDI. Further, liver function data collected on consumers actively taking the Charlotte's Web FSHE did not indicate liver disease in the consumer population. Therefore, it is unclear why your Office contends "…none of the clinical and pre-clinical studies that you provided adequately address certain reported toxicity endpoints of CBD such as hepatotoxicity…".

Charlotte's Web requests that FDA reconsider and correct the statement in the Letter dated July 23, 2021 to remove indication that there is a safety concern related to hepatoxicity at the suggested use as described in the NDI 1202. As such, it is clear that safety related to hepatoxicity was adequately addressed in both pre-clinical and in human use studies. Under the proposed conditions of use the Charlotte's Web FSHE is reasonably expected to be safe.

2.3. Reproductive toxicity

[2] EPX-03645-1120_EPIDIOLEX_(cannabidiol)_USPI

[3] FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy | FDA

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As stated in the Amendment to NDI 1202, the 90-day oral toxicity study in rats examined the prostate, seminal vesicles, epididymides and testes from all dose groups grossly as well as histologically. In addition, the testes and epididymides were weighed from all dose groups and the absolute and relative organ weights were evaluated. There were no test material related changes in any of the absolute or relative tissue weights as compared to the control animals. No test material related macroscopic abnormalities or histopathological changes were reported in any of these tissues. In summary, macroscopic and histopathological evaluation of the specified male reproductive tissues demonstrated that there were no test material related changes in any of these tissues following daily dosing for 90 days as well as after the 28-day recovery period. Based on this information, we conclude there is no indication that adverse effects to the male reproductive system are induced by oral administration of the Charlotte's Web FSHE at the doses tested. Additionally, there were no findings in the female reproductive organs that would indicate any issues with reproduction.

To immediately provide data related to evaluation reproductive organs, we have included the following information from the 90-Day Final Report:

- Summary of mean terminal body and organ weights for main test animals
- Summary of mean terminal body and organ weights for recovery animals
- Summary of mean organ-to-body weight ratios for main test animals
- Summary of mean organ-to-body weight ratios for recovery animals
- Summary of mean organ-to-brain weight ratios for main test animals
- Summary of mean organ-to-brain weight ratios for recovery animals
- Histopathology Report Appendix A. Histopathology Incidence Tables (Expanded Summary Report of Histopathology Day 94/95 Animals).
- Appendix B. Histopathology Incidence Tables (Expanded Summary Report of Histopathology Day 126 Animals).

As FDA has raised the concern of reproductive toxicity based on results seen in CBD isolate Epidiolex, we can compare nonclinical toxicology information provided in the medication guide for Epidiolex[2], in which no impairment of fertility was observed in male or female rats at oral administration of CBD isolate at 75, 150 or 250 mg/kg/day. The Charlotte's Web FSHE article contains 6.27% naturally occurring CBD. The 400 mg/kg/day group, the conservative NOAEL established in the Charlotte's Web 90-day oral toxicity study in rats, equates to approximately 25 mg/kg CBD bw/day. The reproductive study using up to 250 mg/kg bw/day CBD isolate in the rat did not show any impact on reproduction. The naturally occurring amount of CBD contained in the Charlotte's Web study established NOAEL is 1/10 of this amount. This provides clear

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evidence that both the 90-day oral toxicity study as well as the CBD isolate study clearly indicate that the use of the NDI under the proposed conditions of use is reasonably expected to be safe and does not pose a safety concern related to reproductive toxicity.

2.4. Correction and Clarification requests.

Data and conclusions were provided in a peer reviewed journal that established the NOAEL of the article subject of the NDI 1202. Additional data tables relevant in support of the established NOAEL are provided herein. The peer reviewed published article as well as the additional data provided clearly show neither hepatoxicity nor changes to reproductive organs were established by this study. Additionally, an observational study to assess if liver health is impacted in consumers ingesting commercially available CBD containing products found no indication of clinical liver disease in these consumers. While the article subject of NDI 1202, Charlotte's Web FSHE contains natural levels of CBD, the daily amount of CBD intake from the article is an order of magnitude less than an amount of CBD isolate shown to **not** cause reproductive toxicity in male or female rats.

Based on the detail provided above and in the summary in this section, we request the following clarification/reconsideration and/or corrections:

- Correct that the NOAEL has been adequately established as 400 mg/kg bw/day or clarify why data and conclusions published in an unbiased peer review journal is not an acceptable method for disseminating scientific information to establish a NOAEL
- Correct the statement that "none of the clinical and pre-clinical studies that you provided adequately address certain reported toxicity endpoints of CBD such as hepatotoxicity and reproductive toxicity."

3. History of Use Data to Support Safety

The FDA letter dated July 23, 2021, includes a statement that "…your submission provided two years of marketing for NDI 1202 as evidence of history of use, which is insufficient to establish the safety of your ingredient when used under the proposed conditions of use."

The NDI 1202 included sales data for 2018- October 2020 (2 years and 10 months). The NDI 1202 Amendment added adverse events from 2017 and 2018 for a total of 3.5 years of adverse event reporting. The NDI 1202 also included information provided by the Realm of Caring's call center that collected information from consumers and included that from 2015 to 2020 over 36,000 inquiries from over 26,000 individuals were specific to Charlotte's Web products and that during this period, only one adverse event

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was reported.

As such, we request that the statement be clarified to indicate that while we provided commercial invoices dating back two years additional evidence was provided which indicates that the NDI had been marketed for over four years and Charlotte's Web included 3.5 years of adverse event reporting.

4. Conclusion

In light of the above factual inaccuracies in FDA's July 23, 2021 letter, we ask that FDA reconsider its response to NDI 1202 and, at a minimum, amend its letter so that the facts are correct.

We have been working with FDA to develop a clear and strong regulatory framework for full spectrum hemp products that protects consumers while offering them access to these important products. We will continue to do so. We are, however, puzzled about how the agency intends to move forward to develop this framework. Since the enactment of the 2018 Farm Bill, FDA has: indicated publicly that it wants to ensure consumer access to safe CBD-containing products; had a public meeting and opened a docket *two years ago* to obtain information from stakeholders on these products; begun to prepare and then withdrawn a draft formal enforcement discretion policy; and now responded to NDI 1202 in the way it has. Meanwhile, the industry has grown substantially and includes many actors who do not use anything remotely approaching the quality and safety controls that Charlotte's Web employs. The need for a clear regulatory framework -- soon -- is clear and we will continue to work for that outcome.

Tim Orr

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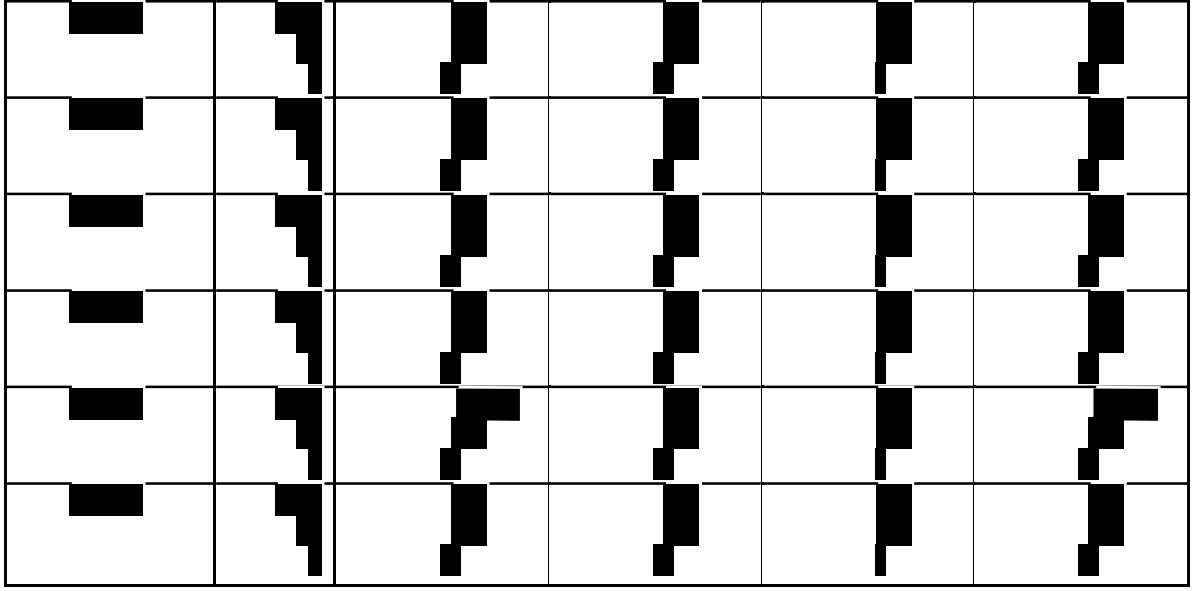

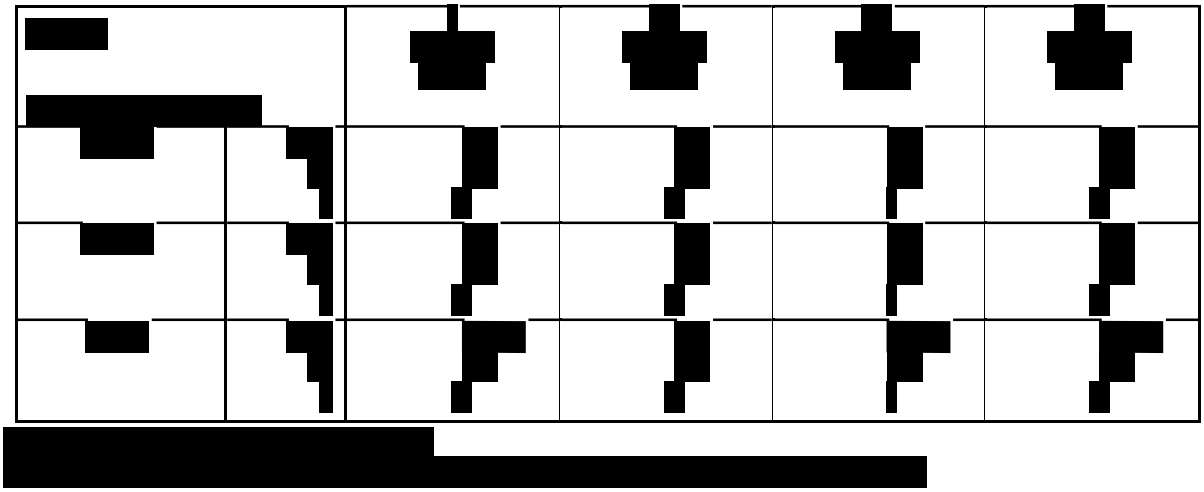

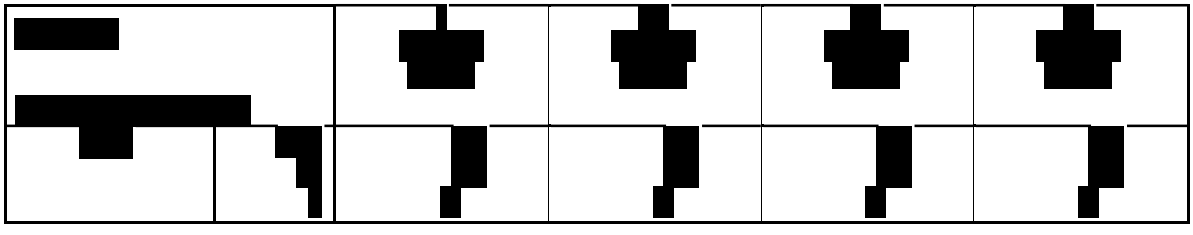

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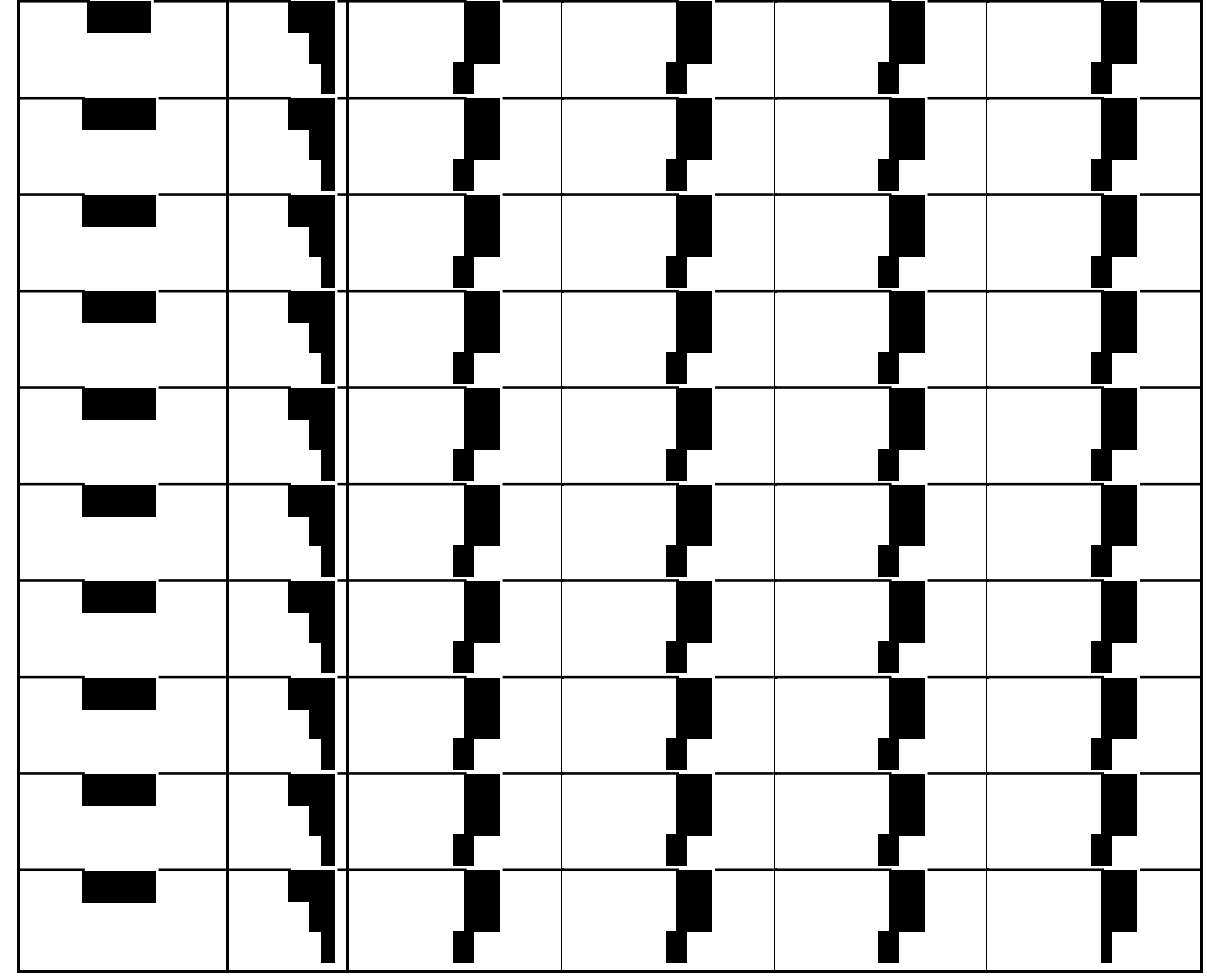

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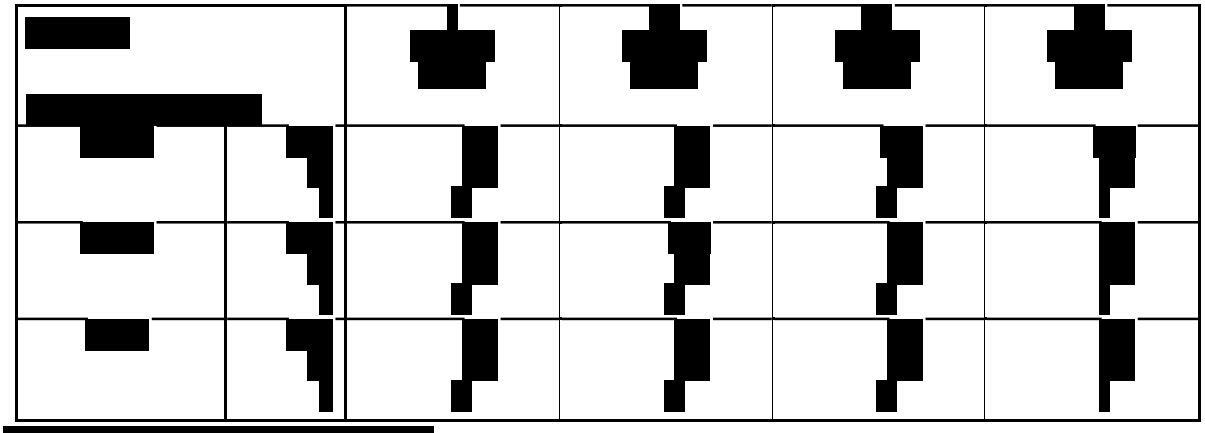

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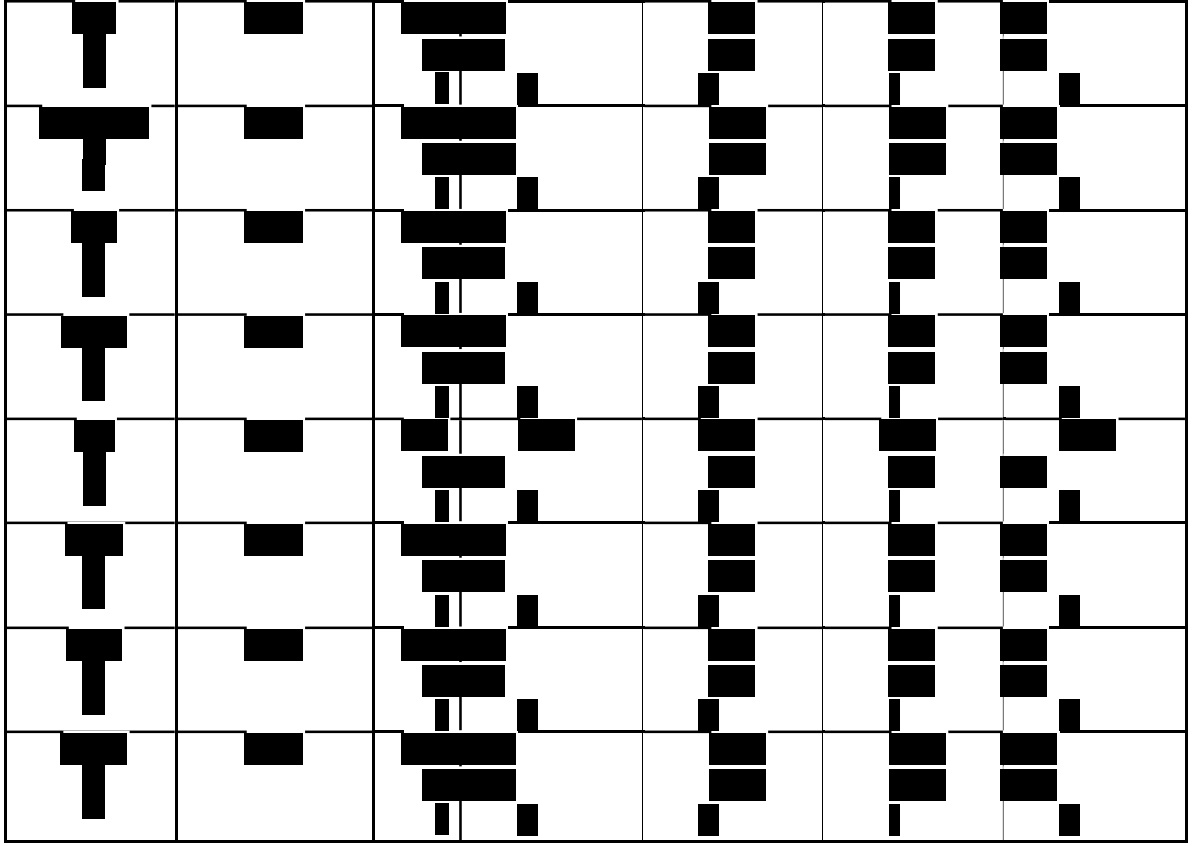

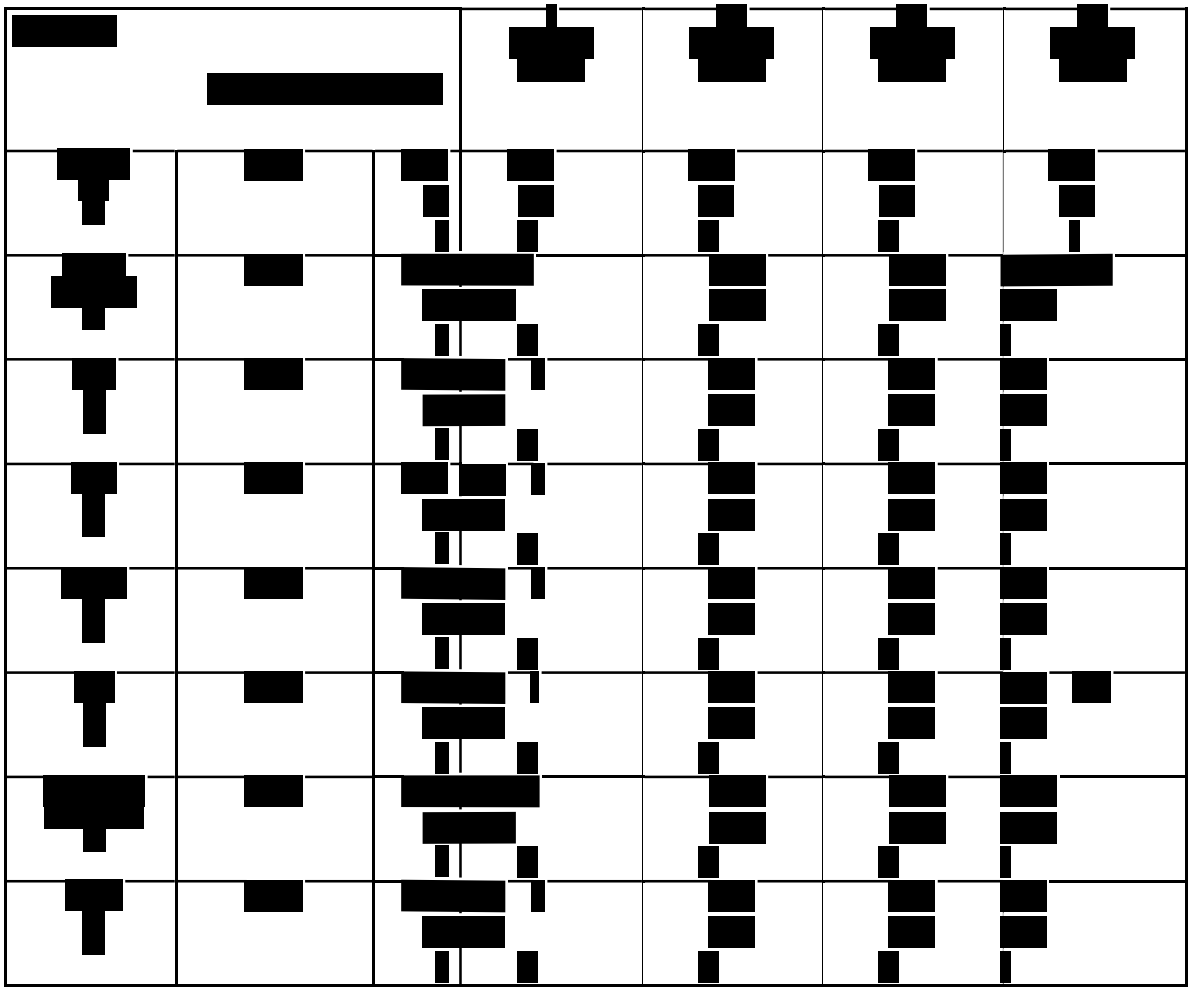

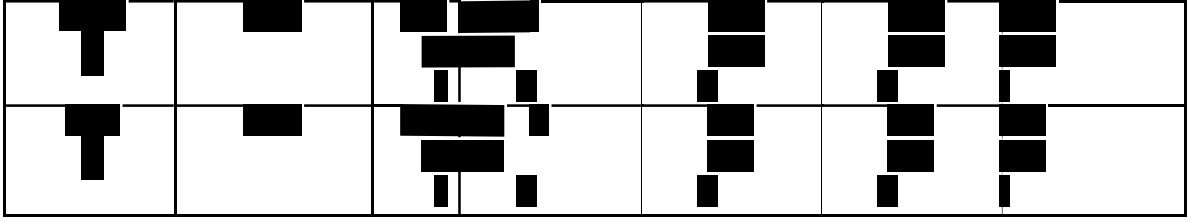

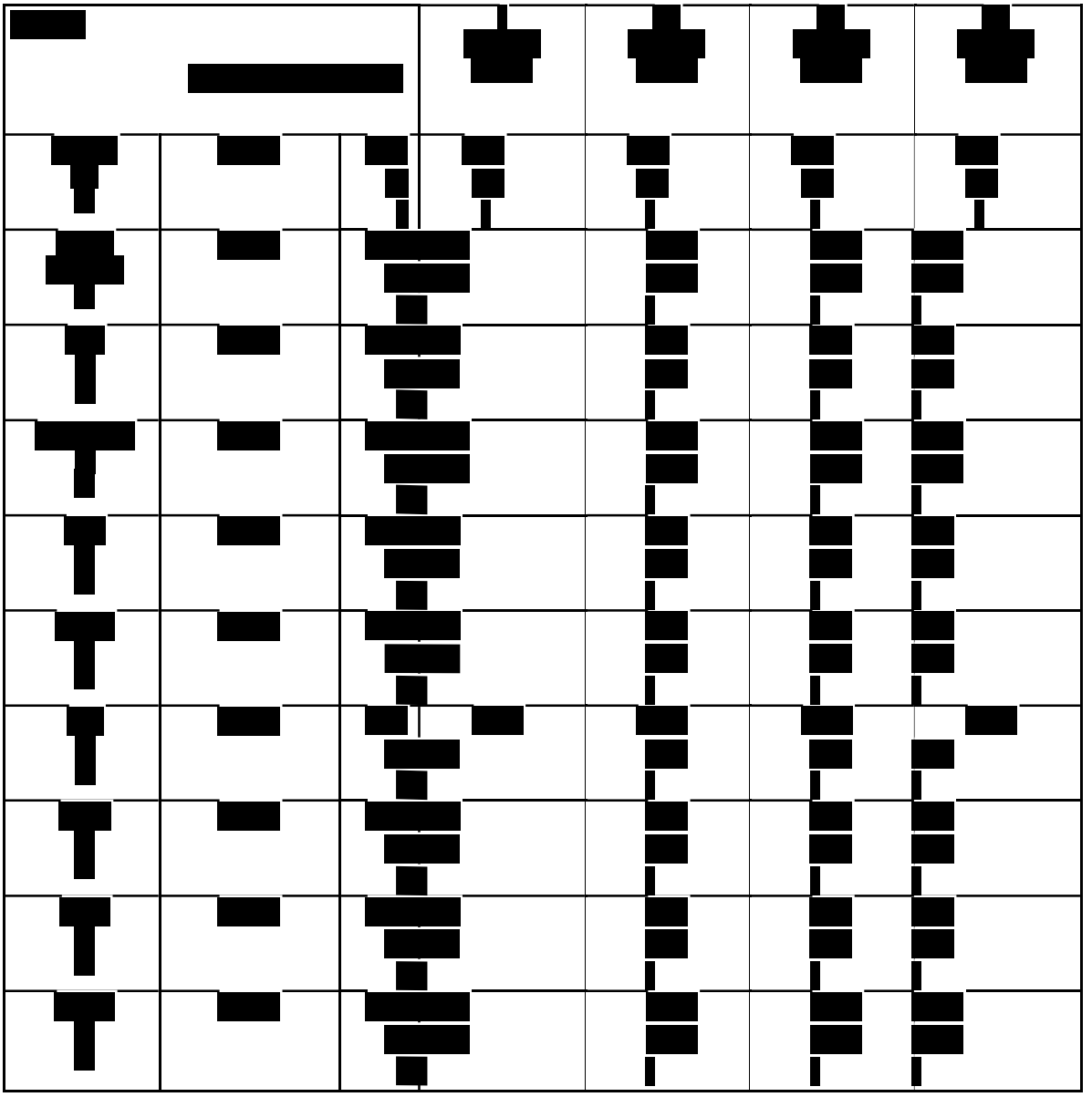

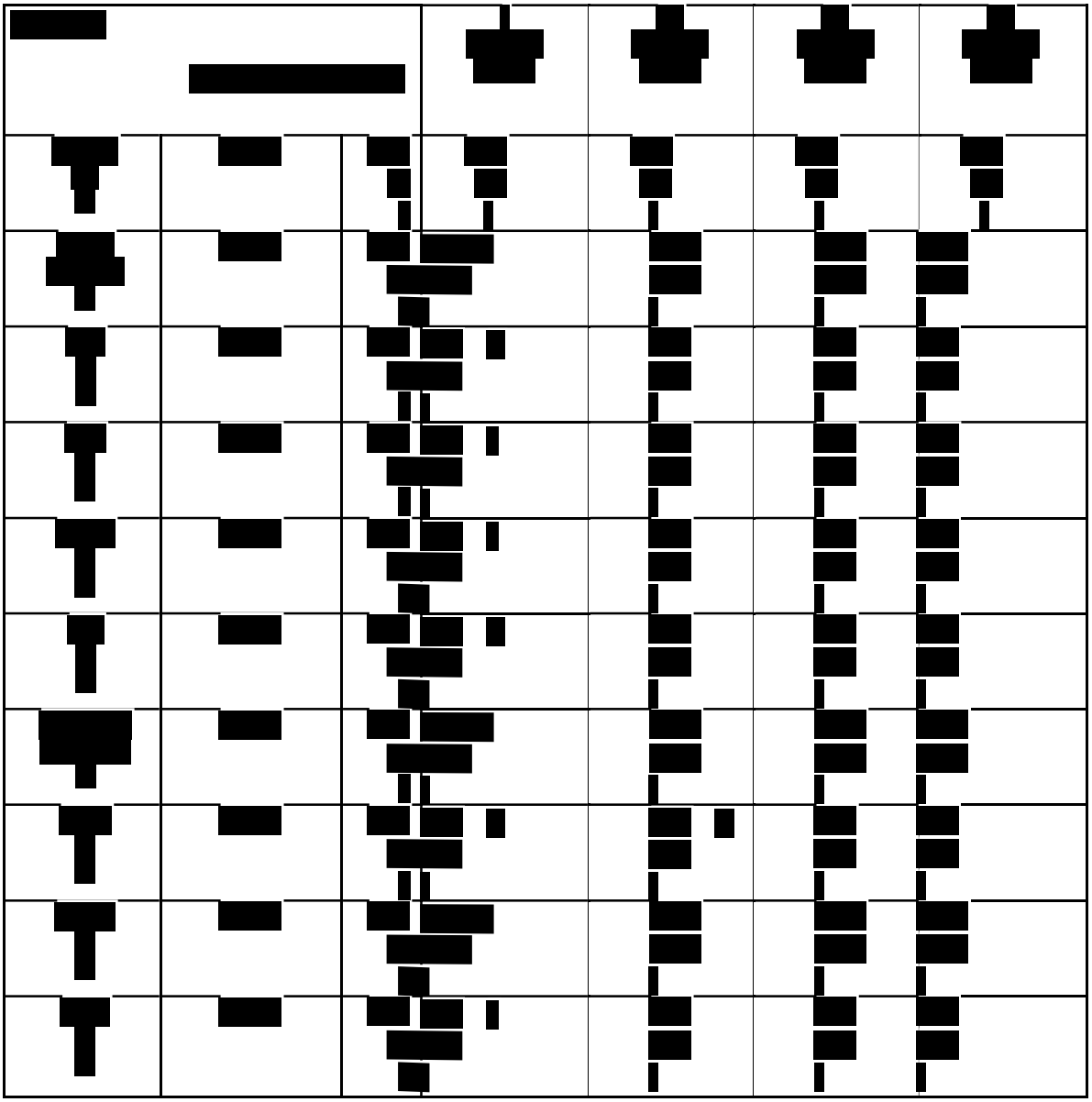

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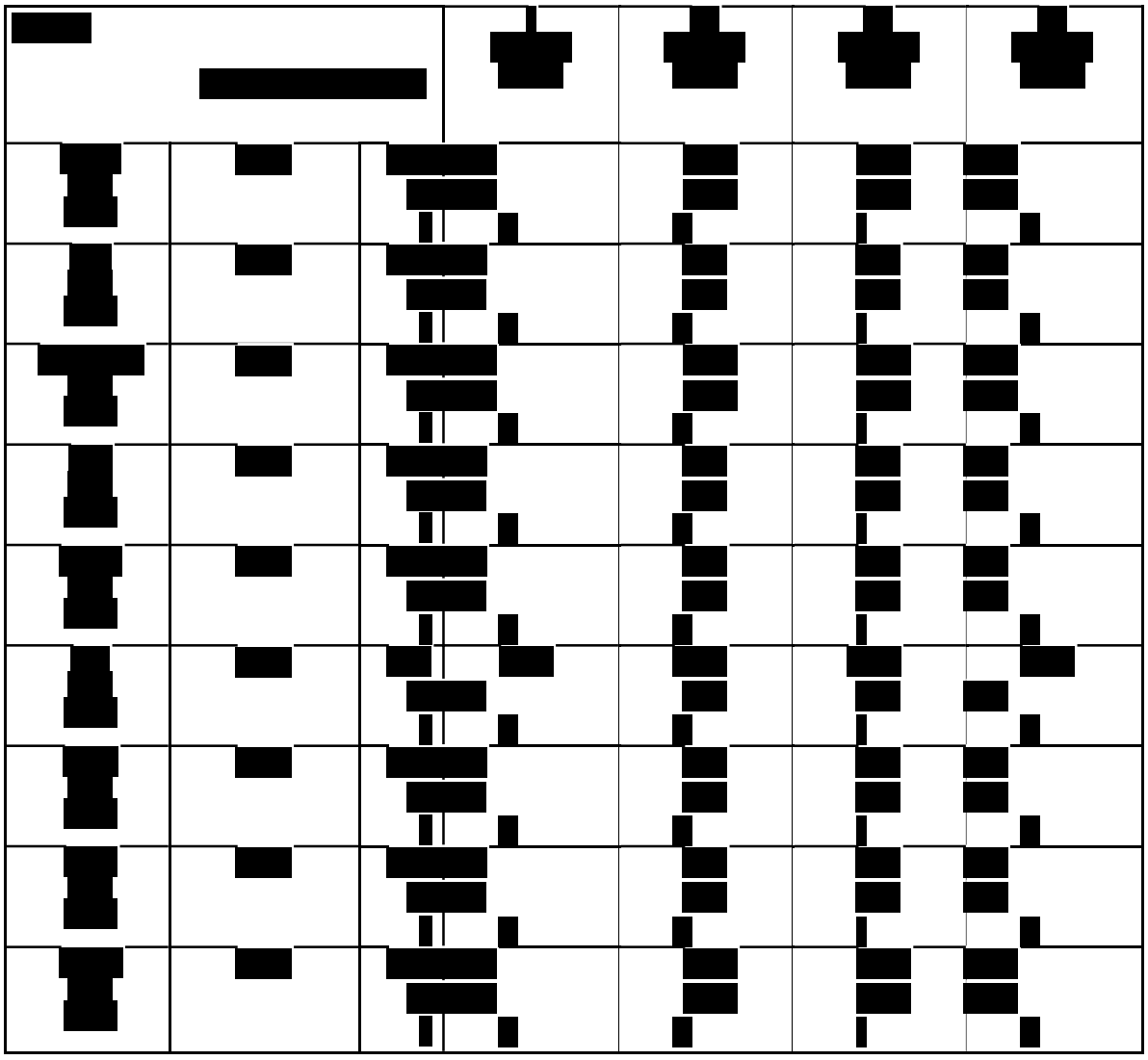

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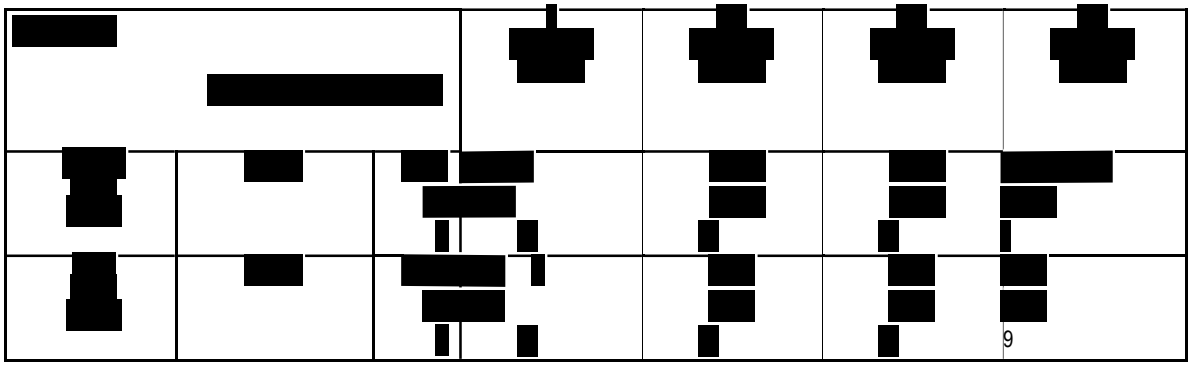

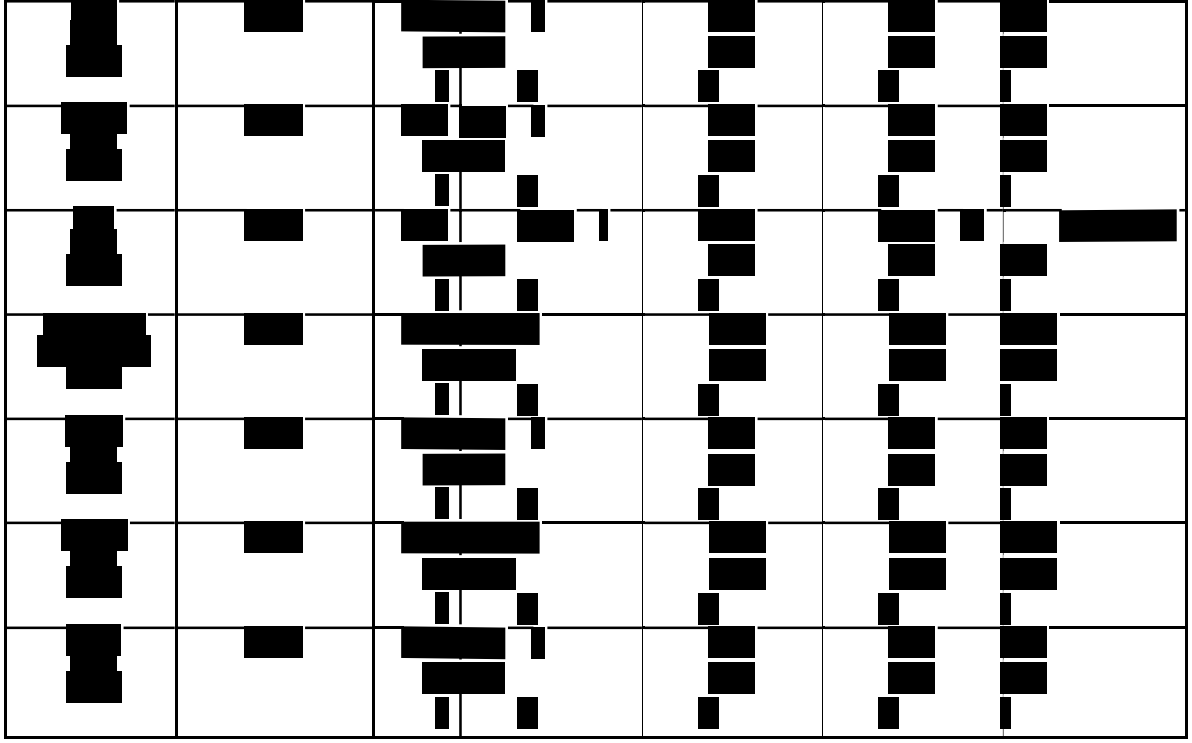

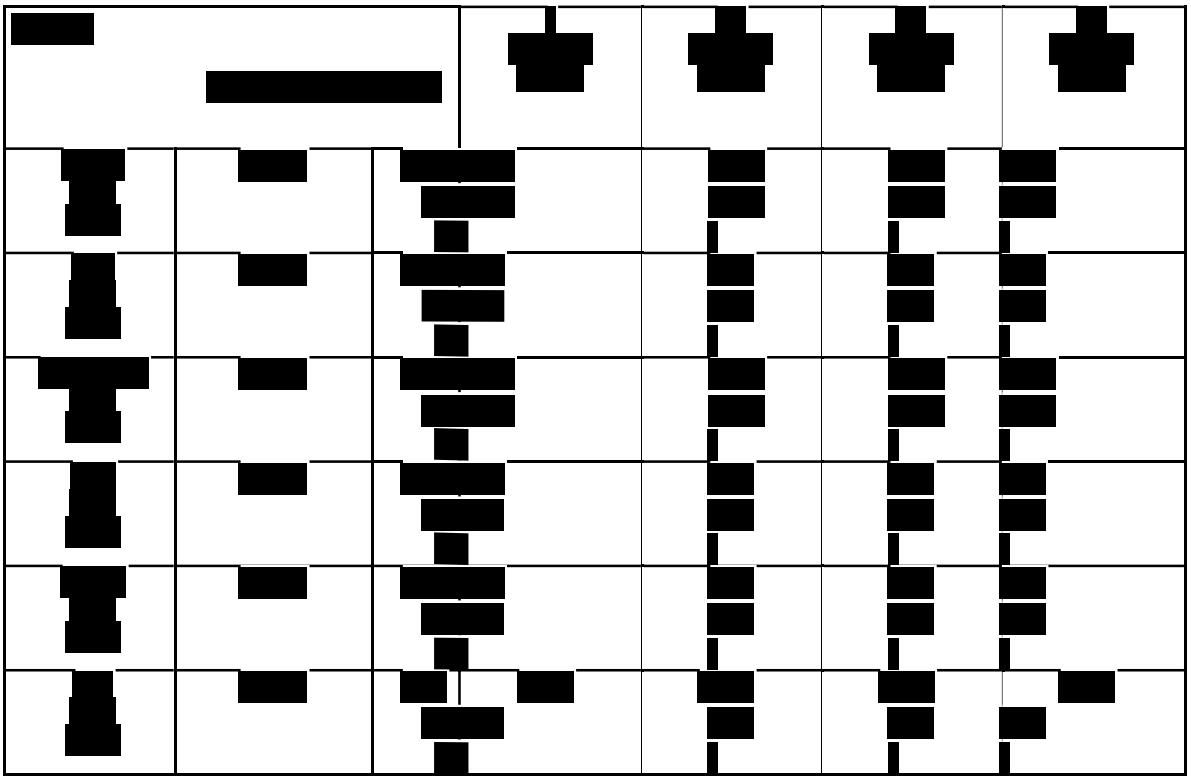

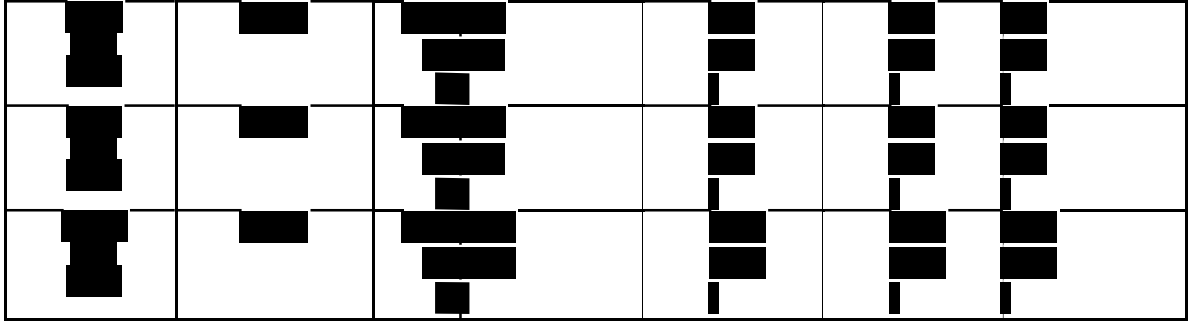

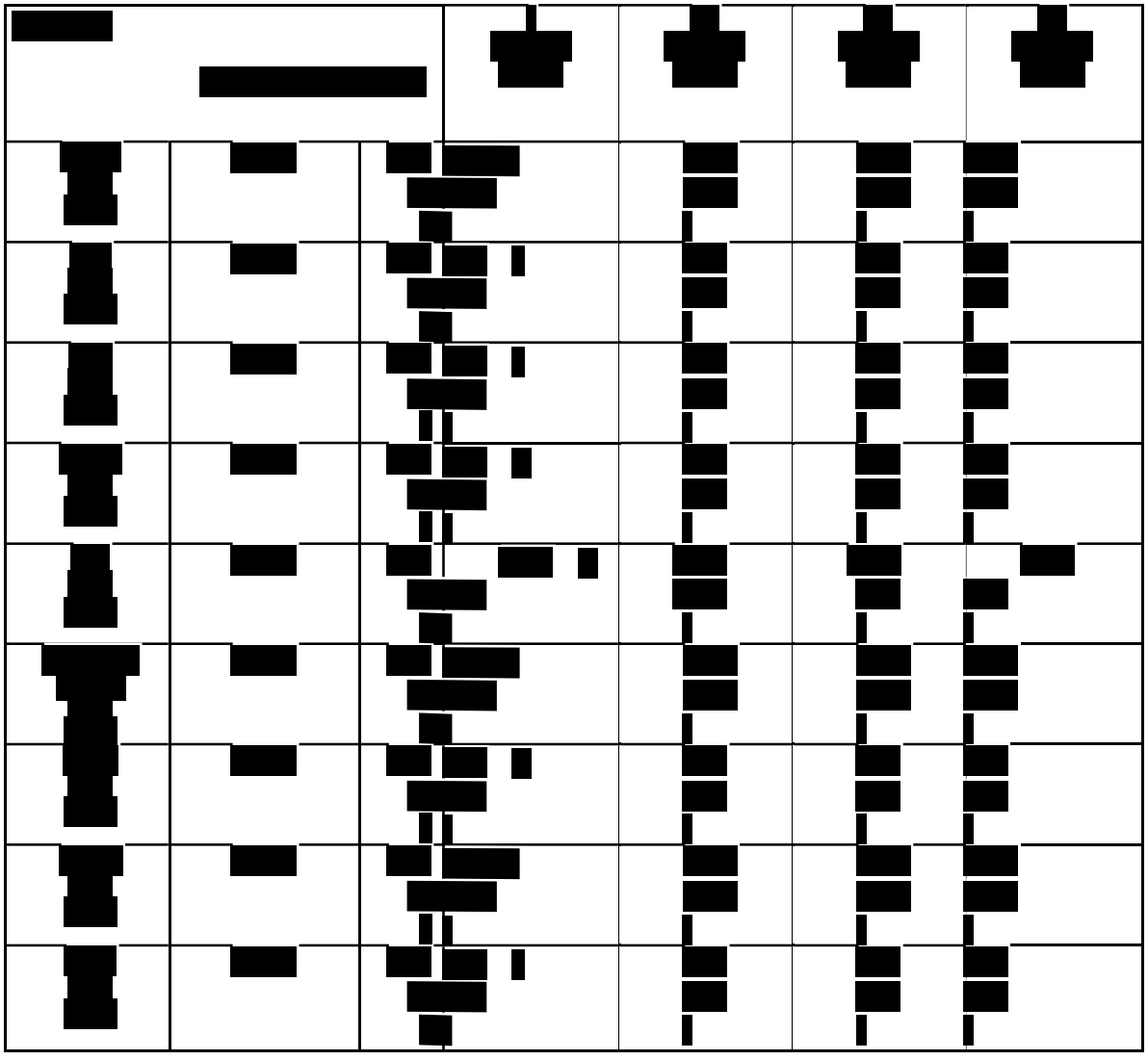

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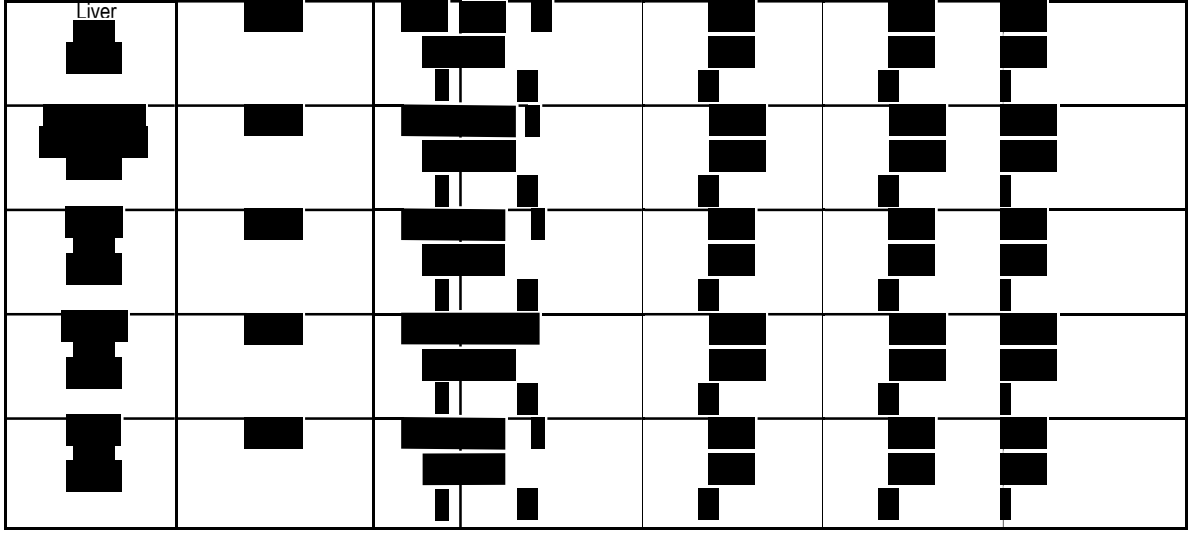
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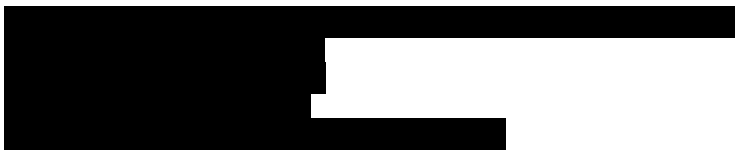

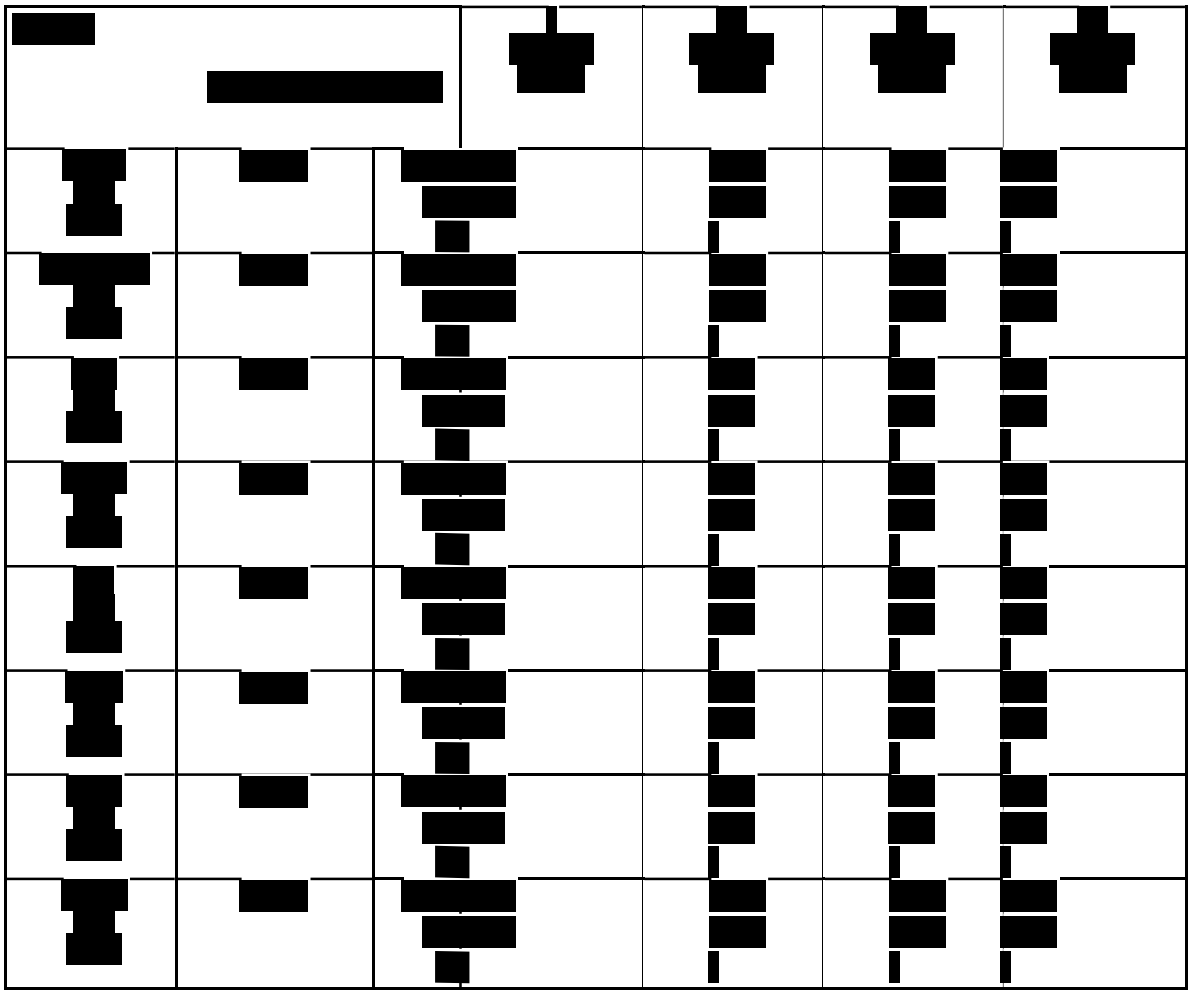

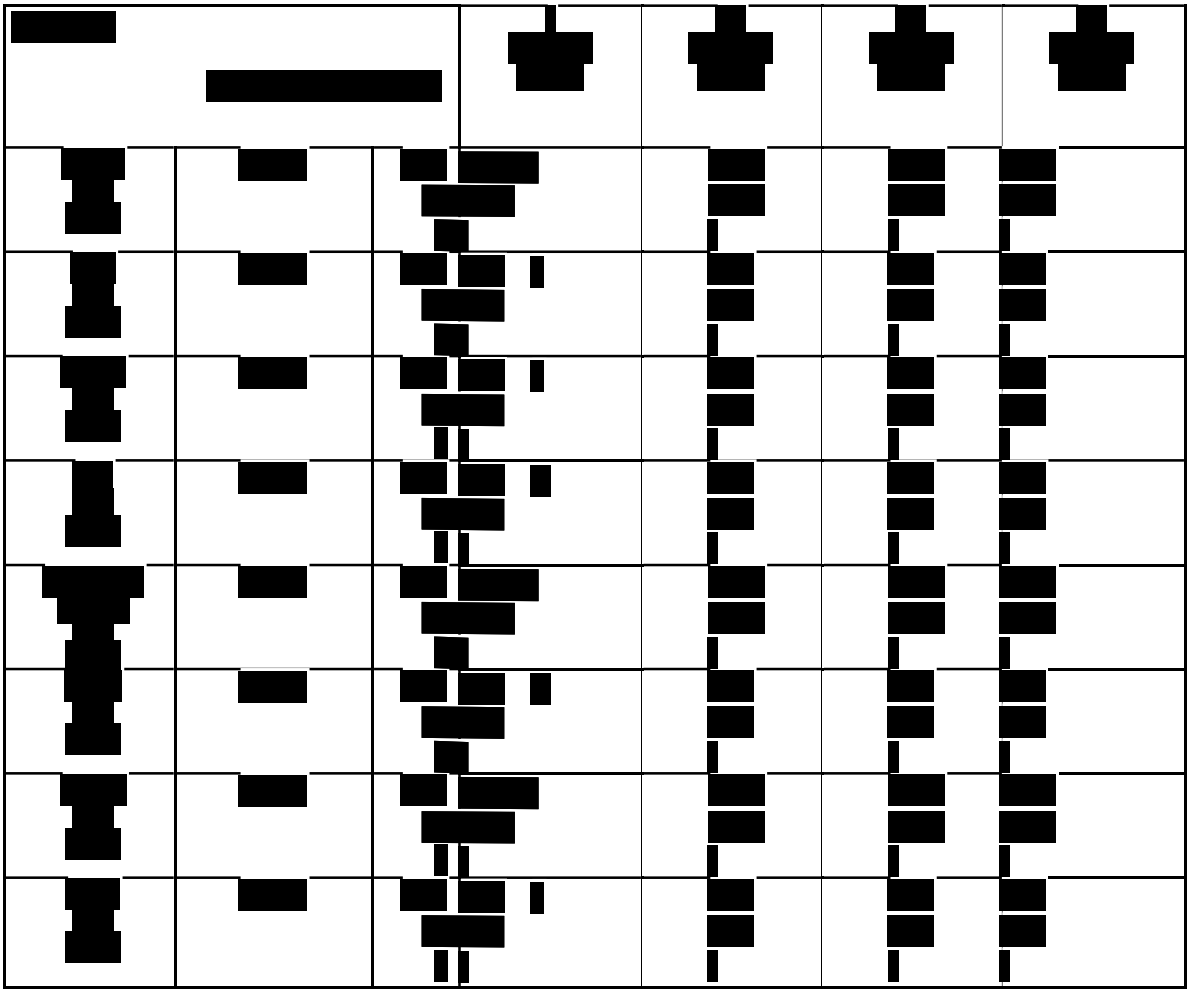

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